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Interinstitutional File: 2022/0140(COD)

Council of the European Union

> SAN 23 PHARM 5 COMPET 45 MI 34 DATAPROTECT 10 CODEC 59

NOTE	
From:	General Secretariat of the Council
То:	Delegations
Subject:	Proposal for a Regulation on the European Health Data Space - 4-column table

Delegations will find enclosed the four column table on the above mentioned proposal. This document contains in Annex A the explanations on the layout of the table used in this document and in Annex B the text of the Commission proposal, changes to the proposal approved by the Coreper on 6 December 2023, the amendments voted by the European Parliament on 13 December 2023.

ANNEX A

Explanation of the table layout

Commission proposal	EP amendments voted on 13 December 2023	Text approved by Coreper on 6 December 2023	Tentatively agreed text, compromise proposals and comments
	 Plain text in this column is text from the Commission proposal that the European Parliament proposes to maintain. <u>Text in blue underlined bold italics in this column is text that the EP proposes to add to the Commission proposal.</u> Text in red italics strikethrough in this column is text that the EP proposes to delete. When an empty cell in this column is on the same row as a Commission proposal, in means that that text was not changed by the EP. 	 Plain text in this column is text from the Commission proposal that Council wishes to maintain. Text in bold in this column is text that Council has agreed to add. Text in strikethrough in this column is text that Council has agreed to delete. 	This column will contain comments, compromise proposals and tentatively agreed text.

Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the European Health Data Space (Text with EEA relevance)

2022/0140(COD)

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
		Formula			
1	2022/0140 (COD)		2022/0140 (COD)	2022/0140 (COD)	
		Proposal Title			
	Proposal for a		Proposal for a	Proposal for a	
2	REGULATION OF T EUROPEAN PARLIAMENT AND THE COUNCIL		REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL	REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL	

	Commission Propo	osal		EP Mandate	Council Mandate	Draft Agreement
	on the European Health Data Space (Text with EEA relevar			on the European Health Data Space (Text with EEA relevance)	on the European Health Data Space (Text with EEA relevance)	
	F	Formula				
3	3 THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,			THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,	THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,	
Citation 1						
4	Having regard to the Tr on the Functioning of th	Ŧ		having regard to the Treaty on the Functioning of the	Having regard to the Treaty on the Functioning of the	

	Commission Propos	osal	EP Mandate	Council Mandate	Draft Agreement
	European Union, and in particular Articles 16 an 114 thereof,		European Union, and in particular Articles 16 and 114 thereof,	European Union, and in particular Articles 16 and 114 thereof,	
	С	Citation 2			
5	Having regard to the proposal from the Europ Commission,	pean	Having regard to the proposal from the European Commission,	Having regard to the proposal from the European Commission,	
Citation 3					
6	After transmission of the draft legislative act to the		After transmission of the draft legislative act to the	After transmission of the draft legislative act to the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	national parliaments,		national parliaments,	national parliaments,	
	Citatic	n 4			
7	Having regard to the opinion of the European Economic and Social Committee ¹ , 1. OJ C , , p		Having regard to the opinion of the European Economic and Social Committee ¹ , 1. OJ C , , p	Having regard to the opinion of the European Economic and Social Committee ¹ , 1. OJ C , , p	
	Citatio	n 5			
8	Having regard to the		Having regard to the	Having regard to the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	opinion of the Committee of the Regions ¹ ,		opinion of the Committee of the Regions ¹ ,	opinion of the Committee of the Regions ¹ ,	
	1. OJ C , , p		1. OJ C , , p	1. OJ C , , p	
	Citatic	on 6			
9	Acting in accordance with the ordinary legislative procedure,		Acting in accordance with the ordinary legislative procedure,	Acting in accordance with the ordinary legislative procedure,	
	Formu	ıla			
10					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Whereas:		Whereas:	Whereas:	
	Recita	1			
	(1) The aim of this		(1) The aim of this	(1) The aim of this	
	Regulation is to establish		Regulation is to establish	Regulation is to establish	
	the European Health Data		the European Health Data	the European Health Data	
	Space ('EHDS') in order to		Space ('EHDS') in order to	Space ('EHDS') in order to	
	improve access to and		improve access to and	improve access to and	
11	control by natural persons		control by natural persons	control by natural persons	
11	over their personal		over their personal	over their personal	
	electronic health data in the		electronic health data in the	electronic health data in the	
	context of healthcare		context of healthcare	context of healthcare	
	(primary use of electronic		(primary use of electronic	(primary use of electronic	
	health data), as well as for		health data), as well as for	health data), as well as for	
	other purposes that would		better achieving other	other purposes that would	
	benefit the society such as		purposes <u>in the health</u>	benefit the society such as	
	research, innovation,		sector that would benefit	research, innovation,	

nission Proposal	EP Mandate	Council Mandate	Draft Agreement
naking, patient	the society such as research,	policy-making, patient	
personalised	such as innovation, policy-	safety, personalised	
e, official statistics	making, <i>health threats</i>	medicine, official statistics	
atory activities	preparedness and response,	or regulatory activities	
ary use of electronic	patient safety, personalised	(secondary use of electronic	
ata). In addition, the	medicine, official statistics	health data). In addition, the	
o improve the	or regulatory activities	goal is to improve the	
ing of the internal	(secondary use of electronic	functioning of the internal	
by laying down a	health data). In addition, the	market by laying down a	
legal framework in	goal is to improve the	uniform legal framework in	
ar for the	functioning of the internal	particular for the	
ment, marketing	market by laying down a	development, marketing and	
of electronic health	uniform legal and technical	use of electronic health	
ystems ('EHR	framework in particular for	record systems ('EHR	
') in conformity	the development, marketing	systems') in conformity	
ion values.	and use of electronic health	with Union values.	
	record systems ('EHR		
	systems') in conformity		
	with Union values.		
	haking, patient bersonalised e, official statistics atory activities ary use of electronic ata). In addition, the o improve the ing of the internal by laying down a legal framework in ar for the ment, marketing of electronic health ystems ('EHR ') in conformity	haking, patientthe society such as research; such as innovation, policy- making, health threatsee, official statisticsmaking, health threatsatory activitiespreparedness and response,ary use of electronicpatient safety, personalisedata). In addition, themedicine, official statisticso improve theor regulatory activitiesing of the internal(secondary use of electronicby laying down ahealth data). In addition, thelegal framework ingoal is to improve thearf or thefunctioning of the internalment, marketingmarket by laying down aof electronic healthuniform legal and technicalystems ('EHRframework in particular forthe development, marketingand use of electronic healthresonationand use of electronic healthresonationand use of electronic healthrecord systems ('EHRsystems') in conformity	haking, patientthe society such as research, such as innovation, policy- making, health threatspolicy-making, patient safety, personalisede, official statistics atory activitiesmaking, health threats preparedness and response, patient safety, personalisedmedicine, official statistics or regulatory activitiesatory activities ary use of electronic ata). In addition, the o improve the ing of the internal by laying down a legal framework in art for the ment, marketing of electronic health(secondary use of electronic functioning of the internal market by laying down a uniform legal and technical the development, marketing and use of electronic health record systems ('EHR ') in conformitymaking, health draw making, health draw in conformityion values.making, health draw systems') in conformitymaking, health draw making, patient systems') in conformity

	Commission Prop	osal		EP Mandate	Council Mandate	Draft Agreement
		Recital	1a			
11a				(1a) The EHDS is intended to constitute a key component in the creation of a strong and resilient European Health Union to better protect the health of Union citizens, prevent and address future pandemics and improve the resilience of Union healthcare systems.		
		Recital	1b			
11b						

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			(1b) This Regulation should complement Union programmes such as the EU4Health Programme, Digital Europe Programme, Connecting Europe Facility and Horizon Europe. The Commission should ensure that Union programmes complement and facilitate the implementation of the European Health Data Space.		
	Recital	2			
12	(2) The COVID-19		(2) The COVID-19	(2) The COVID-19	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
pandemic has highlighted	pandemic has highlighted	pandemic has highlighted	
the imperative of having	the imperative of having	the imperative of having	
timely access to electronic	timely access to <i>quality</i>	timely access to electronic	
health data for health	electronic health data for	health data for health threats	
threats preparedness and	health threats preparedness	preparedness and response,	
response, as well as for	and response, as well as for	as well as for diagnosis and	
diagnosis and treatment and	prevention, diagnosis and	treatment and secondary use	
secondary use of health	treatment <mark>and</mark> through the	of health data. Such timely	
data. Such timely access	secondary use of health	access would have	
would have contributed,	data. Such timely access	contributed, through	
through efficient public	would have contributed <mark>can</mark>	efficient public health	
health surveillance and	potentially contribute,	surveillance and	
monitoring, to a more	through efficient public	monitoring, to a more	
effective management of	health surveillance and	effective management of the	
the pandemic, and	monitoring, to a more	pandemic, and ultimately	
ultimately would have	effective management of the	would have helped to save	
helped to save lives. In	pandemic, to a reduction of	lives. In 2020, the	
2020, the Commission	costs and to improving the	Commission urgently	
urgently adapted its Clinical	response to health threats	adapted its Clinical Patient	
Patient Management	and ultimately can help <mark>and</mark>	Management System,	
System, established by	ultimately would have	established by Commission	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Commission Implementing	helped to save more lives in	Implementing Decision	
Decision (EU) 2019/1269 ¹ , to allow Member States to	<u>the future</u> . In 2020, the Commission urgently	(EU) 2019/1269 ¹ , to allow Member States to share	
share electronic health data of COVID-19 patients	adapted its Clinical Patient Management System,	electronic health data of COVID-19 patients moving	
moving between healthcare providers and Member	established by Commission Implementing Decision	between healthcare providers and Member	
States during the peak of the pandemic, but this was	(EU) 2019/1269 ¹ ,- ¹ to allow Member States to share	States during the peak of the pandemic, but this was only	
only an emergency solution,	electronic health data of	an emergency solution,	
showing the need for a structural approach at	COVID-19 patients moving between healthcare	showing the need for a structural approach at	
Member States and Union level.	providers and Member States during the peak of the	Member States and Union level.	
	pandemic, but this was only an emergency solution,		
1. Commission Implementing Decision (EU) 2019/1269 of 26	showing the need for a structural <i>and consistent</i>	1. Commission Implementing Decision (EU) 2019/1269 of 26	
July 2019 amending Implementing Decision	approach at Member States	July 2019 amending Implementing Decision	
2014/287/EU setting out criteria for establishing and evaluating	and Union level <u>on access</u> to electronic health data in	2014/287/EU setting out criteria for establishing and evaluating	

Comm	ission Proposal		EP Mandate	Council Mandate	Draft Agreement
and their M facilitating information establishing	eference Networks embers and for the exchange of and expertise on and evaluating such DJ L 200, 29.7.2019,		order to steer effective policy responses and contribute to high standards of human health.	European Reference Networks and their Members and for facilitating the exchange of information and expertise on establishing and evaluating such Networks (OJ L 200, 29.7.2019, p. 35).	
			 Commission Implementing Decision (EU) 2019/1269 of 26 July 2019 amending Implementing Decision 2014/287/EU setting out criteria for establishing and evaluating European Reference Networks and their Members and for facilitating the exchange of information and expertise on establishing and evaluating such Networks (OJ L 200, 29.7.2019, p. 35). 		
	Recita	13			

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	(3) The COVID-19 crisis	(3) The COVID-19 crisis	(3) The COVID-19 crisis	
	strongly anchored the work	strongly anchored the work	strongly anchored the work	
	of the eHealth Network, a	of the eHealth Network, a	of the eHealth Network, a	
	voluntary network of digital	voluntary network of digital	voluntary network of digital	
	health authorities, as the	health authorities, as the	health authorities, as the	
	main pillar for the	main pillar for the	main pillar for the	
	development of mobile	development of mobile	development of mobile	
	contact tracing and warning	contact tracing and warning	contact tracing and warning	
13	applications and the	applications and the	applications and the	
	technical aspects of the EU	technical aspects of the EU	technical aspects of the EU	
	Digital COVID Certificates.	Digital COVID Certificates.	Digital COVID Certificates.	
	It also highlighted the need	It also highlighted the need	It also highlighted the need	
	for sharing electronic health	for sharing electronic health	for sharing electronic health	
	data that are findable,	data that are findable,	data that are findable,	
	accessible, interoperable	accessible, interoperable	accessible, interoperable	
	and reusable ('FAIR	and reusable ('FAIR	and reusable ('FAIR	
	principles'), and ensuring	principles'), and ensuring	principles'), and ensuring	
	that electronic health data	that <u>the necessary</u>	that electronic health data	
	are as open as possible and	electronic health data are as	are as open as possible and	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
as	s closed as necessary.	open as possible and as	as closed as necessary.	
S	ynergies between the	closed as	Synergies between the	
E	EHDS, the European Open	necessary<u>available</u> while	EHDS, the European Open	
S	cience Cloud ¹ and the	respecting the principle of	Science Cloud ¹ and the	
Е	European Research	data minimisation.	European Research	
Ir	nfrastructures should be	Synergies between the	Infrastructures should be	
eı	nsured, as well as lessons	EHDS, the European Open	ensured, as well as lessons	
le	earned from data sharing	Science Cloud ¹ and the	learned from data sharing	
so	olutions developed under	European Research	solutions developed under	
th	he European COVID-19	Infrastructures should be	the European COVID-19	
D	Data Platform.	ensured, as well as lessons	Data Platform.	
		learned from data sharing		
-		solutions developed under		
1	. EOSC Portal (eosc-portal.eu).	the European COVID-19	1. EOSC Portal (eosc-portal.eu).	
1.	. Dobe i oran (cose poraneu).	Data Platform.	1. Lobe i oftai (cose portai.ed).	
		1. EOSC Portal (eosc-portal.eu).		
		1. 2000 1 ortar (cose-portar.cd).		

	Commission Propo	osal	EP Mandate	Council Mandate	Draft Agreement
	Я	Recital 3a			
13a			(3a) Given the sensitivity of personal health data, this Regulation seeks to provide sufficient safeguards at both Union and national level to ensure a high degree of data protection, security, confidentiality and ethical use. Such safeguards are necessary to promote trust in safe handling of the health data of natural persons for primary and secondary uses. To achieve those objectives, pursuant to Article 9(4) of		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		Regulation (EU) 2016/679, Member States can impose further conditions, including limitations, with regard to the processing of genetic data, biometric data or data concerning health.		
	Recital 4			
14	 (4) The processing of personal electronic health data is subject to the provisions of Regulation (EU) 2016/679 of the European Parliament and of the Council¹ and, for Union institutions and bodies, 	 (4) The processing of personal electronic health data is subject to the provisions of Regulation (EU) 2016/679 of the European Parliament and of the Council¹, <i>Regulation</i> (EU) 2018/1725 of the 	 (4) The processing of personal electronic health data is subject to the provisions of Regulation (EU) 2016/679 of the European Parliament and of the Council¹ and, for Union institutions and bodies, 	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Regulation (EU) 2018/1725 of the European Parliament and of the Council ² . References to the provisions of Regulation (EU) 2016/679 should be understood also as references to the corresponding provisions of	<i>European Parliament and</i> of the Council ² , as regards and, for Union institutions, bodies, offices and agencies and bodies, and Regulation (EU) 2018/17252022/868 ³ of the European Parliament and of the Council ² . References to	Regulation (EU) 2018/1725 of the European Parliament and of the Council ² . References to the provisions of Regulation (EU) 2016/679 should be understood also as references to the corresponding provisions of	
- -	Regulation (EU) 2018/1725 for Union institutions and bodies, where relevant. 	the provisions of Regulation (EU) 2016/679 should be understood also as references to the corresponding provisions of Regulation (EU) 2018/1725 for Union institutions,	Regulation (EU) 2018/1725 for Union institutions and bodies, where relevant. 	
	the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection	<i>bodies, offices and</i> agencies -and bodies , where relevant. <u>In relation to</u> <u>mixed datasets, where</u> personal and non-personal	the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
 Regulation) (OJ L 119, 4.5.2016, p. 1). 2. Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39). 	data are inextricably linked, and where it is difficult to distinguish between those categories thereby resulting in the possibility of inferring personal data from non- personal data, the provisions of Regulation (EU) 2016/679 and of this Regulation concerning personal electronic health data should apply.	 Regulation) (OJ L 119, 4.5.2016, p. 1). 2. Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39). 	
	1. Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and		

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	repealing Directive 95/46/EC		
	(General Data Protection		
	Regulation) (OJ L 119, 4.5.2016,		
	p. 1).		
	2. Regulation (EU) 2018/1725 of		
	the European Parliament and of		
	the Council of 23 October 2018 on		
	the protection of natural persons		
	with regard to the processing of		
	personal data by the Union		
	institutions, bodies, offices and		
	agencies and on the free		
	movement of such data, and		
	repealing Regulation (EC) No		
	45/2001 and Decision No		
	1247/2002/EC (OJ L 295,		
	21.11.2018, p. 39).		
	<u>3. Regulation (EU) 2022/868 of</u>		
	the European Parliament and of		
	the Council of 30 May 2022 on		
	European data governance and		
	amending Regulation (EU)		
	2018/1724 (Data Governance		
	<u>Act) (OJ L 152, 3.6.2022, p. 1).</u>		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Recita	l 4a			
14a			(4a) The implementation of the EHDS should take into consideration the European ethical principles for digital health adopted by the eHealth network ¹ on 26 January 2022. Monitoring the application of those ethical principles should be one of the tasks of the EHDS Board.		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			14 of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare.		
	Recital	5			
15	(5) More and more Europeans cross national borders to work, study, visit relatives or to travel. To facilitate the exchange of health data, and in line with the need for empowering citizens, they should be able to access their health data in an electronic format that can be recognised and accepted across the Union. Such personal electronic		(5) More and more Europeans cross national borders to work, study, visit relatives or to travel. To facilitate the exchange of health data, and in line with the need for empowering citizens, they should be able to access their health data in an electronic format that can be recognised and accepted across the Union. Such personal electronic	(5) More and more Europeans cross national borders to work, study, visit relatives or to travel. To facilitate the exchange of health data, and in line with the need for empowering citizens, they should be able to access their health data in an electronic format that can be recognised and accepted across the Union. Such personal electronic	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
health data could include	health data could include	health data could include	
personal data related to the	personal data related to the	personal data related to the	
physical or mental health of	physical or mental health of	physical or mental health of	
a natural person, including	a natural person, including	a natural person, including	
the provision of health care	the provision of health care	the provision of health care	
services, which reveal	services, which reveal	services, which reveal	
information about their	information about their	information about their	
health status, personal data	health status, personal data	health status, personal data	
relating to the inherited or	relating to the inherited or	relating to the inherited or	
acquired genetic	acquired genetic	acquired genetic	
characteristics of a natural	characteristics of a natural	characteristics of a natural	
person which give unique	person which give unique	person which give unique	
information about the	information about the	information about the	
physiology or the health of	physiology or the health of	physiology or the health of	
that natural person and	that natural person and	that natural person and	
which result, in particular,	which result, in particular,	which result, in particular,	
from an analysis of a	from an analysis of a	from an analysis of a	
biological sample from the	biological sample from the	biological sample from the	
natural person in question,	natural person in question,	natural person in question,	
as well as data determinants	as well as data determinants	as well as data determinants	
of health, such as	of health, such as	of health, such as	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
behaviour, environmental,	behaviour, environmental,	behaviour, environmental,	
physical influences,	physical influences, medical	physical influences, medical	
medical care, social or	care, social or educational	care, social or educational	
educational factors.	factors. Electronic health	factors. Electronic health	
Electronic health data also	data also includes data that	data also includes data that	
includes data that has been	has been initially collected	has been initially collected	
initially collected for	for research, statistics,	for research, statistics,	
research, statistics, policy	health threat assessment,	policy making or regulatory	
making or regulatory	policy making or regulatory	purposes and may be made	
purposes and may be made	purposes and may be made	available according to the	
available according to the	available according to the	rules in Chapter IV. The	
rules in Chapter IV. The	rules in Chapter IV. The	electronic health data	
electronic health data	electronic health data	concern all categories of	
concern all categories of	concern all categories of	those data, irrespective to	
those data, irrespective to	those data, irrespective to	the fact that such data is	
the fact that such data is	the fact that such data is	provided by the data subject	
provided by the data subject	provided by the data subject	or other natural or legal	
or other natural or legal	or other natural or legal	persons, such as health	
persons, such as health	persons, such as health	professionals, or is	
professionals, or is	professionals, or is	processed in relation to a	
processed in relation to a	processed in relation to a	natural person's health or	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	natural person's health or well-being and should also include inferred and derived data, such as diagnostics, tests and medical		natural person's health or well-being and should also include inferred and derived data, such as diagnostics, tests and medical	well-being and should also include inferred and derived data, such as diagnostics, tests and medical examinations, as well as	
	examinations, as well as data observed and recorded by automatic means.		examinations, as well as data observed and recorded by automatic means.	data observed and recorded by automatic means.	
	Recita	l 5a			
15a			(5a) The scope of this Regulation should not cover natural persons who are not Union citizens, or third-country nationals not legally residing on the territory of the Member		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			States. Therefore, where <u>Member States require</u> <u>electronic registration of</u> <u>health data or where health</u> <u>data holders register health</u> <u>data regarding those</u> <u>natural persons, processors</u> <u>can only process the</u> <u>electronic health data of</u> <u>such persons, in</u> <u>accordance with Articles</u> <u>6(1) and 9(2) of Regulation</u> <u>(EU) 2016/679 including</u> <u>for any secondary use.</u>		
	Recita	al 5a			
15b				(5a) In health systems,	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		personal electronic health	
		data is usually gathered in	
		electronic health records,	
		which typically contain a	
		natural person's medical	
		history, diagnoses and	
		treatment, medications,	
		allergies, immunisations,	
		as well as radiology	
		images and laboratory	
		results, spread between	
		different entities from the	
		health system (general	
		practitioners, hospitals,	
		pharmacies, care	
		services). In order to	
		enable that electronic	
		health data be accessed,	
		shared and changed by	
		the natural persons or	
		health professionals, some	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		Member States have taken	
		the necessary legal and	
		technical measures and set	
		up centralised	
		infrastructures connecting	
		EHR systems used by	
		healthcare providers and	
		natural persons.	
		Alternatively, some	
		Member States support	
		public and private	
		healthcare providers to set	
		up personal health data	
		spaces to enable	
		interoperability between	
		different healthcare	
		providers. Several	
		Member States have also	
		supported or provided	
		health data access services	
		for patients and health	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		professionals (for instance	
		through patients or health	
		professional portals).	
		They have also taken	
		measures to ensure the	
		EHR systems or wellness	
		applications are able to	
		transmit electronic health	
		data with the central EHR	
		system (some Member	
		States do this by ensuring,	
		for instance, a system of	
		certification). However,	
		not all Member States	
		have put in place such	
		systems, and the Member	
		States that have	
		implemented them have	
		done so in a fragmented	
		manner. In order to	
		facilitate the free	

Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			movement of personal health data across the Union and avoid negative consequences for patients when receiving healthcare in cross-border context, Union action is needed in order to ensure individuals have improved access to their own personal electronic health data and are empowered to share it. [[RECITAL (7) MOVED BEFORE RECITAL (6)]]	
Recital	6			

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
16	(6) Chapter III of Regulation (EU) 2016/679 sets out specific provisions concerning the rights of natural persons in relation to the processing of their personal data. EHDS builds upon these rights and further develops some of them. The EHDS should support the coherent implementation of those rights as applied to electronic health data, regardless of the Member State in which the personal electronic health data are processed, type of healthcare provider, sources	(6) Chapter III of Regulation (EU) 2016/679 sets out specific provisions concerning the rights of natural persons in relation to the processing of their personal data. EHDS builds upon these rights and further develops some of them. The EHDS should support the coherent implementation of those rights as applied to electronic health data, regardless of the Member State in which the personal electronic health data are processed, type of healthcare provider, sources	 (6) Chapter III of Regulation (EU) 2016/679 sets out specific provisions concerning the rights of natural persons in relation to the processing of their personal data. The EHDS builds upon these rights and further develops complements some of them. The EHDS should support the coherent implementation of those rights as applied to personal electronic health data;. These rights apply regardless of the Member State in which the personal electronic health data are 	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
of data or Member State of	of data or Member State of	processed, type of	
affiliation of the natural	affiliation of the natural	healthcare provider, sources	
person. The rights and rules	person. The rights and rules	of data or Member State of	
related to the primary use of	related to the primary use of	affiliation of the natural	
personal electronic health	personal electronic health	person. The rights and rules	
data under Chapter II and	data under Chapter II and	related to the primary use of	
III of this Regulation	III of this Regulation	personal electronic health	
concern all categories of	concern all categories of	data under Chapter II and	
those data, irrespective of	those data, irrespective of	III of this Regulation	
how they have been	how they have been	concern all categories of	
collected or who has	collected or who has	those data, irrespective of	
provided hem, of the legal	provided hem, of the legal	how they have been	
ground for the processing	ground for the processing	collected or who has	
under Regulation (EU)	under Regulation (EU)	provided hemthem, of the	
2016/679 or the status of	2016/679 or the status of	legal ground for the	
the controller as a public or	the controller as a public or	processing under	
private organisation of the	private organisation of the	Regulation (EU) 2016/679	
legal ground for their	legal ground for their	or the status of the	
processing.	processing.	controller as a public or	
		private organisation. The	
		enhanced rights of access	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				and portability of personal electronic health data should be without prejudice to the rights of access and portability as established under Regulation (EU) 2016/679. Natural persons continue to have those rights under the conditions set out in that regulation-of the legal ground for their processing.	
	Recita	17			
17					

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
(7) In health systems,	(7) In health systems,	(7) In health systems,	
personal electronic health	personal electronic health	personal electronic health	
data is usually gathered in	data is usually gathered in	data is usually gathered in	
electronic health records,	electronic health records,	electronic health records,	
which typically contain a	which typically contain a	which typically contain a	
natural person's medical	natural person's medical	natural person's medical	
history, diagnoses and	history, diagnoses and	history, diagnoses and	
treatment, medications,	treatment, medications,	treatment, medications,	
allergies, immunisations, as	allergies, immunisations, as	allergies, immunisations, as	
well as radiology images	well as radiology images	well as radiology images	
and laboratory results,	and laboratory results, and	and laboratory results,	
spread between different	other complementary	spread between different	
entities from the health	diagnosis and therapeutics	entities from the health	
system (general	<u>results</u> , spread between	system (general	
practitioners, hospitals,	different entities from the	practitioners, hospitals,	
pharmacies, care services).	health system (general	pharmacies, care services).	
In order to enable that	practitioners, hospitals,	In order to enable that	
electronic health data to be	pharmacies, care services).	electronic health data to be	
accessed, shared and	In order to enable that	accessed, shared and	
changed by the natural	electronic health data to be	changed by the natural	
persons or health	accessed, shared and	persons or health	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
professionals, some	changed by the natural	professionals, some	
Member States have taken	persons or health	Member States have taken	
the necessary legal and	professionals, some	the necessary legal and	
technical measures and set	Member States have taken	technical measures and set	
up centralised	the necessary legal and	up centralised	
infrastructures connecting	technical measures and set	infrastructures connecting	
EHR systems used by	up centralised	EHR systems used by	
healthcare providers and	infrastructures connecting	healthcare providers and	
natural persons.	EHR systems used by	natural persons.	
Alternatively, some	healthcare providers and	Alternatively, some	
Member States support	natural persons.	Member States support	
public and private	Alternatively, some	public and private	
healthcare providers to set	Member States support	healthcare providers to set	
up personal health data	public and private	up personal health data	
spaces to enable	healthcare providers to set	spaces to enable	
interoperability between	up personal health data	interoperability between	
different healthcare	spaces to enable	different healthcare	
providers. Several Member	interoperability between	providers. Several Member	
States have also supported	different healthcare	States have also supported	
or provided health data	providers. Several Member	or provided health data	
access services for patients	States have also supported	access services for patients	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
and health professionals	or provided health data	and health professionals (for	
(for instance through	access services for patients	instance through patients or	
patients or health	and health professionals (for	health professional portals).	
professional portals). They	instance through patients or	They have also taken	
have also taken measures to	health professional portals).	measures to ensure that	
ensure that EHR systems or	They have also taken	EHR systems or wellness	
wellness applications are	measures to ensure that	applications are able to	
able to transmit electronic	EHR systems or wellness	transmit electronic health	
health data with the central	applications are able to	data with the central EHR	
EHR system (some	transmit electronic health	system (some Member	
Member States do this by	data with the central EHR	States do this by ensuring,	
ensuring, for instance, a	system (some Member	for instance, a system of	
system of certification).	States do this by ensuring,	certification). However, not	
However, not all Member	for instance, a system of	all Member States have put	
States have put in place	certification). However, not	in place such systems, and	
such systems, and the	all Member States have put	the Member States that have	
Member States that have	in place such systems, and	implemented them have	
implemented them have	the Member States that have	done so in a fragmented	
done so in a fragmented	implemented them have	manner. In order to	
manner. In order to	done so in a fragmented	facilitate the free movement	
facilitate the free movement	manner. In order to	of personal health data	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
of personal health data	facilitate the free movement	across the Union and avoid	
across the Union and avoid	of personal health data	negative consequences for	
negative consequences for	across the Union and avoid	patients when receiving	
patients when receiving	negative consequences for	healthcare in cross-border	
healthcare in cross-border	patients when receiving	context, Union action is	
context, Union action is	healthcare in cross-border	needed in order to ensure	
needed in order to ensure	context, Union action is	individuals have improved	
individuals have improved	needed in order to ensure	acessaccess to their own	
acess to their own personal	individuals have improved	personal electronic health	
electronic health data and	acessaccess to their own	data and are empowered to	
are empowered to share it.	personal electronic health	share it.	
	data and are empowered to		
	share it. <u>To that end</u> ,		
	Member States should		
	<u>ensure a common standard</u>		
	<u>is in place for the exchange</u>		
	<u>of electronic health data to</u>		
	<u>ensure and facilitate its</u>		
	transfer and translation		
	into the Union's official		
	languages. In this respect,		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			appropriate funding and support at Union and national level should be fairly distributed and considered as a means of reducing fragmentation, heterogeneity, and division and to achieve a system that is user-friendly and intuitive in all Member States.		
	Recita	18			
18	 (8) The right of access to data by a natural person, established by Article 15 of Regulation (EU) 2016/679, 		 (8) The right of access to data by a natural person, established by Article 15 of Regulation (EU) 2016/679, 	 (8) The right of access to data by a natural person, established by Article 15 of Regulation (EU) 2016/679, 	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
should be further developed	should be further developed	should be further-developed	
in the health sector. Under	in the health sector. Under	complemented in the health	
Regulation (EU) 2016/679,	Regulation (EU) 2016/679,	sector. Under Regulation	
controllers do not have to	controllers do not have to	(EU) 2016/679, controllers	
provide access	provide access immediately.	do not have to provide	
immediately. While patient	While patient portals,	access immediately. While	
portals, mobile applications	mobile applications and	patient portals, mobile	
and other personal health	other personal health data	applications and other	
data access services exist in	access services exist in	personal health data access	
many places, including	many places, including	services exist in many	
national solutions in some	national solutions in some	places, including national	
Member States, the right of	Member States, the right of	solutions in some Member	
access to health data is still	access to health data is still	States, the right of access to	
commonly implemented in	commonly implemented in	health data is still	
many places through the	many places through the	commonly implemented in	
provision of the requested	provision of the requested	many places through the	
health data in paper format	health data in paper format	provision of the requested	
or as scanned documents,	or as scanned documents,	health data in paper format	
which is time-consuming.	which is time-consuming.	or as scanned documents,	
This may severely impair	This may severely impair	which is time-consuming	
timely access to health data	timely access to health data	for the controller, such as	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
by natural persons, and may	by natural persons, and may	a hospital or other	
have a negative impact on	have a negative impact on	healthcare provider	
natural persons who need	natural persons who need	providing access. This	
such access immediately	such access immediately	slows down . This may	
due to urgent circumstances	due to urgent circumstances	severely impair timely	
pertaining to their health	pertaining to their health	access to health data by	
condition.	condition.	natural persons, and may	
		have a negative impact on	
		natural persons whoif they	
		need such access	
		immediately due to urgent	
		circumstances pertaining to	
		their health condition. For	
		that reason, it is necessary	
		to provide a more efficient	
		way for natural persons to	
		access their own personal	
		electronic health data.	
		They should have the	
		right to have free of	
		charge, immediate access,	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		adhering to technological	
		practicability, to certain	
		defined priority categories	
		of personal electronic	
		health data, such as the	
		patient summary, through	
		an electronic health data	
		access service. The scope	
		of this complementary	
		right established under	
		this Regulation and the	
		conditions for exercising it	
		differ in certain ways	
		from the right of access	
		under Article 15 of	
		Regulation (EU) 2016/679.	
		The latter covers all	
		personal data held by a	
		controller and is exercised	
		against an individual	
		controller, which then has	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				up to a month to reply to a request. The right to access personal electronic health data under this Regulation is limited to the categories of data falling within its scope, is exercised via an electronic health data access service, and provides an immediate answer. {Article 8A}	
	Recital	9			
19	(9) At the same time, it		(9) At the same time, it	(9) At the same time, it	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
should be considered that	should be considered that	should be considered that	
immediate access to certain	immediate access of	immediate access to certain	
types of personal electronic	natural persons to certain	types of personal electronic	
health data may be harmful	types of <u>their</u> personal	health data may be harmful	
for the safety of natural	electronic health data may	for the safety of natural	
persons, unethical or	be harmful for the safety of	persons , or unethical or	
inappropriate. For example,	natural persons, unethical or	inappropriate. For example,	
it could be unethical to	inappropriate. For example,	it could be unethical to	
inform a patient through an	it could be unethical to	inform a patient through an	
electronic channel about a	inform a patient through an	electronic channel about a	
diagnosis with an incurable	electronic channel about a	diagnosis with an incurable	
disease that is likely to lead	diagnosis with an incurable	disease that is likely to lead	
to their swift passing	disease that is likely to lead	to their swift passing	
instead of providing this	to their swift passing	instead of providing this	
information in a	instead of providing this	information in a	
consultation with the	information in a	consultation with the patient	
patient first. Therefore, a	consultation with the patient	first. Therefore, a possibility	
possibility for limited	first. Therefore, a possibility	for limited exceptions in the	
exceptions in the	for limited exceptions in the	implementationit should be	
implementation of this right	implementation of this right	possible to delay the	
should be ensured. Such an	should be ensured. Such an	provision of this right	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
exception may be imposed	exception may be imposed	should be ensured. Such an	
by the Member States	by the Member States	exception may be imposed	
where this exception	where this exception	by theaccess in such	
constitutes a necessary and	constitutes a necessary and	situations for a limited	
proportionate measure in a	proportionate measure in a	amount of time. Member	
democratic society, in line	democratic society, in line	States where thisshould be	
with the requirements of	with the requirements of	able to define such an	
Article 23 of Regulation	Article 23 of Regulation	exception where it	
(EU) 2016/679. Such	(EU) 2016/679. Such	constitutes a necessary and	
restrictions should be	restrictions should be	proportionate measure in a	
implemented by delaying	implemented by delaying	democratic society, in line	
the display of the concerned	the display of the concerned	with the requirements of	
personal electronic health	personal electronic health	Article 23 of Regulation	
data to the natural person	data to the natural person	(EU) 2016/679Such	
for a limited period. Where	for a limited period. Where	restrictions should be	
health data is only available	health data is only available	implemented by delaying	
on paper, if the effort to	on paper, if the effort to	the display of the concerned	
make data available	make data available	personal electronic health	
electronically is	electronically is	data to the natural person	
disproportionate, there	disproportionate, there <mark>, for</mark>	for a limited period. Where	
should be no obligation that	instance until the moment	health data is only available	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
such health data is	where the patient and the	on paper, if the effort to	
converted into electronic	health professional get in	make data available	
format by Member States.	contact. Member States	electronically is	
Any digital transformation	should be no obligation that	disproportionate, there	
in the healthcare sector	<mark>such</mark> encouraged to require	should be no obligation that	
should aim to be inclusive	<u>that</u> health data <mark>is</mark> available	such health data is	
and benefit also natural	prior to the implementation	converted into electronic	
persons with limited ability	of this Regulation be	format by Member States.	
to access and use digital	converted into an electronic	Any digital transformation	
services. Natural persons	format <i>through a process</i>	in the healthcare sector	
should be able to provide an	facilitated by Member	should aim to be inclusive	
authorisation to the natural	States. Any digital	and benefit also natural	
persons of their choice,	transformation in the	persons with limited ability	
such as to their relatives or	healthcare sector should aim	to access and use digital	
other close natural persons,	to be inclusive and benefit	services. Natural persons	
enabling them to access or	also natural persons with	should be able to provide an	
control access to their	limited ability to access and	authorisation to the natural	
personal electronic health	use digital services. Natural	persons of their choice, such	
data or to use digital health	persons should be able to	as to their relatives or other	
services on their behalf.	provide an authorisation to	close natural persons,	
Such authorisations may	the natural persons of their	enabling them to access or	

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also be useful for	choice, such as to their	control access to their	
convenience reasons in	relatives or other close	personal electronic health	
other situations. Proxy	natural persons, enabling	data or to use digital health	
services should be	them to access or control	services on their behalf.	
established by Member	access to their personal	Such authorisations may	
States to implement these	electronic health data or to	also be useful for	
authorisations, and they	use digital health services	convenience reasons in	
should be linked to personal	on their behalf. Such	other situations. Proxy	
health data access services,	authorisations may also be	services should be	
such as patient portals on	useful for convenience	established by Member	
patient-facing mobile	reasons in other situations.	States to implement these	
applications. The proxy	Proxy services should be	authorisations, and they	
services should also enable	established by Member	should be linked to personal	
guardians to act on behalf	States to implement these	health data access services,	
of their dependent children;	authorisations, and they	such as patient portals on	
in such situations,	should be linked to personal	patient-facing mobile	
authorisations could be	health data access services,	applications. The proxy	
automatic. In order to take	such as patient portals on	services should also enable	
into account cases in which	patient-facing mobile	guardians to act on behalf of	
the display of some	applications. The proxy	their dependent children; in	
personal electronic health	services should also enable	such situations,	

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data of minors to their	guardians to act on behalf of	authorisations could be	
guardians could be contrary	their dependent children; in	automatic. In order to take	
to the interests or will of the	such situations,	into account cases in which	
minor, Member States	authorisations could be	the display of some	
should be able to provide	automatic. In order to take	personal electronic health	
for such limitations and	into account cases in which	data of minors to their	
safeguards in national law,	the display of some	guardians could be contrary	
as well as the necessary	personal electronic health	to the interests or will of the	
technical implementation.	data of minors to their	minor, Member States	
Personal health data access	guardians could be contrary	should be able to provide	
services, such as patient	to the interests or will of the	for such limitations and	
portals or mobile	minor, Member States	safeguards in national law,	
applications, should make	should be able to provide	as well as the necessary	
use of such authorisations	for such limitations and	technical implementation.	
and thus enable authorised	safeguards in national law,	Personal health data access	
natural persons to access	as well as the necessary	services, such as patient	
personal electronic health	technical implementation.	portals or mobile	
data falling within the remit	Personal health data access	applications, should make	
of the authorisation, in	services, such as patient	use of such authorisations	
order for them to produce	portals or mobile	and thus enable authorised	
the desired effect.	applications, should make	natural persons to access	

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			use of such authorisations and thus enable authorised natural persons to access personal electronic health data falling within the remit of the authorisation, in order for them to produce the desired effect.	<pre>personal electronic health data falling within the remit of the authorisation, in order for them to produce the desired effect. {Article 8A(3)} [[MOVED TO RECITAL 15B]]</pre>	
	Recital	10			
20	(10) Some Member States allow natural persons to add		(10) Some Member States allow natural persons to add	(10) Some Member States allow natural persons to add	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
electronic health data to	electronic health data to	electronic health data to	
their EHRs or to store	their EHRs or to store	their EHRs or to store	
additional information in	additional information in	additional information in	
their separate personal	their separate personal	their separate personal	
health record that can be	health record that can be	health record that can be	
accessed by health	accessed by health	accessed by health	
professionals. However,	professionals. However, this	professionals, to	
this is not a common	is not a common practice in	complement the	
practice in all Member	all Member States and	information available to	
States and therefore should	therefore should be	them. However, this is not	
be established by the EHDS	established by the EHDS	a common practice in all	
across the EU. Information	across the EU. Information	Member States and	
inserted by natural persons	inserted by natural persons	therefore should be	
may not be as reliable as	may not be as reliable as	established by the EHDS	
electronic health data	electronic health data	across the EUleft to	
entered and verified by	entered and verified by	Member States.	
health professionals,	health professionals and	Information inserted by	
therefore it should be	does not have the same	natural persons may not be	
clearly marked to indicate	clinical or legal value as	as reliable as electronic	
the source of such	information provided by a	health data entered and	
additional data. Enabling	<u>health professional</u> ,	verified by health	

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natural persons to more	therefore it should be	professionals , . Therefore,	
easily and quickly access	clearly marked to indicate	where Member States	
their electronic health data	the source of such	provide for this right, it	
also further enables them to	additional data and should	should be clearly	
notice possible errors such	<u>be validated only by a</u>	distinguishable from data	
as incorrect information or	health professional. More	provided by it should be	
incorrectly attributed	<u>specifically, relevant fields</u>	clearly marked to indicate	
patient records and have	<u>in the EHR should be</u>	the source of such	
them rectified using their	<u>clearly marked</u> . Enabling	additional data. Enabling	
rights under Regulation	natural persons to more	natural persons to more	
(EU) 2016/679. In such	easily and quickly access	easily and quickly access	
cases, natural person should	their electronic health data	their electronic health data	
be enabled to request	also further enables them to	also further enables them to	
rectification of the incorrect	notice possible errors such	notice possible errors such	
electronic health data	as incorrect information or	as incorrect information or	
online, immediately and	incorrectly attributed patient	incorrectly attributed patient	
free of charge, for example	records and have them	records and have them	
through the personal health	rectified using their rights	rectified using their rights	
data access service. Data	under Regulation (EU)	under Regulation (EU)	
rectification requests should	2016/679. In such cases,	2016/679. In such	
be assessed and, where	natural person should be	cases, professionals. This	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
relevant, implemented by	enabled to request	possibility for natural	
the data controllers on case	rectification of the incorrect	person should be enabled to	
by case basis, if necessary	electronic health data	request rectification of the	
involving health	online, immediately and	incorrectpersons to add	
professionals.	free of charge, for example	and complement personal	
	through the personal health	electronic health data	
	data access service. Data	online, immediately and	
	rectification requests should	free of charge, for example	
	be assessed and, where	through the personalshould	
	relevant, implemented by	not entitle them to change	
	the data controllers on case	personal electronic health	
	by case basis, if necessary	data access service. Data	
	involving health	rectification requests should	
	professionals, with a	be assessed and, where	
	relevant specialisation,	relevant, implemented by	
	responsible for the natural	the data controllers on case	
	<u>person's treatment</u> .	by case basis, if necessary	
		involving provided by	
		health professionals.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				{Article 8B} [[PART OF RECITAL (10) MOVED TO RECITAL (10A)]]	
	Recital	10a	L		
20a				(10a) Enabling natural persons to more easily and quickly access their personal electronic health data also further enables them to notice possible errors such as incorrect information or incorrectly	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		attributed patient records.	
		In such cases, natural	
		persons should be enabled	
		to request rectification of	
		the incorrect electronic	
		health data online,	
		immediately and free of	
		charge, for example	
		through a personal health	
		data access service. Such	
		rectification requests	
		should then be treated by	
		the relevant data	
		controllers in line with	
		Regulation (EU) 2016/679.	
		In this situation, the	
		health data access service	
		forwards the request for	
		rectification under	
		Regulation (EU) 2016/679	
		to the competent	

Commission P	roposal	EP Mandate	Council Mandate	Draft Agreement
			controller. This facilitates	
			the exercise of this right	
			for the natural person,	
			who can submit requests	
			through the health data	
			access service instead of	
			contacting controllers	
			individually. It also helps	
			the controller, who will	
			receive assurance that the	
			requester is in fact the	
			data subject, as the	
			requester will be reliably	
			identified and	
			authenticated by the	
			health data access service.	
			To further facilitate the	
			exercise of existing data	
			subject rights under	
			Regulation (EU) 2016/679,	
			Member States may also	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				provide possibilities to submit requests to exercise them through their health data access services, complementing the possibility to contact the controller directly.	
	Recita	11			
21	(11) Natural personsshould be furtherempowered to exchangeand to provide access topersonal electronic health		(11) Natural persons should be further empowered to exchange and to provide access to personal electronic health data to the health	(11) Natural persons should be further empowered to exchange and to provide access to personal electronic health data to the health	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
data to the health	professionals of their	professionals of their	
professionals of their	choice, going beyond the	choice, going beyond and	
choice, going beyond the	right to data portability as	complementing the right to	
right to data portability as	established in Article 20 of	data portability as	
established in Article 20 of	Regulation (EU) 2016/679	established in Article 20 of	
Regulation (EU) 2016/679.	and to download their	Regulation (EU) 2016/679.	
This is necessary to tackle	<u>health data</u> . This is	This is necessary to tackle	
objective difficulties and	necessary to tackle	objective difficulties and	
obstacles in the current state	objective difficulties and	obstacles in the current state	
of play. Under Regulation	obstacles in the current state	of play. Under Regulation	
(EU) 2016/679, portability	of play. Under Regulation	(EU) 2016/679, portability	
is limited only to data	(EU) 2016/679, portability	is limited only to data	
processed based on consent	is limited only to data	processed based on consent	
or contract, which excludes	processed based on consent	or contract,- which	
data processed under other	or contract, which excludes	excludes data processed	
legal bases, such as when	data processed under other	under other legal bases,	
the processing is based on	legal bases, such as when	such as when the processing	
law, for example when their	the processing is based on	is based on law, for	
processing is necessary for	law, for example when their	example when their	
the performance of a task	processing is necessary for	processing is necessary for	
carried out in the public	the performance of a task	the performance of a task	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
interest or in the exercise of	carried out in the public	carried out in the public	
official authority vested in	interest or in the exercise of	interest or in the exercise of	
the controller. It only	official authority vested in	official authority vested in	
concerns data provided by	the controller. It only	the controller. It only	
the data subject to a	concerns data provided by	concerns datawere provided	
controller, excluding many	the data subject to a	by the data subject to a	
inferred or indirect data,	controller, excluding many	controller, excluding many	
such as diagnoses, or tests.	inferred or indirect data,	inferred or indirect data,	
Finally, under Regulation	such as diagnoses, or tests.	such as diagnoses, or tests.	
(EU) 2016/679, the natural	Finally, under Regulation	Finally, under Regulation	
person has the right to have	(EU) 2016/679, the natural	(EU) 2016/679, the natural	
the personal data	person has the right to have	person has the right to have	
transmitted directly from	the personal data	the personal data	
one controller to another	transmitted directly from	transmitted directly from	
only where technically	one controller to another	one controller to another	
feasible. That Regulation,	only where technically	only where technically	
however, does not impose	feasible. That Regulation,	feasible. That Regulation,	
an obligation to make this	however, does not impose	however, does not impose	
direct transmission	an obligation to make this	an obligation to make this	
technically feasible. All	direct transmission	direct transmission	
these elements limit the	technically feasible. All	technically feasible. All	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	data portability and may		these elements limit the data	these elements limit the data	
	limit its benefits for		portability and may limit its	portability and may limit its	
	provision of high-quality,		benefits for provision of	benefits for provision of	
	safe and efficient healthcare		high-quality, safe and	high-quality, safe and	
	services to the natural		efficient healthcare services	efficient healthcare services	
	person.		to the natural person.	to the natural person.	
				{Article 8D} [[RECITAL (11) MERGED WITH RECITAL (12)]]	
	Recital	12			
22					
	(12) Natural persons		(12) Natural persons should	(12) Natural persons should	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
should be able to exercise	be able to exercise control	be able to exercise control	
control over the	over the transmission of	over the transmission of	
transmission of personal	personal electronic health	personal electronic health	
electronic health data to	data to other healthcare	data to other healthcare	
other healthcare providers.	providers. Healthcare	providers. Healthcare	
Healthcare providers and	providers and other	providers and other	
other organisations	organisations providing	organisations providing	
providing EHRs should	EHRs should facilitate the	EHRs should facilitate the	
facilitate the exercise of this	exercise of this right.	exercise of this right.	
right. Stakeholders such as	Stakeholders such as	Stakeholders such as	
healthcare providers, digital	healthcare providers, digital	healthcare providers, digital	
health service providers,	health service providers,	health service providers,	
manufacturers of EHR	manufacturers of EHR	manufacturers of EHR	
systems or medical devices	systems or medical devices	systems or medical devices	
should not limit or block	should not limit or block the	should not limit or block the	
the exercise of the right of	exercise of the right of	exercise of the right of	
portability because of the	portability because of the	portability because of the	
use of proprietary standards	use of proprietary standards	use of proprietary standards	
or other measures taken to	or other measures taken to	or other measures taken to	
limit the portability. For	limit the portability. In	limit the portability. For	
these reasons, the	accordance with	these reasons, the	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
framework laid down by	Regulation (EU) 2016/679,	framework laid down by	
this Regulation builds on	<u>healthcare providers</u>	this Regulation-builds on	
the right to data portability	should follow the data	extends the right to data	
established in Regulation	minimisation principle	portability established in	
(EU) 2016/679 by ensuring	when accessing personal	Regulation (EU) 2016/679	
that natural persons as data	health data, limiting the	by ensuring that natural	
subjects can transmit their	data accessed to data that	persons as data subjects can	
electronic health data,	are strictly necessary and	transmit their electronic	
including inferred data,	justified for a given service.	health data, including	
irrespective of the legal	For these reasons, the	inferred data in the	
basis for processing the	framework laid down by	European electronic	
electronic health data. This	this Regulation builds on	health record exchange	
right should apply to	the right to data portability	format, irrespective of the	
electronic health data	established in Regulation	legal basis for processing	
processed by public or	(EU) 2016/679 by ensuring	the electronic health data.	
private controllers,	that natural persons as data	Health professionals-This	
irrespective of the legal	subjects can transmit their	right should apply to	
basis for processing the data	electronic health data,	electronic health data	
under in accordance with	including inferred data,	processed by public or	
the Regulation (EU)	irrespective of the legal	private controllers,	
2016/679. This right should	basis for processing the	irrespective of the legal	

Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
apply to all electronic health data.		electronic health data. This right should apply to electronic health data processed by public or private controllers, irrespective of the legal basis for processing the data under in accordance with the Regulation (EU) 2016/679. This right should apply to all electronic health data.	basis for processing the data under in accordance with the Regulation (EU) 2016/679. This right should apply to all refrain from hindering the implementation of the rights of natural persons, such as refusing to take into account electronic health data originating from another Member State and provided in the interoperable and reliable European electronic health datarecord exchange format.	
Recita	al 12a			

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
22a			(12a) Moreover, the access to personal health records should be transparent to natural persons. The health data access services should provide detailed information on accesses to data, such as when and which healthcare providers or other individuals accessed which data. To ensure uniform implementation, the Commission should be empowered to lay down detailed elements in an implementing act.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				{Article 8E, transparency part}	
	Recita	13			
23	(13) Natural persons may not want to allow access to some parts of their personal electronic health data while enabling access to other parts. Such selective sharing of personal electronic health data should be supported. However, such restrictions may have life threatening		 (13) Natural persons may not want to allow access to some parts of their personal electronic health data while enabling access to other parts. Such selective sharing of personal electronic health data should be supported. However, <i>natural persons</i> <i>should be informed of the</i> <i>patient safety risks</i> 	 (13) Natural persons may not want to allow access to some parts of their personal electronic health data while enabling access to other parts. Such selective sharing of personal electronic health data should be supported. However, such restrictions may have life threatening consequences and, 	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
consequences and,	associated with limiting	therefore, access to personal	
therefore, access to personal	access to health data.	electronic health data	
electronic health data	However, such restrictions	should be possible to	
should be possible to	may have life threatening	protect vital interests as an	
protect vital interests as an	consequences and,	emergency override.	
emergency override.	therefore, access to personal	According to Regulation	
According to Regulation	electronic health data	(EU) 2016/679, vital	
(EU) 2016/679, vital	should be possible to	interests refer to situations	
interests refer to situations	protect vital interests as an	in which it is necessary to	
in which it is necessary to	emergency override.	protect an interest which is	
protect an interest which is	According to Regulation	essential for the life of the	
essential for the life of the	(EU) 2016/679, vital	data subject or that of	
data subject or that of	interests refer to situations	another natural person.	
another natural person.	in which it is necessary to	Processing of personal	
Processing of personal	protect an interest which is	electronic health data based	
electronic health data based	essential for the life of the	on the vital interest of	
on the vital interest of	data subject or that of	another natural person	
another natural person	another natural person.	should in principle take	
should in principle take	Processing of personal	place only where the	
place only where the	electronic health data based	processing cannot be	
processing cannot be	on the vital interest of	manifestly based on another	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
manifestly based on another	another natural person	legal basis. More specific	
legal basis. More specific	should in principle take	legal provisions on the	
legal provisions on the	place only where the	mechanisms of restrictions	
mechanisms of restrictions	processing cannot be	placed by the natural person	
placed by the natural person	manifestly based on another	on parts of their personal	
on parts of their personal	legal basis. More specific	electronic health data	
electronic health data	legal provisions on the	shouldmay be provided by	
should be provided by	mechanisms of restrictions	Member States in national	
Member States in national	placed by the natural person	law. In particular, this	
law. Because the	on parts of their personal	right may be restricted in	
unavailability of the	electronic health data	a justified and	
restricted personal	should be provided by	proportionate manner, for	
electronic health data may	Member States in national	purposes such as the	
impact the provision or	law . , <i>in particular as</i>	preservation of public	
quality of health services	regards medical liability in	health in the case of highly	
provided to the natural	the event that restrictions	contagious and hazardous	
person, he/she should	have been placed by the	diseases. Because the	
assume responsibility for	natural person, Because the	unavailability of the	
the fact that the healthcare	unavailability of the	restricted personal	
provider cannot take the	restricted personal	electronic health data may	
data into account when	electronic health data may	impact the provision or	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	providing health services.		impact the provision or quality of health services provided to the natural person, he/she should assume responsibility for the fact that the healthcare provider cannot take the data into account when providing health services.	quality of health services provided to the natural person, he/she they should assume responsibility for the fact that the healthcare provider cannot take the data into account when providing health services. Article 8E, restriction part + Article 7A(3)}	
	Recital	13a			
23a				(13a) In addition, due to the different sensitivities	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		in the Member States on	
		the degree of patients'	
		control over their health	
		data, Member States	
		should be able to provide	
		for an absolute right to	
		object without an	
		emergency override, both	
		for cross-border access	
		and for access internal to	
		that Member State. If they	
		choose to do so, they	
		should establish the rules	
		and specific safeguards	
		regarding such	
		mechanisms. Such rules	
		and specific safeguards	
		may also relate to specific	
		categories of personal	
		electronic health data, for	
		example genetic data.	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		Such a right to object	
		means that personal	
		electronic health data	
		relating to the persons	
		who made use of it would	
		not be made available	
		through the services set up	
		under the EHDS beyond	
		the healthcare provider	
		that provided the	
		treatment. If a natural	
		person has exercised this	
		right to object healthcare	
		providers will still	
		document treatment	
		provided in accordance	
		with the applicable rules,	
		and will be able to access	
		the data registered by	
		them. Natural persons	
		who made use of such a	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				right to object should be able to reverse their decision. Should they do so, personal electronic health data generated during the period of the objection might not be available via the access services and MyHealth@EU.	
	Recita	14			
24	(14) In the context of the EHDS, natural persons		(14) In the context of the EHDS, natural persons	(14) In the context of the EHDS, natural persons	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
should be able to exercise	should be able to exercise	should be able to exercise	
their rights as they are	their rights as they are	their rights as they are	
enshrined in Regulation	enshrined in<mark>under this</mark>	enshrined in Regulation	
(EU) 2016/679. The	Regulation without	(EU) 2016/679. The	
supervisory authorities	prejudice to Regulation	supervisory authorities	
established pursuant to	(EU) 2016/679. The	established pursuant to	
Article 51 of Regulation	supervisory authorities	Article 51 of Regulation	
(EU) 2016/679 should	established pursuant to	(EU) 2016/679 should	
remain competent, in	Article 51 of Regulation	remain competent, in	
particular to monitor the	(EU) 2016/679 should	particular to monitor the	
processing of personal	remain competent, in	processing of personal	
electronic health data and to	particular to monitor the	electronic health data and to	
address any complaints	processing of personal	address any complaints	
lodged by the natural	electronic health data and to	lodged by the natural	
persons. In order to carry	address any complaints	persons. In order to carry	
out their tasks in the health	lodged by the natural	out their tasks in the health	
sector and uphold the	persons. In order to carry	sector and uphold the	
natural persons' rights,	out their tasks in the health	natural persons' rights,	
digital health authorities	sector and uphold the	digital health authorities	
should cooperate with the	natural persons' rights,	should cooperate with the	
supervisory authorities	digital health authorities	supervisory authorities	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	under Regulation (EU) 2016/679.	should cooperate with the supervisory authorities under Regulation (EU) 2016/679.	under Regulation (EU) 2016/679. [[MOVED TO RECITAL (16A)]]	
	Recital 15			
25	 (15) Article 9(2), point (h), of Regulation (EU) 2016/679 provides for exceptions where the processing of senstitive data is necessary for the purposes of preventive or occupational medicine, for 	 (15) Article 9(2), point (h), of Regulation (EU) 2016/679 provides for exceptions where the processing of <i>senstitivesensitive</i> data is necessary for the purposes of preventive or 	(15) Article 9(2), point (h), of Regulation (EU) 2016/679 provides for exceptions where the processing of senstitive data is necessary for the purposes of preventive or occupational medicine, for	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
the assessment of the	occupational medicine, for	the assessment of the	
working capacity of the	the assessment of the	working capacity of the	
employee, medical	working capacity of the	employee, Timely and full	
diagnosis, the provision of	employee, medical	access of health	
health care or treatment or	diagnosis, the provision of	professionals to the	
the management of health	health care or treatment or	medical records of	
care systems and services	the management of health	patients is fundamental	
on the basis of Union or	care systems and services	for ensuring continuity of	
Member State law. This	on the basis of Union or	care and avoiding	
Regulation should provide	Member State law. This	duplications and errors.	
conditions and safeguards	Regulation should provide	However, due to a lack of	
for the processing of	conditions and safeguards	interoperability, in many	
electronic health data by	for the processing of	cases, health professionals	
healthcare providers and	electronic health data by	cannot access the complete	
health professionals in line	healthcare providers and	medical records of their	
with Article 9(2), point (h),	health professionals in line	patients and cannot make	
of Regulation (EU)	with Article 9(2), point (h),	optimal medical decisions	
2016/679 with the purpose	of Regulation (EU)	for their diagnosis and	
of accessing personal	2016/679 with the purpose	treatment, which adds	
electronic health data	of accessing personal	considerable costs for	
provided by the natural	electronic health data	both, the provision of	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
person or transmitted from	provided by the natural	health care or treatment or	
other healthcare providers.	person or transmitted from	the management of systems	
However, this Regulation	other healthcare providers.	and natural persons and	
should be without prejudice	However, this Regulation	may lead to worse health	
to the national laws	should be without prejudice	outcomes for natural	
concerning the processing	to the national laws	persons. Electronic health	
of health data, including the	concerning the processing	data made available in	
legislation establishing	of health data <u>outside the</u>	interoperable format,	
categories of health	scope of this Regulation,	which can be transmitted	
professionals that can	including for other	between healthcare	
process different categories	secondary use purposes	providers can also reduce	
of electronic health data.	<u>established by this</u>	the administrative burden	
	Regulation , including the	on health professionals of	
	legislation establishing	manually entering or	
	categories of health	copying health care data	
	professionals that can	between electronic	
	process different categories	systems. Therefore, health	
	of electronic health data.	professionals should be	
		provided with appropriate	
		electronic means, such as	
		health professional portals	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		or other health	
		professional access and	
		services, to use personal	
		electronic health data for	
		the exercise of their duties.	
		Providing this service to	
		health professionals is a	
		task in the public interest	
		assigned by-on the basis of	
		Union or Member State	
		law. this Regulation should	
		provide whose performance	
		requires the processing of	
		personal data in the sense	
		of Article 6(1)(e) of	
		Regulation (EU) 2016/679.	
		This Regulation provides	
		conditions and safeguards	
		for the processing of	
		electronic health data by	
		healthcare providers and	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		health professionalsin the	
		health professional access	
		service in line with Article	
		9(2), point (h) , of	
		Regulation (EU) 2016/679	
		with the purpose of	
		accessing personal	
		electronic health data	
		provided by the natural	
		person or transmitted from	
		other healthcare providers,	
		such as detailed provisions	
		on logging to provide	
		transparency towards	
		data subjects. However,	
		this Regulation should be	
		without prejudice to the	
		national laws concerning	
		the processing of health	
		data for the delivery of	
		healthcare, including the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				legislation establishing categories of health professionals that can process different categories of electronic health data. {Article 7B}	
	Recita	l 15a			
25a				(15aa) In accordance with the general principles of European Union law, which include the fundamental rights guaranteed by Articles 7 and 8 of the Charter, a	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		particular high level of	
		protection and security	
		should be ensured when	
		processing personal	
		electronic health data for	
		primary use, by means of	
		appropriate technical and	
		organisational measures.	
		In this respect, this	
		Regulation is without	
		prejudice to a	
		requirement under	
		national law, with regards	
		to the national context,	
		according to which, where	
		personal electronic health	
		data are processed by	
		healthcare providers for	
		the provision of	
		healthcare or by the	
		national contact point for	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			digital health connected to MyHealth@EU, the storage of personal electronic health data referred to in Article 5 for the purpose of primary use is located within the European Union in line with Union law and international commitments"	
	Recital 15b			
25b			(15a) In order to facilitate the exercise of the complementary access and portability rights	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		established under this	
		Regulation, Member	
		States should establish one	
		or more electronic health	
		data access services. These	
		services may be provided	
		as an online patient	
		portal, via a mobile	
		application or other	
		means. They should be	
		designed in an accessible	
		way, including for persons	
		with disabilities. Proving	
		such a service to enable	
		natural persons with easy	
		access to their personal	
		electronic health data is a	
		substantial public interest.	
		The processing of	
		personal electronic health	
		data in these services is	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				necessary for the performance of that task assigned by this Regulation in the sense of Articles 6(1)(e) and 9(2) of Regulation (EU) 2016/679. {Article 8G(1)}	
	Recita	15c	_		
25c				(15b) Natural persons should be able to provide an authorisation to the natural persons of their choice, such as to their relatives or other close	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		natural persons, enabling	
		them to access or control	
		access to their personal	
		electronic health data or	
		to use digital health	
		services on their behalf.	
		Such authorisations may	
		also be useful for	
		convenience reasons in	
		other situations. Proxy	
		services for enabling such	
		authorisations should be	
		established by Member	
		States to implement these	
		authorisations, and they	
		should be linked to	
		personal health data	
		access services, such as	
		patient portals or patient-	
		facing mobile	
		applications. The proxy	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		services should also enable	
		guardians to act on behalf	
		of their dependent	
		children; in such	
		situations, authorisations	
		could be automatic. In	
		order to take into account	
		cases in which the display	
		of some personal	
		electronic health data of	
		minors to their guardians	
		could be contrary to the	
		interests or the will of the	
		minor, Member States	
		should be able to provide	
		for such limitations and	
		safeguards in national	
		law, as well as the	
		necessary technical	
		implementation. Personal	
		health data access	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		services, such as patient	
		portals or mobile	
		applications, should make	
		use of such authorisations	
		and thus enable	
		authorised natural	
		persons to access personal	
		electronic health data	
		falling within the remit of	
		the authorisation, in order	
		for them to produce the	
		desired effect. Digital	
		proxy solutions should be	
		aligned with Regulation	
		[] [eID regulation	
		COM/2021/281 final] and	
		the technical specifications	
		of the European Digital	
		Identity Wallet to ensure a	
		horizontal solution with	
		increased user-	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		friendliness. This should	
		contribute to reduce both	
		administrative and	
		financial burdens for	
		Member States by	
		lowering the risk of	
		developing parallel	
		systems that are not	
		interoperable across the	
		Union.	
		{Article 8G(2) and (3)}	
		[[MOVED FROM RECITAL	
		(9) AND AMMENDED]]	

	Commission Propo	osal	EP Mandate	Council Mandate	Draft Agreement
	F	Recital 15d			
25d				(15c) In some Member States, health care is provided by primary care management teams, defined as groups of healthcare professionals centred on primary care (general practitioners), who carry out their primary care activities based on a healthcare plan drawn up by them. Also, other types of healthcare teams exist in several Member States for other care purposes. In the context of primary use of	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			health data in the European Health Data Space, access should be provided to the healthcare professional of such teams. {Article 7A}	
	Recital 16			
26	(16) Timely and full access of health professionals to the medical records of patients is fundamental for ensuring continuity of care and avoiding duplications	(16) Timely and full access of health professionals to the medical records of patients is fundamental for ensuring continuity of care <i>and</i> , avoiding duplications	(16) Timely and full access of health professionals to the medical records of patients is fundamental for ensuring continuity of care and avoiding duplications	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
and errors. However, due to	and errors and reducing	and errors. However, due to	
a lack of interoperability, in	<u>costs</u> . However, due to a	a lack of interoperability, in	
many cases, health	lack of interoperability, in	many cases, health	
professionals cannot access	many cases, health	professionals cannot access	
the complete medical	professionals cannot access	the complete medical	
records of their patients and	the complete medical	records of their patients and	
cannot make optimal	records of their patients and	cannot make optimal	
medical decisions for their	cannot make optimal	medical decisions for their	
diagnosis and treatment,	medical decisions for their	diagnosis and treatment,	
which adds considerable	diagnosis and treatment,	which adds considerable	
costs for both health	which adds considerable	costs for both health	
systems and natural persons	costs for both health	systems and natural persons	
and may lead to worse	systems and natural persons	and may lead to worse	
health outcomes for natural	and may lead to worse	health outcomes for natural	
persons. Electronic health	health outcomes for natural	persons. Electronic health	
data made available in	persons. Electronic health	data made available in	
interoperable format, which	data made available in	interoperable format, which	
can be transmitted between	interoperable format, which	can be transmitted between	
healthcare providers can	can be transmitted between	healthcare providers can	
also reduce the	healthcare providers can	also reduce the	
administrative burden on	also reduce the	administrative burden on	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
health professionals of	administrative burden on	health professionals of	
manually entering or	health professionals of	manually entering or	
copying health data	manually entering or	copying health data between	
between electronic systems.	copying health data between	electronic systems.	
Therefore, health	electronic systems.	Therefore, health	
professionals should be	Therefore, health	professionals should be	
provided with appropriate	professionals should be	provided with appropriate	
electronic means, such as	provided with appropriate	electronic means, such as	
health professional portals,	electronic means, such as	health professional portals,	
to use personal electronic	appropriate electronic and	to use personal electronic	
health data for the exercise	digital devices and health	health data for the exercise	
of their duties. Moreover,	professional portals, to use	of their duties. Moreover,	
the access to personal	personal electronic health	the access to personal health	
health records should be	data for the exercise of their	records should be	
transparent to the natural	duties on a need-to-know	transparent to the natural	
persons and natural persons	basis . Moreover, the access	persons and natural persons	
should be able to exercise	to personal health records	should be able to exercise	
full control over such	should be transparent to the	full control over such	
access, including by	natural persons and natural	access, including by	
limiting access to all or part	persons should be able to	limiting access to all or part	
of the personal electronic	exercise full control over	of the personal electronic	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
health data in their records.	such access, including by	health data in their records.	
Health professionals should	limiting access to all or part	Health professionals should	
refrain from hindering the	of the personal electronic	refrain from hindering the	
implementation of the	health data in their records.	implementation of the rights	
rights of natural persons,	Health professionals should	of natural persons, such as	
such as refusing to take into	refrain from hindering the	refusing to take into account	
account electronic health	implementation of the rights	electronic health data	
data originating from	of natural persons, such as	originating from another	
another Member State and	refusing to take into account	Member State and provided	
provided in the	electronic health data	in the interoperable and	
interoperable and reliable	originating from another	reliable European electronic	
European electronic health	Member State and provided	health record exchange	
record exchange format.	in the interoperable and	format.	
	reliable European electronic		
	health record exchange		
	format. This Regulation		
	should not be construed or		
	interpreted as limiting the		
	obligation of health		
	professionals to comply		
	with the applicable law,		

Commission Proposa	վ	EP Mandate	Council Mandate	Draft Agreement
		codes of conduct, deontological guidelines or other provisions governing ethical conduct with respect to sharing or accessing information, particularly in life- threatening or extreme situations. For that purpose, providers of electronic health records should keep a record of who has accessed data in the previous 36 months and which data they accessed.		
Re	cital 16a			
26a				

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	(16a) Health professionals		
	are faced with a profound		
	<u>change in the context of</u>		
	digitalisation and		
	implementation of the		
	<u>EHDS. Health</u>		
	professionals need to		
	<u>develop their digital health</u>		
	<u>literacy and digital skills.</u>		
	<u>Therefore, health</u>		
	professionals who qualify		
	<u>as micro enterprises, as</u>		
	<u>defined in Article 2 of the</u>		
	<u>Annex to Commission</u> <u>Recommendation</u>		
	2003/361/EC ¹ , should be		
	temporarily exempted from		
	the obligations laid down		
	in this Regulation, in order		
	to avoid a disproportionate		
	administrative burden for		

	Commission Proposa	al	EP Mandate	Council Mandate	Draft Agreement
			micro enterprises. During the period of exemption, Member States should enable health professionals working as micro enterprises to take digital literacy courses to be able to prepare to work in EHR systems.		
	Re	ecital 16a			
26b					

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		(16a) The supervisory	
		authorities established	
		pursuant to Article 51 of	
		Regulation (EU) 2016/679	
		are competent for the	
		monitoring and	
		enforcement of that	
		Regulation, in particular	
		to monitor the processing	
		of personal electronic	
		health data and to address	
		any complaints lodged by	
		the natural persons. This	
		notably includes the	
		forwarding of complaints	
		that falls within the other	
		authorities' competences.	
		The EHDS establishes	
		additional rights for	
		natural persons in	
		primary use, going beyond	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		the access and portability	
		rights enshrined in	
		Regulation (EU) 2016/679,	
		complementing those	
		rights. These additional	
		rights should also be	
		enforced by the	
		supervisory authorities	
		established pursuant to	
		Article 51 of Regulation	
		(EU) 2016/679. Digital	
		health authorities should	
		cooperate with the	
		supervisory authorities	
		established pursuant to	
		Regulation (EU) 2016/679.	
		The supervisory authority	
		or authorities responsible	
		for monitoring and	
		enforcement of the	
		processing of personal	

electronic health data for primary use in compliance with the regulation should be competent to impose administrative fines. The legal system of Denmark and Ireland does not allow for administrative fines as set out in this Regulation. The rules on administrative fines may be applied in such a manner that in Denmark and Ireland the fines are imposed by the competent national courts as a criminal penalty, provided that such an application of the rules has an equivalent	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
with the regulation should be competent to impose administrative fines. The legal system of Denmark and Ireland does not allow for administrative fines as set out in this Regulation. The rules on administrative fines may be applied in such a manner that in Denmark and Ireland the fines are imposed by the competent national courts as a criminal penalty, provided that such an application of the rules has an equivalent			electronic health data for	
Image: space s			primary use in compliance	
administrative fines. The legal system of Denmark and Ireland does not allow for administrative fines as set out in this Regulation. The rules on administrative fines may be applied in such a manner that in Denmark and Ireland the fines are imposed by the competent national courts as a criminal penalty, provided that such an application of the rules has an equivalent			with the regulation should	
Image: set of the			be competent to impose	
Image: state s			administrative fines. The	
Image: set out in this Regulation.The rules onadministrative fines maybe applied in such amanner that in Denmarkand Ireland the fines areimposed by the competentnational courts as acriminal penalty, providedthat such an application ofthe rules has an equivalent			legal system of Denmark	
Image: set out in this Regulation.The rules onadministrative fines maybe applied in such amanner that in Denmarkand Ireland the fines areimposed by the competentnational courts as acriminal penalty, providedthat such an application ofthe rules has an equivalent			and Ireland does not allow	
The rules on administrative fines may be applied in such a manner that in Denmark and Ireland the fines are imposed by the competent national courts as a criminal penalty, provided that such an application of the rules has an equivalent			for administrative fines as	
Image: state s			set out in this Regulation.	
be applied in such a manner that in Denmark and Ireland the fines are imposed by the competent national courts as a criminal penalty, provided that such an application of the rules has an equivalent			The rules on	
Image: Sector of the sector			administrative fines may	
Image: space s			be applied in such a	
Imposed by the competent national courts as a criminal penalty, provided that such an application of the rules has an equivalent			manner that in Denmark	
national courts as a criminal penalty, provided that such an application of the rules has an equivalent			and Ireland the fines are	
criminal penalty, provided that such an application of the rules has an equivalent			imposed by the competent	
that such an application of the rules has an equivalent			national courts as a	
the rules has an equivalent			criminal penalty, provided	
			that such an application of	
			the rules has an equivalent	
effect to administrative			effect to administrative	
fines imposed by			fines imposed by	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				supervisory authorities. In any event, the fines imposed shall be effective, proportionate and	
				dissuasive. MOVED FROM RECITAL (14) AND AMENDED]]	
				{Article 11A}	
	Recital	16b			
26c				(16b) Recognising the importance of ethical	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		principles and the principle of doctor-patient confidentiality, Member States should strive to adhere to ethical principles and to respect the principle of doctor-	
		 patient confidentiality in the application of this Regulation. In particular, the European ethical principles for digital health provide guidance to practitioners, researchers, 	
		innovators, policy-makers and regulators at Union and Member State level for the application of the Regulation. The possibilities offered by the Regulation in terms of,	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				inter alia, the promotion of better diagnosis, treatment and well-being of natural persons, should be attained without prejudice to the observance of ethical imperatives and the principle of doctor-patient confidentiality.	
	Recital 16	с			
26d				(16c) The processing of health data for the purpose of law enforcement should not fall within the scope of	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				primary or secondary use of electronic health data in the meaning of this Regulation.	
	Recita	17			
27	(17) The relevance of different categories of electronic health data for different healthcare scenarios varies. Different categories have also achieved different levels of maturity in standardisation, and therefore the implementation of mechanisms for their		(17) The relevance of different categories of electronic health data for different healthcare scenarios varies. Different categories have also achieved different levels of maturity in standardisation, and therefore the implementation of mechanisms for their	(17) The relevance of different categories of electronic health data for different healthcare scenarios varies. Different categories have also achieved different levels of maturity in standardisation, and therefore the implementation of mechanisms for their	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
exchange may be more or	exchange may be more or	exchange may be more or	
less complex depending on	less complex depending on	less complex depending on	
the category. Therefore, the	the category. Therefore, the	the category. Therefore, the	
improvement of	improvement of	improvement of	
interoperability and data	interoperability and data	interoperability and data	
sharing should be gradual	sharing should be gradual	sharing should be gradual	
and prioritisation of	and prioritisation of	and prioritisation of	
categories of electronic	categories of electronic	categories of electronic	
health data is needed.	health data is needed.	health data is needed.	
Categories of electronic	Categories of electronic	Categories of electronic	
health data such as patient	health data such as patient	health data such as patient	
summary, electronic	summary, electronic	summary, electronic	
prescription and	prescription and	prescription and	
dispensation, laboratory	dispensation, laboratory	dispensation, laboratory	
results and reports, hospital	results and reports, hospital	results and reports, hospital	
discharge reports, medical	discharge reports, medical	discharge reports, medical	
images and reports have	images and reports have	images and reports have	
been selected by the	been selected by the	been selected by the	
eHealth Network as most	eHealth Network as most	eHealth Network as most	
relevant for the majority of	relevant for the majority of	relevant for the majority of	
healthcare situations and	healthcare situations and	healthcare situations and	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
should be considered as	should be considered as	should be considered as	
priority categories for	priority categories for	priority categories for	
Member States to	Member States to	Member States to	
implement access to them	implement access to them	implement access to them	
and their transmission.	and their transmission.	and their transmission.	
When further needs for the	When further needs for the	When further needs for the	
exchange of more	exchange of more	exchange of more	
categories of electronic	categories of electronic	categories of electronic	
health data are identified for	health data are identified for	health data are identified for	
healthcare purposes, the list	healthcare purposes, the list	healthcare purposes, the list	
of priority categories should	of priority categories should	of priority categories should	
be expanded. The	be expanded . <i>The</i>	be expanded. The	
Commission should be	Commission should be	Commission should be	
empowered to extend the	empowered to extend the	empowered to extend the	
list of priority categories,	list of priority categories,	list of priority categories,	
after analysing relevant	after analysing relevant	after analysing relevant	
aspects related to the	aspects related to the	aspects related to the	
necessity and possibility for	necessity and possibility for	necessity and possibility for	
the exchange of new	the exchange of new	the exchange of new	
datasets, such as their	datasets, such as their	datasets, such as their	
support by systems	support by systems	support by systems	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	established nationally or regionally by the Member States. Particular attention should be given to the data exchange in border regions of neighbouring Member States where the provision of cross-border health services is more frequent and needs even quicker procedures than across the Union in general.		established nationally or regionally by the Member States. Particular attention should be given to the data exchange in border regions of neighbouring Member States where the provision of cross-border health services is more frequent and needs even quicker procedures than across the Union in general.	established nationally or regionally by the Member States. Particular attention should be given to the data exchange in border regions of neighbouring Member States where the provision of cross-border health services is more frequent and needs even quicker procedures than across the Union in general.	
	Recital	18			
28	(18) Access and sharing of electronic health data should be enabled for all		(18) Access and sharing of electronic health data should be enabled for all the	(18) Access and sharing of electronic health data should be enabled for all the	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
the data that exist in the	data that exist in the EHR of	data that exist in the EHR of	
EHR of a natural person,	a natural person, when	a natural person, when	
when technically feasible.	technically feasible.	technically feasible.	
However, some electronic	However, some electronic	However, some electronic	
health data may not be	health data may not be	health data may not be	
structured or coded, and the	structured or coded, and the	structured or coded, and the	
transmission between	transmission between	transmission between	
healthcare providers may be	healthcare providers may be	healthcare providers may be	
limited or only possible in	limited or only possible in	limited or only possible in	
formats that do not allow	formats that do not allow	formats that do not allow	
for translation (when data is	for translation (when data is	for translation (when data is	
shared cross-borders). In	shared cross-borders). In	shared cross-borders). In	
order to provide enough	order to provide enough	order to provide enough	
time to prepare for	time to prepare for	time to prepare for	
implementation, dates of	implementation, dates of	implementation, dates of	
deferred application should	deferred application should	deferred application should	
be determined to allow for	be determined to allow for	be determined to allow for	
achieving legal,	achieving legal,	achieving legal,	
organisational, semantic	organisational, semantic and	organisational, semantic and	
and technical readiness for	technical readiness for the	technical readiness for the	
the transmission of different	transmission of different	transmission of different	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	categories of electronic health data. When need for the exchange of new categories of electronic health data is identified, related dates of application should be determined in order to allow for the implementation of this exchange.		categories of electronic health data. When need for the exchange of new categories of electronic health data is identified, related dates of application should be determined in order to allow for the implementation of this exchange.	categories of electronic health data. When need for the exchange of new categories of electronic health data is identified, related dates of application should be determined in order to allow for the implementation of this exchange.	
	Recital	19			
29	(19) The level ofavailability of personalhealth and genetic data inan electronic format variesbetween Member States.		 (19) The level of availability of personal health and genetic data in an electronic format varies between Member States. 	 (19) The level of availability of personal health and genetic data in an electronic format varies between Member States. 	

Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
The EHDS should make it	TI	he EHDS should make it	The EHDS should make it	
easier for natural persons to	ea	asier for natural persons to	easier for natural persons to	
have those data available in	ha	ave those data available in	have those data available in	
electronic format. This	el	lectronic format as well as	electronic format. This	
would also contribute to the	<u>_fo</u>	or them to have better	would also contribute to the	
achievement of the target of	<u>co</u>	ontrol over accessing and	achievement of the target of	
100% of Union citizens	<u>sh</u>	haring their personal	100% of Union citizens	
having access to their	el	l <u>ectronic health data</u> . This	having access to their	
electronic health records by	w	ould also contribute to the	electronic health records by	
2030, as referred to in the	ac	chievement of the target of	2030, as referred to in the	
Policy Programme "Path to	10	00% of Union citizens	Policy Programme "Path to	
the Digital Decade". In	ha	aving access to their	the Digital Decade". In	
order to make electronic	el	lectronic health records by	order to make electronic	
health data accesible and	20	030, as referred to in the	health data	
transmissible, such data	Po	olicy Programme "Path to	accesible accessible and	
should be accessed and	th	ne Digital Decade". In	transmissible, such data	
transmitted in an	or	rder to make electronic	should be accessed and	
interoperable common	he	ealth data	transmitted in an	
European electronic health	æ	ccesible<mark>accessible</mark> and	interoperable common	
record exchange format, at	tra	ansmissible, such data	European electronic health	
least for certain categories	sh	nould be accessed and	record exchange format, at	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
of electronic health data,	transmitted in an	least for certain categories	
such as patient summaries,	interoperable common	of electronic health data,	
electronic prescriptions and	European electronic health	such as patient summaries,	
dispensations, medical	record exchange format, at	electronic prescriptions and	
images and image reports,	least for certain categories	dispensations, medical	
laboratory results and	of electronic health data,	images and image reports,	
discharge reports, subject to	such as patient summaries,	laboratory results and	
transition periods. Where	electronic prescriptions and	discharge reports, subject to	
personal electronic health	dispensations, medical	transition periods. Where	
data is made available to a	images and image reports,	personal electronic health	
healthcare provider or a	laboratory results and	data is made available to a	
pharmacy by a natural	discharge reports, subject to	healthcare provider or a	
person, or is transmitted by	transition periods. Where	pharmacy by a natural	
another data controller in	personal electronic health	person, or is transmitted by	
the European electronic	data is made available to a	another data controller in	
health record exchange	healthcare provider or a	the European electronic	
format, the electronic health	pharmacy by a natural	health record exchange	
data should be read and	person, or is transmitted by	format, the electronic health	
accepted for the provision	another data controller in	data should be read and	
of healthcare or for	the European electronic	accepted for the provision	
dispensation of a medicinal	health record exchange	of healthcare or for	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
product, thus supporting the	format, the electronic health	dispensation of a medicinal	
provision of the health care	data should be read and	product, thus supporting the	
services or the dispensation	accepted for the provision	provision of the health care	
of the electronic	of healthcare or for	services or the dispensation	
prescription. Commission	dispensation of a medicinal	of the electronic	
Recommendation (EU)	product, thus supporting the	prescription. Commission	
2019/243 ¹ provides the	provision of the health care	Recommendation (EU)	
foundations for such a	services or the dispensation	$2019/243^1$ provides the	
common European	of the electronic	foundations for such a	
electronic health record	prescription. Commission	common European	
exchange format. The use	Recommendation (EU)	electronic health record	
of European electronic	2019/243 ¹ provides the	exchange format. The use of	
health record exchange	foundations for such a	European electronic health	
format should become more	common European	record exchange format	
generalised at EU and	electronic health record	should become more	
national level. While the	exchange format. The	generalised at EU and	
eHealth Network under	interoperability of the	national level. While the	
Article 14 of Directive	EHDS should contribute to	eHealth Network under	
2011/24/EU of the	a high quality of European	Article 14 of Directive	
European Parliament and of	health data sets. The use of	2011/24/EU of the	
the Council ² recommended	European electronic health	European Parliament and of	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Member States to use the	record exchange format	the Council ² recommended	
European electronic health	should become more	Member States to use the	
record exchange format in	generalised at EU and	European electronic health	
procurements, in order to	national level. While the	record exchange format in	
improve interoperability,	eHealth Network under	procurements, in order to	
uptake was limited in	Article 14 of Directive	improve interoperability,	
practice, resulting in	2011/24/EU of the	uptake was limited in	
fragmented landscape and	European Parliament and of	practice, resulting in	
uneven access to and	the Council ² recommended	fragmented landscape and	
portability of electronic	Member States to use the	uneven access to and	
health data.	European electronic health	portability of electronic	
	record exchange format in	health data.	
	procurements, in order to		
1. Commission Recommendation	improve interoperability,		
(EU) 2019/243 of 6 February	uptake was limited in	1. Commission Recommendation	
2019 on a European Electronic	practice, resulting in	(EU) 2019/243 of 6 February	
Health Record exchange format	fragmented landscape and	2019 on a European Electronic	
(OJ L 39, 11.2.2019, p. 18).	uneven access to and	Health Record exchange format	
2. Directive 2011/24/EU of the	portability of electronic	(OJ L 39, 11.2.2019, p. 18).	
European Parliament and of the	health data.	2. Directive 2011/24/EU of the	
Council of 9 March 2011 on the		European Parliament and of the	
application of patients' rights in		Council of 9 March 2011 on the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	cross-border healthcare (OJ L 88, 4.4.2011, p. 45).		 Commission Recommendation (EU) 2019/243 of 6 February 2019 on a European Electronic Health Record exchange format (OJ L 39, 11.2.2019, p. 18). Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare (OJ L 88, 4.4.2011, p. 45). 	application of patients' rights in cross-border healthcare (OJ L 88, 4.4.2011, p. 45).	
	Recital	20			
30	(20) While EHR systems are widely spread, the level of digitalisation of health		(20) While EHR systems are widely spread, the level of digitalisation of health	(20) While EHR systems are widely spread, the level of digitalisation of health	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
data varies in Member	data varies in Member	data varies in Member	
States depending on data	States depending on data	States depending on data	
categories and on the	categories and on the	categories and on the	
coverage of healthcare	coverage of healthcare	coverage of healthcare	
providers that register	providers that register	providers that register	
health data in electronic	health data in electronic	health data in electronic	
format. In order to support	format. In order to support	format. In order to support	
the implementation of data	the implementation of data	the implementation of data	
subjects' rights of access to	subjects' rights of access to	subjects' rights of access to	
and exchange of electronic	and exchange of electronic	and exchange of electronic	
health data, Union action is	health data, Union action is	health data, Union action is	
needed to avoid further	needed to avoid further	needed to avoid further	
fragmentation. In order to	fragmentation. In order to	fragmentation. In order to	
contribute to a high quality	contribute to a high quality	contribute to a high quality	
and continuity of	and continuity of	and continuity of	
healthcare, certain	healthcare, certain	healthcare, certain	
categories of health data	categories of health data	categories of health data	
should be registered in	should be registered in	should be registered in	
electronic format	electronic format	electronic format	
systematically and	systematically and	systematically and	
according to specific data	according to specific data	according to specific data	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
quality requirements. The	quality requirements. The	quality requirements. The	
European electronic health	European electronic health	European electronic health	
record exchange format	record exchange format	record exchange format	
should form the basis for	should form the basis for	should form the basis for	
specifications related to the	specifications related to the	specifications related to the	
registration and exchange	registration and exchange of	registration and exchange of	
of electronic health data.	electronic health data. The	electronic health data. The	
The Commission should be	Commission should be	Commission should be	
empowered to adopt	empowered to adopt	empowered to adopt	
implementing acts for	implementingdelegated acts	implementing acts for	
determining additional	for determining-additional	determining additional	
aspects related to the	aspects related to the	aspects related to the	
registration of electronic	registration of electronic	registration of electronic	
health data, such as	health data, such as	health data, such as	
categories of healthcare	categories of healthcare	categories of healthcare	
providers that are to register	providers that are to	providers that are to register	
health data electronically,	register health data	health data electronically,	
categories of data to be	electronically, categories of	categories of data to be	
registered electronically, or	data to be registered	registered electronically, or	
data quality requirements.	electronically, or data	data quality requirements.	
	quality requirements.	The European electronic	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		health record exchange	
		format may have two	
		profiles: a simple	
		technical specification for	
		use applicable to EHR	
		systems and a detailed	
		technical specification for	
		cross-border use, which	
		should only apply to the	
		national contact points for	
		MyHealth@EU. At the	
		national level, the	
		European electronic	
		health record exchange	
		format should include the	
		technical specifications for	
		the 'European	
		interoperability	
		component for EHR	
		systems'. Also,	
		harmonised technical	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		specifications for the	
		'European logging	
		component for EHR	
		systems' should be defined	
		by means of implementing	
		acts. These two	
		components are mainly	
		focused on data	
		transformation, although	
		they may imply indirect	
		requirements for data	
		registry and data	
		presentation in EHR	
		systems at the national	
		level. Given the purposes	
		of these components and	
		the wide scope of the	
		definition of EHR systems	
		in this Regulation,	
		conformance assessment	
		of the harmonised	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		components should be by	
		means of self-certification.	
		The Commission should	
		establish a testing	
		environment to facilitate	
		such self-certification.	
		Member States should	
		retain the competence to	
		define requirements	
		relating to any other	
		components of EHR	
		systems and the terms and	
		conditions for connection	
		of healthcare providers to	
		their respective national	
		infrastructures, which	
		may be subject to third-	
		party assessment at the	
		national level. The cross-	
		border specifications of	
		the European electronic	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			health record exchange format should be complemented by further cybersecurity, technical and semantic interoperability, operations and service management specifications for cross- border use in the MyHealth@EU infrastructure, defined by means of implementing acts.	
	Recital 20a			
30a		(20a) In order to support		

Commission Proposal	EP Mar	ndate Council Manda	te Draft Agreement
	the successful implementation EHDS and the effective condit European healt cooperation, th Commission and States should a time-based targ implement cond improved health interoperability Union with a red objectives and h including in res disease-specific interoperability should be revie assessed in an o report.	n of the creation of tions for th data th data te and Member typee on typee on type of type of type of type of type of type of type of type of type of type of type of	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Recita	21			
	(21) Under Article 168 of		(21) Under Article 168 of	(21) Under Article 168 of	
	the Treaty Member States		the Treaty on the	the Treaty Member States	
	are responsible for their		Functioning of the	are responsible for their	
	health policy, in particular		<u>European Union (TFEU),</u>	health policy, in particular	
	for decisions on the services		Member States are	for decisions on the services	
	(including telemedicine)		responsible for their health	(including telemedicine)	
31	that they provide and		policy, in particular for	that they provide and	
	reimburse. Different		decisions on the services	reimburse. Different	
	reimbursement policies		(including telemedicine)	reimbursement policies	
	should, however, not		that they provide and	should, however, not	
	constitute barriers to the		reimburse. Different	constitute barriers to the	
	free movement of digital		reimbursement policies	free movement of digital	
	health services such as		should, however, not	health services such as	
	telemedicine, including		constitute barriers to the	telemedicine, including	
	online pharmacy services.		free movement of digital	online pharmacy services.	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
When digital services	health services such as	When digital services	
accompany the physical	telemedicine, including	accompany the physical	
provision of a healthcare	online pharmacy services.	provision of a healthcare	
service, the digital service	When digital services	service, the digital service	
should be included in the	accompany the physical	should be included in the	
overall care provision.	provision of a healthcare	overall care provision.	
	service, the digital service		
	should be included in the		
	overall care provision.		
	Telemedicine is becoming		
	an increasingly important		
	<u>tool that can provide</u>		
	patients with access to care		
	and tackle inequities and		
	has the potential to reduce		
	health inequalities and		
	reinforce the free		
	movement of Union		
	citizens across borders.		
	Digital and other		
	technological tools can		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			facilitate the provision of care in remote regions. However, telemedicine should not be viewed as a replacement for in-person medicine, as there are certain conditions and procedures that require in- person physical examination and intervention.		
	Recita	122			
32	 (22) Regulation (EU) No 910/2014 of the European Parliament and of the Council¹ lays down the 		 (22) Regulation (EU) No 910/2014 of the European Parliament and of the Council¹ lays down the 	 (22) Regulation (EU) No 910/2014 of the European Parliament and of the Council¹ lays down the 	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
conditions under which	conditions under which	conditions under which	
Members States perform	Members States perform	Members States perform	
identification of natural	identification of natural	identification of natural	
persons in cross-border	persons in cross-border	persons in cross-border	
situations using	situations using	situations using	
identification means issued	identification means issued	identification means issued	
by another Member State,	by another Member State,	by another Member State,	
establishing rules for the	establishing rules for the	establishing rules for the	
mutual recognition of such	mutual recognition of such	mutual recognition of such	
electronic identification	electronic identification	electronic identification	
means. The EHDS requires	means. The EHDS requires	means. The EHDS requires	
a secure access to electronic	a secure access to electronic	a secure access to electronic	
health data, including in	health data, including in	health data, including in	
cross-border scenarios	cross-border scenarios	cross-border scenarios	
where the health	where the health	where the health	
professional and the natural	professional and the natural	professional and the natural	
person are from different	person are from different	person are from different	
Member States, to avoid	Member States, to avoid	Member States, to avoid	
cases of unauthorised	cases of unauthorised	cases of unauthorised	
access. At the same time,	access. At the same time,	access. At the same time,	
the existence of different	the existence of different	the existence of different	

Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
means of electronic		means of electronic	means of electronic	
identification should not be		identification should not be	identification should not be	
a barrier for exercising the		a barrier for exercising the	a barrier for exercising the	
rights of natural persons		rights of natural persons and	rights of natural persons and	
and health professionals.		health professionals.	health professionals. The	
The rollout of interoperable	,	Therefore, natural persons	rollout of interoperable,	
cross-border identification		and health professionals	cross-border identification	
and authentication		should have the right to	and authentication	
mechanisms for natural		electronic identification	mechanisms for natural	
persons and health		using any recognised	persons and health	
professionals across the		electronic identification,	professionals across the	
EHDS requires		including eID schemes	EHDS requires	
strengthening cooperation		where such are offered.	strengthening cooperation at	
at Union level in the		The rollout of interoperable,	Union level in the European	
European Health Data		cross-border identification	Health Data Space Board	
Space Board ('EHDS		and authentication	('EHDS Board').As the	
Board').As the rights of the		mechanisms for natural	rights of the natural persons	
natural persons in relation		persons and health	in relation to the access and	
to the access and		professionals across the	transmission of personal	
transmission of personal		EHDS requires	electronic health data	
electronic health data		strengthening cooperation at	should be implemented	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
should be implemented	Union level in the European	uniformly across the Union,	
uniformly across the Union,	Health Data Space Board	a strong governance and	
a strong governance and	('EHDS Board'). As the	coordination is necessary at	
coordination is necessary at	rights of the natural persons	both Union and Member	
both Union and Member	in relation to the access and	State level. Member States	
State level. Member States	transmission of personal	should establish relevant	
should establish relevant	electronic health data	digital health authorities for	
digital health authorities for	should be implemented	the planning and	
the planning and	uniformly across the Union,	implementation of standards	
implementation of	a strong governance and	for electronic health data	
standards for electronic	coordination is necessary at	access, transmission and	
health data access,	both Union and Member	enforcement of rights of	
transmission and	State level. Member States	natural persons and health	
enforcement of rights of	should establish relevant	professionals. In addition,	
natural persons and health	digital health authorities for	governance elements are	
professionals. In addition,	the planning and	needed in Member States to	
governance elements are	implementation of	facilitate the participation of	
needed in Member States to	standards for electronic	national actors in the	
facilitate the participation	health data access,	cooperation at Union level,	
of national actors in the	transmission and	channelling expertise and	
cooperation at Union level,	enforcement of rights of	advising the design of	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
channelling expertise and	natural persons and health	solutions necessary to	
advising the design of	professionals. In addition,	achieve the goals of the	
solutions necessary to	governance elements are	EHDS. Digital health	
achieve the goals of the	needed in Member States to	authorities exist in most of	
EHDS. Digital health	facilitate the participation	the Member States and they	
authorities exist in most of	of national actors in the	deal with EHRs,	
the Member States and they	cooperation at Union level,	interoperability, security or	
deal with EHRs,	channelling expertise and	standardisation. Digital	
interoperability, security or	advising the design of	health authorities should be	
standardisation. Digital	solutions necessary to	established in all Member	
health authorities should be	achieve the goals of the	States, as separate	
established in all Member	EHDS. Digital health	organisations or as part of	
States, as separate	authorities exist in most of	the currently existing	
organisations or as part of	the Member States and they	authorities.	
the currently existing	deal with EHRs,		
authorities.	interoperability, security or		
	standardisation. Digital	1. Regulation (EU) No 910/2014	
	health authorities should be	of the European Parliament and of	
1. Regulation (EU) No 910/2014	established in all Member	the Council of 23 July 2014 on	
of the European Parliament and of	States, as separate	electronic identification and trust services for electronic transactions	
the Council of 23 July 2014 on	organisations or as part of	in the internal market and	
electronic identification and trust			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	services for electronic transactions in the internal market and repealing Directive 1999/93/EC (OJ L 257, 28.8.2014, p. 73).		the currently existing authorities.	repealing Directive 1999/93/EC (OJ L 257, 28.8.2014, p. 73).	
			1. Regulation (EU) No 910/2014 of the European Parliament and of the Council of 23 July 2014 on electronic identification and trust services for electronic transactions in the internal market and repealing Directive 1999/93/EC (OJ L 257, 28.8.2014, p. 73).	THE REST OF THE RECITAL MOVED TO (22B)	
	Recital	22a		L	
32a			(22a) <u>Member States</u> should establish relevant digital health authorities for the planning and		

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	implementation of		
	standards for electronic		
	health data access and		
	<u>transmission and the</u>		
	enforcement of the rights		
	of natural persons and		
	<u>health professionals. In</u>		
	addition, governance		
	<u>elements are needed in</u>		
	<u>Member States to facilitate</u>		
	the participation of		
	<u>national actors in the</u>		
	<u>cooperation at Union level,</u>		
	<u>channelling expertise and</u>		
	<u>advising on the design of</u>		
	solutions necessary to		
	achieve the goals of the		
	EHDS. Digital health		
	authorities exist in most of		
	the Member States and		
	they deal with EHRs,		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			interoperability, security or standardisation. Digital health authorities should be established in all Member States, as separate organisations or as part of currently existing authorities.		
	Recital	22a			
32b				(22a) Natural persons should be provided with sufficient tools for exercising their rights related to the personal electronic health data. Member States should	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		therefore ensure that	
		electronic health data	
		access services are made	
		available for natural	
		persons and their	
		representatives. Such	
		services may be	
		implemented for instance	
		through online portals or	
		mobile applications, at	
		national or regional level,	
		or by healthcare	
		providers. Electronic	
		health data access services	
		should implement the	
		rights of natural persons	
		regardless of their	
		Member State of	
		affiliation, and should	
		therefore support the	
		identification of natural	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Commission Proposal	EP Mandate	persons using anyelectronic identificationmeans recognisedpursuant to Article 6 ofRegulation (EU) No910/2014. Considering thepossibility of identitymatching challenges incross-border situations,supplementary accesstokens or codes may needto be issued by MemberStates to natural personswho arrive from otherMember States andreceive healthcare. TheCommission should beempowered to adopt	Draft Agreement
		implementing acts for the interoperable, cross- border identification and	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				authentication of natural persons and health professionals, including any supplementary mechanisms that are necessary for ensuring the possibility for natural persons to exercise their rights to personal electronic health data in cross-border situations.	
	Recita	l 22b			
32c				(22b) As the rights of the natural persons in relation to the access and transmission of personal	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		electronic health data	
		should be implemented	
		uniformly across the	
		Union, a strong	
		governance and	
		coordination is necessary	
		at both Union and	
		Member State level.	
		Member States should	
		establish relevant digital	
		health authorities for the	
		planning and	
		implementation of	
		standards for electronic	
		health data access,	
		transmission and	
		enforcement of rights of	
		natural persons and	
		health professionals. In	
		addition, governance	
		elements are needed in	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	LP Mandate	Member States to facilitate the participation of national actors in the cooperation at Union level, channelling expertise and advising the design of solutions necessary to achieve the goals of the EHDS. Digital health authorities exist in most of the Member States and they deal with EHRs, interoperability, security or standardisation. Digital health authorities should be established in all Member States, as separate organisations or as part of the currently	Draft Agreement
		existing authorities.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Recita	1 23			
	(23) Digital health		(23) Digital health	(23) Digital health	
	authorities should have		authorities should have	authorities should have	
	sufficient technical skills,		sufficient technical skills,	sufficient technical skills,	
	possibly bringing together		possibly bringing together	possibly bringing together	
	experts from different		experts from different	experts from different	
	organisations. The activities		organisations. The activities	organisations. The activities	
33	of digital health authorities		of digital health authorities	of digital health authorities	
	should be well-planned and		should be well-planned and	should be well-planned and	
	monitored in order to		monitored in order to ensure	monitored in order to ensure	
	ensure their efficiency.		their efficiency. Digital	their efficiency. Digital	
	Digital health authorities		health authorities should	health authorities should	
	should take necessary		take necessary measures to	take necessary measures to	
	measures to ensuring rights		ensuring rights of natural	ensuring rights of natural	
	of natural persons by setting		persons by setting up	persons by setting up	
	up national, regional, and		national, regional, and local	national, regional, and local	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
local technical solutions	technical solutions such as	technical solutions such as	
such as national EHR,	national EHR, patient	national EHR, patient	
patient portals, data	portals, data intermediation	portals, data intermediation	
intermediation systems.	systems. When doing so,	systems. When doing so,	
When doing so, they should	they should apply common	they should apply common	
apply common standards	standards and specifications	standards and specifications	
and specifications in such	in such solutions, promote	in such solutions, promote	
solutions, promote the	the application of the	the application of the	
application of the standards	standards and specifications	standards and specifications	
and specifications in	in procurements and use	in procurements and use	
procurements and use other	other innovative means	other innovative means	
innovative means including	including reimbursement of	including reimbursement of	
reimbursement of solutions	solutions that are compliant	solutions that are compliant	
that are compliant with	with interoperability and	with interoperability and	
interoperability and security	security requirements of the	security requirements of the	
requirements of the EHDS.	EHDS. <u><i>Member States</i></u>	EHDS. To carry out their	
To carry out their tasks, the	should ensure that	tasks, the digital health	
digital health authorities	appropriate training	authorities should cooperate	
should cooperate at national	initiatives are undertaken.	at national and Union level	
and Union level with other	<u>In particular, health</u>	with other entities,	
entities, including with	professionals should be	including with insurance	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
insurance bodies, healthcare	informed and trained with	bodies, healthcare	
providers, manufacturers of	respect to their rights and	providers, manufacturers of	
EHR systems and wellness	obligations under this	EHR systems and wellness	
applications, as well as	Regulation. To carry out	applications, as well as	
stakeholders from health or	their tasks, the digital health	stakeholders from health or	
information technology	authorities should cooperate	information technology	
sector, entities handling	at national and Union level	sector, entities handling	
reimbursement schemes,	with other entities,	reimbursement schemes,	
health technology	including with insurance	health technology	
assessment bodies,	bodies, healthcare	assessment bodies,	
medicinal products	providers, <i>health</i>	medicinal products	
regulatory authorities and	professionals,	regulatory authorities and	
agencies, medical devices	manufacturers of EHR	agencies, medical devices	
authorities, procurers and	systems and wellness	authorities, procurers and	
cybersecurity or e-ID	applications, as well as	cybersecurity or e-ID	
authorities.	other stakeholders from	authorities.	
	health or information		
	technology sector, entities		
	handling reimbursement		
	schemes, health technology		
	assessment bodies,		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			medicinal products regulatory authorities and agencies, medical devices authorities, procurers and cybersecurity or e-ID authorities.		
	Recital	24			
34	(24) Access to and transmission of electronic health data is relevant in cross-border healthcare situations, as it may support continuity of healthcare when natural persons travel to other Member States or change their place of		(24) Access to and transmission of electronic health data is relevant in cross-border healthcare situations, as it may support continuity of healthcare when natural persons travel to other Member States or change their place of	(24) Access to and transmission of electronic health data is relevant in cross-border healthcare situations, as it may support continuity of healthcare when natural persons travel to other Member States or change their place of	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
residence. Continuity of	residence. Continuity of	residence. Continuity of	
care and rapid access to	care and rapid access to	care and rapid access to	
personal electronic health	personal electronic health	personal electronic health	
data is even more important	data is even more important	data is even more important	
for residents in border	for residents in border	for residents in border	
regions, crossing the border	regions, crossing the border	regions, crossing the border	
frequently to get health	frequently to get health	frequently to get health	
care. In many border	care. In many border	care. In many border	
regions, some specialised	regions, some specialised	regions, some specialised	
health care services may be	health care services may be	health care services may be	
available closer across the	available closer across the	available closer across the	
border rather than in the	border rather than in the	border rather than in the	
same Member State. An	same Member State. An	same Member State. An	
infrastructure is needed for	infrastructure is needed for	infrastructure is needed for	
the transmission of personal	the transmission of personal	the transmission of personal	
electronic health data across	electronic health data across	electronic health data across	
borders, in situations where	borders, in situations where	borders, in situations where	
a natural person is using	a natural person is using	a natural person is using	
services of a healthcare	services of a healthcare	services of a healthcare	
provider established in	provider established in	provider established in	
another Member State. A	another Member State. A	another Member State. A	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
voluntary infrastructure for	voluntary infrastructure for	voluntary infrastructure for	
that purpose,	that purpose,	that purpose,	
MyHealth@EU, has been	MyHealth@EU, has been	MyHealth@EU, has been	
established as part of the	established as part of the	established as part of the	
actions provided for in	actions provided for in	actions provided for in	
Article 14 of Directive	Article 14 of Directive	Article 14 of Directive	
2011/24/EU. Through	2011/24/EU. Through	2011/24/EU. Through	
MyHealth@EU, Member	MyHealth@EU, Member	MyHealth@EU, Member	
States started to provide	States started to provide	States started to provide	
natural persons with the	natural persons with the	natural persons with the	
possibility to share their	possibility to share their	possibility to share their	
personal electronic health	personal electronic health	personal electronic health	
data with healthcare	data with healthcare	data with healthcare	
providers when travelling	providers when travelling	providers when travelling	
abroad. To further support	abroad. To further support	abroad. To further support	
such possibilities, the	such possibilities, the	such possibilities, the	
participation of Member	participation of Member	participation of Member	
States in the digital	States in the digital	States in the digital	
infrastructure	infrastructure	infrastructure	
MyHealth@EU should	MyHealth@EU should	MyHealth@EU should	
become mandatory. All	become mandatory. All	become mandatory. All	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Commission ProposalMember States should join the infrastructure and connect healthcare providers and pharmacies to it, as this is necessary for the implementation of the rights of natural persons to access and make use of their personal electronic health data regardless of the Member State. The infrastructure should be gradually expanded to support further categories of electronic health data.	EP Mandate Member States should join the infrastructure and connect healthcare providers and pharmacies to it, as this is necessary for the implementation of the rights of natural persons to access and make use of their personal electronic health data regardless of the Member State. The infrastructure should be gradually expanded to support further categories of electronic health data, <i>and</i>	Council Mandate Member States should join the infrastructure and connect healthcare providers andincluding pharmacies to it, as this is necessary for the implementation of the rights of natural persons established under this Regulation to access and make use of their personal electronic health data regardless of the Member State. The infrastructure should be gradually	Draft Agreement
	funding as well as other means of support at Union level should be considered.	expanded to support further categories of electronic health data.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Recital	125			
35	(25) In the context of MyHealth@EU, a central platform should provide a common infrastructure for the Member States to ensure connectivity and interoperability in an efficient and secure way. In order to guarantee compliance with data protection rules and to provide a risk management framework for the transmission of personal electronic health data, the Commission should, by means of implementing		(25) In the context of MyHealth@EU, a central platform should provide a common infrastructure for the Member States to ensure connectivity and interoperability in an efficient and secure way. In order to guarantee compliance with data protection rules and to provide a risk management framework for the transmission of personal electronic health data, the Commission should, by means of implementing	(25) In the context of MyHealth@EU, a central platform should provide provides a common infrastructure for the Member States to ensure connectivity and interoperability in an efficient and secure way to support cross-border healthcare. The Commission should, as a processor on behalf of the Member States, provide this infrastructure. In order to guarantee compliance with data	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
acts, allocate specific	acts, allocate specific	protection rules and to	
responsibilities among the	responsibilities with time-	provide a risk management	
Member States, as joint	based targets among the	framework for the	
controllers, and prescribe its	Member States, as joint	transmission of personal	
own obligations, as	controllers, and prescribe its	electronic health data,	
processor.	own obligations, as	specific responsibilities of	
	processor.	the Member States, as	
		controllers, and the the	
		Commission's obligations	
		should , by means of be laid	
		down in detail in	
		implementing acts, allocate	
		specific responsibilities	
		among the Member States,	
		as joint controllers, and	
		prescribe its own	
		obligations, as processor.	
		This Regulation provides	
		the legal basis for the	
		processing of personal	
		electronic health data in	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				this infrastructure as a task carried out in the public interest assigned by Union law in the sense of Article 6(1)(e) of Regulation (EU) 2016/679. This processing is necessary for the provision of healthcare, as mentioned in Article 9(2)(h) of that Regulation, in cross-border situations.	
	Recital	26			
36	(26) In addition to services in MyHealth@EU for the exchange of personal		(26) In addition to services in MyHealth@EU for the exchange of personal	(26) In addition to services in MyHealth@EU for the exchange of personal	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
electronic health data based	electronic health data based	electronic health data based	
on the European electronic	on the European electronic	on the European electronic	
health record exchange	health record exchange	health record exchange	
format, other services or	format, other services or	format, other services or	
supplementary	supplementary	supplementary	
infrastructures may be	infrastructures may be	infrastructures may be	
needed for example in cases	needed for example in cases	needed for example in cases	
of public health	of public health	of public health	
emergencies or where the	emergencies or where the	emergencies or where the	
architecture of	architecture of	architecture of	
MyHealth@EU is not	MyHealth@EU is not	MyHealth@EU is not	
suitable for the	suitable for the	suitable for the	
implementation of some use	implementation of some use	implementation of some use	
cases. Examples of such use	cases. Examples of such use	cases. Examples of such use	
cases include support for	cases include support for	cases include support for	
vaccination card	vaccination card	vaccination card	
functionalities, including	functionalities, including	functionalities, including	
the exchange of information	the exchange of information	the exchange of information	
on vaccination plans, or	on vaccination plans, or	on vaccination plans, or	
verification of vaccination	verification of vaccination	verification of vaccination	
certificates or other health-	certificates or other health-	certificates or other health-	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
related certificates. This	related certificates. This	related certificates. This	
would be also important for	would be also important for	would be also important for	
introducing additional	introducing additional	introducing additional	
functionality for handling	functionality for handling	functionality for handling	
public health crises, such as	public health crises, such as	public health crises, such as	
support for contact tracing	support for contact tracing	support for contact tracing	
for the purposes of	for the purposes of	for the purposes of	
containing infectious	containing infectious	containing infectious	
diseases. Connection of	diseases. Connection of	diseases. Connection of	
national contact points for	national contact points for	national contact points for	
digital health of third	digital health of third	digital health of third	
countries or interoperability	countries or interoperability	countries or interoperability	
with digital systems	with digital systems	with digital systems	
established at international	established at international	established at international	
level should be subject to a	level should be subject to a	level should be subject to a	
check ensuring the	check ensuring the	check ensuring the	
compliance of the national	compliance of the national	compliance of the national	
contact point with the	contact point with the	contact point with the	
technical specifications,	technical specifications,	technical specifications,	
data protection rules and	data protection rules and	data protection rules and	
other requirements of	other requirements of	other requirements of	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	MyHealth@EU. A decision to connect a national contact point of a third country should be taken by data controllers in the joint controllership group for MyHealth@EU.	MyHealth@EU. A decision to connect a national contact point of a third country should be taken by data controllers in the joint controllership group for MyHealth@EU.	MyHealth@EU. A decision to connect a national contact point of a third country should be taken by data controllers in the joint controllership group for MyHealth@EU.	
	Recital 27			
37	(27) In order to ensure respect for the rights of natural persons and health professionals, EHR systems marketed in the internal market of the Union should be able to store and transmit, in a secure way,	(27) In order to ensure respect for the rights of natural persons and health professionals, EHR systems marketed in the internal market of the Union should be able to store and transmit, in a secure way,	(27) In order to ensureenable seamless exchange of electronic health and contribute to ensuring respect for the rights of natural persons and health professionals, EHR systems marketed in the	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
high quality electronic	high quality electronic	internalSingle Market of the	
health data. This is a key	health data. This is a key	Union should be able to	
principle of the EHDS to	principle of the EHDS to	store and transmit, in a	
ensure the secure and free	ensure the secure and free	secure way, high quality	
movement of electronic	movement of electronic	electronic health data.	
health data across the	health data across the	ThisIt is a key	
Union. To that end, a	Union. To that end, a	principleobjective of the	
mandatory self-certification	mandatory self-certification	EHDS to ensure the secure	
scheme for EHR systems	scheme for EHR systems	and free movement of	
processing one or more	processing one or more	electronic health data across	
priority categories of	priority categories of	the Union. To that end, a	
electronic health data	electronic health data	mandatory self-certification	
should be established to	should be established to	schemescheme of self-	
overcome market	overcome market	conformity assessment for	
fragmentation while	fragmentation while	EHR systems processing	
ensuring a proportionate	ensuring a proportionate	one or more priority	
approach. Through this self-	approach. Through this self-	categories of electronic	
certification, EHR systems	certification, EHR systems	health data should be	
should prove compliance	should prove compliance	established to overcome	
with essential requirements	with essential requirements	market fragmentation while	
on interoperability and	on interoperability and	ensuring a proportionate	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
security, set at Union level.	security, set at Union level.	approach. Through this self-	
In relation to security,	In relation to security,	certificationself-	
essential requirements	essential requirements	assessment, EHR systems	
should cover elements	should cover elements	shouldwill prove	
specific to EHR systems, as	specific to EHR systems, as	compliance with	
more general security	more general security	essentialthe requirements	
properties should be	properties should be	on interoperability, security	
supported by other	supported by other	and logging for	
mechanisms such as	mechanisms such as	communication of	
cybersecurity schemes	cybersecurity schemes	personal electronic health	
under Regulation (EU)	under Regulation (EU)	data established by the	
2019/881 of the European	2019/881 of the European	two mandatory EHR	
Parliament and of the	Parliament and of the	components harmonised	
Council ¹ .	Council ¹ .	by this Regulation, namely	
		the 'European EHR	
		systems exchange	
1. Regulation (EU) 2019/881 of	1. Regulation (EU) 2019/881 of	interoperability	
the European Parliament and of	the European Parliament and of	component' and the	
the Council of 17 April 2019 on	the Council of 17 April 2019 on	'European logging	
ENISA (the European Union	ENISA (the European Union	component for EHR	
Agency for Cybersecurity) and on	Agency for Cybersecurity) and on	systems' and security, set at	
information and communications	information and communications		

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
technology cybersecurity certification and repealing Regulation (EU) No 526/2013 (Cybersecurity Act) (OJ L 151, 7.6.2019, p. 15).	technology cybersecurity certification and repealing Regulation (EU) No 526/2013 (Cybersecurity Act) (OJ L 151, 7.6.2019, p. 15).	Union level. In relation to security of those components, these; essential requirements should cover elements specific to EHR systems, as more general security properties should be supported by other mechanisms such as eybersecurity schemes under-Regulation (EU) 2019/881 of the European Parliament and of the Council ⁴ [] [Cyber- Resilience Act COM/2022/454 final].	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			the Council of 17 April 2019 on ENISA (the European Union Agency for Cybersecurity) and on information and communications technology cybersecurity certification and repealing Regulation (EU) No 526/2013 (Cybersecurity Act) (OJ L 151, 7.6.2019, p. 15).	
	Recital 28			
38	(28) While EHR systems specifically intended by the manufacturer to be used for processing one or more specific categories of electronic health data should be subject to mandatory self-	(28) While EHR systems specifically intended by the manufacturer to be used for processing one or more specific categories of electronic health data should be subject to mandatory self-certification,	(28) While EHR systems specifically intended by the manufacturer to be used for processing one or more specific categories of electronic health data should be subject to mandatory self-certification,	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	certification, software for general purposes should not be considered as EHR systems, even when used in a healthcare setting, and should therefore not be required to comply with the provisions of Chapter III.		software for general purposes should not be considered as EHR systems, even when used in a healthcare setting, and should therefore not be required to comply with the provisions of Chapter III.	software for general purposes should not be considered as EHR systems, even when used in a healthcare setting, and should therefore not be required to comply with the provisions of Chapter III.	
	Recital	l 28a			
38a				(28a) This Regulation imposes a mandatory self- conformity assessment scheme for the two mandatory harmonised EHR components of EHR systems, to ensure that	

Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			EHR systems placed on the Union market are able to exchange data in the European electronic health record exchange format and that they have the required logging capabilities. The declaration of conformity by the manufacturer is justified by ensuring that these requirements are guaranteed in a proportionate way, without imposing an undue burden on Member States and manufacturers.	
Recital	l 28b			

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
38b			(28b) In order to promote the smooth functioning of the internal market for electronic health data, digital health products and services, as much transparency as possible should be ensured as regards national regulations establishing requirements for EHR systems and provisions on their conformity assessment in relation to aspects other than the harmonised components of EHR systems under the regulation. It is essential for the Commission to	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			have the necessary information regarding those national requirements in order to ensure that they do not impede or adversely interact with the harmonised components of EHR systems.	
	Recital 29			
39	 (29) Software or module(s) of software which falls within the definition of a medical device or high-risk artificial intelligence (AI) system should be certified 	(29) Software or module(s) of software which falls within the definition of a medical device or high-risk artificial intelligence (AI) system should be certified	(29) Software or module(s) of software which falls within the definition of a medical device, in vitro diagnostic medical devices or high-risk artificial	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
in accordance with	in accordance with	intelligence (AI) system	
Regulation (EU) 2017/745	Regulation (EU) 2017/745	should be certified in	
of the European Parliament	of the European Parliament	accordance with Regulation	
and of the Council ¹ and	and of the Council ¹ and	(EU) 2017/745, Regulation	
Regulation [] of the	Regulation [] of the	(EU) 2017/746 of the	
European Parliament and of	European Parliament and of	European Parliament and of	
the Council [AI Act	the Council [AI Act	the Council ¹ and Regulation	
COM/2021/206 final], as	COM/2021/206 final], as	[] of the European	
applicable. The essential	applicable. The essential	Parliament and of the	
requirements on	requirements on	Council [AI Act	
interoperability of this	interoperability of this	COM/2021/206 final], as	
Regulation should only	Regulation should only	applicable. The essential	
apply to the extent that the	apply to the extent that the	requirements on	
manufacturer of a medical	manufacturer of a medical	interoperability of this	
device or high-risk AI	device or high-risk AI	Regulation should only	
system, which is providing	system, which is providing	apply to the extent that the	
electronic health data to be	electronic health data to be	manufacturer of a medical	
processed as part of the	processed as part of the	device, in vitro diagnostic	
EHR system, claims	EHR system, claims	medical devices, or high-	
interoperability with such	interoperability with such	risk AI system, which is	
EHR system. In such case,	EHR system. In such case,	providing electronic health	

Commission	Proposal	EP Mandate	Council Mandate	Draft Agreement
the provisions of specifications for systems should	or EHR	the provisions on common specifications for EHR systems should be	data to be processed as part of the EHR system, claims interoperability with such	
applicable to the devices and hig systems.		applicable to those medical devices and high-risk AI systems.	EHR system. In such case, the provisions on common specifications for EHR	
			systems should be applicable to those medical devices, in vitro diagnostic	
1. Regulation (EU) the European Parlia the Council of 5 Ap medical devices, ar	ament and of oril 2017 on	1. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending	medical devices, and high- risk AI systems.	
EC) No 1223/2002	EC, Regulation and Regulation	Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing	1. Regulation (EU) 2017/745 of	
Council Directives and 93/42/EEC (O. 5.5.2017, p. 1).	90/385/EEC	Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).	the European Parliament and of the Council of 5 April 2017 on	
5.5.2017, p. 1).		5.5.2017, p. 1).	medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117,	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				5.5.2017, p. 1).	
	Recita	al 30			
	(30) To further support		(30) To further support	(30) To further support	
	interoperability and		interoperability and	interoperability and	
	security, Member States		security, Member States	security, Member States	
	may maintain or define		may maintain or define	may maintain or define	
	specific rules for the		specific rules for the	specific rules for the	
40	procurement,		procurement,	procurement,	
-10	reimbursement, financing		reimbursement, financing or	reimbursement, financing or	
	or use of EHR systems at		use of EHR systems at	use of EHR systems at	
	national level in the context		national level in the context	national level in the context	
	of the organisation, delivery		of the organisation, delivery	of the organisation, delivery	
	or financing of health		or financing of health	or financing of health	
	services. Such specific rules		services. Such specific rules	services. Such specific rules	
	should not impede the free		should not impede the free	should not impede the free	
	movement of EHR systems		movement of EHR systems	movement of EHR systems	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
:	in the Union. Some	in the Union. Some	in the Union. Some	
-	Member States have	Member States have	Member States have	
-	introduced mandatory	introduced mandatory	introduced mandatory	
	certification of EHR	certification of EHR	certification of EHR	
:	systems or mandatory	systems or mandatory	systems or mandatory	
:	interoperability testing for	interoperability testing for	interoperability testing for	
1	their connection to national	their connection to national	their connection to national	
	digital health services. Such	digital health services. Such	digital health services. Such	
]	requirements are commonly	requirements are commonly	requirements are commonly	
1	reflected in procurements	reflected in procurements	reflected in procurements	
	organised by healthcare	organised by healthcare	organised by healthcare	
]	providers, national or	providers, national or	providers, national or	
1	regional authorities.	regional authorities.	regional authorities.	
-	Mandatory certification of	Mandatory certification of	Mandatory certification of	
-	EHR systems at Union level	EHR systems at Union level	EHR systems at Union level	
:	should establish a baseline	should establish a baseline	should establish a baseline	
1	that can be used in	that can be used in	that can be used in	
]	procurements at national	procurements at national	procurements at national	
	level.	level.	level.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Recital	31			
41	(31) In order to guarantee effective exercise by patients of their rights under this Regulation, where healthcare providers develop and use an EHR system 'in house' to carry out internal activities without placing it on the market in return of payment or remuneration, they should also comply with this Regulation. In that	31	(31) In order to guarantee effective exercise by patients of their rights under this Regulation, where healthcare providers develop and use an EHR system 'in house' to carry out internal activities without placing it on the market in return of payment or remuneration, they should also comply with this Regulation. In that	(31) In order to guarantee effective exercise by patients of their rights under this Regulation, where healthcare providers develop and use an EHR system 'in house' to carry out internal activities without placing it on the market in return of payment or remuneration, they should also comply with this Regulation. In that	
	context, such healthcare providers should comply		context, such healthcare providers should comply	context, such healthcare providers should comply	
	with all requirements applicable to the		with all requirements applicable to the	with all requirements applicable to the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	manufacturers.		manufacturers.	manufacturers for such 'in house'-developed system that they put into service. However, such healthcare providers may need additional time to prepare. For that reason, these requirements should only apply to such systems after an extended transition period.	
	Recital	32			
42	(32) It is necessary to provide for a clear and proportionate division of obligations corresponding		(32) It is necessary to provide for a clear and proportionate division of obligations corresponding	(32) It is necessary to provide for a clear and proportionate division of obligations corresponding	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement		
	to the role of each operator in the supply and distribution process of EHR systems. Economic operators should be responsible for compliance in relation to their respective roles in such process and should ensure that they make available on the market only EHR systems which comply with relevant requirements.		to the role of each operator in the supply and distribution process of EHR systems. Economic operators should be responsible for compliance in relation to their respective roles in such process and should ensure that they make available on the market only EHR systems which comply with relevant requirements.	to the role of each operator in the supply and distribution process of EHR systems. Economic operators should be responsible for compliance in relation to their respective roles in such process and should ensure that they make available on the market only EHR systems which comply with relevant requirements.			
	Recital 33						
43	(33) Compliance with essential requirements on		(33) Compliance with essential requirements on	(33) Compliance with essential requirements on			

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
interoperability and security	interoperability and security	interoperability and security	
should be demonstrated by	should be demonstrated by	should be demonstrated by	
the manufacturers of EHR	the manufacturers of EHR	the manufacturers of EHR	
systems through the	systems through the	systems through the	
implementation of common	implementation of common	implementation of common	
specifications. To that end,	specifications. To that end,	specifications. To that end,	
implementing powers	implementing powers	implementing powers	
should be conferred on the	should be conferred on the	should be conferred on the	
Commission to determine	Commission to determine	Commission to determine	
such common specifications	such common specifications	such common specifications	
regarding datasets, coding	regarding datasets, coding	regarding datasets, coding	
systems, technical	systems, technical	systems, technical	
specifications, including	specifications, including	specifications, including	
standards, specifications	standards, specifications	standards, specifications	
and profiles for data	and profiles for data	and profiles for data	
exchange, as well as	exchange, as well as	exchange, as well as	
requirements and principles	requirements and principles	requirements and principles	
related to security,	related to security,	related to security,	
confidentiality, integrity,	confidentiality, integrity,	confidentiality, integrity,	
patient safety and	patient safety and protection	patient safety and protection	
protection of personal data	of personal data as well as	of personal data as well as	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	as well as specifications and requirements related to identification management and the use of electronic identification. Digital health authorities should contribute to the development of such common specifications.		specifications and requirements related to identification management and the use of electronic identification. Digital health authorities should contribute to the development of such common specifications.	specifications and requirements related to identification management and the use of electronic identification. Digital health authorities should contribute to the development of such common specifications.	
	Recital	1 34			
44	(34) In order to ensure an appropriate and effective enforcement of the requirements and obligations laid down in Chapter III of this		(34) In order to ensure an appropriate and effective enforcement of the requirements and obligations laid down in Chapter III of this	(34) In order to ensure an appropriate and effective enforcement of the requirements and obligations laid down in Chapter III of this	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Regulation, the system of	Regulation, the system of	Regulation, the system of	
market surveillance and	market surveillance and	market surveillance and	
compliance of products	compliance of products	compliance of products	
established by Regulation	established by Regulation	established by Regulation	
(EU) 2019/1020 should	(EU) 2019/1020 should	(EU) 2019/1020 should	
apply. Depending on the	apply. Depending on the	apply. Depending on the	
organisation defined at	organisation defined at	organisation defined at	
national level, such market	national level, such market	national level, such market	
surveillance activities could	surveillance activities could	surveillance activities could	
be carried out by the digital	be carried out by the digital	be carried out by the digital	
health authorities ensuring	health authorities ensuring	health authorities ensuring	
the proper implementation	the proper implementation	the proper implementation	
of Chapter II or a separate	of Chapter II or a separate	of Chapter II or a separate	
market surveillance	market surveillance	market surveillance	
authority responsible for	authority responsible for	authority responsible for	
EHR systems. While	EHR systems. While	EHR systems. While	
designating digital health	designating digital health	designating digital health	
authorities as market	authorities as market	authorities as market	
surveillance authorities	surveillance authorities	surveillance authorities	
could have important	could have important	could have important	
practical advantages for the	practical advantages for the	practical advantages for the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	implementation of health and care, any conflicts of interest should be avoided, for instance by separating different tasks.		implementation of health and care, any conflicts of interest should be avoided, for instance by separating different tasks.	implementation of health and care, any conflicts of interest should be avoided, for instance by separating different tasks.	
	Recita	l 34a			
44a			(34a) EHR systems could qualify as medical devices under Regulation (EU) 2017/745 or in-vitro diagnostic devices under Regulation (EU) 2017/746 of the European Parliament and of the Council ¹ . While those EHR systems need to fulfil the		

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	requirements under each		
	applicable regulation, Member States should take		
	appropriate measures to		
	ensure that the respective		
	<u>conformity assessment is</u> <u>carried out as a joint or</u>		
	coordinated procedure, as		
	appropriate, inter alia by		
	encouraging the same		
	notified bodies to become		
	<u>responsible for the</u> <u>conformity assessment</u>		
	under each applicable		
	regulation.		
	<u>1</u> . <u>Regulation (EU) 2017/746 of</u> the European Parliament and of		
	the Council of 5 April 2017 on in		
	<u>vitro diagnostic medical devices</u>		
	and repealing Directive 98/79/EC		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).		
	Recital	1 35			
45	(35) Users of wellness applications, such as mobile applications, should be informed about the capacity of such applications to be connected and to supply data to EHR systems or to national electronic health solutions, in cases where data produced by wellness applications is useful for healthcare purposes. The capability of those		(35) Users of wellness applications, such as mobile applications, should be informed about the capacity of such applications to be connected and to supply data to EHR systems or to national electronic health solutions, in cases where data produced by wellness applications is useful for healthcare purposes. The capability of those	(35) Users of wellness applications, such as mobile applications, should be informed about the capacity of such applications to be connected and to supply data to EHR systems or to national electronic health solutions, in cases where data produced by wellness applications is useful for healthcare purposes. The capability of those	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
applications to export data	applications to export data	applications to export data	
in an interoperable format is	in an interoperable format is	in an interoperable format is	
also relevant for data	also relevant for data	also relevant for data	
portability purposes. Where	portability purposes. Where	portability purposes. Where	
applicable, users should be	applicable, users should be	applicable, users should be	
informed about the	informed about the	informed about the	
compliance of such	compliance of such	compliance of such	
applications with	applications with	applications with	
interoperability and security	interoperability and security	interoperability and security	
requirements. However,	requirements. However,	requirements. However,	
given the large number of	given the large number of	given the large number of	
wellness applications and	wellness applications and	wellness applications and	
the limited relevance for	the limited relevance for	the limited relevance for	
healthcare purposes of the	healthcare purposes of the	healthcare purposes of the	
data produced by many of	data produced by many of	data produced by many of	
them, a certification scheme	them, a certification scheme	them, a certification scheme	
for these applications would	for these applications would	for these applications would	
not be proportionate. A	not be proportionate. A	not be proportionate. A	
voluntary labelling scheme	voluntary mandatory	voluntary labelling scheme	
should therefore be	labelling scheme <u>for</u>	should therefore be	
established as an	wellness applications	established as an	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
appropriate mechanism for	claiming interoperability	appropriate mechanism for	
enabling the transparency	<u>with EHR systems</u> should	enabling the transparency	
for the users of wellness	therefore be established as	for the users of wellness	
applications regarding	an appropriate mechanism	applications regarding	
compliance with the	for enabling the	compliance with the	
requirements, thereby	transparency for the users of	requirements, thereby	
supporting users in their	wellness applications	supporting users in their	
choice of appropriate	regarding compliance with	choice of appropriate	
wellness applications with	the requirements, thereby	wellness applications with	
high standards of	supporting users in their	high standards of	
interoperability and	choice of appropriate	interoperability and	
security. The Commission	wellness applications with	security. The Commission	
may set out in	high standards of	may set out in	
implementing acts the	interoperability and	implementing acts the	
details regarding the format	security. The Commission	details regarding the format	
and content of such label.	mayshould set out in	and content of such label.	
	implementing acts the		
	details regarding the format		
	and content of such label.		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Recital	35a	·		
45a				(35a) Member States should remain free to regulate the use of wellness applications as referred to in Article 31 in the context of the provision of healthcare, provided that such rules are in compliance with Union law.	
	Recital	36			
46	(36) The distribution of		(36) The distribution of	(36) The distribution of	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
information on certified	information on certified	information on certified	
EHR systems and labelled	EHR systems and labelled	EHR systems and labelled	
wellness applications is	wellness applications is	wellness applications is	
necessary to enable	necessary to enable	necessary to enable	
procurers and users of such	procurers and users of such	procurers and users of such	
products to find	products to find	products to find	
interoperable solutions for	interoperable solutions for	interoperable solutions for	
their specific needs. A	their specific needs. A	their specific needs. A	
database of interoperable	database of interoperable	database of interoperable	
EHR systems and wellness	EHR systems and wellness	EHR systems and wellness	
applications, which are not	applications, which are not	applications, which are not	
falling within the scope of	falling within the scope of	falling within the scope of	
Regulations (EU) 2017/745	Regulations (EU) 2017/745	Regulations (EU) 2017/745	
and [] [AI act	and [] [AI act	and [] [AI act	
COM/2021/206 final]	COM/2021/206 final]	COM/2021/206 final]	
should therefore be	should therefore be	should therefore be	
established at Union level,	established at Union level,	established at Union level,	
similar to the European	similar to the European	similar to the European	
database on medical	database on medical devices	database on medical devices	
devices (Eudamed)	(Eudamed) established by	(Eudamed) established by	
established by Regulation	Regulation (EU) 2017/745.	Regulation (EU) 2017/745.	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
(EU) 2017/745. The	The objectives of the EU	The objectives of the EU	
objectives of the EU	database of interoperable	database of interoperable	
database of interoperable	EHR systems and wellness	EHR systems and wellness	
EHR systems and wellness	applications should be to	applications should be to	
applications should be to	enhance overall	enhance overall	
enhance overall	transparency, to avoid	transparency, to avoid	
transparency, to avoid	multiple reporting	multiple reporting	
multiple reporting	requirements and to	requirements and to	
requirements and to	streamline and facilitate the	streamline and facilitate the	
streamline and facilitate the	flow of information. For	flow of information. For	
flow of information. For	medical devices and AI	medical devices and AI	
medical devices and AI	systems, the registration	systems, the registration	
systems, the registration	should be maintained under	should be maintained under	
should be maintained under	the existing databases	the existing databases	
the existing databases	established respectively	established respectively	
established respectively	under Regulations (EU)	under Regulations (EU)	
under Regulations (EU)	2017/745 and [] [AI act	2017/745 and [] [AI act	
2017/745 and [] [AI act	COM/2021/206 final], but	COM/2021/206 final], but	
COM/2021/206 final], but	the compliance with	the compliance with	
the compliance with	interoperability	interoperability	
interoperability	requirements should be	requirements should be	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	requirements should be indicated when claimed by manufacturers, to provide information to procurers.		indicated when claimed by manufacturers, to provide information to procurers.	indicated when claimed by manufacturers, to provide information to procurers.	
	Recita	l 36a			
46a			(36a) The uptake of real- world data and real-world evidence, including patient-reported outcomes, for evidence-based regulatory and policy purposes as well as for research, health technology assessment and clinical objectives should be encouraged. Real-world		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			data and real-world evidence have the potential to complement health data currently made available.		
	Recita	137			
47	(37) For the secondary use of the clinical data for research, innovation, policy making, regulatory purposes, patient safety or the treatment of other natural persons, the possibilities offered by Regulation (EU) 2016/679 for a Union law should be used as a basis and rules		(37) For the secondary use of <i>the clinicalpersonal</i> <i>electronic health</i> data for research, innovation, policy making, regulatory purposes, patient safety or the treatment of other natural persons, the possibilities offered by Regulation (EU) 2016/679 for a Union law should be	(37) Without hindering or replacing contractual or other voluntary mechanisms in place, this Regulation is aimed at establishing a common mechanism to access electronic health data for secondary use, which makes it mandatory for data holders to make the	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
and mechanisms and	used as a basis and for rules	data they hold available	
providing suitable and	and mechanisms-and	on the basis of a data	
specific measures to	providing suitable and	permit or a data request.	
safeguard the rights and	specific measures to	For the secondary use of	
freedoms of the natural	safeguard the rights and	electronic health -the	
persons. This Regulation	freedoms of the natural	elinical data for research,	
provides the legal basis in	persons. For the purpose of	innovation, policy making,	
accordance with Articles	processing electronic	regulatory purposes, patient	
9(2) (g), (h), (i) and (j) of	health data for secondary	safety or the treatment of	
Regulation (EU) 2016/679	use, one of the legal bases	other natural persons, the	
for the secondary use of	set out in Article 6(1),	possibilities offered by	
health data, establishing the	<u>points (a), (c), (e) or (f), of</u>	Regulation Regulations	
safeguards for processing,	Regulation (EU) 2016/679	(EU) 2016/679 for a and	
in terms of lawful purposes,	combined with Article 9(2)	(EU) 2018/1725 for Union	
trusted governance for	of that Regulation should	lawlaws should be used as a	
providing access to health	<u>be required. The most</u>	basis and rules and	
data (through health data	relevant processing	mechanisms and	
access bodies) and	condition listed in Article	providingfor the	
processing in a secure	9(2) of Regulation (EU)	processing as well as	
environment, as well as	2016/679 in this context is	suitable and specific	
modalities for data	that of substantial public	measures to safeguard the	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
processing, set out in the	interest, the provision of	rights and freedoms of the	
data permit. At the same	<u>health or social care,</u>	natural persons. This	
time, the data applicant	public interest in the area	Regulation provides thea	
should demonstrate a legal	<u>of public health and</u>	legal basis in accordance	
basis pursuant to Article 6	<u>research. Hence,</u> this	with Regulation (EU)	
of Regulation (EU)	Regulation provides the	2016/679 and (EU)	
2016/679, based on which	legal basis in accordance	2018/1725 for the	
they could request access to	with Article 6 and Articles	secondary use of personal	
data pursuant to this	9(2) (g), (h), (i) and (j) of	electronic health data	
Regulation and should fulfil	Regulation (EU) 2016/679	including the safeguards	
the conditions set out in	for the secondary use of	to permit the processing of	
Chapter IV. More	health data, establishing the	special categories of data,	
specifically: for processing	safeguards for processing,	in accordance with	
of electronic health data	in terms of lawful purposes,	Articles 9(2) (g), (h), (i) and	
held by the data holder	trusted governance for	(j) of Regulation (EU)	
pursuant to this Regulation,	providing access to health	2016/679 for the secondary	
this Regulation creates the	data (through health data	use of health data,	
legal obligation in the sense	access bodies) and	establishing the safeguards	
of Article 6(1) point (c) of	processing in a secure	for processing and Articles	
Regulation (EU) 2016/679	environment, as well as	10(2) (g), (h), (i) and (j) of	
for disclosing the data by	modalities for data	(EU) 2018/1725, in terms	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
the data holder to health	processing, set out in the	of lawful purposes, trusted	
data access bodies, while	data permit. At the same	governance for providing	
the legal basis for the	time, the data applicant	access to health data	
purpose of the initial	should demonstrate a legal	(through health data access	
processing (e.g. delivery of	basis pursuant to Article 6	bodies) and processing in a	
care) is unaffected. This	of Regulation (EU)	secure environment, as well	
Regulation also meets the	2016/679, based on which	as modalities for data	
conditions for such	they could request access to	processing, set out in the	
processing pursuant to	data pursuant to this	data permit. At the same	
Articles 9(2) (h),(i),(j) of	Regulation and should fulfil	time, the data	
the Regulation (EU)	the conditions set out in	applicantConsequently,	
2016/679. This Regulation	Chapter IV. More	Member States may no	
assigns tasks in the public	specifically for processing	longer maintain or	
interest to the health data	of electronic health data	introduce under Article	
access bodies (running the	held by the <u>health</u> data	9(4) of Regulation (EU)	
secure processing	holder pursuant to this	2016/679 further	
environment, processing	Regulation, this Regulation	conditions, including	
data before they are used,	creates the legal obligation	limitations and specific	
etc.) in the sense of Article	in the sense of Article $6(1)_{\mathbf{L}}$	provisions requesting the	
6(1)(e) of Regulation (EU)	point (c), of Regulation	consent of natural	
2016/679 to the health data	(EU) 2016/679 for	persons, with regard to	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
access bodies, and meets	disclosing the data by the	the processing for	
the requirements of Article	health data holder to health	secondary use of personal	
9(2)(h),(i),(j) of the	data access bodies, while	electronic health data	
Regulation (EU) 2016/679.	the legal basis for the	under this Regulation. At	
Therefore, in this case, this	purpose of the initial	the same time data	
Regulation provides the	processing (e.g. delivery of	applicants should	
legal basis under Article 6	care) is unaffected. This	demonstrate a legal basis	
and meets the requirements	Regulation also meets the	pursuant to Article 6 of	
of Article 9 of that	conditions for such	Regulation (EU) 2016/679	
Regulation on the	processing pursuant to	or Article 5 of Regulation	
conditions under which	Articles 9(2) (h),(i),(j) of the	(EU) 2018/1725, where	
electronic health data can	Regulation (EU) 2016/679.	applicable, based on which	
be processed. In the case	This Regulation assigns	they could request access to	
where the user has access to	tasks in the public interest	electronic health data	
electronic health data (for	to the health data access	pursuant to this Regulation	
secondary use of data for	bodies (running the secure	and should fulfil the	
one of the purposes defined	processing environment,	conditions set out in	
in this Regulation), the data	processing data before they	Chapter IV. More	
user should demonstrate its	are used, etc.) in the sense	specifically:, for processing	
legal basis pursuant to	of Article 6(1)(e) of	of electronic health data	
Articles 6(1), points (e) or	Regulation (EU) 2016/679	held by the data holder	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
(f), of Regulation (EU)	to the health data access	pursuant to this	
2016/679 and explain the	bodies, and meets the	Regulation, health data	
specific legal basis on	requirements of Article	holders this Regulation	
which it relies as part of the	9(2)(h),(i)<mark>6(1), point (e)</mark>,(j)	creates the legal obligation	
application for access to	of the of Regulation (EU)	in the sense of Article 6(1)	
electronic health data	2016/679 . <i>Therefore, in this</i>	point (c) of Regulation (EU)	
pursuant to this Regulation:	case, this Regulation	2016/679, in accordance	
on the basis of the	provides the legal basis	with Article 9(2)(i) and (j)	
applicable legislation,	under Article 6 and meets	of the same Regulation for	
where the legal basis under	the requirements of Article	making available the	
Regulation (EU) 2016/679	9 of that Regulation on the	personal electronic health	
is Article 6(1), point (e), or	conditions under which	for disclosing the data by	
on Article 6(1), point (f), of	electronic health data can	the health data holder to	
Regulation (EU) 2016/679.	be processed. In the case	health data access bodies,	
If the user relies upon a	where the user has access	while the legal basis for the	
legal basis offered by	to electronic health data	purpose of the initial	
Article 6(1), point (e), it	(for secondary use of data	processing (e.g. providing	
should make reference to	for onc<mark>9(2), points (g) to</mark>	delivery of carehealthcare)	
another EU or national law,	(j), of the purposes defined	is unaffected. This	
different from this	in this Regulation), the data	Regulation also meets the	
Regulation, mandating the	user should demonstrate its	conditions for such	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
user to process personal	legal basis pursuant to	processing pursuant to	
health data for the	Articles 6(1), points (e) or	Articles 9(2) (h),(i),(j) of	
compliance of its tasks. If	(f), of Regulation (EU)	the Regulation (EU)	
the lawful ground for	2016/679. At the same time,	2016/679. This Regulation	
processing by the user is	<u>the</u> -and explain the specific	assigns tasks in the public	
Article 6(1), point (f), of	legal basis on which it	interest-to the health data	
Regulation (EU) 2016/679,	relies as part of the	access bodies (running the	
in this case it is this	application for access to	secure processing	
Regulation that provides the	electronic-health data	environment, processing	
safeguards. In this context,	pursuant to this Regulation:	data before they are used,	
the data permits issued by	on the basis of the	etc.) in the sense of Article	
the health data access	applicable legislation,	6(1)(e) of Regulation (EU)	
bodies are an administrative	where the legal basis under	2016/679 to the health data	
decision defining the	Regulation (EU) 2016/679	access bodies, and meets the	
conditions for the access to	is Article 6(1), point (e), or	requirements of Article	
the data.	onaccess body should	9(2)(h),(i),(j) of the	
	verify the compliance with	Regulation (EU) 2016/679 .	
	Article 6(1), point (f), 6 of	Therefore, in this case, this	
	Regulation (EU) 2016/679 .	Regulation provides the	
	If the user relies upon a	legal basis under Article 6	
	legal basis offered by	and meets the requirements	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Article 6(1), point (e), it	of Article 9 of that	
	should make reference to	Regulation for the health	
	another EU or national law,	data access body's	
	different from this	processing of personal	
	Regulation, mandating the	electronic health data	
	user to process personal	when the body is fulfilling	
	health data <mark>, combined with</mark>	its tasks of gathering,	
	<u>Article 9(2) thereof, based</u>	combining, preparing,	
	on which they should be	including	
	<u>able to issue a data permit</u>	pseudonymisation and	
	for the compliance of its	anonymisation of the data,	
	tasks. If the lawful ground	and makes those data	
	for processing by the user is	available to the health	
	Article 6(1), point (f), of	data user for secondary	
	Regulation (EU) 2016/679,	use on the conditions under	
	in this case it is<mark>of personal</mark>	which electronic health data	
	<u>electronic health data</u>	can be processed basis of a	
	pursuant to this Regulation	data permit or a data	
	that provides the	request. In the case where	
	safeguards. In this context,	the health data user has	
	the data permits issued by	access to personal	

Commission	Proposal	EP Mandate	Council Mandate	Draft Agreement
		the health data access	electronic health data (for	
		bodies are an	secondary use of data for	
		administrative decision	one of the purposes defined	
		defining the conditions for	in this Regulation), the	
		the access to the data <mark>should</mark>	health data user should	
		fulfil the requirements and	demonstrate its legal basis	
		conditions set out in	pursuant to Articles 6(1),	
		Chapter IV of this	points (e) or (f), of	
		Regulation.	Regulation (EU) 2016/679	
			or pursuant to Article	
			5(1), point (a) of	
			Regulation (EU)	
			2018/1725 and explain the	
			specific legal basis on	
			which it relies as part of the	
			application for access to	
			electronic health data	
			pursuant to this Regulation:	
			on the basis of the	
			applicable legislation,	
			where the. If the health	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		data user relies upon a	
		legal basis under Regulation	
		(EU) 2016/679 isoffered by	
		Article 6(1), point (e) , or on	
		Article 6(1), point (f), of	
		Regulation (EU) 2016/679 .	
		If the user relies upon a	
		legal basis offered by	
		Article 6(1), point (e) or	
		Article 5(1), point (a) of	
		Regulation (EU)	
		2018/1725, it should make	
		reference to another	
		EUUnion or national law,	
		different from this	
		Regulation, mandating the	
		health data user to process	
		personal health data for the	
		compliance of its tasks. If	
		the lawful ground for	
		processing by the health	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			data user is Article 6(1), point (f), of Regulation (EU) 2016/679, in this case it is this Regulation that provides the safeguards. In this context, the data permits issued by the health data access bodies are an administrative decision defining the conditions for the access to the data.	
	Recital 37a			
47a		(37a) In the case where the health data user has access to electronic health data for secondary use of		

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	data for one of the		
	<u>purposes defined in this</u>		
	Regulation, the health data		
	<u>user should demonstrate</u>		
	the specific legal ground		
	<u>on which it relies as part of</u>		
	the application for access		
	<u>to electronic health data</u>		
	<u>pursuant to this</u>		
	Regulation, namely, on the		
	<u>basis of the applicable law,</u>		
	where the legal basis under		
	<u>Regulation (EU) 2016/679</u>		
	<u>is Article 6(1), point (e), or</u>		
	<u>Article 6(1), point (f),</u>		
	<u>thereof. If the health data</u>		
	<u>user relies upon the ground</u>		
	provided for in Article 6(1),		
	<u>point (e), it should make</u>		
	<u>reference to another Union</u>		
	<u>or national law, requiring</u>		

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	the user to process		
	<u>personal health data for</u>		
	the compliance of its tasks.		
	<u>If the ground for</u>		
	processing by the health		
	data user is Article 6(1),		
	point (f), of Regulation		
	(EU) 2016/679, appropriate		
	and necessary safeguards		
	should be determined in		
	accordance with this		
	Regulation. In this context,		
	the data permits issued by		
	the health data access		
	bodies should be an		
	administrative decision		
	defining the conditions for		
	the access to the data.		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Reci	tal 37a			
47b				(37a) The secondary use of electronic health data can bring great societal benefits. To achieve this goal, it is important that data sets made available for secondary use by the present Regulation are as complete as possible. This Regulation provides the necessary safeguards to mitigate certain risks involved in the realisation of those benefits. The secondary use of electronic health data is based on pseudonymised	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		or anonymised data, in	
		order to preclude the	
		identification of the data	
		subjects. However, to	
		balance the need of data	
		users to have exhaustive	
		and representative	
		datasets with the	
		autonomy of natural	
		persons over data that are	
		considered particularly	
		sensitive, Member State	
		should be able to allow	
		natural persons to	
		indicate that they do not	
		wish for their personal	
		electronic health data to	
		be made available for	
		secondary use pursuant to	
		this Regulation. To do so,	
		Member States may	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Commission Proposal Image: Co	EP Mandate	introduce a specific right to object from the processing of personal electronic health data for secondary use which complements the right to object set out by article 21 of Regulation (EU) 2016/679. It is appropriate to leave Member States free to decide to introduce	
		and modulate such a right as it involves a balance between individual autonomy and the availability of health data for secondary use purposes, which is best made at national level, taking into account Member States' specific	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		situations and historical	
		experiences. Should a	
		Member State choose to	
		provide for such a right, it	
		should also define how	
		and where to exercise it	
		and facilitate its exercise.	
		This right can be	
		implemented at the level	
		of the health data holder	
		that is subject to a legal	
		obligation to make data	
		available to the health	
		data access body, at the	
		level of the health data	
		intermediary entity, or at	
		the level of the health data	
		access body, or at several	
		levels. As such a right can	
		affect the representativity	
		of datasets, statistics	
1			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				providing sufficient information for data users shall be available at Member State level to assess the impact of the exercise of this right on the utility of the dataset. Where a Member State does not introduce a specific right to object in accordance with article 35F of this regulation, solely Article 21 of Regulation (EU) 2016/679 will apply.	
	Recita	138			
48					

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
(38) In the context of the	(38) In the context of the	(38) In the context of the	
EHDS, the electronic health	EHDS, the electronic health	EHDS, the electronic health	
data already exists and is	data already exists and is	data already exists and is	
being collected by	being collected by	being collected by	
healthcare providers,	healthcare providers,	healthcare providers,	
professional associations,	professional associations,	professional associations,	
public institutions,	public institutions,	public institutions,	
regulators, researchers,	regulators, researchers,	regulators, researchers,	
insurers etc. in the course of	insurers etc. in the course of	insurers etc. in the course of	
their activities. Some	their activities. Some	their activities. Some	
categories of data are	categories of data are	categories of data are	
collected primarily for the	collected primarily for the	collected primarily for the	
provisions of healthcare	provisions of healthcare	provisions of healthcare	
(e.g. electronic health	(e.g. electronic health	(e.g. electronic health	
records, genetic data,	records, genetic data, claims	records, genetic data, claims	
claims data, etc.), others are	data, etc.), others are	data, etc.), others are	
collected also for other	collected also for other	collected also for other	
purposes such as research,	purposes such as research,	purposes such as research,	
statistics, patient safety,	statistics, patient safety,	statistics, patient safety,	
regulatory activities or	regulatory activities or	regulatory activities or	
policy making (e.g. disease	policy making (e.g. disease	policy making (e.g. disease	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
registries, policy making	registries, policy making	registries, policy making	
registries, registries	registries, registries	registries, registries	
concerning the side effects	concerning the side effects	concerning the side effects	
of medicinal products or	of medicinal products or	of medicinal products or	
medical devices, etc.). For	medical devices, etc.). For	medical devices, etc.). For	
instance, European	instance, European	instance, European	
databases that facilitate data	databases that facilitate data	databases that facilitate data	
(re)use are available in	(re)use are available in	(re)use are available in	
some areas, such as cancer	some areas, such as cancer	some areas, such as cancer	
(European Cancer	(European Cancer	(European Cancer	
Information System) or rare	Information System) or rare	Information System) or rare	
diseases (European	diseases (European	diseases (European	
Platform on Rare Disease	Platform on Rare Disease	Platform on Rare Disease	
Registration, ERN	Registration, ERN	Registration, ERN	
registries, etc.). These data	registries, etc.). These data	registries, etc.). These data	
should also be made	should also be made	should also be made	
available for secondary use.	available for secondary use.	available for secondary use.	
However, much of the	However, much of the	However, much of the	
existing health-related data	existing health-related data	existing health-related data	
is not made available for	is not made available for	is not made available for	
purposes other than that for	purposes other than that for	purposes other than that for	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
which they were collected.	which they were collected.	which they were collected.	
This limits the ability of	This limits the ability of	This limits the ability of	
researchers, innovators,	researchers, innovators,	researchers, innovators,	
policy-makers, regulators	policy-makers, regulators	policy-makers, regulators	
and doctors to use those	and doctors to use those	and doctors to use those	
data for different purposes,	data for different purposes,	data for different purposes,	
including research,	including research,	including research,	
innovation, policy-making,	innovation, policy-making,	innovation, policy-making,	
regulatory purposes, patient	regulatory purposes, patient	regulatory purposes, patient	
safety or personalised	safety or personalised	safety or personalised	
medicine. In order to fully	medicine. In order to fully	medicine. In order to fully	
unleash the benefits of the	unleash the benefits of the	unleash the benefits of the	
secondary use of electronic	secondary use of electronic	secondary use of electronic	
health data, all data holders	health data, all <u>health</u> data	health data, all data holders	
should contribute to this	holders should contribute to	should contribute to this	
effort in making different	this effort in making	effort in making different	
categories of electronic	different categories of	categories of electronic	
health data they are holding	electronic health data they	health data they are holding	
available for secondary use.	are holding available for	available for secondary use.	
	secondary use provided that		
	<u>such effort is always made</u>		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		through effective and secured processes, such as aggregation and randomisation, and with due respect for professional duties, such as confidentiality duties.		
	Recital 39			
49	(39) The categories of electronic health data that can be processed for secondary use should be broad and flexible enough to accommodate the evolving needs of data users, while remaining	(39) The categories of electronic health data that can be processed for secondary use should be broad and flexible enough to accommodate the evolving needs of <u>health</u> data users, while remaining	(39) The categories of electronic health data that can be processed for secondary use should be broad and flexible enough to accommodate the evolving needs of data users, while remaining	

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limited to data related to	limited to data related to	limited to data related to	
health or known to	health or known to	health or known to	
influence health. It can also	influence health. It can also	influence health. It can also	
include relevant data from	include relevant data from	include relevant data from	
the health system	the health system	the health system	
(electronic health records,	(electronic health records,	(electronic health records,	
claims data, disease	claims data, disease	claims data, disease	
registries, genomic data	registries, genomic data	registries, genomic data	
etc.), as well as data with an	etc.), as well as data with an	etc.), as well as data with an	
impact on health (for	impact on health (for	impact on health (for	
example consumption of	example consumption of	example consumption of	
different substances,	different substances,	different substances,	
homelessness, health	homelessness, health	homelessness, health	
insurance, minimum	insurance, minimum	insurance, minimum	
income, professional status,	income, professional<mark>socio-</mark>	income, professional status,	
behaviour, including	economic status, behaviour,	behaviour, including	
environmental factors (for	including environmental	environmental factors (for	
example, pollution,	factors (for example,	example, pollution,	
radiation, use of certain	pollution, radiation, use of	radiation, use of certain	
chemical substances). They	certain chemical	chemical substances). They	
can also include person-	substances). They can also	can also include person-	

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generated data, such as data	include person-generated	generated data, such as data	
from medical devices,	data, such as<mark>automatically</mark>	from medical devices,	
wellness applications or	generated data from	wellness applications or	
other wearables and digital	medical devices , wellness	other wearables and digital	
health applications. The	applications or other	health applications. The	
data user who benefits from	wearables and digital	data user who benefits from	
access to datasets provided	health and person-	access to datasets provided	
under this Regulation could	generated data, such as	under this Regulation could	
enrich the data with various	wellness applications. The	enrich the data with various	
corrections, annotations and	<u>health</u> data user who	corrections, annotations and	
other improvements, for	benefits from access to	other improvements, for	
instance by supplementing	datasets provided under this	instance by supplementing	
missing or incomplete data,	Regulation could enrich the	missing or incomplete data,	
thus improving the	data with various	thus improving the	
accuracy, completeness or	corrections, annotations and	accuracy, completeness or	
quality of data in the	other improvements, for	quality of data in the	
dataset. To support the	instance by supplementing	dataset. To support the	
improvement of the original	missing or incomplete data,	improvement of the original	
database and further use of	thus improving the	database and further use of	
the enriched dataset, the	accuracy, completeness or	the enriched dataset, the	
dataset with such	quality of data in the	dataset with such	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
improvements and a	dataset. <i>Health data users</i>	improvements and a	
description of the changes	should be encouraged to	description of the changes	
should be made available	report critical errors in	should be made available	
free of charge to the	datasets to health data	free of charge to the original	
original data holder. The	access bodies. To support	data holder. The data holder	
data holder should make	the improvement of the	should make available the	
available the new dataset,	original database and	new dataset, unless it	
unless it provides a justified	further use of the enriched	provides a justified	
notification against it to the	dataset, the dataset with	notification against it to the	
health data access body, for	such improvements and a	health data access body, for	
instance in cases of low	description of the changes	instance in cases of low	
quality of the enrichment.	should be made available	quality of the enrichment.	
Secondary use of non-	free of charge to the original	Secondary use of non-	
personal electronic data	data holder. The data holder	personal electronic data	
should also be ensured. In	should make available the	should also be ensured. In	
particular, pathogen	new dataset, unless it	particular, pathogen	
genomic data hold	provides a justified	genomic data hold	
significant value for human	notification against it to the	significant value for human	
health, as proven during the	health data access body, for	health, as proven during the	
COVID-19 pandemic.	instance in cases of low	COVID-19 pandemic.	
Timely access to and	quality of the enrichment.	Timely access to and	

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sharing of such data has	Secondary use of non-	sharing of such data has	
proven to be essential for	personal electronic data	proven to be essential for	
the rapid development of	should also be ensured. In	the rapid development of	
detection tools, medical	particular, pathogen	detection tools, medical	
countermeasures and	genomic data hold	countermeasures and	
responses to public health	significant value for human	responses to public health	
threats. The greatest benefit	health, as proven during the	threats. The greatest benefit	
from pathogen genomics	COVID-19 pandemic.	from pathogen genomics	
effort will be achieved	Timely access to and	effort will be achieved	
when public health and	sharing of such data has	when public health and	
research processes share	proven to be essential for	research processes share	
datasets and work mutually	the rapid development of	datasets and work mutually	
to inform and improve each	detection tools, medical	to inform and improve each	
other.	countermeasures and	other.	
	responses to public health		
	threats. The greatest benefit		
	from pathogen genomics		
	effort will be achieved		
	when public health and		
	research processes share		
	datasets and work mutually		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			to inform and improve each other.		
	Recita	l 39a			
49a			(39a) In order to guarantee trust in the patient-physician relationship, the principle of professional secrecy and the patient's right to confidentiality should be safeguarded when digitalising healthcare services. A relationship of trust between patients and health professionals and healthcare providers and		

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	other holders of personal		
	<u>health data is a paramount</u>		
	element of the provision of		
	<u>health or social care or</u>		
	<u>treatment. It is within that</u>		
	<u>context that the patient or</u>		
	<u>the legal representative of</u>		
	<u>the patient should have a</u>		
	say in the processing of		
	<u>their health data for</u>		
	secondary use in the form		
	<u>of a right to opt-out of the</u>		
	processing of all or parts of		
	<u>their health data for</u>		
	<u>secondary use for some or</u>		
	<u>all purposes. An easily</u>		
	<u>understandable and</u>		
	<u>accessible opt-out</u>		
	<u>mechanism in a user-</u>		
	<u>friendly format should be</u>		
	provided for in this regard.		

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	However, due to the		
	sensitive nature of human		
	genetic, genomic and		
	<u>proteomic data, data from</u>		
	biobanks and to the nature		
	<u>of the use of data from</u>		
	<u>wellness applications, it is</u>		
	appropriate to provide that		
	<u>the secondary use of such</u>		
	<u>data can only occur</u>		
	following the consent of		
	<u>the natural person</u>		
	<u>concerned in accordance</u>		
	with Article 4(11) of the		
	Regulation (EU) 2016/679.		
	<u>An opt-in mechanism</u>		
	<u>whereby data subjects</u>		
	<u>explicitly consent or give</u>		
	their permission to the		
	processing of part or all of		
	<u>such data for some or all</u>		

Commission Prop	osal	EP Mandate	Council Mandate	Draft Agreement
		secondary use purposes should be envisaged.		
		Where data subjects		
		explicitly consent to the use of parts or all of this data		
		<u>for some or all secondary</u> <u>use purposes, they should</u>		
		<u>be made aware of the</u> <u>sensitive nature of the data</u>		
		<u>they are sharing.</u> <u>Moreover, it is imperative</u>		
		<u>to provide natural persons</u> with sufficient information		
		<u>regarding their right to opt-</u> <u>out, including on the</u>		
		possibility of reconsidering their choice of opting-out		
		and agreeing to some or all of their health data being		
		<u>processed for secondary</u> <u>use at a later point.</u>		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Recital	39a			
49b				(39a) In order to increase the effectiveness of the secondary use of personal electronic health data, and to fully benefit from the possibilities offered by this Regulation in terms of, among others, health research, innovation, policy-making, and regulatory purposes, personal electronic health data for secondary use should be made available	
				prioritising the datasets	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				according to their usefulness, quality and readiness. This Regulation aims to ensure the availability in the EHDS of electronic health data described in Chapter IV that are accessible, ready and suitable for the purpose of creating scientific, innovative and societal value and quality.	
	Recita	l 40			
50	(40) The data holders can be public, non for profit or private health or care		(40) The <u>health</u> data holders <u>in the context of</u> <u>secondary use of electronic</u>	(40) The data holders can be public, non for profit or private health or care	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
providers, public, non for	health data can be public,	providers, public, non for	
profit and private	non for profit or private	profit and private	
organisations, associations	health or care providers,	organisations, associations	
or other entities, public and	public, non for profit and	or other entities, public and	
private entities that carry	private organisations,	private entities that carry	
out research with regards to	associations or other	out research with regards to	
the health sector that	entities, public and private	the health sectorhealthcare	
process the categories of	entities that carry out	or care sectors, entities	
health and health related	research with regards to the	developing products and	
data mentioned above. In	health sector that process	services intended for the	
order to avoid a	the categories of health and	healthcare or care sectors	
disproportionate burden on	health related data	and Union institutions,	
small entities, micro-	mentioned above To the	bodies, offices or agencies	
enterprises are excluded	extent that they process	that process the categories	
from the obligation to make	personal electronic health	of health and	
their data available for	<u>data, health data holders</u>	healthhealthcare data	
secondary use in the	are controllers within the	mentioned above, as well	
framework of EHDS. The	meaning of Regulation	as mortality registries.	
public or private entities	<u>(EU) 2016/679 in the</u>	Also included in the	
often receive public	<u>health or care sector</u> . In	category of data holders	
funding, from national or	order to avoid a	are entities in the care	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Union funds to collect and	disproportionate burden on	sector such as nursing	
process electronic health	small entities, micro-	homes, day-care centres,	
data for research, statistics	enterprises are excluded	entities providing services	
(official or not) or other	from the obligation to make	for people with	
similar purposes, including	their data available for	disabilities, business and	
in area where the collection	secondary use in the	technological activities	
of such data is fragmented	framework of EHDS.	related to care such as	
of difficult, such as rare	Health data access bodies	orthopaedics and	
diseases, cancer etc. Such	should provide specific	companies providing care	
data, collected and	support to small	services. Legal persons	
processed by data holders	enterprises, in particular	developing products and	
with the support of Union	medical practioners and	services intended for the	
or national public funding,	pharmacies, in complying	healthcare or care sectors,	
should be made available	with their obligation to	and wellness applications	
by data holders to health	<u>make data available for</u>	should also be data	
data access bodies, in order	<u>secondary use.</u> The public	holders. This	
to maximise the impact of	or private entities often	consideration applies	
the public investment and	receive public funding,	both if these entities or	
support research,	from national or Union	bodies are developing new	
innovation, patient safety or	funds to collect and process	products or services, or if	
policy making benefitting	electronic health data for	they already have	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
the society. In some	research, statistics (official	products on the	
Member States, private	or not) or other similar	marketdata mentioned	
entities, including private	purposes, including in area	above. In order to avoid a	
healthcare providers and	where the collection of such	disproportionate burden,	
professional associations,	data is fragmented of	natural persons and on	
play a pivotal role in the	difficult, such as rare	small entities, micro-	
health sector. The health	diseases, cancer etc. Such	enterprises are, as a general	
data held by such providers	data, collected and	rule, excluded from the	
should also be made	processed by <i>health</i> data	obligation to make their	
available for secondary use.	holders with the support of	data availableobligations as	
At the same time, data	Union or national public	data holders for secondary	
benefiting from specific	funding, should be made	use in the framework of	
legal protection such as	available by <u><i>health</i></u> data	EHDS. Member States	
intellectual property from	holders to health data access	should, however, be able	
medical device companies	bodies, in order to	to extend the obligations	
or pharmaceutical	maximise the impact of the	of data holders to natural	
companies often enjoy	public investment and	persons and micro-	
copyright protection or	support research,	enterprises in their	
similar types of protection.	innovation, patient safety or	national legislation. Due to	
However, public authorities	policy making benefitting	the diversity in the	
and regulators should have	the society. In some	structure of healthcare	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
access to such data, for	Member States, private	systems of the Member	
instance in the event of	entities, including private	States and the	
pandemics, to verify	healthcare providers and	administrative burden the	
defective devices and	professional associations,	inclusion of the care sector	
protect human health. In	play a pivotal role in the	may entail at the national	
times of severe public	health sector. The health	level, it should be possible	
health concerns (for	data held by such providers	to exclude the care sector	
example, PIP breast	should also be made	from the obligations of	
implants fraud) it appeared	available for secondary use.	data holders by way of	
very difficult for public	At the same time, data	national legislation. In	
authorities to get access to	benefiting from specific	order to reduce the	
such data to understand the	legal protection such as	administrative burden,	
causes and knowledge of	intellectual property from	and in the light of the	
manufacturer concerning	medical device companies	effectiveness and	
the defects of some devices.	or pharmaceutical	efficiency principles,	
The COVID-19 pandemic	companies often enjoy	Member States should be	
also revealed the difficulty	copyright protection or	able to decide, by way of	
for policy makers to have	similar types of protection	national legislation that	
access to health data and	and should be made	for certain categories of	
other data related to health.	available while taking all	data holders their duties	
Such data should be made	<u>necessary measures to</u>	as data holders are to be	

Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
available for public and		protect such rights.	carried out by health data	
regulatory activities,		However, public authorities	intermediation entities.	
supporting public bodies to		and regulators should have	The public or private	
carry out their legal		access to such data, for	entities often receive public	
mandate, while complying		instance in the event of	funding, from national or	
with, where relevant and		pandemics, to verify	Union funds to collect and	
possible, the protection		defective devices and	process electronic health	
enjoyed by commercial		protect human health. In	data for research, statistics	
data. Specific rules in		times of severe public	(official or not) or other	
relation to the secondary		health concerns (for	similar purposes, including	
use of health data should be		example, PIP breast	in areaareas where the	
provided. Data altruism		implants fraud) it appeared	collection of such data is	
activities may be carried ou	t	very difficult for public	fragmented of difficult,	
by different entities, in the		authorities to get access to	such as rare diseases, cancer	
context of Regulation []		such data to understand the	etc. Such data, collected and	
[Data Governance Act		causes and knowledge of	processed by data holders	
COM/2020/767 final] and		manufacturer concerning	with the support of Union	
taking into account the		the defects of some devices.	or national public funding,	
specificities of the health		The COVID-19 pandemic	should be made available by	
sector.		also revealed the difficulty	data holders to health data	
		for policy makers to have	access bodies, in order to	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	access to health data and	maximise the impact of the	
	other data related to health.	public investment and	
	Such data should be made	support research,	
	available for public and	innovation, patient safety or	
	regulatory activities,	policy making benefitting	
	supporting public bodies to	the society. In some	
	carry out their legal	Member States, private	
	mandate, while complying	entities, including private	
	with, where relevant and	healthcare providers and	
	possible, the protection	professional associations,	
	enjoyed by commercial	play a pivotal role in the	
	data. Specific rules in	health sector. The health	
	relation to the secondary	data held by such providers	
	use of health data should be	should also be made	
	provided. Data altruism	available for secondary use.	
	activities may be carried out	At the same time, data	
	by different entities, in the	benefiting from specific	
	context of Regulation []	legal protection such as	
	[Data Governance Act	intellectual property from	
	COM/2020/767 final] and	medical device companies	
	taking into account the	or pharmaceutical	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	specificities of the health	companies often enjoy	
	sector.	copyright protection or	
		similar types of protection.	
		However, public authorities	
		and regulators should have	
		access to such data, for	
		instance in the event of	
		pandemics, to verify	
		defective devices and	
		protect human health. In	
		times of severe public	
		health concerns (for	
		example, PIP breast	
		implants fraud) it appeared	
		very difficult for public	
		authorities to get access to	
		such data to understand the	
		causes and knowledge of	
		manufacturermanufacturer	
		s concerning the defects of	
		some devices. The COVID-	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		19 pandemic also revealed	
		the difficulty for policy	
		makers to have access to	
		health data and other data	
		related to health. Such data	
		should be made available	
		for public and regulatory	
		activities, supporting public	
		bodies to carry out their	
		legal mandate, while	
		complying with, where	
		relevant and possible, the	
		protection enjoyed by	
		commercial data. Specific	
		rules in relation to the	
		secondary use of health data	
		should be provided. Data	
		altruism activities may be	
		carried out by different	
		entities, in the context of	
		Regulation [] [Data	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			Governance Act COM/2020/767 final] and taking into account the specificities of the health sector.	
	Recital 40a			
50a		(40a) Different demographic groups have varying degrees of digital literacy, which can affect natural persons' ability to exercise their rights to control their electronic health data. In addition to the right for natural persons to authorise		

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	another natural person of		
	their choice to access or		
	control their electronic		
	<u>health data on their behalf,</u>		
	<u>Member States should</u>		
	create targeted national		
	<u>digital literacy</u>		
	programmes, including		
	programmes to maximise		
	social inclusion and to		
	<u>ensure all natural persons</u>		
	<u>can effectively exercise</u>		
	<u>their rights under this</u>		
	Regulation. Member States		
	<u>should also provide</u>		
	<u>patient-centric guidance to</u>		
	<u>natural persons in relation</u>		
	<u>to the use of electronic</u>		
	health records and primary		
	<u>use of their personal</u>		
	<u>electronic health data.</u>		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			Guidance should be tailored to the patient's level of digital health literacy, with specific attention to be given to the needs of vulnerable groups.		
	Recita	l 40b			
50b			(40b) <u>Clinical trials and</u> <u>studies are of utmost</u> <u>importance in fostering</u> <u>innovation within the</u> <u>Union for the benefit of</u> <u>Union patients. In order to</u> <u>incentivise continuous</u> <u>Union leadership in this</u> <u>domain, the sharing of the</u>		

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	clinical trials data through		
	the EHDS for secondary		
	use should be consistent		
	with the relevant		
	transparency provisions		
	<u>laid down in Union law</u>		
	including Regulation (EU)		
	/ [proposal for a		
	<u>Regulation on blood,</u>		
	tissue, cells and organs		
	<u>(SoHO) COM(2022)338</u>		
	<u>final], Regulations (EC)</u>		
	<u>No 726/2004¹ and (EU)</u>		
	2019/6² of the European		
	Parliament and of the		
	Council and Directive		
	<u>2001/83/EC of the</u>		
	<u>European Parliament and</u>		
	of the Council ³ regarding		
	<u>veterinary and human</u>		
	medicines and establishing		

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	the EMA, Regulation (EC)		
	<u>No 141/2000 of the</u>		
	European Parliament and		
	of the Council ⁴ related to		
	<u>medicinal products for rare</u>		
	<u>diseases ('orphan</u>		
	medicines'), Regulation		
	(EC) No 1901/2006 of the		
	European Parliament and		
	<u>of the Council⁵ on</u>		
	medicinal products for		
	<u>children, Regulation (EC)</u>		
	<u>No 1394/2007 of the</u>		
	<u>European Parliament and</u>		
	of the Council ⁶ on		
	<u>advanced therapy</u>		
	<u>medicinal products,</u>		
	Regulation (EU) No		
	536/2014 of the European		
	Parliament and of the		
	<u>Council⁷ on clinical trials,</u>		

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	<u>Regulation (EU) No</u> 2017/745 and Regulation (EU) No 2017/746.		
	<u> </u>		
	of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation		
	and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ		
	<u>L 136, 30.4.2004, p. 1).</u> <u>2</u> . <u>Regulation (EU) 2019/6 of the</u> <u>European Parliament and of the</u>		
	Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p.		
	<u>2001/82/EC (05 L 4, 7.1.2019, p.</u> <u>43).</u> <u>3</u> . <u>Directive 2001/83/EC of the</u>		

Com	mission Proposal	EP Mandate	Council Mandate	Draft Agreement
		European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human		
		use (OJ L 311, 28.11.2001, p. 67). 4. <u>Regulation (EC) No 141/2000</u> of the European Parliament and of the Council of 16 December		
		<u>1999 on orphan medicinal</u> <u>products (OJ L 18, 22.1.2000, p.</u> <u>1).</u> <u>5. Regulation (EC) No 1901/2006</u>		
		of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92,		
		<u>Directive 2001/20/EC, Directive</u> 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 378, 27.12.2006, p. 1).		
		<u>6</u> . <u>Regulation (EC) No 1394/2007</u> <u>of the European Parliament and</u> <u>of the Council of 13 November</u>		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 324, 10.12.2007, p. 121). 7. Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ L 158, 27.5.2014, p. 1).		
	Recital	40a			
50c				(40a) Electronic health data protected by intellectual property rights or trade secrets can	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		be very useful for secondary use. While they should be made available to the extent possible, however, this Regulation should not be used to reduce or circumvent such	
		protection. It is for the Health Data Access Body to assess how to preserve this protection while also enabling access to such data for health data users to the extent possible. If it	
		is unable to do so, it should inform the health data user and explain why it is not possible to provide access to such data. Legal, organisational and technical measures to	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		preserve intellectual property rights or trade secrets could include common electronic health data access contractual arrangements, specific obligations in relation to such rights within the data permit, pre-processing the data to generate derived data that protects a trade secret but still has utility for the user or configuration of the secure processing environment so that such data is not accessible by the health data user.	

	Commission Proposa	al	EP Mandate	Council Mandate	Draft Agreement
	Red	ecital 40b			
50d				(40b) Taking into account the specific purposes of the processing, data should be anonymised or pseudonymised as early as possible in the chain of making data available for secondary use. Pseudonymisation and anonymisation can be carried out by the health data access bodies or by the health data holders. As data controllers, health data access bodies and health data holders may delegate these tasks to	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				data processors.	
	Recita	41			
	(41) The secondary use of		(41) The secondary use of	(41) The secondary use of	
	health data under EHDS		health data under EHDS	health data under EHDS	
	should enable the public,		should enable the public,	should enable the public,	
	private, not for profit		private, not for profit	private, not for profit	
	entities, as well as		entities, as well as	entities, as well as	
51	individual researchers to		individual researchers, with	individual researchers to	
51	have access to health data		a demonstrated link to the	have access to health data	
	for research, innovation,		<u>field of public health,</u> to	for research, innovation,	
	policy making, educational		have access to health data	policy making, educational	
	activities, patient safety,		for research, innovation,	activities, patient safety,	
	regulatory activities or		policy making, educational	regulatory activities or	
	personalised medicine, in		activities, patient safety,	personalised medicine, in	
	line with the purposes set		regulatory activities or	line with the purposes set	
	out in this Regulation.		personalised medicine, in	out in this Regulation.	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Access to data for	line with the purposes set	Access to data for	
secondary use should	out in this Regulation.	secondary use should	
contribute to the general	Access to data for	contribute to the general	
interest of the society.	secondary use should	interest of the society.	
Activities for which access	contribute to the general	Activities for which access	
in the context of this	interest of the society. In	in the context of this	
Regulation is lawful may	particular, the secondary	Regulation is lawful may	
include using the electronic	<u>use of health data for</u>	include using the electronic	
health data for tasks carried	research and development	health data for tasks carried	
out by public bodies, such	purposes should contribute	out by public bodies, such	
as exercise of public duty,	to a benefit to society in the	as exercise of public duty,	
including public health	<u>form of new medicines,</u>	including public health	
surveillance, planning and	<u>medical devices, health</u>	surveillance, planning and	
reporting duties, health	care products and services	reporting duties, health	
policy making, ensuring	at affordable and fair	policy making, ensuring	
patient safety, quality of	prices for Union citizens,	patient safety, quality of	
care, and the sustainability	as well as to enhancing	care, and the sustainability	
of health care systems.	access to and the	of health care systems.	
Public bodies and Union	availability of such	Public bodies and Union	
institutions, bodies, offices	products and services in all	institutions, bodies, offices	
and agencies may require to	Member States. Activities	and agencies may require to	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
have regular access to	for which access in the	have regular access to	
electronic health data for an	context of this Regulation is	electronic health data for an	
extended period of time,	lawful may include using	extended period of time,	
including in order to fulfil	the electronic health data	including in order to fulfil	
their mandate, which is	for tasks carried out by	their mandate, which is	
provided by this	public bodies, such as	provided by this Regulation.	
Regulation. Public sector	exercise of public duty,	Public sector bodies may	
bodies may carry out such	including public health	carry out such research	
research activities by using	surveillance, planning and	activities by using third	
third parties, including sub-	reporting duties, health	parties, including sub-	
contractors, as long as the	policy making, ensuring	contractors, as long as the	
public sector body remain	patient safety, quality of	public sector body remain at	
at all time the supervisor of	care, and the sustainability	all timetimes the supervisor	
these activities. The	of health care systems.	of these activities. The	
provision of the data should	Public bodies and Union	provision of the data should	
also support activities	institutions, bodies, offices	also support activities	
related to scientific research	and agencies may require to	related to scientific research	
(including private research),	have regular access to	(including private research),	
development and	electronic health data for an	development and	
innovation, producing	extended period of time,	innovation, producing	
goods and services for the	including in order to fulfil	goods and services for the	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
health or care sectors, such	their mandate, which is	health or care sectors, such	
as innovation activities or	provided by this Regulation.	as innovation activities or	
training of AI algorithms	Public sector bodies may	training of AI algorithms	
that could protect the health	carry out such research	that could protect the health	
or care of natural persons.	activities by using third	or care of natural persons.	
In some cases, the	parties, including sub-	In some cases, the	
information of some natural	contractors, as long as the	information of some natural	
persons (such as genomic	public sector body remain at	persons (such as genomic	
information of natural	all time the supervisor of	information of natural	
persons with a certain	these activities. The	persons with a certain	
disease) could support the	provision of the data should	disease) could support the	
diagnosis or treatment of	also support activities	diagnosis or treatment of	
other natural persons. There	related to scientific research	other natural persons. There	
is a need for public bodies	(including private research),	is a need for public bodies	
to go beyond the emergency	development and	to go beyond the emergency	
scope of Chapter V of	innovation, producing	scope of Chapter V of	
Regulation [] [Data Act	goods and services for the	Regulation [] [Data Act	
COM/2022/68 final].	health or care sectors, such	COM/2022/68 final].	
However, the public sector	as innovation activities or	However, the public sector	
bodies may request the	training of <i>Alartificial</i>	bodies may request the	
support of health data	<i>intelligence</i> algorithms that	support of health data	

Commission	Proposal	EP Mandate	Council Mandate	Draft Agreement
access bodies fo	pr	could protect the health or	access bodies for processing	
processing or lin	nking data.	care of natural persons). In	or linking data. This	
This Regulation	provides a	some cases, the information	Regulation provides a	
channel for pub	lic sector	of some natural persons	channel for public sector	
bodies to obtain	access to	(such as genomic	bodies to obtain access to	
information that	t they	information of natural	information that they	
require for fulfil	lling their	persons with a certain	require for fulfilling their	
tasks assigned to	o them by	disease) could support the	tasks assigned to them by	
law, but does no	ot extend the	diagnosis or treatment of	law, but does not extend the	
mandate of such	n public	other natural persons. There	mandate of such public	
sector bodies. A	iny attempt	is a need for public bodies	sector bodies. Any attempt	
to use the data f	for any	to go beyond the emergency	to use the data for any	
measures detrim	nental to the	scope of Chapter V of	measures detrimental to the	
natural person, t	to increase	Regulation [] [Data Act	natural person, to increase	
insurance premi	iums, to	COM/2022/68 final].	insurance premiums, to	
advertise produc	cts or	However, the public sector	engage in activities	
treatments, or de	evelop	bodies may request the	potentially detrimental to	
harmful product	ts should be	support of health data	the natural persons	
prohibited.		access bodies for processing	related to employment,	
		or linking data. This	pension and banking,	
		Regulation provides a	including mortgaging of	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	channel for public sector	properties, to advertise	
	bodies to obtain access to	products or treatments, or	
	information that they	develop harmful products	
	require for fulfilling their	should be prohibited. This	
	tasks assigned to them by	prohibition applies to the	
	law, but does not extend the	activities contrary to	
	mandate of such public	ethical provisions	
	sector bodies. Any attempt	according to national law,	
	to use the data for any	with the exception of	
	measures detrimental to the	ethical provisions related	
	natural person, to increase	to consent the right to	
	insurance premiums, to	object to the processing of	
	advertise products or	personal data and the	
	treatments, <i>to automate</i>	right to object, which in	
	individual decision-	application of the general	
	<u>making, to re-identify</u>	principle of primacy of	
	natural persons, or develop	Union law, this Regulation	
	harmful products should be	takes precedence over	
	prohibited.	national law.	

	Commission Proj	posal	EP Mandate	Council Mandate	Draft Agreement
		Recital 41a			
51a				(41a) This Regulation does not create an empowerment for the secondary use of health data for the purpose of law enforcement. The prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties by competent authorities is not among the secondary use purposes covered under this Regulation. Therefore, courts and other entities of the justice	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				system cannot be considered data users in the secondary use of health data under this Regulation. In addition, courts and other entities of the justice system are not covered under the definition of data holders, and are therefore not addressees of obligations on data holders under this Regulation.	
	Recita	142			
52	(42) The establishment of one or more health data		(42) The establishment of one or more health data	(42) The establishment of one or more health data	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
access bodies, supporting	access bodies, supporting	access bodies, supporting	
access to electronic health	access to electronic health	access to electronic health	
data in Member States, is an	data in Member States, is an	data in Member States, is an	
essential component for	essential component for	essential component for	
promoting the secondary	promoting the secondary	promoting the secondary	
use of health-related data.	use of health-related data.	use of health-related data.	
Member States should	Member States should	Member States should	
therefore establish one or	therefore establish one or	therefore establish one or	
more health data access	more health data access	more health data access	
body, for instance to reflect	body, for instance to reflect	body, for instance to reflect	
their constitutional,	their constitutional,	their constitutional,	
organisational and	organisational and	organisational and	
administrative structure.	administrative structure.	administrative structure.	
However, one of these	However, one of these	However, one of these	
health data access bodies	health data access bodies	health data access bodies	
should be designated as a	should be designated as a	should be designated as a	
coordinator in case there are	coordinator in case there are	coordinator in case there are	
more than one data access	more than one data access	more than one data access	
body. Where a Member	body. Where a Member	body. Where a Member	
State establishes several	State establishes several	State establishes several	
bodies, it should lay down	bodies, it should lay down	bodies, it should lay down	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
rules at national level to	rules at national level to	rules at national level to	
ensure the coordinated	ensure the coordinated	ensure the coordinated	
participation of those	participation of those bodies	participation of those bodies	
bodies in the EHDS Board.	in the EHDS Board. That	in the EHDS Board. That	
That Member State should	Member State should in	Member State should in	
in particular designate one	particular designate one	particular designate one	
health data access body to	health data access body to	health data access body to	
function as a single contact	function as a single contact	function as a single contact	
point for the effective	point for the effective	point for the effective	
participation of those	participation of those	participation of those	
bodies, and ensure swift	bodies, and ensure swift and	bodies, and ensure swift and	
and smooth cooperation	smooth cooperation with	smooth cooperation with	
with other health data	other health data access	other health data access	
access bodies, the EHDS	bodies, the EHDS Board	bodies, the EHDS Board	
Board and the Commission.	and the Commission. Health	and the Commission. Health	
Health data access bodies	data access bodies may vary	data access bodies may vary	
may vary in terms of	in terms of organisation and	in terms of organisation and	
organisation and size	size (spanning from a	size (spanning from a	
(spanning from a dedicated	dedicated full-fledged	dedicated full-fledged	
full-fledged organization to	organization to a unit or	organization to a unit or	
a unit or department in an	department in an existing	department in an existing	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
existing organization) but	organization) but should	organization) but should	
should have the same	have the same functions,	have the same functions,	
functions, responsibilities	responsibilities and	responsibilities and	
and capabilities. Health data	capabilities. Health data	capabilities. Health data	
access bodies should not be	access bodies should not be	access bodies should not be	
influenced in their decisions	influenced in their decisions	influenced in their decisions	
on access to electronic data	on access to electronic data	on access to electronic data	
for secondary use.	for secondary use, Members	for secondary use.	
However, their	of the governance and	However, their	
independence should not	decision-making bodies	independence should not	
mean that the health data	and staff of each health	mean that the health data	
access body cannot be	data access body should	access body cannot be	
subject to control or	<u>therefore refrain from any</u>	subject to control or	
monitoring mechanisms	action that is incompatible	monitoring mechanisms	
regarding its financial	with their duties and	regarding its financial	
expenditure or to judicial	should not engage in any	expenditure or to judicial	
review. Each health data	incompatible occupation.	review. Each health data	
access body should be	However, their	access body should be	
provided with the financial	independence should not	provided with the financial	
and human resources,	mean that the health data	and human resources,	
premises and infrastructure	access body cannot be	premises and infrastructure	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
necessary for the effective	subject to control or	necessary for the effective	
performance of its tasks,	monitoring mechanisms	performance of its tasks,	
including those related to	regarding its financial	including those related to	
cooperation with other	expenditure or to judicial	cooperation with other	
health data access bodies	review. Each health data	health data access bodies	
throughout the Union. Each	access body should be	throughout the Union. Each	
health data access body	provided with the financial,	health data access body	
should have a separate,	<u>technical</u> and human	should have a separate,	
public annual budget, which	resources, ethics bodies,	public annual budget, which	
may be part of the overall	premises and infrastructure	may be part of the overall	
state or national budget. In	necessary for the effective	state or national budget. In	
order to enable better access	performance of its tasks,	order to enable better access	
to health data and	including those related to	to health data and	
complementing Article 7(3)	cooperation with other	complementing Article 7(3)	
of Regulation [] of the	health data access bodies	of Regulation [] of the	
European Parliament and of	throughout the Union and	European Parliament and of	
the Council [Data	have separate structures	the Council [Data	
Governance Act	for application processing	Governance Act	
COM/2020/767 final],	on the one hand, and	COM/2020/767 final],	
Member States should	anonymisation,	Member States should	
entrust health data access	pseudonymisation and re-	entrust health data access	

Com	nmission Proposal	EP Mandate	Council Mandate	Draft Agreement
bodies	s with powers to take	identification on the other	bodies with powers to take	
decisio	ions on access to and	<u>hand</u> . Each health data	decisions on access to and	
second	dary use of health	access body should have a	secondary use of health	
data. T	This could consist in	separate, public annual	data. This could consist in	
allocat	ating new tasks to the	budget, which may be part	allocating new tasks to the	
compe	etent bodies	of the overall state or	competent bodies	
design	nated by Member	national budget. In order to	designated by Member	
States	s under Article 7(1) of	enable better access to	States under Article 7(1) of	
Regula	lation [] [Data	health data and	Regulation [] [Data	
Gover	rnance Act	complementing Article 7(3)	Governance Act	
COM/	/2020/767 final] or in	of Regulation [] of the	COM/2020/767 final] or in	
design	nating existing or new	European Parliament and of	designating existing or new	
sectora	ral bodies responsible	the Council [Data	sectoral bodies responsible	
for suc	ch tasks in relation to	Governance Act	for such tasks in relation to	
access	s to health data.	COM/2020/767 final],	access to health data.	
		Member States should		
		entrust health data access		
		bodies with powers to take		
		decisions on access to and		
		secondary use of health		
		data. This could consist in		

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	allocating new tasks to the		
	competent bodies		
	designated by Member		
	States under Article 7(1) of		
	Regulation [] [Data		
	Governance Act		
	COM/2020/767 final] or in		
	designating existing or new		
	sectoral bodies responsible		
	for such tasks in relation to		
	access to health data. Given		
	<u>the central role of the</u>		
	<u>health data access bodies</u>		
	<u>in the context of secondary</u>		
	<u>use of electronic health</u>		
	<u>data, and especially</u>		
	regarding the decision-		
	<u>making on granting or</u>		
	<u>refusing a health data</u>		
	permit and preparing the		
	<u>data to make them</u>		

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	available to health data		
	users, the members and		
	staff of such bodies should		
	have the necessary		
	qualifications, experience		
	and skills, including legal		
	and technical expertise as		
	<u>regards the protection of</u>		
	<u>personal data, specifically</u>		
	<u>data concerning health,</u>		
	and expertise in the areas		
	<u>of ethics, healthcare,</u>		
	<u>scientific research,</u>		
	<u>cybersecurity, protection of</u>		
	<u>intellectual property and</u>		
	<u>trade secrets, artificial</u>		
	intelligence and other		
	<u>relevant areas. In addition,</u>		
	the decision-making		
	process regarding the		
	granting or refusal of the		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			health data permit should involve ethical considerations. The staff of health access bodies should not have any conflict of interest that is prejudicial to their independence and the impartiality of their conduct.		
	Recita	43			
53	(43) The health data access bodies should monitor the application of Chapter IV of this Regulation and contribute to its consistent application throughout the		(43) The health data access bodies should monitor the application of Chapter IV of this Regulation and contribute to its consistent application throughout the	(43) The health data access bodies should monitor the application of Chapter IV of this Regulation and contribute to its consistent application throughout the	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Union. For that purpose, the	Union. For that purpose, the	Union. For that purpose, the	
health data access bodies	health data access bodies	health data access bodies	
should cooperate with each	should cooperate with each	should cooperate with each	
other and with the	other and with the	other and with the	
Commission, without the	Commission, without the	Commission, without the	
need for any agreement	need for any agreement	need for any agreement	
between Member States on	between Member States on	between Member States on	
the provision of mutual	the provision of mutual	the provision of mutual	
assistance or on such	assistance or on such	assistance or on such	
cooperation. The health	cooperation. The health data	cooperation. The health data	
data access bodies should	access bodies should also	access bodies should also	
also cooperate with	cooperate with stakeholders,	cooperate with stakeholders,	
stakeholders, including	including patient	including patient	
patient organisations. Since	organisations. <i>The selection</i>	organisations. Since the	
the secondary use of health	procedure for health	secondary use of health data	
data involves the processing	stakeholders should be	involves the processing of	
of personal data concerning	transparent, public and	personal data concerning	
health, the relevant	free of any conflict of	health, the relevant	
provisions of Regulation	interest. Since the	provisions of Regulation	
(EU) 2016/679 apply and	secondary use of health data	(EU) 2016/679 apply and	
the supervisory authorities	involves the processing of	the supervisory authorities	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
under Regulation (EU)	personal data concerning	under Regulation (EU)	
2016/679 and Regulation	health, the relevant	2016/679 and Regulation	
(EU) 2018/1725 should be	provisions of Regulation	(EU) 2018/1725 should be	
tasked with enforcing these	(EU) 2016/679 apply and	tasked with enforcing these	
rules. Moreover, given that	the supervisory authorities	rules. Moreover, given that	
health data are sensitive	under Regulation (EU)	health data are sensitive	
data and in a duty of loyal	2016/679 and Regulation	data and in a duty of loyal	
cooperation, the health data	(EU) 2018/1725 should be	cooperation, the health data	
access bodies should inform	tasked with<mark>remain the only</mark>	access bodies should inform	
the data protection	authorities competent for	the data protection	
authorities of any issues	enforcing these rules.	authorities of any issues	
related to the data	Moreover, given that health	related to the data	
processing for secondary	data are sensitive data and	processing for secondary	
use, including penalties. In	in a duty of loyal	use, including penalties. In	
addition to the tasks	cooperation, the health data	addition to the tasks	
necessary to ensure	access bodies should inform	necessary to ensure	
effective secondary use of	the data protection	effective secondary use of	
health data, the health data	authorities of any issues	health data, the health data	
access body should strive to	related to the data	access body should strive to	
expand the availability of	processing for secondary	expand the availability of	
additional health datasets,	use, including	additional health datasets,	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
support the development of	penalties administrative	support the development of	
AI in health and promote	fines and enforcement	AI in health and promote	
the development of	measures. In addition to the	the development of	
common standards. They	tasks necessary to ensure	common standards. They	
should apply tested	effective secondary use of	should apply tested	
techniques that ensure	health data, the health data	techniques that ensure	
electronic health data is	access body should strive to	electronic health data is	
processed in a manner that	expand the availability of	processed in a manner that	
preserves the privacy of the	additional health datasets,	preserves the privacy of the	
information contained in	support the development of	information contained in the	
the data for which	AI in health and promote	data for which secondary	
secondary use is allowed,	the development of	use is allowed, including	
including techniques for	common standards. They	techniques for	
pseudonymisation,	should apply tested state-of-	pseudonymisation,	
anonymisation,	techniques that	anonymisation,	
generalisation, suppression	ensure electronic health data	generalisation, suppression	
and randomisation of	is processed in a manner	and randomisation of	
personal data. Health data	that preserves the privacy of	personal data. Health data	
access bodies can prepare	the information contained in	access bodies can prepare	
datasets to the data user	the data for which	datasets to the data user	
requirement linked to the	secondary use is allowed,	requirement linked to the	

issued data permit. This including techniques for issued data permit. This includes rules for anonymisation, includes rules for anonymization of microdata anonymisation, anonymization of microdata sets. generalisation, suppression sets. and randomisation of personal data. In that regard, health data access bodies should cooperate across borders and agree on common definitions and techniques. Health data access bodies can prepare datasets to the data user requirement linked to the issued data permit. This	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
includes rules for <i>anonymizationanonymisati</i> <i>on</i> of microdata sets.	issued data permit. This includes rules for anonymization of microdata	including techniques for pseudonymisation, anonymisation, suppression and randomisation of personal data. <i>In that</i> <i>regard, health data access</i> <i>bodies should cooperate</i> <i>across borders and agree</i> <i>on common definitions and</i> <i>techniques.</i> Health data access bodies can prepare datasets to the data user requirement linked to the issued data permit. This includes rules for	issued data permit. This includes rules for anonymization of microdata	

	Commission Proposa	al	EP Mandate	Council Mandate	Draft Agreement
	Rec	ecital 44			
	(44) Considering the administrative burden for	r	(44) <i>Considering the</i> administrative burden for	(44) Considering the administrative burden for	
	health data access bodies t inform the natural persons whose data are used in dat projects within a secure	15	health data access bodies toHealth data access bodies should comply with the obligations laid down in	health data access bodies to inform the natural persons whose data are used in data projects within a secure	
54	processing environment, the exceptions provided for in Article 14(5) of Regulation	n	Article 14 of Regulation (EU) 2016/679 and inform the natural persons whose	processing environment, the exceptions provided for in Article 14(5) of Regulation	
	(EU) 2016/679 should apply. Therefore, health data access bodies should	1	data are used in data projects within a secure processing environment,	(EU) 2016/679 should apply. Therefore, health data access bodies should	
	provide general information concerning the conditions for the secondary use of		The exceptions provided for in Article 14(5) of Regulation (EU) 2016/679	provide general information concerning the conditions for the secondary use of	
	their health data containing the information items liste	c	should<u>could</u> apply. Therefore<mark>Where such</mark>	their health data containing the information items listed	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
in Article 14(1) and, where	exceptions are applied,	in Article 14(1) and, where	
necessary to ensure fair and	health data access bodies	necessary to ensure fair and	
transparent processing,	should provide general	transparent processing,	
Article 14(2) of Regulation	information concerning the	Article 14(2) of Regulation	
(EU) 2016/679, e.g.	conditions for the secondary	(EU) 2016/679, e.g.	
information on the purpose	use of their health data	information on the purpose	
and the data categories	containing the information	and the data categories	
processed. Exceptions from	items listed in Article 14(1)	processed. Exceptions from	
this rule should be made	and, where necessary to	this rule should be made	
when the results of the	ensure fair and transparent	when the results of the	
research could assist in the	processing, Article 14(2) of	research could assist in the	
treatment of the natural	Regulation (EU) 2016/679,	treatment of the natural	
person concerned. In this	e.g. information on the	person concerned. In this	
case, the data user should	purpose and the data	case, the data user should	
inform the health data	categories processed,	inform the health data	
access body, which should	enabling natural persons to	access body, which should	
inform the data subject or	understand whether their	inform the data subject or	
his health professional.	<u>data are being made</u>	his health professional.	
Natural persons should be	available for secondary use	Natural persons should be	
able to access the results of	pursuant to data permits.	able to access the results of	
different research projects	Exceptions from this rule	different research projects	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
on the website of the health	should be made when the	on the website of the health	
data access body, ideally in	results of the research could	data access body, ideally in	
an easily searchable	assist in the treatment of the	an easily searchable	
manner. The list of the data	natural person concerned. In	manner. The list of the data	
permits should also be	this case, the <i>health</i> data	permits should also be made	
made public. In order to	user should inform the	public. In order to promote	
promote transparency in	health data access body,	transparency in their	
their operation, each health	which should inform the	operation, each health data	
data access body should	data subject or his<mark>health</mark>	access body should publish	
publish an annual activity	professional treating the	an annual activity report	
report providing an	natural person concerned	providing an overview of its	
overview of its activities.	<u>or, in the event that the</u>	activities.	
	treating health professional		
	<u>is not traceable, the natural</u>		
	<u>person, with due regard for</u>		
	<u>their stated wish not to be</u>		
	<u>informed, while fully</u>		
	<u>respecting the principles of</u>		
	medical confidentiality and		
	professional secrecy.		
	Natural persons should be		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			able to access the results of different research projects on the website of the health data access body, ideally in an easily searchable manner. The list of the data permits should also be made public. In order to promote transparency in their operation, each health data access body should publish an annual activity report providing an overview of its activities.		
	Recita	1 45			
55	(45) Regulation [] [Data		(45) Regulation [] [Data	(45) Regulation [] [Data	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Governance Act	Governance Act	Governance Act	
COM/2020/767 final] sets	COM/2020/767 final] sets	COM/2020/767 final] sets	
out the general rules for the	out the general rules for the	out the general rules for the	
management of data	management of data	management of data	
altruism. At the same time,	altruism. At the same time,	altruism. At the same time,	
given that the health sector	given that the health sector	given that the health sector	
manages sensitive data,	manages sensitive data,	manages sensitive data,	
additional criteria should be	additional criteria should be	additional criteria should be	
established through the	established through the	established through the	
rulebook foreseen in	rulebook foreseen in	rulebook foreseen in	
Regulation [] [Data	Regulation [] [Data	Regulation [] [Data	
Governance Act	Governance Act	Governance Act	
COM/2020/767 final].	COM/2020/767 final].	COM/2020/767 final].	
Where such a rulebook	Where such a rulebook	Where such a rulebook	
foresees the use of a secure	foresees the use of a secure	foresees the use of a secure	
processing environment for	processing environment for	processing environment for	
this sector, this should	this sector, this should	this sector, this should	
comply with the criteria	comply with the criteria	comply with the criteria	
established in this	established in this	established in this	
Regulation. The health data	Regulation. The health data	Regulation. The health data	
access bodies should	access bodies should	access bodies should	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	cooperate with the bodies designated under Regulation [] [Data Governance Act COM/2020/767 final] to supervise the activity of data altruism organisations in the health or care sector.		cooperate with the bodies designated under Regulation [] [Data Governance Act COM/2020/767 final] to supervise the activity of data altruism organisations in the health or care sector.	cooperate with the bodies designated under Regulation [] [Data Governance Act COM/2020/767 final] to supervise the activity of data altruism organisations in the health or care sector.	
	(46) In order to support the secondary use of electronic	46	(46) In order to support the secondary use of electronic	(46) In order to support the secondary use of electronic	
56	health data, the data holders should refrain from withholding the data, requesting unjustified fees that are not transparent nor		health data, the data holders should refrain from withholding the data, requesting unjustified fees that are not transparent nor	health data, the data holders should refrain from withholding the data, requesting unjustified fees that are not transparent nor	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
proportionate with the costs	proportionate with the costs	proportionate with the costs	
for making data available	for making data available	for making data available	
(and, where relevant, with	(and, where relevant, with	(and, where relevant, with	
marginal costs for data	marginal costs for data	marginal costs for data	
collection), requesting the	collection), requesting the	collection), requesting the	
data users to co-publish the	data users to co-publish the	data users to co-publish the	
research or other practices	research or other practices	research or other practices	
that could dissuade the data	that could dissuade the data	that could dissuade the data	
users from requesting the	users from requesting the	users from requesting the	
data. Where ethical	data. Where ethical	data. Where ethical	
approval is necessary for	approval is necessary for	approval is necessary for	
providing a data permit, its	providing a data permit, its	providing a data permit, its	
evaluation should be based	evaluation should be based	evaluation should be based	
on its own merits. On the	on its own merits. On the	on its own merits. On the	
other hand, Union	other hand, <i>public sector</i>	other hand, Union	
institutions, bodies, offices	<u>bodies and</u> Union	institutions, bodies, offices	
and agencies, including	institutions, bodies, offices	and agencies, including	
EMA, ECDC and the	and agencies, including	EMA, ECDC and the	
Commission, have very	EMA, ECDC and the	Commission, have very	
important and insightful	Commission with a legal	important and insightful	
data. Access to data of such	<u>mandate in the field of</u>	data. Access to data of such	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	institutions, bodies, offices and agencies should be granted through the health data access body where the controller is located.		<i>public health</i> , have very important and insightful data. Access to data of such institutions, bodies, offices and agencies should be granted through the health data access body where the controller is located.	institutions, bodies, offices and agencies should be granted through the health data access body where the controller is located.	
	Recital	47		<u> </u>	
57	(47) Health data access bodies and single data holders should be allowed to charge fees based on the provisions of Regulation [] [Data Governance Act COM/2020/767 final] in		(47) Health data access bodies <i>and single data</i> <i>holders</i> should be allowed to charge fees based on the <i>applicable</i> provisions <i>ofunder this</i> Regulation [] <i>and the provisions of</i>	(47) Health data access bodies and single data holders should be allowed to charge fees based on the provisions of Regulation [] [Data Governance Act COM/2020/767 final]-in	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
relation to their tasks. Such	the [Data Governance Act	relation to their tasks. Such	
fees may take into account	COM/2020/767 final] and	fees may take into account	
the situation and interest of	the [Data Act	the situation and interest of	
SMEs, individual	<u>COM/2022/68 final]</u> in	SMEs, individual	
researchers or public	relation to their tasks. Such	researchers or public	
bodies. Data holders should	fees may take into account	bodies. In particular,	
be allowed to also charge	the situation and interest of	Member States may	
fees for making data	SMEs, individual	establish policies for	
available. Such fees should	researchers or public	health data access bodies	
reflect the costs for	bodies. <u>Health</u> data holders	in their jurisdiction	
providing such services.	should be allowed to also	allowing to charge	
Private data holders may	charge fees for making data	reduced fees to certain	
also charge fees for the	available. Such fees should	categories of data users.	
collection of data. In order	reflect the costs for	On the other hand, health	
to ensure a harmonised	providing such services.	data access bodies should	
approach concerning fee	Private <u>health</u> data holders	be able to cover the costs	
policies and structure, the	may also charge fees for the	of their operation with	
Commission may adopt	collection of data. In order	fees, and this may lead to	
implementing acts.	to ensure a harmonised	higher fees charged to	
Provisions in Article 10 of	approach concerning fee	certain categories of data	
the Regulation [Data Act	policies and structure, the	users, established in a	

Commission Pr	oposal	EP Mandate	Council Mandate	Draft Agreement
COM/2022/68 final	l] should	Commission mayshould	proportionate, justified	
apply for fees charg	ged	adopt implementing acts.	and transparent manner,	
under this Regulation	on.	Provisions in Article 10 of	if servicing their data	
		the Regulation [Data Act	access applications and	
		COM/2022/68 final] should	data requests requires	
		apply for fees charged	more work in aspects such	
		under this Regulation.	as compliance with	
		Public sector bodies and	Chapter V of the GDPR.	
		Union institutions, bodies,	Data holders should be	
		offices and agencies with a	allowed to also charge fees	
		legal mandate in the field	for making data available.	
		of public health should not	Such fees should reflect the	
		be charged fees.	costs for providing such	
			services. Private data	
			holders may also charge	
			fees for the collection of	
			data. In order to ensure a	
			harmonised approach	
			concerning fee policies and	
			structures, the	
			Commission may adopt	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				implementing acts. Provisions in Article 10 of the Regulation [Data Act COM/2022/68 final] should apply for fees charged under this Regulationissue guidelines on fee policies and fee structures.	
	Recital	48			
58	(48) In order to strengthen the enforcement of the rules on the secondary use of electronic health data, appropriate measures that can lead to penalties or temporary or definitive		(48) In order to strengthen the enforcement of the rules on the secondary use of electronic health data, appropriate measures <u>should be envisaged</u> that can lead to	(48) In order to strengthen the enforcement of the rules on the secondary use of electronic health data, appropriate measures that can lead to penalties or temporary or definitive	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
exclusions from the EHDS	penalties<mark>administrative</mark>	exclusions from the EHDS	
framework of the data users	fines or enforcement	framework of the data users	
or data holders that do not	measures by health data	or data holders that do not	
comply with their	access bodies or temporary	comply with their	
obligations. The health data	or definitive exclusions	obligations. The health data	
access body should be	from the EHDS framework	access body should be	
empowered to verify	of the <i>health</i> data users or	empowered to verify	
compliance and give data	<u>health</u> data holders that do	compliance and give data	
users and holders the	not comply with their	users and holders the	
opportunity to reply to any	obligations. The health data	opportunity to reply to any	
findings and to remedy any	access body should be	findings and to remedy any	
infringement. The	empowered to verify	infringement. The	
imposition of penalties	compliance and give health	imposition of penalties	
should be subject to	data users and holders the	should be subject to	
appropriate procedural	opportunity to reply to any	appropriate procedural	
safeguards in accordance	findings and to remedy any	safeguards in accordance	
with the general principles	infringement. When	with the general principles	
of law of the relevant	deciding on the amount of	of law of the relevant	
Member State, including	the administrative fine or	Member State, including	
effective judicial protection	<u>enforcement measure for</u>	effective judicial protection	
and due process.	<u>each individual case,</u>	and due process.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			health data access bodies should take into account the margins for costs and criteria set out in this Regulation The imposition of penalties should be subject to appropriate procedural safeguards in accordance with the general principles of law of the relevant Member State, including effective judicial protection and due process.		
	Recita	l 49		-	
59	(49) Given the sensitivity of electronic health data, it		(49) Given the sensitivity of electronic health data, it	(49) Given the sensitivity of electronic health data, it	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
is necessary to reduce risks	is necessary to reduce risks	is necessary to reduce risks	
on the privacy of natural	on the privacy of natural	on the privacy of natural	
persons by applying the	persons by applying the	persons by applying the	
data minimisation principle	data minimisation principle	data minimisation principle	
as set out in Article 5 (1),	as set out in Article 5 (1),	as set out in Article 5 (1),	
point (c) of Regulation	point (c) of Regulation (EU)	point (c) of Regulation (EU)	
(EU) 2016/679. Therefore,	2016/679. Therefore,	2016/679. Therefore, the	
the use of anonymised	<u>common standards for data</u>	use of anonymised	
electronic health data which	anonymisation should be	electronic health data which	
is devoid of any personal	<u>further developed and the</u>	is devoid of any personal	
data should be made	use of anonymised	data should be made	
available when possible and	electronic health data which	available when possible and	
if the data user asks it. If the	is devoid of any personal	if the data user asks it. If the	
data user needs to use	data should be made	data user needs to use	
personal electronic health	available when possible -and	personal electronic health	
data, it should clearly	if the data user asks it . If	data, it should clearly	
indicate in its request the	the data user needs to use	indicate in its request the	
justification for the use of	personal electronic health	justification for the use of	
this type of data for the	data, it should clearly	this type of data for the	
planned data processing	indicate in its request the	planned data processing	
activity. The personal	justification for the use of	activity. The personal	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
electronic health data	this type of data for the	electronic health data	
should only be made	planned data processing	should only be made	
available in pseudonymised	activity <i>and the health data</i>	available in pseudonymised	
format and the encryption	access body should	format and the encryption	
key can only be held by the	<u>determine the validity of</u>	key can only be held by the	
health data access body.	that justification. The	health data access body.	
Data users should not	personal electronic health	Data users should not	
attempt to re-identify	data should only be made	attempt to re-identify	
natural persons from the	available in pseudonymised	natural persons from the	
dataset provided under this	format and the encryption	dataset provided under this	
Regulation, subject to	key can only be held by the	Regulation, subject to	
administrative or possible	health data access body.	administrative or possible	
criminal penalties, where	When providing access to	criminal penalties, where	
the national laws foresee	an anonymised or	the national laws foresee	
this. However, this should	pseudonymised dataset, a	this. However, this should	
not prevent, in cases where	health data access body	not prevent, in cases where	
the results of a project	should use state-of-the-art	the results of a project	
carried out based on a data	anonymisation or	carried out based on a data	
permit has a health benefit	pseudonymisation	permit has a health benefit	
or impact to a concerned	technology, ensuring to the	or impact to a concerned	
natural person (for instance,	<u>maximum extent possible</u>	natural person (for instance,	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
discovering treatments or	that natural persons	discovering treatments or	
risk factors to develop a	cannot be re-identified.	risk factors to develop a	
certain disease), the data	<u>Health</u> data users should	certain disease), the data	
users would inform the	not attempt to re-identify	users would inform the	
health data access body,	natural persons from the	health data access body,	
which in turn would inform	dataset provided under this	which in turn would inform	
the concerned natural	Regulation, subject to	the concerned natural	
person(s). Moreover, the	administrative <i>fines and the</i>	person(s). Moreover, the	
applicant can request the	<u>enforcement measures laid</u>	applicant can request the	
health data access bodies to	<u>down in this Regulation</u> or	health data access bodies to	
provide the answer to a data	possible criminal penalties,	provide the answer to a data	
request, including in	where the national laws	request, including in	
statistical form. In this case,	foresee this. However, this	statistical form. In this case,	
the data users would not	should not prevent, in cases	the data users would not	
process health data and the	where the results of a	process health data and the	
health data access body	project carried out based on	health data access body	
would remain sole	a data permit has a	would remain sole	
controller for the data	significant health benefit or	controller for the data	
necessary to provide the	impact to a concerned	necessary to provide the	
answer to the data request.	natural person (for instance,	answer to the data request.	
	discovering treatments or		

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	risk factors to develop a		
	certain disease), the <i>health</i>		
	data users wouldto inform		
	the health data access body,		
	which in turn would inform		
	the <i>treating health</i>		
	professional of the		
	concerned natural person (s).		
	Moreover, the or, in the		
	event that the treating		
	health professional is not		
	traceable, the natural		
	<u>person, with due regard for</u>		
	any stated wish not to be		
	<u>informed. To that end, the</u>		
	<u>health data user should be</u>		
	guided by ethical		
	principles, and guidelines		
	from EMA and the ECDC		
	as regards what constitutes		
	<u>a significant finding.</u>		

Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
		Moreover, a health data applicant can request the health data access bodies to provide the answer to a health data request, including in an anonymised or aggregated statistical formformat. In this case, the health data user data users would not process health data and the health data access body would remain sole controller for the data necessary to provide the answer to the health data request.		
Recita	150			

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	(50) In order to ensure that	(50) In order to ensure that	(50) In order to ensure that	
	all health data access bodies	all health data access bodies	all health data access bodies	
	issue permits in a similar	issue permits in a similar	issue permits in a similar	
	way, it is necessary to	way, it is necessary to	way, it is necessary to	
	establish a standard	establish a standard	establish a standard	
	common process for the	common process for the	common process for the	
	issuance of data permits,	issuance of data permits,	issuance of data permits,	
	with similar requests in	with similar requests in	with similar requests in	
60	different Member States.	different Member States.	different Member States.	
	The applicant should	The <i>health data</i> applicant	The applicant should	
	provide health data access	should provide health data	provide health data access	
	bodies with several	access bodies with several	bodies with several	
	information elements that	information elements that	information elements that	
	would help the body	would help the body	would help the body	
	evaluate the request and	evaluate the	evaluate the request and	
	decide if the applicant may	request<u>application</u> and	decide if the applicant may	
	receive a data permit for	decide if the applicant may	receive a data permit for	
	secondary use of data, also	receive a data permit for	secondary use of data, also	
	ensuring coherence between	secondary use of data, also	ensuring coherence between	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
different health data access	ensuring coherence between	different health data access	
bodies. Such information	different health data access	bodies. Such information	
include: the legal basis	bodies. Such information	include: the legal basis	
under Regulation (EU)	includeincludes: the legal	under Regulation (EU)	
2016/679 to request access	basis under Regulation	2016/679 to request access	
to data (exercise of a task in	(EU) 2016/679 to request	to data (exercise of a task in	
the public interest assigned	access to data (exercise of a	the public interest assigned	
by law or legitimate	task in the public interest	by law or legitimate	
interest), purposes for	assigned by law or	interest), purposes for	
which the data would be	legitimate interest),	which the data would be	
used, description of the	purposes for which the data	used, description of the	
needed data and possible	would be used, <i>the identity</i>	needed data and possible	
data sources, a description	of the health data applicant	data sources, a description	
of the tools needed to	as well as the specific	of the tools needed to	
process the data, as well as	persons who are authorised	process the data, as well as	
characteristics of the secure	to have access to the	characteristics of the secure	
environment that are	<u>electronic health data in</u>	environment that are	
needed. Where data is	the secure processing	needed. Where data is	
requested in pseudonymised	environment and how they	requested in pseudonymised	
format, the data applicant	are qualified vis-à-vis the	format, the data applicant	
should explain why this is	<u>intended secondary use,</u>	should explain why this is	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
necessary and why	description of the needed	necessary and why	
anonymous data would not	data and possible data	anonymous data would not	
suffice. An ethical	sources, a description of the	suffice. An ethical	
assessment may be	tools needed to process the	assessment may be	
requested based on national	data, as well as	requested based on national	
law. The health data access	characteristics of the secure	law. The health data access	
bodies and, where relevant	environment that are	bodies and, where relevant	
data holders, should assist	needed, a description of the	data holders, should assist	
data users in the selection	safeguards planned to	data users in the selection of	
of the suitable datasets or	prevent any other use,	the suitable datasets or data	
data sources for the	misuse or possible re-	sources for the intended	
intended purpose of	<u>identification, and an</u>	purpose of secondary use.	
secondary use. Where the	explanation of the expected	Where the applicant needs	
applicant needs anonymised	benefits of the secondary	anonymised statistical data,	
statistical data, it should	<u>use</u> . Where data is	it should submit a data	
submit a data request	requested in pseudonymised	request application,	
application, requiring the	format, the <i>health</i> data	requiring the health data	
health data access body to	applicant should explain	access body to provide	
provide directly the result.	why this is necessary and	directly the result. In order	
In order to ensure a	why anonymous data would	to ensure a harmonised	
harmonised approach	not suffice. An ethical	approach between health	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
between health data access	assessment may be	data access bodies, the	
bodies, the Commission	requested based on national	Commission should support	
should support the	law. <u>A thorough</u>	the harmonisation of data	
harmonisation of data	assessment of the health	application, as well as data	
application, as well as data	data access	request.	
request.	bodiesapplications and		
	documents submitted by		
	<u>the health data applicant</u>		
	should be required and the		
	health data access body		
	should only issue a data		
	permit if all the conditions		
	set out in this Regulation		
	are met. The health data		
	access body and, where		
	relevant <u>health</u> data		
	holders, should assist health		
	data users in the selection of		
	the suitable datasets or data		
	sources for the intended		
	purpose of secondary use.		

C	ommission Proposal	EP Mandate	Council Mandate	Draft Agreement
		Where the <i>health</i> applicant		
		needs <u>data in an</u>		
		anonymised and		
		aggregated statistical		
		dataformat, it should		
		submit a data request		
		application, requiring the		
		health data access body to		
		provide directly the result.		
		<u>A refusal of a data permit</u>		
		<u>by the health data body</u>		
		<u>should not preclude the</u>		
		<u>health data applicant from</u>		
		<u>submitting a new data</u>		
		access application. In order		
		to ensure a harmonised		
		approach between health		
		data access bodies and to		
		<u>limit an unnecessary</u>		
		administrative burden for		
		the health data applicants		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			to the greatest extent possible, the Commission should support the harmonisation of health data access applicationsdata application, as well as health data requests, including by establishing, by means of implementing acts, templates for health data access applications and requestsdata request.		
	Recita	l 50a			
60a			<u>(50a)</u> <u>A standard ethics</u> <u>assessment should be</u>		

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Commission Proposal	EP Mandatecarried out by ethics bodieswithin health data accessbodies. Such assessmentbodies. Such assessmentshould be an importantpart of the process.However, where the healthdata applicant hadpreviously obtained theapproval of the competentethics committee inaccordance with nationallaw for research purposesfor which they arerequesting data throughthe EHDS, the health dataapplicant should make thatinformation available tothe health data access bodyas part of the data access	Council Mandate	Draft Agreement
	application.		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Recita	151			
	(51) As the resources of		(51) As the resources of	(51) As the resources of	
	health data access bodies		health data access bodies	health data access bodies	
	are limited, they can apply		are limited, they can apply	are limited, they can apply	
	prioritisation rules, for		prioritisation rules, for	prioritisation rules, for	
	instance prioritising public		instance prioritising public	instance prioritising public	
	institutions before private		institutions before private	institutions before private	
61	entities, but they should not		entities, but they should not	entities, but they should not	
	make any discrimination		make any discrimination	make any discrimination	
	between the national or		between the national or	between the national or	
	from organisations from		from organisations from	from organisations from	
	other Member States within		other Member States within	other Member States within	
	the same category of		the same category of	the same category of	
	priorities. The data user		priorities. The <i>health</i> data	priorities. The data user	
	should be able to extend the		user should be able to	should be able to extend the	
	duration of the data permit		extend the duration of the	duration of the data permit	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
in order, for example, to	data permit in order, for	in order, for example, to	
allow access to the datasets	example, to allow access to	allow access to the datasets	
to reviewers of scientific	the datasets to reviewers of	to reviewers of scientific	
publication or to enable	scientific publication or to	publication or to enable	
additional analysis of the	enable additional analysis of	additional analysis of the	
dataset based on the initial	the dataset based on the	dataset based on the initial	
findings. This would	initial findings. This would	findings. This would require	
require an amendment of	require an amendment of	an amendment of the data	
the data permit and may be	the <i>health</i> data permit and	permit and may be subject	
subject to an additonal fee.	may be subject to an	to an additonal additional	
However, in all the cases,	additonaladditional fee.	fee. However, in all the	
the data permit should	However, in all the cases,	cases, the data permit	
reflect theses additionals	the data permit should	should reflect theses	
uses of the dataset.	reflect theses	additionals uses of the	
Preferably, the data user	additionalsadditional uses	dataset. Preferably, the data	
should mention them in	of the dataset. Preferably,	user should mention them in	
their initial request for the	the <u><i>health</i></u> data user should	their initial request for the	
issuance of the data permit.	mention them in their initial	issuance of the data permit.	
In order to ensure a	request for the issuance of	In order to ensure a	
harmonised approach	the data permit. In order to	harmonised approach	
between health data access	ensure a harmonised	between health data access	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	bodies, the Commission should support the harmonisation of data permit.		approach between health data access bodies, the Commission should support the harmonisation of data permit.	bodies, the Commission should support the harmonisation of data permit.	
	Recita	I 52			
62	(52) As the COVID-19 crisis has shown, the Union institutions, bodies, offices and agencies, especially the Commission, need access to health data for a longer period and on a recurring basis. This is may be the case not only in specific circumstances in times of		(52) As the COVID-19 crisis has shown, the Union institutions, bodies, offices and agencies <u>with a legal</u> <u>mandate in the field of</u> <u>public health</u> , especially the Commission, need access to health data for a longer period and on a recurring basis. This <u>is</u> -may be the	(52) As the COVID-19 crisis has shown, the Union institutions, bodies, offices and agencies, especially the Commission, need access to health data for a longer period and on a recurring basis. This is may be the case not only in specific circumstances in times of	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	crisis but also to provide scientific evidence and technical support for Union policies on a regular basis. Access to such data may be required in specific Member States or throughout the whole territory of the Union.		case not only <i>infor</i> specific circumstances <i>stipulated by</i> <u>Union or national law</u> in times of crisis but also to provide scientific evidence and technical support for Union policies on a regular basis. Access to such data may be required in specific Member States or throughout the whole territory of the Union.	crisis but also to provide scientific evidence and technical support for Union policies on a regular basis. Access to such data may be required in specific Member States or throughout the whole territory of the Union.	
	Recital	153			
63	(53) For requests to access electronic health data from a single data holder in a		deleted	<i>(53)</i> For requests to access electronic health data from a single data holder in a	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
single Member State and in		single Member State and in	
order to alieviate the		order to alieviate the	
administrative burden for		administrative burden for	
heath data access bodies of		heath data access bodies of	
managing such request, the		managing such request, the	
data user should be able to		data user should be able to	
request this data directly		request this data directly	
from the data holder and the		from the data holder and the	
data holder should be able		data holder should be able	
to issue a data permit while		to issue a data permit while	
complying with all the		complying with all the	
requirements and		requirements and	
safeguards linked to such		safeguards linked to such	
request and permit. Multi-		request and permit. Multi-	
country requests and		country requests and	
requests requiring		requests requiring	
combination of datasets		combination of datasets	
from several data holders		from several data holders	
should always be		should always be	
channelled through health		channelled through health	
data access bodies. The data		data access bodies. The data	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	holder should report to the			holder should report to the	
	health data access bodies			health data access bodies	
	about any data permits or			about any data permits or	
	data requests they provide.			data requests they provide.	
	Recita	al 54			
	(54) Given the sensitivity		(54) Given the sensitivity	(54) Given the sensitivity	
	of electronic health data,		of electronic health data,	of electronic health data,	
	data users should not have		data users should not have	data users should not have	
	an unrestricted access to		an unrestricted access to	an unrestricted access to	
64	such data. All secondary		such data <mark>, <i>in accordance</i></mark>	such data. All secondary use	
	use access to the requested		<u>with the data minimisation</u>	access to the requested	
	electronic health data		principle. All secondary use	electronic health data	
	should be done through a		access to the requested	should be done through a	
	secure processing		electronic health data	secure processing	
	environment. In order to		should be done through a	environment. In order to	
	ensure strong technical and		secure processing	ensure strong technical and	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
security safeguards for the	environment. In order to	security safeguards for the	
electronic health data, the	ensure strong technical and	electronic health data, the	
health data access body or,	security safeguards for the	health data access body or,	
where relevant, single data	electronic health data, the	where relevant, single data	
holder should provide	health data access body or,	holder should provide	
access to such data in a	where relevant, single data	access to such data in a	
secure processing	holder should provide	secure processing	
environment, complying	access to such data in a	environment, complying	
with the high technical and	secure processing	with the high technical and	
security standards set out	environment, complying	security standards set out	
pursuant to this Regulation.	with the high technical and	pursuant to this Regulation.	
Some Member States took	security standards set out	Some Member States took	
measures to locate such	pursuant to this Regulation.	measures to locate such	
secure environments in	Some Member States took	secure environments in	
Europe. The processing of	measures to locate such	Europe. The processing of	
personal data in such a	secure environments in	personal data in such a	
secure environment should	Europe. The processing of	secure environment should	
comply with Regulation	personal data in such a	comply with Regulation	
(EU) 2016/679, including,	secure environment should	(EU) 2016/679, including,	
where the secure	comply with Regulation	where the secure	
environment is managed by	(EU) 2016/679, including,	environment is managed by	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
a third party, the	where the secure	a third party, the	
requirements of Article 28	environment is managed by	requirements of Article 28	
and, where applicable,	a third party, the	and, where applicable,	
Chapter V. Such secure	requirements of Article 28	Chapter V. Such secure	
processing environment	and, where applicable,	processing environment	
should reduce the privacy	Chapter V. <i>Nevertheless, in</i>	should reduce the privacy	
risks related to such	order to ensure the proper	risks related to such	
processing activities and	supervision and security of	processing activities and	
prevent the electronic	personal data, such	prevent the electronic health	
health data from being	environments need to be	data from being transmitted	
transmitted directly to the	located in the Union if they	directly to the data users.	
data users. The health data	are used to access personal	The health data access body	
access body or the data	health data. Such secure	or the data holder providing	
holder providing this	processing environment	this service should remain	
service should remain at all	should reduce the privacy	at all time in control of the	
time in control of the access	risks related to such	access to the electronic	
to the electronic health data	processing activities and	health data with access	
with access granted to the	prevent the electronic health	granted to the data users	
data users determined by	data from being transmitted	determined by the	
the conditions of the issued	directly to the data users.	conditions of the issued data	
data permit. Only non-	The health data access body	permit. Only non-personal	

Commission Proposa	1	EP Mandate	Council Mandate	Draft Agreement
personal electronic health		or the data holder providing	electronic health data which	
data which do not contain		this service should remain	do not contain any	
any electronic health data		at all time in control of the	electronic health data	
should be extracted by the	;	access to the electronic	should be extracted by the	
data users from such secu	re	health data with access	data users from such secure	
processing environment.		granted to the data users	processing environment.	
Thus, it is an essential		determined by the	Thus, it is an essential	
safeguard to preserve the		conditions of the issued data	safeguard to preserve the	
rights and freedoms of		permit. Only non-personal	rights and freedoms of	
natural persons in relation		electronic health data which	natural persons in relation	
to the processing of their		do not contain any	to the processing of their	
electronic health data for		electronic health data	electronic health data for	
secondary use. The		should be extracted by the	secondary use. The	
Commission should assis		data users from such secure	Commission should assist	
the Member State in		processing environment.	the Member State in	
developing common		Thus, it is an essential	developing common	
security standards in orde	r	safeguard to preserve the	security standards in order	
to promote the security an	d	rights and freedoms of	to promote the security and	
interoperability of the		natural persons in relation	interoperability of the	
various secure		to the processing of their	various secure	
environments.		electronic health data for	environments.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			secondary use. The Commission should assist the Member State in developing common security standards in order to promote the security and interoperability of the various secure environments.		
	Recital	55			
65	(55) For the processing of electronic health data in the scope of a granted permit, the health data access bodies and the data users should be joint controllers		 (55) For the processing of electronic health data in the scope of a granted permit, the health data <i>holders, the</i> <i>health data</i> access bodies and the <i>health</i> data users 	(55) For the processing of electronic health data in the scope of a granted permit, the health data access bodies and the data users should be joint controllers	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
in the sense of Article 26 of	should <u>each, in turn, be</u>	in the sense of Article 26 of	
Regulation (EU) 2016/679,	deemed a controller for a	Regulation (EU) 2016/679,	
meaning that the	specific part of the process	meaning that the obligations	
obligations of joint	and according to their	of joint controllers under	
controllers under that	respective roles therein.	that Regulation will apply.	
Regulation will apply. To	The health data holder	To support health data	
support health data access	should be deemed	access bodies and data	
bodies and data users, the	<u>controller for the</u>	users, the Commission	
Commission should, by	disclosure of the requested	should, by means of an	
means of an implementing	<u>personal electronicbe joint</u>	implementing act, provide a	
act, provide a template for	controllers in the sense of	template for the joint	
the joint controller	Article 26 of Regulation	controller arrangements	
arrangements health data	(EU) 2016/679, meaning	health data access bodies	
access bodies and data users	that the obligations of joint	and data users will have to	
will have to enter into. In	controllers under that	enter into. In order to	
order to achieve an	Regulation will apply. To	achieve an inclusive and	
inclusive and sustainable	support health data access	sustainable framework for	
framework for multi-	bodies and data users<mark>to the</mark>	multi-country secondary use	
country secondary use of	<u>health data access body</u> ,	of electronic health data, a	
electronic health data, a	while the health data	cross-border infrastructure	
cross-border infrastructure	<u>access body the</u>	should be established.	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
should be established.	Commission should, by	HealthData@EU should	
HealthData@EU should	means of an implementing	accelerate the secondary use	
accelerate the secondary	act, provide a template for	of electronic health data	
use of electronic health data	the joint controller	while increasing legal	
while increasing legal	arrangements<mark> in turn be</mark>	certainty, respecting the	
certainty, respecting the	deemed controller for the	privacy of natural persons	
privacy of natural persons	processing of the personal	and being interoperable.	
and being interoperable.	<u>electronic health data</u>	Due to the sensitivity of	
Due to the sensitivity of	when preparing the data	health data, principles such	
health data, principles such	and making them available	as "privacy by design" and	
as "privacy by design" and	to the health data user. The	"bring questions to data	
"bring questions to data	health data access bodies	instead of moving data"	
instead of moving data"	and data users will have to	should be respected	
should be respected	enter into. In order to	whenever possible.	
whenever possible.	achieve an inclusive and	Authorised participants in	
Authorised participants in	sustainable framework for	HealthData@EU could be	
HealthData@EU could be	multi-country secondary use	health data access bodies,	
health data access bodies,	of electronic<mark>user should be</mark>	research infrastructures	
research infrastructures	deemed controller for the	established as an European	
established as an European	processing of personal	Research Infrastructure	
Research Infrastructure	<u>electronic health data in</u>	Consortium ('ERIC') under	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Consortium ('ERIC') under	pseudonymised form in the	Council Regulation (EC)	
Council Regulation (EC)	secure processing	No 723/2009 ¹ or similar	
No 723/2009 ¹ or similar	environment pursuant to	structures established under	
structures established under	<u>its data permit. The health</u>	another Union legislation,	
another Union legislation,	data access body should be	as well as other types of	
as well as other types of	deemed a processor for	entities, including	
entities, including	processing carried out by	infrastructures under the	
infrastructures under the	<u>the</u> health data , <i>a cross</i>-	European Strategy Forum	
European Strategy Forum	border infrastructure	on Research Infrastructures	
on Research Infrastructures	should be established <mark>user</mark>	(ESFRI), infrastructures	
(ESFRI), infrastructures	pursuant to a data permit	federated under the	
federated under the	in the secure processing	European Open Science	
European Open Science	<u>environment</u> .	Cloud (EOSC). Other	
Cloud (EOSC). Other	HealthData@EU should	authorised participants	
authorised participants	accelerate the secondary use	should obtain the approval	
should obtain the approval	of electronic health data	of the joint controllership	
of the joint controllership	while increasing legal	group for joining	
group for joining	certainty, respecting the	HealthData@EU. On the	
HealthData@EU. On the	privacy of natural persons	other hand,	
other hand,	and being interoperable.	HealthData@EU should	
HealthData@EU should	Due to the sensitivity of	enable the secondary use of	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
enable the secondary use of	health data, principles such	different categories of	
different categories of	as "privacy by design"	electronic health data,	
electronic health data,	<u>"privacy by default",</u> and	including linking of the	
including linking of the	"bring questions to data	health data with data from	
health data with data from	instead of moving data"	other data spaces such as	
other data spaces such as	should be respected	environment, agriculture,	
environment, agriculture,	whenever possible.	social etc. The Commission	
social etc. The Commission	Authorised participants in	could provide a number of	
could provide a number of	HealthData@EU could be	services within	
services within	health data access bodies,	HealthData@EU, including	
HealthData@EU, including	research infrastructures	supporting the exchange of	
supporting the exchange of	established as an European	information amongst health	
information amongst health	Research Infrastructure	data access bodies and	
data access bodies and	Consortium ('ERIC') under	authorised participants for	
authorised participants for	Council Regulation (EC)	the handling of cross-border	
the handling of cross-border	No 723/2009 ¹ or similar	access requests, maintaining	
access requests,	structures established under	catalogues of electronic	
maintaining catalogues of	another Union legislation,	health data available	
electronic health data	as well as other types of	through the infrastructure,	
available through the	entities, including	network discoverability and	
infrastructure, network	infrastructures under the	metadata queries,	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
discoverability and	European Strategy Forum	connectivity and	
metadata queries,	on Research Infrastructures	compliance services. The	
connectivity and	(ESFRI), infrastructures	Commission may also set	
compliance services. The	federated under the	up a secure environment,	
Commission may also set	European Open Science	allowing data from different	
up a secure environment,	Cloud (EOSC). Other	national infrastructures to	
allowing data from different	authorised participants	be transmitted and analysed,	
national infrastructures to	should obtain the approval	at the request of the	
be transmitted and	of the joint controllership	controllers. The	
analysed, at the request of	group for joining	Commission digital strategy	
the controllers. The	HealthData@EU. On the	promote the linking of the	
Commission digital strategy	other hand,	various common European	
promote the linking of the	HealthData@EU should	data spaces. For the health	
various common European	enable the secondary use of	sector, interoperability with	
data spaces. For the health	different categories of	the sectors such as the	
sector, interoperability with	electronic health data,	environmental, social,	
the sectors such as the	including linking of the	agricultural sectors may be	
environmental, social,	health data with data from	relevant for additional	
agricultural sectors may be	other data spaces such as	insights on health	
relevant for additional	environment, agriculture,	determinants. For the sake	
insights on health	social etc. The Commission	of IT efficiency,	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
determinants. For the sake of IT efficiency, rationalisation and interoperability of data exchanges, existing systems for data sharing should be reused as much as possible, like those being built for the exchange of evidences under the once only technical system of Regulation (EU) 2018/1724 of the European Parliament and of the Council².1. Council Regulation (EC) No 723/2009 of 25 June 2009 on the Community legal framework for a European Research Infrastructure Consortium (ERIC) (OJ L 206, 8.8.2009, p. 1).	could provide a number of services within HealthData@EU, including supporting the exchange of information amongst health data access bodies and authorised participants for the handling of cross-border access requests, maintaining catalogues of electronic health data available through the infrastructure, network discoverability and metadata queries, connectivity and compliance services. The Commission may also set up a secure environment, allowing data from different national infrastructures to be transmitted and analysed,	rationalisation and interoperability of data exchanges, existing systems for data sharing should be reused as much as possible, like those being built for the exchange of evidences under the once only technical system of Regulation (EU) 2018/1724 of the European Parliament and of the Council ² .	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
2. Regulation (EU) 2018/1724 of the European Parliament and of the Council of 2 October 2018 establishing a single digital gateway to provide access to information, to procedures and to assistance and problem-solving services and amending Regulation (EU) No 1024/2012 (OJ L 295, 21.11.2018, p. 1).	at the request of the controllers. The Commission digital strategy promote the linking of the various common European data spaces. For the health sector, interoperability with the sectors such as the environmental, social, agricultural sectors may be relevant for additional insights on health determinants. For the sake of IT efficiency, rationalisation and interoperability of data exchanges, existing systems for data sharing should be reused as much as possible, like those being built for the exchange of evidences	the Council of 2 October 2018 establishing a single digital gateway to provide access to information, to procedures and to assistance and problem-solving services and amending Regulation (EU) No 1024/2012 (OJ L 295, 21.11.2018, p. 1).	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	under the once only		
	technical system of		
	Regulation (EU) 2018/1724		
	of the European Parliament		
	and of the Council ² .		
	1. Council Regulation (EC) No		
	723/2009 of 25 June 2009 on the		
	Community legal framework for a		
	European Research Infrastructure		
	Consortium (ERIC) (OJ L 206,		
	8.8.2009, p. 1).		
	o.o.2009, p. 1 <i>)</i> .		
	2. Regulation (EU) 2018/1724 of		
	the European Parliament and of		
	the Council of 2 October 2018		
	establishing a single digital		
	gateway to provide access to		
	information, to procedures and to		
	assistance and problem-solving		
	services and amending Regulation		
	(EU) No 1024/2012 (OJ L 295,		
	21.11.2018, p. 1).		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Recita	156			
	(56) In case of cross-border registries or databases, such as the registries of		(56) In case of cross-border registries or databases, such as the registries of European	(56) In case of cross-border registries or databases, such as the registries of European	
	European Reference		Reference Networks for Rare Diseases, which	Reference Networks for Rare Diseases, which	
66	Diseases, which receive		receive data from different healthcare providers in	receive data from different healthcare providers in	
00	healthcare providers in several Member States, the		several Member States, the health data access body	several Member States, the health data access body	
	health data access body where the coordinator of the		where the coordinator of the registry is located should be	where the coordinator of the registry is located should be	
	registry is located should be responsible for providing		responsible for providing access to data.	responsible for providing access to data.	
	access to data.				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Recital	57			
	(57) The authorisation		(57) The authorisation	(57) The authorisation	
	process to gain access to		process to gain access to	process to gain access to	
	personal health data in		personal health data in	personal health data in	
	different Member States		different Member States can	different Member States can	
	can be repetitive and		be repetitive and	be repetitive and	
	cumbersome for data users.		cumbersome for data users.	cumbersome for data users.	
67	Whenever possible,		Whenever possible,	Whenever possible,	
	synergies should be		synergies should be	synergies should be	
	established to reduce the		established to reduce the	established to reduce the	
	burden and barriers for data		burden and barriers for data	burden and barriers for data	
	users. One way to achieve		users. One way to achieve	users. One way to achieve	
	this aim is to adhere to the		this aim is to adhere to the	this aim is to adhere to the	
	"single application"		"single application"	"single application"	
	principle whereby, with one		principle whereby, with one	principle whereby, with one	
	application, the data user		application, the data user	application, the data user	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	obtain authorisation from		obtain authorisation from	obtain authorisation from	
	multiple health data access		multiple health data access	multiple health data access	
	bodies in different Member		bodies in different Member	bodies in different Member	
	States.		States.	States.	
	Recital	58			
	(58) The health data access		(58) The health data access	(58) The health data access	
	bodies should provide		bodies should provide	bodies should provide	
	information about the		information about the	information about the	
	available datasets and their		available datasets and their	available datasets and their	
68	characteristics so that data		characteristics so that data	characteristics so that data	
	users can be informed of		users can be informed of	users can be informed of	
	elementary facts about the		elementary facts about the	elementary facts about the	
	dataset and assess their		dataset and assess their	dataset and assess their	
	possible relevance to them.		possible relevance to them.	possible relevance to them.	
	For this reason, each dataset		For this reason, each dataset	For this reason, each dataset	
	should include, at least,		should include, at least,	should include, at least,	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
information concerning the	information concerning the	information concerning the	
source, nature of data and	source, nature of data and	source, nature of data and	
conditions for making data	conditions for making data	conditions for making data	
available. Therefore, an EU	available. Therefore, an EU	available. Therefore, an EU	
datasets catalogue should	datasets catalogue should be	datasets catalogue should be	
be established to facilitate	established to facilitate the	established to facilitate the	
the discoverability of	discoverability of datasets	discoverability of datasets	
datasets available in the	available in the EHDS; to	available in the EHDS; to	
EHDS; to help data holders	help data holders to publish	help data holders to publish	
to publish their datasets; to	their datasets; to provide all	their datasets; to provide all	
provide all stakeholders,	stakeholders, including the	stakeholders, including the	
including the general	general public, also taking	general public, also taking	
public, also taking into	into account people with	into account people with	
account people with	disabilities, with	disabilities, with	
disabilities, with	information about datasets	information about datasets	
information about datasets	placed on the EHDS (such	placed on the EHDS (such	
placed on the EHDS (such	as quality and utility labels,	as quality and utility labels,	
as quality and utility labels,	dataset information sheets);	dataset information sheets);	
dataset information sheets);	to provide the data users	to provide the data users	
to provide the data users	with up-to-date data quality	with up-to-date data quality	
with up-to-date data quality	and utility information	and utility information	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	and utility information		about datasets.	about datasets.	
	about datasets.				
	Recita	59			
	(59) Information on the		(59) Information on the	(59) Information on the	
	quality and utility of		quality and utility of	quality and utility of	
	datasets increases the value		datasets increases the value	datasets increases the value	
	of outcomes from data		of outcomes from data	of outcomes from data	
	intensive research and		intensive research and	intensive research and	
69	innovation significantly,		innovation significantly,	innovation significantly,	
	while, at the same time,		while, at the same time,	while, at the same time,	
	promoting evidence-based		promoting evidence-based	promoting evidence-based	
	regulatory and policy		regulatory and policy	regulatory and policy	
	decision-making.		decision-making. Improving	decision-making. Improving	
	Improving the quality and		the quality and utility of	the quality and utility of	
	utility of datasets through		datasets through informed	datasets through informed	
	informed customer choice		customer choice and	customer choice and	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
and harmonising related	harmonising related	harmonising related	
requirements at Union	requirements at Union level,	requirements at Union level,	
level, taking into account	taking into account existing	taking into account existing	
existing Union and	Union and international	Union and international	
international standards,	standards, guidelines,	standards, guidelines,	
guidelines,	recommendations for data	recommendations for data	
recommendations for data	collection and data	collection and data	
collection and data	exchange (i.e. FAIR	exchange (i.e. FAIR	
exchange (i.e. FAIR	principles: Findable,	principles: Findable,	
principles: Findable,	Accessible, Interoperable	Accessible, Interoperable	
Accessible, Interoperable	and Reusable), benefits also	and Reusable), benefits also	
and Reusable), benefits also	data holders, health	data holders, health	
data holders, health	professionals, natural	professionals, natural	
professionals, natural	persons and the Union	persons and the Union	
persons and the Union	economy overall. A data	economy overall. A data	
economy overall. A data	quality and utility label for	quality and utility label for	
quality and utility label for	datasets would inform data	datasets would inform data	
datasets would inform data	users about the quality and	users about the quality and	
users about the quality and	utility characteristics of a	utility characteristics of a	
utility characteristics of a	dataset and enable them to	dataset and enable them to	
dataset and enable them to	choose the datasets that best	choose the datasets that best	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
choose the datasets that best	fit their needs. The data	fit their needs. The data	
fit their needs. The data	quality and utility label	quality and utility label	
quality and utility label	should not prevent datasets	should not prevent datasets	
should not prevent datasets	from being made available	from being made available	
from being made available	through the EHDS, but	through the EHDS, but	
through the EHDS, but	provide a transparency	provide a transparency	
provide a transparency	mechanism between data	mechanism between data	
mechanism between data	holders and data users. For	holders and data users. For	
holders and data users. For	example, a dataset that does	example, a dataset that does	
example, a dataset that does	not fulfil any requirement of	not fulfil any requirement of	
not fulfil any requirement	data quality and utility	data quality and utility	
of data quality and utility	should be labelled with the	should be labelled with the	
should be labelled with the	class representing the	class representing the	
class representing the	poorest quality and utility,	poorest quality and utility,	
poorest quality and utility,	but should still be made	but should still be made	
but should still be made	available. Expectations set	available. Expectations set	
available. Expectations set	in frameworks described in	in frameworks described in	
in frameworks described in	Article 10 of Regulation	Article 10 of Regulation	
Article 10 of Regulation	[] [AI Act	[] [AI Act	
[] [AI Act	COM/2021/206 final] and	COM/2021/206 final] and	
COM/2021/206 final] and	its relevant documentation	its relevant documentation	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	its relevant documentation specified in Annex IV should be taken into account when developing the data quality and utility framework. Member States should raise awareness about the data quality and utility label through communication activities. The Commission could support these activities.		specified in Annex IV should be taken into account when developing the data quality and utility framework. <i>The labels</i> <i>should be subject to the</i> <i>evaluation by the health</i> <i>data access bodies.</i> Member States should raise awareness about the data quality and utility label through communication activities. The Commission could support these activities.	specified in Annex IV should be taken into account when developing the data quality and utility framework. Member States should raise awareness about the data quality and utility label through communication activities. The Commission could support these activities.	
	Recital 60				
70					

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
(60) The EU datasets	(60) The EU datasets	(60) The EU datasets	
catalogue should minimise	catalogue should minimise	catalogue should minimise	
the administrative burden	the administrative burden	the administrative burden	
for the data holders and	for the data holders and	for the data holders and	
other database users; be	other database users; be	other database users; be	
user-friendly, accessible	user-friendly, accessible and	user-friendly, accessible and	
and cost-effective, connect	cost-effective, connect	cost-effective, connect	
national data catalogues and	national data catalogues and	national data catalogues and	
avoid redundant registration	avoid redundant registration	avoid redundant registration	
of datasets. The EU datasets	of datasets. The EU datasets	of datasets. The EU datasets	
catalogue could be aligned	catalogue could be aligned	catalogue could be aligned	
with the data.europa.eu	with the data.europa.eu	with the data.europa.eu	
initiative and without	initiative and without	initiative and without	
prejudice to the	prejudice to the	prejudice to the	
requirements set out in the	requirements set out in the	requirements set out in the	
Regulation [] [Data	Regulation [] [Data	Regulation [] [Data	
Governance Act	Governance Act	Governance Act	
COM/2020/767 final].	COM/2020/767 final].	COM/2020/767 final].	
Member states should	Member states should	Member states should	
ensure that national data	ensure that national data	ensure that national data	
catalogues are interoperable	catalogues are interoperable	catalogues are interoperable	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	with existing dataset catalogues from European research infrastructures and other relevant data sharing infrastructures.		with existing dataset catalogues from European research infrastructures and other relevant data sharing infrastructures.	with existing dataset catalogues from European research infrastructures and other relevant data sharing infrastructures.	
	Recita	61			
71	(61) Cooperation and work is ongoing between different professional organisations, the Commission and other institutions to set up minimum data fields and other characteristics of different datasets (registries for instance). This work is		(61) Cooperation and work is ongoing between different professional organisations, the Commission and other institutions to set up minimum data fields and other characteristics of different datasets (registries for instance). This work is	(61) Cooperation and work is ongoing between different professional organisations, the Commission and other institutions to set up minimum data fields and other characteristics of different datasets (registries for instance). This work is	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
more advanced in areas	more advanced in areas	more advanced in areas	
such as cancer, rare	such as cancer, rare	such as cancer, rare	
diseases, and statistics and	diseases, cardiovascular	diseases, and statistics and	
shall be taken into account	and metabolic diseases,	shallshould be taken into	
when defining new	<u>risk factor assessment,</u> and	account when defining new	
standards. However, many	statistics and shall be taken	standards. However, many	
datasets are not harmonised,	into account when defining	datasets are not harmonised,	
raising comparability issues	new standards and disease-	raising comparability issues	
and making cross-border	specific harmonised	and making cross-border	
research difficult.	templates for structured	research difficult.	
Therefore, more detailed	data elements. However,	Therefore, more detailed	
rules should be set out in	many datasets are not	rules should be set out in	
implementing acts to ensure	harmonised, raising	implementing acts to ensure	
a harmonised provision,	comparability issues and	a harmonised provision,	
coding and registration of	making cross-border	coding and registration of	
electronic health data.	research difficult.	electronic health data. Such	
Member States should work	Therefore, more detailed	datasets may include data	
towards delivering	rules should be set out in	from registries of rare	
sustainable economic and	implementing acts to ensure	diseases, orphan drugs	
social benefits of European	a harmonised provision,	databases, cancer	
electronic health systems	coding and registration of	registries and registries of	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
and services and	electronic health data.	highly relevant infectious	
interoperable applications,	Member States should work	diseases. Member States	
with a view to achieving a	towards delivering	should work towards	
high level of trust and	sustainable economic and	delivering sustainable	
security, enhancing	social benefits of European	economic and social	
continuity of healthcare and	electronic health systems	benefits of European	
ensuring access to safe and	and services and	electronic health systems	
high-quality healthcare.	interoperable applications,	and services and	
	with a view to achieving a	interoperable applications,	
	high level of trust and	with a view to achieving a	
	security, enhancing	high level of trust and	
	continuity of healthcare and	security, enhancing	
	ensuring access to safe and	continuity of healthcare and	
	high-quality healthcare.	ensuring access to safe and	
	Existing health data	high-quality healthcare.	
	infrastructures and		
	registries put in place by		
	institutions and		
	stakeholders can contribute		
	to defining and		
	implementing data		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			standards, to ensuring interoperability and should be leveraged to allow for continuity and build on existing expertise.		
	Recita	162			
72	 (62) The Commission should support Member States in building capacity and effectiveness in the area of digital health systems for primary and secondary use of electronic health data. Member States should be supported to strengthen their capacity. Activities at 		 (62) The Commission should support Member States in building capacity and effectiveness in the area of digital health systems for primary and secondary use of electronic health data. Member States should be supported to strengthen their capacity. Activities at 	 (62) The Commission should support Member States in building capacity and effectiveness in the area of digital health systems for primary and secondary use of electronic health data. Member States should be supported to strengthen their capacity. Activities at 	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Union level, such as benchmarking and exchange of best practices are relevant measures in this respect.		Union level, such as benchmarking and exchange of best practices are relevant measures in this respect.	Union level, such as benchmarking and exchange of best practices are relevant measures in this respect.	
	Recita	l 62a			
72a			(62a) Improving digital health literacy for both natural persons and their health professionals is key in order to achieve trust, safety and appropriate use of health data and thus to achieve successful implementation of this Regulation. Improving		

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	digital health literacy is		
	<u>fundamental in order to</u>		
	empower natural persons		
	<u>to have true control over</u>		
	<u>their health data and</u>		
	actively manage their		
	<u>health and care, and</u>		
	<u>understand the</u>		
	implications of the		
	management of such data		
	for both primary and		
	<u>secondary use. Member</u>		
	<u>States, including regional</u>		
	<u>and local authorities,</u>		
	should therefore support		
	<u>digital health literacy and</u>		
	<u>public awareness, while</u>		
	<u>ensuring that the</u>		
	implementation of this		
	Regulation contributes to		
	<u>reducing inequalities and</u>		

Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
		does not discriminate against people lacking digital skills. Particular attention should be given to persons with disabilities and vulnerable groups including migrants and the elderly. Health professionals and IT operators should have sufficient training in working with new digital infrastructures to ensure cybersecurity and ethical management of health data.		
Recit	al 63			

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	(63) The use of funds	(63) The use of funds	(63) The use of funds	
	should also contribute to	should also contribute to	should also contribute to	
	attaining the objectives of	attaining the objectives of	attaining the objectives of	
	the EHDS. Public	the EHDS. Public	the EHDS. Public	
	procurers, national	procurers, national	procurers, national	
	competent authorities in the	competent authorities in the	competent authorities in the	
	Member States, including	Member States, including	Member States, including	
	digital health authorities	digital health authorities and	digital health authorities and	
73	and health data access	health data access bodies, as	health data access bodies, as	
	bodies, as well as the	well as the Commission	well as the Commission	
	Commission should make	should make references to	should make references to	
	references to applicable	applicable technical	applicable technical	
	technical specifications,	specifications, standards	specifications, standards	
	standards and profiles on	and profiles on	and profiles on	
	interoperability, security	interoperability, security	interoperability, security	
	and data quality, as well as	and data quality, as well as	and data quality, as well as	
	other requirements	other requirements	other requirements	
	developed under this	developed under this	developed under this	
	Regulation when defining	Regulation when defining	Regulation when defining	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
the conditions for public	the conditions for public	the conditions for public	
procurement, calls for	procurement, calls for	procurement, calls for	
proposals and allocation of	proposals and allocation of	proposals and allocation of	
Union funds, including	Union funds, including	Union funds, including	
structural and cohesion	structural and cohesion	structural and cohesion	
funds.	funds. <i>To procure or fund</i>	funds.	
	services provided by		
	controllers and processors		
	established in the Union		
	that process personal		
	electronic health data, they		
	should be required to		
	demonstrate that they will		
	store the data in the Union		
	and that they are not		
	subject to third country law		
	that conflicts with Union		
	data protection rules.		
	Union funds should be		
	distributed transparently		
	and sufficiently among the		

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	<u>Member States, ensuring it</u>		
	is adequate and taking into		
	account different levels of		
	health system digitalisation		
	and the costs involved in		
	making national data		
	<u>infrastructures</u>		
	interoperable and		
	<u>compatible with the</u>		
	requirements of the EHDS.		
	<u>Making data available for</u>		
	<u>secondary use requires</u>		
	additional resources for		
	<u>healthcare systems, in</u>		
	<u>particular public systems.</u>		
	<u>That additional burden for</u>		
	<u>public entities should be</u>		
	addressed and minimised		
	to the greatest possible		
	<u>extent during the</u>		
	<u>implementation phase of</u>		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			<u>the EHDS.</u>		
	Recita	63a			
			(63a) The economic costs		
			of implementing this Regulation should be		
			borne at both Member		
			<u>State and Union level, and</u> <u>a fair sharing of that</u>		
73a			burden between national		
			and Union funds should be		
			<u>found. The initial Union</u> <u>funding to achieve a timely</u>		
			application of the EHDS is		
			limited to what can be		
			mobilised under the 2021-		
			<u>2027 Multiannual</u>		

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	<u>Financial Framework</u>		
	(MFF) where EUR 220		
	<u>million can be made</u>		
	<u>available under the</u>		
	EU4Health and Digital		
	Europe programmes. The		
	successful and coherent		
	application of the EHDS		
	<u>across all Member States</u>		
	<u>will however require</u>		
	<u>higher funding. The</u>		
	implementation of the		
	<u>EHDS requires appropriate</u>		
	<u>investments in capacity</u>		
	<u>building and training and a</u>		
	<u>well-funded commitment to</u>		
	public consultation and		
	<u>engagement. The</u>		
	Commission should		
	<u>therefore mobilise further</u>		
	<u>resources for the EHDS as</u>		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			part of the review of the 2021-2027 MFF and for the forthcoming MFF under the principle that new initiatives should be matched with new funding.		
	Recita	l 63a			
73b				(63a) Any judgment of a third-country court or tribunal and any decision of a third-country administrative authority requiring a digital health authority, a health data access body or a health data user to transfer or	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		give access to anonymous	
		non-personal electronic	
		health data within the	
		scope of this Regulation	
		held in the Union should	
		be recognised or	
		enforceable in any	
		manner only if based on	
		an international	
		agreement, such as a	
		mutual legal assistance	
		treaty, in force between	
		the requesting third	
		country and the Union or	
		any such agreement	
		between the requesting	
		third country and a	
		Member State, compliant	
		with Union law.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Recital	l 64			
74	(64) Certain categories of electronic health data can remain particularly sensitive even when they are in anonymised format and thus non-personal, as already specifically foreseen in the Data Governance Act. Even in situations of the use of state of the art anonymization techniques, there remains a residual risk that the capacity to re-identify could be or become available, beyond the means reasonably likely to be		(64) Certain categories of electronic health data can remain particularly sensitive even when they are in anonymised format and thus non-personal, as already specifically foreseen in the Data Governance Act. Even in situations of the use of state of the art anonymization techniques, there remains a residual risk that the capacity to re- identify could be or become available, beyond the means reasonably likely to be used. Such residual risk is present	(64) Certain categories of electronic health data can remain particularly sensitive even when they are in anonymised format and thus non-personal, as already specifically foreseen in the Data Governance Act. Even in situations of the use of state of the art anonymization techniques, there remains a residual risk that the capacity to re- identify could be or become available, beyond the means reasonably likely to be used. Such residual risk is present	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
used. Such residual risk is	in relation to rare diseases	in relation to rare diseases	
present in relation to rare	(a life-threatening or	(a life-threatening or	
diseases (a life-threatening	chronically debilitating	chronically debilitating	
or chronically debilitating	condition affecting not more	condition affecting not more	
condition affecting not	than five in 10 thousand	than five in 10 thousand	
more than five in 10	persons in the Union),	persons in the Union),	
thousand persons in the	where the limited numbers	where the limited numbers	
Union), where the limited	of case reduce the	of case reduce the	
numbers of case reduce the	possibility to fully	possibility to fully	
possibility to fully	aggregate the published data	aggregate the published data	
aggregate the published	in order to preserve the	in order to preserve the	
data in order to preserve the	privacy of natural persons	privacy of natural persons	
privacy of natural persons	while also maintaining an	while also maintaining an	
while also maintaining an	appropriate level of	appropriate level of	
appropriate level of	granularity in order to	granularity in order to	
granularity in order to	remain meaningful. It can	remain meaningful. It can	
remain meaningful. It can	affect different types of	affect different types of	
affect different types of	health data depending on	health data depending on	
health data depending on	the level of granularity and	the level of granularity and	
the level of granularity and	description of the	description of the	
description of the	characteristics of data	characteristics of data	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
characteristics of data	subjects, the number of	subjects, the number of	
subjects, the number of	people affected or and for	people affected or and for	
people affected or and for	instance in cases of data	instance in cases of data	
instance in cases of data	included in electronic health	included in electronic health	
included in electronic	records, disease registries,	records, disease registries,	
health records, disease	biobanks, person generated	biobanks, person generated	
registries, biobanks, person	data etc. where the	data etc. where the	
generated data etc. where	identification characteristics	identification characteristics	
the identification	are broader and where, in	are broader and where, in	
characteristics are broader	combination with other	combination with other	
and where, in combination	information (e.g. in very	information (e.g. in very	
with other information (e.g.	small geographical areas) or	small geographical areas) or	
in very small geographical	through the technological	through the technological	
areas) or through the	evolution of methods which	evolution of methods which	
technological evolution of	had not been available at the	had not been available at the	
methods which had not	moment of anonymisation,	moment of anonymisation,	
been available at the	can lead to the re-	can lead to the re-	
moment of anonymisation,	identification of the data	identification of the data	
can lead to the re-	subjects using means that	subjects using means that	
identification of the data	are beyond those reasonably	are beyond those reasonably	
subjects using means that	likely to be used. The	likely to be used. The	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
are beyond those	realisation of such risk of	realisation of such risk of	
reasonably likely to be	re-identification of natural	re-identification of natural	
used. The realisation of	persons would present a	persons would present a	
such risk of re-	major concern and is likely	major concern and is likely	
identification of natural	to put the acceptance of the	to put the acceptance of the	
persons would present a	policy and rules on	policy and rules on	
major concern and is likely	secondary use provided for	secondary use provided for	
to put the acceptance of the	in this Regulation at risk.	in this Regulation at risk.	
policy and rules on	Furthermore, aggregation	Furthermore, aggregation	
secondary use provided for	techniques are less tested	techniques are less tested	
in this Regulation at risk.	for non-personal data	for non-personal data	
Furthermore, aggregation	containing for example	containing for example	
techniques are less tested	trade secrets, as in the	trade secrets, as in the	
for non-personal data	reporting on clinical trials,	reporting on clinical trials,	
containing for example	and enforcement of	and enforcement of	
trade secrets, as in the	breaches of trade secrets	breaches of trade secrets	
reporting on clinical trials,	outside the Union is more	outside the Union is more	
and enforcement of	difficult in the absence of a	difficult in the absence of a	
breaches of trade secrets	sufficient international	sufficient international	
outside the Union is more	protection standard.	protection standard.	
difficult in the absence of a	Therefore, for these types of	Therefore, for these types of	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
sufficient international	health data, there remains a	health data, there remains a	
protection standard.	risk for re-identification	risk for re-identification	
Therefore, for these types	after the anonymisation or	after the anonymisation or	
of health data, there	aggregation, which could	aggregation, which could	
remains a risk for re-	not be reasonably mitigated	not be reasonably mitigated	
identification after the	initially. This falls within	initially. This falls within	
anonymisation or	the criteria indicated in	the criteria indicated in	
aggregation, which could	Article 5(13) of Regulation	Article 5(13) of Regulation	
not be reasonably mitigated	[] [Data Governance Act	[] [Data Governance Act	
initially. This falls within	COM/2020/767 final].	COM/2020/767 final].	
the criteria indicated in	These types of health data	These types of health data	
Article 5(13) of Regulation	would thus fall within the	would thus fall within the	
[] [Data Governance Act	empowerment set out in	empowerment set out in	
COM/2020/767 final].	Article 5(13) of Regulation	Article 5(13) of Regulation	
These types of health data	[] [Data Governance Act	[] [Data Governance Act	
would thus fall within the	COM/2020/767 final] for	COM/2020/767 final] for	
empowerment set out in	transfer to third countries.	transfer to third countries.	
Article 5(13) of Regulation	The protective measures,	The protective measures,	
[] [Data Governance Act	proportional to the risk of	proportional to the risk of	
COM/2020/767 final] for	re-identification, would	re-identification, would	
transfer to third countries.	need to take into account	need to take into account	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	The protective measures,		the specificities of different	the specificities of different	
	proportional to the risk of		data categories or of	data categories or of	
	re-identification, would		different anonymization or	different anonymization or	
	need to take into account		aggregation techniques and	aggregation techniques and	
	the specificities of different		will be detailed in the	will be detailed in the	
	data categories or of		context of the Delegated	context of the Delegated	
	different anonymization or		Act under the empowerment	Act under the empowerment	
	aggregation techniques and		set out in Article 5(13) of	set out in Article 5(13) of	
	will be detailed in the		Regulation [] [Data	Regulation [] [Data	
	context of the Delegated		Governance Act	Governance Act	
	Act under the		COM/2020/767 final].	COM/2020/767 final].	
	empowerment set out in				
	Article 5(13) of Regulation				
	[] [Data Governance Act				
	COM/2020/767 final].				
	Recita	64a			
	Necita				
74a					

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	(64a) The functioning of		
	the EHDS involves		
	processing of a large		
	<u>quantity of personal and</u>		
	<u>non-personal health data</u>		
	<u>of a highly sensitive</u>		
	nature. Article 8(3) of the		
	<u>Charter of Fundamental</u>		
	<u>Rights of the European</u>		
	<u>Union (the 'Charter')</u>		
	requires control over the		
	processing of such health		
	<u>data by an independent</u>		
	authority. The control of		
	the compliance with the		
	requirements of protection		
	and security by an		
	independent supervisory		
	authority, carried out on		
	the basis of Union law, is		
	<u>an essential component of</u>		

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	the protection of		
	individuals with regard to		
	the processing of personal		
	<u>data and cannot be fully</u>		
	<u>ensured in the absence of a</u>		
	<u>requirement to retain the</u>		
	<u>electronic health data in</u>		
	<u>question within the Union.</u>		
	Therefore, taking into		
	account the need to		
	<u>mitigate the risks of</u>		
	<u>unlawful access and</u>		
	<u>ineffective supervision, in</u>		
	<u>compliance with the</u>		
	<u>principle of</u>		
	proportionality, this		
	Regulation should require		
	Member States to store		
	<u>electronic health data</u>		
	<u>within the Union. Such</u>		
	<u>storage requirements</u>		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			should ensure a uniform high level of protection for data subjects across the Union, preserve the proper functioning of the internal market, in line with Article 114 TFEU, which constitutes the legal basis of this Regulation, and serve to enhance citizens' trust in the EHDS.		
	Recita	l 64a			
74b				(64a) The processing of large amounts of personal health data for the purposes foreseen in the	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		EHDS, as part of data	
		processing activities in the	
		context of servicing data	
		access applications, data	
		permits and data requests	
		entails higher risks of	
		unauthorised access to	
		such personal data, as well	
		as the possibility of	
		cybersecurity incidents.	
		Personal health data are	
		particularly sensitive as	
		they often constitute	
		intimate information,	
		covered by medical	
		secrecy, the disclosure of	
		which to unauthorised	
		third parties can cause	
		significant distress.	
		Taking fully into	
		consideration the	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		principles outlined in the	
		case law of the Court of	
		Justice of the European	
		Union, this Regulation	
		ensures full respect for	
		fundamental rights, for	
		the right to privacy and	
		for the principle of	
		proportionality. In order	
		to ensure the full integrity	
		and confidentiality of	
		personal electronic health	
		data under the	
		Regulation, to guarantee a	
		particularly high level of	
		protection and security,	
		and to reduce the risk of	
		unlawful access to that	
		personal electronic health	
		data, the Regulation	
		makes provision for	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				personal electronic health data to be stored and processed within the Union for the purpose of carrying out the tasks foreseen by this Regulation, unless an adequacy decision pursuant to Article 45 of Regulation (EU) 2016/679 applies.	
	Recita	l 64b			
74c			(64b) The obligation to store electronic health data in the Union does not preclude transfers of those		

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	data to third countries or		
	international organisations		
	by means of granting		
	access to electronic health		
	data. Access to data		
	through the secure		
	processing environment		
	<u>can entail the transfer of</u>		
	<u>personal data, as defined in</u>		
	Chapter V of Regulation		
	<u>(EU) 2016/679. It is</u>		
	possible to reconcile a		
	general requirement to		
	<u>store personal data in the</u>		
	Union with specific		
	<u>transfers being allowed in</u>		
	<u>compliance with Union law</u>		
	<u>on personal data</u>		
	protection, for instance in		
	<u>the context of scientific</u>		
	<u>research, provision of care</u>		

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	or international		
	cooperation. In particular,		
	when personal data are		
	transferred from the Union		
	to controllers, processors		
	or other recipients in third		
	<u>countries or to</u>		
	<u>international</u>		
	organisations, the level of		
	protection of natural		
	persons ensured in the		
	Union under Regulation		
	(EU) 2016/679 should not		
	<u>be undermined, including</u>		
	<u>in cases of onward</u>		
	<u>transfers of personal data</u>		
	from the third country or		
	international organisation		
	<u>to controllers, processors in</u>		
	<u>the same or another third</u>		
	<u>country or international</u>		

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	organisation. Transfers of		
	personal health data to		
	third countries and		
	international organisations		
	<u>can only be carried out in</u>		
	full compliance with		
	Chapter V of Regulation		
	<u>(EU) 2016/679. For</u>		
	<u>instance, controllers and</u>		
	processors processing		
	<u>personal electronic health</u>		
	<u>data remain subject to</u>		
	<u>Article 48 of that</u>		
	<u>Regulation on transfers or</u>		
	<u>disclosures not authorised</u>		
	by Union law and should		
	<u>comply with this provision</u>		
	<u>in the case of an access</u>		
	request stemming from a		
	<u>third country. In</u>		
	accordance with the		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			conditions of Article 9(4) of Regulation (EU) 2016/679, Member States can maintain or introduce further conditions, including limitations, in relation to transfers of personal health data to third countries or international organisations.		
	Recita	l 64c			
74d			(64c) <u>Access to electronic</u> <u>health data for entities</u> <u>from third countries should</u> <u>take place only on the basis</u>		

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	of the reciprocity principle.		
	<u>Making available of health</u>		
	<u>data to a third country can</u>		
	take place only where the		
	Commission has		
	<u>established by means of a</u>		
	<u>delegated act that the third</u>		
	<u>country concerned allows</u>		
	<u>for the use of health data</u>		
	by Union entities under the		
	same conditions and with		
	<u>the same safeguards as</u>		
	<u>within the Union. The</u>		
	Commission should		
	<u>monitor that list and</u>		
	<u>provide for a periodic</u>		
	<u>review thereof. Where the</u>		
	Commission finds that a		
	<u>third country no longer</u>		
	<u>ensures access on the same</u>		
	<u>terms , that third country</u>		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			<u>should be removed from</u> <u>that list.</u>		
	Recita	1 65			
75	(65) In order to promote the consistent application of this Regulation, a European Health Data Space Board (EHDS Board) should be set up. The Commission should participate in its activities and chair it. It should contribute to the consistent application of this Regulation throughout the Union, including by helping Member State to		(65) In order to promote the consistent application of this Regulation, <u>including</u> <u>cross-border</u> <u>interoperability of health</u> <u>data, and potential</u> <u>mechanisms of funding</u> <u>support to ensure equal</u> <u>development of data</u> <u>systems across the Union</u> <u>in respect of the primary</u> <u>and secondary use of</u> <u>electronic health data</u> , a	(65) In order to promote the consistent application of this Regulation, a European Health Data Space Board (EHDS Board) should be set up. The Commission should participate in its activities and chair it. It should contribute to the consistent application of this Regulation throughout the Union, including by helping Member State to	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
coordinate the use of	European Health Data	coordinate the use of	
electronic health data for	Space Board (EHDS Board)	electronic health data for	
healthcare, certification, but	should be set up. The	healthcare, certification, but	
also concerning the	Commission should	also concerning the	
secondary use of electronic	participate in its activities	secondary use of electronic	
health data. Given that, at	and chair it. <mark>#<u>The EHDS</u></mark>	health data. Given that, at	
national level, digital health	Board should contribute to	national level, digital health	
authorities dealing with the	the consistent application of	authorities dealing with the	
primary use of electronic	this Regulation throughout	primary use of electronic	
health data may be different	the Union, including by	health data may be different	
to the health data access	helping Member State to	to the health data access	
bodies dealing with the	coordinate the use of	bodies dealing with the	
secondary use of electronic	electronic health data for	secondary use of electronic	
health data, the functions	healthcare, certification, but	health data, the functions	
are different and there is a	also concerning the	are different and there is a	
need for distinct	secondary use of electronic	need for distinct	
cooperation in each of these	health data. Given that, at	cooperation in each of these	
areas, the EHDS Board	national level, digital health	areas, the EHDS Board	
should be able to set up	authorities dealing with the	should be able to set up	
subgroups dealing with	primary use of electronic	subgroups dealing with	
these two functions, as well	health data may be different	these two functions, as well	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
as other subgroups, as	to the health data access	as other subgroups, as	
needed. For an efficient	bodies dealing with the	needed. For an efficient	
working method, the digital	secondary use of electronic	working method, the digital	
health authorities and health	health data, the functions	health authorities and health	
data access bodies should	are different and there is a	data access bodies should	
create networks and links at	need for distinct	create networks and links at	
national level with different	cooperation in each of these	national level with different	
other bodies and authorities,	areas, the EHDS Board	other bodies and authorities,	
but also at Union level.	should be able to set up	but also at Union level.	
Such bodies could comprise	subgroups dealing with	Such bodies could comprise	
data protection authorities,	these two functions, as well	data protection authorities,	
cybersecurity, eID and	as other subgroups, as	cybersecurity, eID and	
standardisation bodies, as	needed. For an efficient	standardisation bodies, as	
well as bodies and expert	working method, the digital	well as bodies and expert	
groups under Regulations	health authorities and health	groups under Regulations	
[], [], [] and []	data access bodies should	[], [], [] and []	
[Data Governance Act,	create networks and links at	[Data Governance Act, Data	
Data Act, AI Act and	national level with different	Act, AI Act and	
Cybersecurity Act].	other bodies and authorities,	Cybersecurity Act].	
	but also at Union level.		
	Such bodies could comprise		

data protection authorities, cybersecurity, eID and standardisation bodies, as well as bodies and expert groups under Regulations [], [], [] and []	
standardisation bodies, as well as bodies and expert groups under Regulations	
well as bodies and expert groups under Regulations	
groups under Regulations	
[], [], []	
[Data Governance Act, Data	
Act, AI Act and	
Cybersecurity Act]. <i>The</i>	
EHDS Board should	
operate in line with its	
<u>Code of Conduct,</u>	
impartially, independently,	
in the public interest and	
transparently, with open	
publication of meeting	
dates and minutes of its	
discussions as well as of an	
annual report. It is	
<u>furthermore appropriate to</u>	
lay down sufficient	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			guarantees to ensure that members of the EHDS Board do not have any conflicts of interest.		
	Recita	l 65a			
75a			(65a) An advisory forum should be set up to advise the EHDS Board in the fulfilment of its tasks by providing stakeholder input on matters pertaining to this Regulation. The advisory forum should be composed of representatives of patients, consumers, health		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement	
			professionals, industry, scientific researchers and academia. It should have a balanced composition and represent the views of different relevant stakeholders. Both commercial and non- commercial interests should be represented.			
	Recital 66					
76	(66) In order to manage the cross-border infrastructures for primary and secondary use of electronic health data, it is necessary to		(66) In order to manage the cross-border infrastructures for primary and secondary use of electronic health data, it is necessary to	(66) In order to manage the cross-border infrastructures for primary and secondary use of electronic health data, it is necessary to		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement	
	create the Joint controllership group for authorised participants (e.g. to ensure the compliance with data protection rules and this Regulation for the processing operations performed in such infrastructures).		create the Joint controllership group for authorised participants (e.g. to ensure the compliance with data protection rules and this Regulation for the processing operations performed in such infrastructures).	create the Joint controllership group for authorised participants (e.g. to ensure the compliance with data protection rules and this Regulation for the processing operations performed in such infrastructures).		
	Recital 66a					
76a			(66a) Any natural person should have the right to lodge a complaint with a digital health authority or with a health data access body, in particular in the			

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Member State of his or her		
	habitual residence, and the		
	right to an effective judicial		
	remedy in accordance with		
	<u>Article 47 of the Charter if</u>		
	<u>the natural person</u>		
	<u>considers that his or her</u>		
	<u>rights under this</u>		
	Regulation have been		
	infringed or where the		
	digital health authority or		
	<u>health data access body</u>		
	<u>does not act on a</u>		
	<u>complaint, partially or</u>		
	<u>wholly rejects or dismisses</u>		
	<u>a complaint or does not act</u>		
	where such action is		
	<u>necessary to protect the</u>		
	<u>rights of the natural</u>		
	<u>person. The investigation</u>		
	<u>following a complaint</u>		

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	should be carried out,		
	subject to judicial review,		
	to the extent that is		
	appropriate in the specific		
	<u>case. The digital health</u>		
	<u>authority or health data</u>		
	access body should inform		
	<u>the natural person of the</u>		
	progress and the outcome		
	<u>of the complaint within a</u>		
	reasonable period. If the		
	<u>case requires further</u>		
	investigation or		
	coordination with another		
	<u>digital health authority or</u>		
	<u>health data access body,</u>		
	intermediate information		
	<u>should be given to the</u>		
	<u>natural person. In order to</u>		
	facilitate the submission of		
	<u>complaints, each digital</u>		

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	health authority and health		
	data access body should		
	take measures such as		
	providing a complaint		
	<u>submission form which can</u>		
	<u>also be completed</u>		
	<u>electronically, without</u>		
	<u>excluding the possibility of</u>		
	<u>using other means of</u>		
	<u>communication. Where the</u>		
	complaint concerns the		
	<u>rights of natural persons,</u>		
	<u>the health data access body</u>		
	should inform the		
	supervisory authorities		
	under Regulation (EU)		
	2016/679 and send them a		
	<u>copy of the complaint.</u>		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Recita	al 66b			
76b			(66b) Where a natural person considers that his or her rights under this Regulation have been infringed, he or she should have the right to mandate a not-for-profit body, organisation or association which is constituted in accordance with the law of a Member State, has statutory objectives which are in the public interest and is active in the field of the protection of personal data, to lodge a complaint on his or her behalf.		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Recita	il 66c			
			<u>(66c)</u> <u>Any natural or legal</u> person has the right to		
			<u>bring an action for</u> annulment of decisions of		
			the EHDS Board before the Court of Justice under		
76c			the conditions provided for in Article 263 TFEU. As		
			addressees of such decisions, the digital health		
			authorities or health data access bodies concerned		
			which wish to challenge		
			<u>them have to bring an</u> action within two months		

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	of being notified of them,		
	in accordance with Article		
	263 TFEU. In accordance		
	with Article 263 TFEU, a		
	<u>health data holder, a</u>		
	<u>health data applicant, a</u>		
	<u>health data user or a</u>		
	<u>complainant can bring an</u>		
	<u>action for annulment</u>		
	against the decisions of the		
	EHDS Board which		
	<u>concern them within two</u>		
	months of their publication		
	<u>on the website of the</u>		
	EHDS Board Without		
	prejudice to this right		
	<u>under Article 263 TFEU,</u>		
	<u>each natural or legal</u>		
	person should have an		
	<u>effective judicial remedy</u>		
	<u>before the competent</u>		

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	national court against a		
	decision of a digital health		
	authority or health data		
	access body which		
	produces legal effects		
	concerning that person.		
	Such a decision concerns		
	<u>in particular the exercise of</u>		
	<u>investigative, corrective</u>		
	and authorisation powers		
	by the health data access		
	body or the dismissal or		
	rejection of complaints.		
	<u>However, the right to an</u>		
	<u>effective judicial remedy</u>		
	<u>does not encompass</u>		
	<u>measures taken by digital</u>		
	<u>health authorities and</u>		
	health data access bodies		
	which are not legally		
	<u>binding, such as opinions</u>		

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	issued or advice provided.		
	Proceedings against a		
	digital health authority or		
	<u>health data access body</u>		
	<u>should be brought before</u>		
	the courts of the Member		
	State where the digital		
	<u>health authority or health</u>		
	<u>data access body is</u>		
	established and should be		
	<u>conducted in accordance</u>		
	with that Member State's		
	<u>procedural law. Those</u>		
	<u>courts should exercise full</u>		
	jurisdiction, which should		
	include jurisdiction to		
	<u>examine all questions of</u>		
	<u>fact and law relevant to the</u>		
	dispute before them. Where		
	<u>a complaint has been</u>		
	<u>rejected or dismissed by a</u>		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			digital health authority or health data access body, the complainant can bring proceedings before the courts in the same Member State.		
	Recita	l 66d			
76d			(66d) Where a court seised of proceedings against a decision by a digital health authority or health data access body has reason to believe that proceedings concerning the same access to electronic health data by the same health		

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	<u>data user, such as for the</u>		
	same purpose for		
	processing for secondary		
	<u>use, are brought before a</u>		
	<u>competent court in another</u>		
	<u>Member State, it should</u>		
	<u>contact that court in order</u>		
	<u>to confirm the existence of</u>		
	<u>such related proceedings.</u>		
	If related proceedings are		
	pending before a court in		
	<u>another Member State, any</u>		
	<u>court other than the court</u>		
	<u>first seised should be able</u>		
	<u>to stay its proceedings or be</u>		
	<u>able to, on request of one</u>		
	<u>of the parties, decline</u>		
	jurisdiction in favour of the		
	<u>court first seised if that</u>		
	<u>court has jurisdiction over</u>		
	the proceedings in question		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			and its law permits the consolidation of such related proceedings. Proceedings should be deemed to be related where they are so closely connected that it is expedient to hear and determine them together in order to avoid the risk of irreconcilable judgments resulting from separate proceedings.		
Recital 66e					
76e			(66e) For proceedings against a health data		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			holder or health data user, the plaintiff should have the choice of bringing the action before the courts of the Member States where the health data holder or health data user has an establishment or where the natural person resides, unless the health data holder is a public authority of a Member State acting in the exercise of its public powers.		
	Recita	l 66f			
76f			(66f) The digital health		

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	authority, health data		
	access body, health data		
	holder or health data user		
	should compensate any		
	<u>damage which a person</u>		
	<u>could suffer as a result of</u>		
	processing that infringes		
	this Regulation. The digital		
	<u>health authority, health</u>		
	<u>data access body, health</u>		
	<u>data holder or health data</u>		
	<u>user should be exempt</u>		
	<u>from liability if it proves</u>		
	<u>that it was not in any way</u>		
	responsible for the damage.		
	The concept of damage		
	<u>should be broadly</u>		
	<u>interpreted in the light of</u>		
	the case-law of the Court		
	<u>of Justice in a manner</u>		
	which fully reflects the		

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	objectives of this		
	Regulation. This is without		
	prejudice to any claims for		
	damage deriving from the		
	violation of other rules in		
	<u>Union or national law.</u>		
	Processing that infringes		
	this Regulation should also		
	include processing that		
	infringes delegated and		
	implementing acts adopted		
	<u>in accordance with this</u>		
	Regulation and national		
	law specifying rules related		
	<u>to this Regulation. Natural</u>		
	persons should receive full		
	and effective compensation		
	for the damage they have		
	suffered. Where digital		
	<u>health authorities, health</u>		
	<u>data access bodies, health</u>		

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	data holders or health data		
	users are involved in the		
	same processing, each		
	<u>actor should be held liable</u>		
	for the entire extent of the		
	<u>damage. However, where</u>		
	<u>they are joined to the same</u>		
	judicial proceedings, in		
	accordance with Member		
	<u>State law, it should be</u>		
	possible to apportion		
	<u>compensation according to</u>		
	<u>the responsibility of each</u>		
	<u>digital health authority,</u>		
	<u>health data access body,</u>		
	<u>health data holder or</u>		
	<u>health data user for the</u>		
	damage caused by the		
	processing, provided that		
	<u>full and effective</u>		
	<u>compensation of the</u>		

Commission Proposal		EP Mandate	Council Mandate	Draft Agreement			
		natural person who suffered the damage is ensured. Any digital health authority, health data access body, health data holder or health data user which has paid full compensation should be able to subsequently institute recourse proceedings against other digital health authorities, health data access bodies, health data users involved in the same processing.					
Recita	Recital 66g						

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
76g		(66g)Where specific ruleson jurisdiction arecontained in thisRegulation, in particular asregards proceedingsseeking a judicial remedyincluding compensation,against a digital healthauthority, health dataholder or health data user,general jurisdiction rulessuch as those of Regulation(EU) No 1215/2012 of theEuropean Parliament andof the Council ¹ should notprejudice the application ofsuch specific rules.		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			<u>1. Regulation (EU) No 1215/2012</u> of the European Parliament and of the Council of 12 December 2012 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters (OJ L 351, 20.12.2012, p. 1).		
	Recita	l 66h			
76h			(66h) In order to strengthen the enforcement of the rules of this Regulation, penalties including administrative fines should be imposed for		

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	any infringement of this		
	Regulation, in addition to,		
	or instead of, appropriate		
	measures imposed by the		
	<u>digital health authority or</u>		
	<u>health data access body</u>		
	pursuant to this		
	<u>Regulation. In the case of a</u>		
	<u>minor infringement or if</u>		
	<u>the fine likely to be</u>		
	imposed would constitute a		
	<u>disproportionate burden</u>		
	<u>for a natural person, it</u>		
	<u>should be possible to issue</u>		
	<u>a reprimand instead of a</u>		
	<u>fine. Due regard should</u>		
	<u>however be given to the</u>		
	<u>nature, gravity and</u>		
	<u>duration of the</u>		
	<u>infringement, the</u>		
	intentional character of the		

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	infringement, actions taken		
	to mitigate the damage		
	suffered, the degree of		
	<u>responsibility or any</u>		
	<u>relevant previous</u>		
	infringements, the manner		
	<u>in which the infringement</u>		
	<u>became known to the</u>		
	<u>digital health authority or</u>		
	<u>health data access body,</u>		
	compliance with measures		
	ordered against the health		
	<u>data holder or health data</u>		
	<u>user, adherence to a code</u>		
	<u>of conduct and any other</u>		
	aggravating or mitigating		
	<u>factor. The imposition of</u>		
	<u>penalties, including</u>		
	<u>administrative fines,</u>		
	<u>should be subject to</u>		
	<u>appropriate procedural</u>		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			safeguards in accordance with the general principles of Union law and the Charter, including effective judicial protection and due process.		
	Recita	l 66i			
76i			(66i) Member States should be able to lay down the rules on criminal penalties for infringements of this Regulation, including for infringements of national rules adopted pursuant to and within the limits of this		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			Regulation. Such criminal penalties could also involve the deprivation of profits obtained through infringements of this Regulation. However, the imposition of criminal penalties for infringements of such national rules and of administrative penalties should not lead to a breach of the principle of ne bis in idem, as interpreted by the Court of Justice.		
	Recita	l 66j			
76j			(66j) It is appropriate to		

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	<u>lay down provisions</u>		
	enabling health data access		
	bodies to apply		
	administrative fines for		
	<u>certain infringements of</u>		
	this Regulation whereby		
	<u>certain infringements are</u>		
	<u>to be regarded as serious</u>		
	<u>infringements, such as the</u>		
	<u>re-identification of natural</u>		
	<u>persons, downloading</u>		
	<u>personal health data</u>		
	outside of the secure		
	processing environment		
	and processing of data for		
	<u>prohibited uses or outside a</u>		
	<u>data permit. This</u>		
	<u>Regulation should indicate</u>		
	infringements and the		
	<u>upper limit and criteria for</u>		
	setting the related		

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	administrative fines, which		
	should be determined by		
	the competent health data		
	access body in each		
	<u>individual case, taking into</u>		
	account all the relevant		
	<u>circumstances of the</u>		
	<u>specific situation, with due</u>		
	<u>regard in particular to the</u>		
	<u>nature, gravity and</u>		
	duration of the		
	infringement and of its		
	<u>consequences and the</u>		
	<u>measures taken to ensure</u>		
	<u>compliance with the</u>		
	obligations under this		
	<u>Regulation and to prevent</u>		
	<u>or mitigate the</u>		
	<u>consequences of the</u>		
	<u>infringement. Where</u>		
	<u>administrative fines are</u>		

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	imposed on an		
	undertaking, an		
	undertaking should be		
	<u>understood to be an</u>		
	<u>undertaking in accordance</u>		
	with Articles 101 and 102		
	TFEU for those purposes.		
	<u>Where administrative fines</u>		
	<u>are imposed on persons</u>		
	<u>that are not an</u>		
	undertaking, the health		
	data access body should		
	take account of the general		
	<u>level of income in the</u>		
	<u>Member State as well as</u>		
	<u>the economic situation of</u>		
	<u>the person in considering</u>		
	<u>the appropriate amount of</u>		
	the fine. The consistency		
	<u>mechanism could also be</u>		
	<u>used to promote the</u>		

Commission Propo	osal	EP Mandate	Council Mandate	Draft Agreement
		consistent application of administrative fines. It should be for the Member States to determine whether and to which extent public authorities should be subject to administrative fines. Imposing an administrative fine or giving a warning does not affect the application of other powers of the health data access bodies or of other penalties under this Regulation.		
F	Recital 66k	l	1	
76k				

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Commission Proposal	(66k) The legal systems of Denmark and Estonia do not provide for administrative fines as set out in this Regulation. It should be possible to apply the rules on administrative fines in a manner such that in Denmark the fine is imposed by competent national courts as a criminal penalty, and that in Estonia the fine is imposed by the supervisory authority in the framework of a misdemeanour procedure, provided that	Council Mandate	Draft Agreement
	<u>such an application of the</u> <u>rules in those Member</u> <u>States has an equivalent</u> <u>effect to administrative</u>		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			fines imposed by supervisory authorities. Therefore the competent national courts should take into account the recommendation by the health data access body initiating the fine. In any event, the fines imposed should be effective, proportionate and dissuasive.		
	Recital	661			
761			(661) Where this Regulation does not harmonise administrative		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			penalties or where necessary in other cases, for example in cases of serious infringements of this Regulation, Member States should implement a system which provides for effective, proportionate and dissuasive penalties. The nature of such penalties, criminal or administrative, should be determined by national law.		
	Recit	al 67			
77	(67) Since the objectives of this Regulation: to		(67) Since the objectives of this Regulation: to empower	(67) Since the objectives of this Regulation: to empower	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
empower natural persons	natural persons through	natural persons through	
through increased control of	increased control of their	increased control of their	
their personal health data	personal health data and	personal health data and	
and support their free	support their free movement	support their free movement	
movement by ensuring that	by ensuring that health data	by ensuring that health data	
health data follows them; to	follows them; to foster a	follows them; to foster a	
foster a genuine single	genuine single market for	genuine single market for	
market for digital health	digital health services and	digital health services and	
services and products; to	products; to ensure a	products; to ensure a	
ensure a consistent and	consistent and efficient	consistent and efficient	
efficient framework for the	framework for the reuse of	framework for the reuse of	
reuse of natural persons'	natural persons' health data	natural persons' health data	
health data for research,	for research, innovation,	for research, innovation,	
innovation, policy-making	policy-making and	policy-making and	
and regulatory activities	regulatory activities cannot	regulatory activities cannot	
cannot be sufficiently	be sufficiently achieved by	be sufficiently achieved by	
achieved by the Member	the Member States, through	the Member States, through	
States, through coordination	coordination measures	coordination measures	
measures alone, as shown	alone, as shown by the	alone, as shown by the	
by the evaluation of the	evaluation of the digital	evaluation of the digital	
digital aspects of the	aspects of the Directive	aspects of the Directive	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Directive 2011/24/EU but	2011/24/EU but can rather,	2011/24/EU but can rather,	
can rather, by reason of	by reason of harmonising	by reason of harmonising	
harmonising measures for	measures for rights of	measures for rights of	
rights of natural persons in	natural persons in relation	natural persons in relation	
relation to their electronic	to their electronic health	to their electronic health	
health data, interoperability	data, interoperability of	data, interoperability of	
of electronic health data and	electronic health data and a	electronic health data and a	
a common framework and	common framework and	common framework and	
safeguards for the primary	safeguards for the primary	safeguards for the primary	
and secondary use of	and secondary use of	and secondary use of	
electronic health data, be	electronic health data, be	electronic health data, be	
better achieved at Union	better achieved at Union	better achieved at Union	
level, the Union may adopt	level, the Union may adopt	level, the Union may adopt	
measures, in accordance	measures, in accordance	measures, in accordance	
with the principle of	with the principle of	with the principle of	
subsidiarity as set out in	subsidiarity as set out in	subsidiarity as set out in	
Article 5 of the Treaty on	Article 5 of the Treaty on	Article 5 of the Treaty on	
European Union. In	European Union. In	European Union. In	
accordance with the	accordance with the	accordance with the	
principle of proportionality	principle of proportionality	principle of proportionality	
as set out in that Article,	as set out in that Article,	as set out in that Article,	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	this Regulation does not go beyond what is necessary in order to achieve those objectives.	this Regulation does not go beyond what is necessary in order to achieve those objectives.	this Regulation does not go beyond what is necessary in order to achieve those objectives.	
	Recital 68			
78	(68) In order to ensure that EHDS fulfils its objectives, the power to adopt acts in accordance with Article 290 Treaty on the Functioning of the European Union should be delegated to the Commission in respect of different provisions of primary and secondary use of electronic health data. It	(68) In order to ensure that EHDS fulfils its objectives, the power to adopt acts in accordance with Article 290 Treaty on the Functioning of the European Union should be delegated to the Commission in respect of different provisions of primary and secondary use of electronic health data. It	EHDS fulfils its objectives, the power to adopt acts in	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
is of particular importance	is of particular importance	is of particular importance	
that the Commission carry	that the Commission carry	that the Commission carry	
out appropriate	out appropriate	out appropriate	
consultations during its	consultations during its	consultations during its	
preparatory work, including	preparatory work, including	preparatory work, including	
at expert level, and that	at expert level, and that	at expert level, and that	
those consultations be	those consultations be	those consultations be	
conducted in accordance	conducted in accordance	conducted in accordance	
with the principles laid	with the principles laid	with the principles laid	
down in the Inter-	down in the Inter-	down in the Inter-	
institutional Agreement of	institutional Agreement of	institutional Agreement of	
13 April 2016 on Better	13 April 2016 on Better	13 April 2016 on Better	
Law-Making ¹ . In particular,	Law-Making ¹ . In particular,	Law-Making ¹ . In particular,	
to ensure equal	to ensure equal participation	to ensure equal participation	
participation in the	in the preparation of	in the preparation of	
preparation of delegated	delegated acts, the	delegated acts, the	
acts, the European	European Parliament and	European Parliament and	
Parliament and the Council	the Council receive all	the Council receive all	
receive all documents at the	documents at the same time	documents at the same time	
same time as Member	as Member States' experts,	as Member States' experts,	
States' experts, and their	and their experts	and their experts	

	Commission Proposal	EP Mandate	Council Mandate Draft Agreement	
	experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts. 	to meetings of Commission to respert groups dealing with exp the preparation of delegated the acts.	<pre>vstematically have access o meetings of Commission apert groups dealing with e preparation of delegated ets OJ L 123, 12.5.2016, p. 1.</pre>	
	Recital 69			
79	(69) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission. Those powers should be exercised	uniform conditions for the implementation of thisuni implementationRegulation, implementing powers should be conferred on the Commission. Thosepow on	9) In order to ensure hiform conditions for the hplementation of this egulation, implementing owers should be conferred h the Commission. Those owers should be exercised	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	in accordance with		in accordance with	in accordance with	
	Regulation (EU) No		Regulation (EU) No	Regulation (EU) No	
	182/2011 of the European		182/2011 of the European	182/2011 of the European	
	Parliament and of the		Parliament and of the	Parliament and of the	
	Council ¹ .		Council ¹ .	Council ¹ .	
	1. Regulation (EU) No 182/2011		1. Regulation (EU) No 182/2011	1. Regulation (EU) No 182/2011	
	of the European Parliament and of		of the European Parliament and of	of the European Parliament and of	
	the Council of 16 February 2011		the Council of 16 February 2011	the Council of 16 February 2011	
	laying down the rules and general		laying down the rules and general	laying down the rules and general	
	principles concerning mechanisms		principles concerning mechanisms	principles concerning mechanisms	
	for control by the Member States		for control by the Member States	for control by the Member States	
	of the Commission's exercise of		of the Commission's exercise of	of the Commission's exercise of	
	implementing powers (OJ L 55,		implementing powers (OJ L 55,	implementing powers (OJ L 55,	
	28.2.2011, p. 13).		28.2.2011, p. 13).	28.2.2011, p. 13).	
	Recital	l 69a			
79a					
174					

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	(69a) In accordance with		
	Article 42 of Regulation		
	<u>(EU) 2018/1725, the</u>		
	Commission should, when		
	preparing delegated acts or		
	implementing acts, consult		
	<u>the European Data</u>		
	Protection Supervisor		
	where there is an impact		
	on the protection of		
	individuals' rights and		
	<u>freedoms with regard to the</u>		
	processing of personal		
	<u>data, and where such an</u> act is of particular		
	importance for the		
	protection of individuals'		
	rights and freedoms with		
	regard to the processing of		
	personal data, the		
	Commission can also		
	Commission can also		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		consult the European Data Protection Board. The Commission should moreover consult the European Data Protection Board in the cases specified in Regulation (EU) 2016/679 and when relevant in the context of this Regulation.		
	Recital 70			
80	(70) Member States should take all necessary measures to ensure that the provisions of this Regulation are implemented, including by	(70) Member States should take all necessary measures to ensure that the provisions of this Regulation are implemented, including by	(70) Member States should take all necessary measures to ensure that the provisions of this Regulation are implemented, including by	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
laying down effective,	laying down effective,	laying down effective,	
proportionate and	proportionate and	proportionate and	
dissuasive penalties for	dissuasive penalties for their	dissuasive penalties for their	
their infringement. For	infringement. When	infringement. For certain	
certain specific	<u>deciding on the amount of</u>	specific infringements,	
infringements, Member	the penalty for each	Member States should take	
States should take into	<u>individual case</u> For certain	into account the margins	
account the margins and	specific infringements,	and criteria set out in this	
criteria set out in this	Member States should take	Regulation.	
Regulation.	into account the margins		
	and criteria set out in this		
	Regulation. <u><i>Re-</i></u>		
	identification of natural		
	persons should be		
	considered a particularly		
	<u>serious breach of this</u>		
	Regulation. Member States		
	<u>should be able to consider</u>		
	<u>criminalising re-</u>		
	identification by health		
	<u>data users so that it serves</u>		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			<u>as a deterrent measure.</u>		
	Recital	171			
	(71) In order to assess		(71) In order to assess	(71) In order to assess	
	whether this Regulation		whether this Regulation	whether this Regulation	
	reaches its objectives		reaches its objectives	reaches its objectives	
	effectively and efficiently,		effectively and efficiently,	effectively and efficiently,	
	is coherent and still relevant		is coherent and still relevant	is coherent and still relevant	
81	and provides added value at		and provides added value at	and provides added value at	
01	Union level the		Union level the	Union level the	
	Commission should carry		Commission should carry	Commission should carry	
	out an evaluation of this		out an evaluation of this	out an evaluation of this	
	Regulation. The		Regulation. The	Regulation. The	
	Commission should carry		Commission should carry	Commission should carry	
	out a partial evaluation of		out a partial evaluation of	out a partial evaluation of	
	this Regulation 5 years after		this Regulation 5 years after	this Regulation 5 years after	
	its entry into force, on the		its entry into force, on the	its entry into force, on the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	self-certification of EHR systems, and an overall evaluation 7 years after the entry into force of this Regulation. The Commission should submit reports on its main findings following each evaluation to the European Parliament and to the Council, the European Economic and Social Committee and the Committee of the Regions.		self-certification of EHR systems, and an overall evaluation 7 years after the entry into force of this Regulation. The Commission should submit reports on its main findings following each evaluation to the European Parliament and to the Council, the European Economic and Social Committee and the Committee of the Regions.	self-certification of EHR systems, and an overall evaluation 7 years after the entry into force of this Regulation. The Commission should submit reports on its main findings following each evaluation to the European Parliament and to the Council, the European Economic and Social Committee and the Committee of the Regions.	
	Recital 72				
82	(72) For a successful cross- border implementation of		(72) For a successful cross- border implementation of	(72) For a successful cross- border implementation of	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	EHDS, the European Interoperability Framework ¹ to ensure legal, organisational, semantic and technical interoperability should be considered as common reference. 		EHDS, the European Interoperability Framework ¹ to ensure legal, organisational, semantic and technical interoperability should be considered as common reference.	EHDS, the European Interoperability Framework ¹ to ensure legal, organisational, semantic and technical interoperability should be considered as common reference. 	
83	(73) The evaluation of the digital aspects of Directive	/3	(73) The evaluation of the digital aspects of Directive	(73) The evaluation of the digital aspects of Directive	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	2011/24/EU shows limited effectiveness of eHealth Network, but also strong potential for EU work in this area, as shown by the work during pandemic. Therefore, the article 14 of the Directive will be repealed and replaced by the current Regulation and the Directive will be amended accordingly.		2011/24/EU shows limited effectiveness of eHealth Network, but also strong potential for EU work in this area, as shown by the work during pandemic. Therefore, the article 14 of the Directive will be repealed and replaced by the current Regulation and the Directive will be amended accordingly.	2011/24/EU shows limited effectiveness of eHealth Network, but also strong potential for EU work in this area, as shown by the work during pandemic. Therefore, the article 14 of the Directive will be repealed and replaced by the current Regulation and the Directive will be amended accordingly.	
	Recital	74			
84	(74) The European Data Protection Supervisor and the European Data		(74) The European Data Protection Supervisor and the European Data	(74) The European Data Protection Supervisor and the European Data	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Protection Board were consulted in accordance with Article 42 of Regulation (EU) 2018/1725 and delivered an opinion on [].	Protection Board were consulted in accordance with Article 42 of Regulation (EU) 2018/1725 and delivered <i>anJoint</i> opinion <i>n. 03/2022 on 12</i> <i>July 2022on []</i> .	Protection Board were consulted in accordance with Article 42 of Regulation (EU) 2018/1725 and delivered an opinion on [].	
	Recital 75			
85	(75) This Regulation should not affect the application of the rules of competition, and in particular Articles 101 and 102 of the Treaty. The measures provided for in this Regulation should not	(75) This Regulation should not affect the application of the rules of competition, and in particular Articles 101 and 102 of the Treaty. The measures provided for in this Regulation should not	(75) This Regulation should not affect the application of the rules of competition, and in particular Articles 101 and 102 of the Treaty. The measures provided for in this Regulation should not	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	be used to restrict competition in a manner contrary to the Treaty.		be used to restrict competition in a manner contrary to the Treaty.	be used to restrict competition in a manner contrary to the Treaty.	
	Recital	1 76			
86	(76) Given the need for technical preparation, this Regulation should apply from [12 months after entry into force],		(76) Given the need for technical preparation, this Regulation should apply from [4224 months after entry into force],	(76) Given the need for technical preparation, this Regulation should apply from [12 months after entry into force],	
	Formu	la			
87	HAVE ADOPTED THIS		HAVE ADOPTED THIS	HAVE ADOPTED THIS	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	REGULATION:		REGULATION:	REGULATION:	
	Chapte	er l		L	<u> </u>
88	Chapter I General provisions		Chapter I General provisions	Chapter I General provisions	
	Article	1			
89	Article 1 Subject matter and scope		Article 1 Subject matter and scope	Article 1 Subject matter and scope	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	1(1)			
90	1. This Regulation establishes the European Health Data Space ('EHDS') by providing for rules, common standards and practices, infrastructures and a governance framework for the primary and secondary use of electronic health data.		1. This Regulation establishes the European Health Data Space ('EHDS') by providing for rules, common standards and practices, infrastructures and a governance framework for the primary and secondary use of electronic health data.	1. This Regulation establishes the European Health Data Space ('EHDS') by providing for common rules,-common standards and practices, infrastructures and a governance framework with a view to facilitating access to electronic health data for the purposes of primary and secondary use of-electronic health these data.	
	Article 2	1(2)			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
91	2. This Regulation:		2. This Regulation:	2. This Regulation:	
	Article	1(2), point (a)			
92	(a) strengthens the rights of natural persons in relation to the availability and control of their electronic health data;		(a) <i>strengthensspecifies</i> the rights of natural persons in relation to the availability ² <i>sharing</i> and control of their electronic health data;	(a) strengthensspecifies and complements the rights laid down in the Regulation (EU) 2016/679 of natural persons in relation to the availability and controlprimary and secondary use of their personal electronic health data;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	e 1(2), point (b)			
93	(b) lays down rules for the placing on the market, making available on the market or putting into service of electronic health records systems ('EHR systems') in the Union;		(b) lays down rules for the placing on the market, making available on the market or putting into service of electronic health records systems ('EHR systems') in the Union;	(b) lays down common rules for electronic health records systems ('EHR systems') in relation to two mandatory software components, namely the 'European interoperability component for EHR-the placing on the market, making available on the market or putting into service of electronic health records systems' and the ('European logging component for EHR systems' as defined in	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				Article 2(2), subparagraphs (nc) and (nd) and wellness applications that claim interoperability with EHR systems in relation to those two components in the Union for primary use;	
	Article	1(2), point (c)			
94	(c) lays down rules and mechanisms supporting the secondary use of electronic health data;		(c) lays down rules and mechanisms supporting the secondary use of electronic health data;	(c) lays down common rules and mechanisms supporting the for primary and secondary use of electronic health data;	

	Commission Propo	osal	EP Mandate	Council Mandate	Draft Agreement
		Article 1(2), point (d)	·		
95	(d) establishes a manda cross-border infrastruct enabling the primary us electronic health data a the Union;	cture ise of	(d) establishes a mandatory cross-border infrastructure enabling the primary use of electronic health data across the Union;	(d) establishes a mandatory cross-border infrastructure enabling the primary use of personal electronic health data across the Union;	
	,	Article 1(2), point (e)			
96	for the secondary use of		(e) establishes a mandatory cross-border infrastructure for the secondary use of electronic health data.	(e) establishes a mandatory cross-border infrastructure for the secondary use of electronic health data-;	

	Commission Prop	osal		EP Mandate	Council Mandate	Draft Agreement		
	Article 1(2), point (f)							
96a					(f) establishes governance and coordination on national and European level for both primary and secondary use of electronic health data.			
		Article 1	.(3)					
97	97		3. This Regulation applies to:	3. This Regulation applies to:				
	Article 1(3), point (a)							

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
98	(a) manufacturers and suppliers of EHR systems and wellness applications placed on the market and put into service in the Union and the users of such products;		(a) manufacturers and suppliers of EHR systems and wellness applications, <i>and of products claiming</i> <i>interoperability with EHR</i> <i>systems</i> , placed on the market and put into service in the Union and the users of such products;	(a) manufacturers and suppliers of EHR systems and wellness applications placed on the market and put into service in the Union and the users of such products;	
	Article 1(3	3), point (b)			
99	(b) controllers and processors established in the Union processing electronic health data of		(b) controllers and processors established in the Union processing electronic health data of	(b) controllers and processors established in the Union processing electronic health data of	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Union citizens and third- country nationals legally residing in the territories of Member States;		Union citizens and third- country nationals legally residing in the territories of Member States;	Union citizens and third- country nationals legally residing in the territories of Member States;	
	Article	e 1(3), point (c)			
100	(c) controllers and processors established in a third country that has been connected to or are interoperable with MyHealth@EU, pursuant to Article 12(5);		(c) controllers and processors established in a third country that has been connected to or are interoperable with MyHealth@EU, pursuant to Article 12(5);	(c) controllers and processors established in a third country that has been connected to or are interoperable with MyHealth@EU, pursuant to Article 12(5);	
	Article	e 1(3), point (d)			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
101	(d) data users to whom electronic health data are made available by data holders in the Union.		(d) data users to whom electronic health data are made available by data holders in the Union.	(d) data users to whom electronic health data are made available by data holders in the Union.	
	Article	e 1(3a)			
101a				3a. This Regulation shall be without prejudice to Regulations (EU) 2016/679, (EU) 2018/1725, (EU) No 536/2014 and (EC) No 223/2009.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	1(4)			
102	4. This Regulation shall be without prejudice to other Union legal acts regarding access to, sharing of or secondary use of electronic health data, or requirements related to the processing of data in relation to electronic health data, in particular Regulations (EU) 2016/679, (EU) 2018/1725, [] [Data Governance Act COM/2020/767 final] and [] [Data Act COM/2022/68 final].		4. This Regulation shall be without prejudice to other Union legal acts regarding access to, sharing of or secondary use of electronic health data, or requirements related to the processing of data in relation to electronic health data, in particular Regulations (EU) 2016/679, (EU) 2018/1725, <i>(EU)</i> 2022/868 and [] [Data <i>Governance Act</i> <i>COM/2022/68</i> final] and <i>[] [Data Act</i> <i>COM/2022/68</i>	4. This Regulation-shall be without prejudice to complements other Union legal acts regarding access to, sharing of or secondary use of electronic health data, or requirements related to the processing of data in relation to electronic health data, in particular Regulations (EU) 2016/679, (EU) 2018/1725;2022/868 and [] [Data Governance Act COM/2020/767Act COM/2022/68 final]. In the event of a specific conflict with these	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			final Directive 2002/58/EC of the European Parliament and of the Council ¹ . 1. Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications) (OJ L 201, 31.7.2002, p. 37).	Regulations, the rules set out in this Regulation shall prevail-and [] [Data Act COM/2022/68 final].	
	Articl	le 1(4a)			
102a			<u>4a.</u> <u>References to the</u>		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			provisions of Regulation (EU) 2016/679 shall be understood also as references to the corresponding provisions of Regulation (EU) 2018/1725 for Union institutions and bodies, where relevant.		
	Article	1(5)			
103	5. This Regulation shall be without prejudice to Regulations (EU) 2017/745 and [] [AI Act COM/2021/206 final], as regards the security of		5. This Regulation shall be without prejudice to Regulations (EU) 2017/745 and [] [AI Act COM/2021/206 final], as regards the security of	 5. This Regulation shall be without prejudice to Regulations (EU) 2017/745, (EU) 2017/746 and [] [AI Act COM/2021/206 final], as regards the security– of 	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	medical devices and AI systems that interact with EHR systems.		medical devices and AI systems that interact with EHR systems.	medical devices, in vitro diagnostic medical devices and AI systems that interact with EHR systems.	
	Article	e 1(5a)			
103a			5a. This Regulation shall be without prejudice to Regulation (EU) No 536/2014 and Directive (EU) 2016/943 ¹ . 1. Directive (EU) 2016/943 of the European Parliament and of the Council of 8 June 2016 on the protection of undisclosed know- how and business information		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			<u>(trade secrets) against their</u> <u>unlawful acquisition, use and</u> <u>disclosure (OJ L 157, 15.6.2016,</u> <u>p. 1).</u>		
	Article	1(6)			
104	6. This Regulation shall not affect the rights and obligations laid down in Union or national law concerning data processing for the purposes of reporting, complying with information requests or demonstrating or verifying compliance with legal obligations.		6. This Regulation shall not affect the rights and obligations laid down in Union or national law concerning data processing for the purposes of reporting, complying with information requests or demonstrating or verifying compliance with legal obligations.	6. This Regulation shall not affect the rights and obligations laid down in be without prejudice to Union or national law concerningregarding electronic health data processing for the purposes of reporting, complying with access to information requests or demonstrating or verifying compliance	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			with legal obligations or Union or national law regarding the granting of access to and disclosure of official documents. [[AMENDED AND MOVED TO ARTICLE 6A]] [MOD.SU.1.rev1]	
	Article 1(6a)			
104a			6a. This Regulation shall be without prejudice to specific provisions in Union or national law	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Commission Proposal	EP Mandate	Council Mandate providing for access to electronic health data for further processing by public bodies of the Member States, Union institutions, bodies and agencies, or by private entities entrusted under Union or national law with a task of public interest, for the purpose of carrying out such task. Further, this Regulation shall not affect access to electronic health data for secondary use agreed in the framework of contractual or administrative arrangements between	Draft Agreement
		public or private entities.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	1(7)			
104b				7. This Regulation shall not apply to the processing of electronic health data for purposes of public security, national security, defence and law enforcement, including the prevention, investigation, detection and prosecution of criminal offences. The powers of competent authorities for the prevention, investigation,	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement		
				of criminal offences established by law to obtain electronic health data are unaffected. Likewise, electronic health data held by courts for the purpose of judicial proceedings are out of scope of this Regulation.			
	Article	2					
105	Article 2 Definitions		Article 2 Definitions	Article 2 Definitions			
	Article 2(1)						

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
106	1. For the purposes of this Regulation, following definitions shall apply:		1. For the purposes of this Regulation, following definitions shall apply:	1. For the purposes of this Regulation, following definitions shall apply:	
	Artic	le 2(1), point (a)	·		
107	(a) the definitions in Regulation (EU) 2016/679;		(a) the definitions in Regulation (EU) 2016/679;	 (a) the definitions inof 'personal data', 'processing', 'pseudonymisation', 'controller', 'processor', 'third party', 'consent', 'genetic data', 'data concerning health', 'international organisation' pursuant to 	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				Article 4(1), (2), (5), (7), (8), (10), (11), (13), (15) and (26) of the Regulation (EU) 2016/679;	
	Article 2(1),	, point (b)			
108	 (b) the definitions of 'healthcare', 'Member State of affiliation', 'Member State of treatment', 'health professional', 'healthcare provider', 'medicinal product' and 'prescription', pursuant to Article 3 (a), (c), (d), (f), (g), (i) and (k) of Article 3 of the Directive 2011/24/EU; 		(b) the definitions of 'healthcare', 'Member State of affiliation', 'Member State of treatment', 'health professional', 'healthcare provider', 'medicinal product' and 'prescription', pursuant to Article 3 (a), (c), (d), (f), (g), (i) and (k) of Article 3 of the Directive 2011/24/EU;	 (b) the definitions of 'healthcare', 'Member State of affiliation', 'Member State of treatment', 'health professional', 'healthcare provider', 'medicinal product' and 'prescription', pursuant to Article 3 (a), (c), (d), (f), (g), (i) and (k) of Article 3- of the Directive 2011/24/EU; 	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	2(1), point (c)			
109	(c) the definitions of 'data', 'access', 'data altruism', 'public sector body' and 'secure processing environment', pursuant to Article 2 (1), (8), (10), (11) and (14) of [Data Governance Act COM/2020/767 final];		 (c) the definitions of 'data', 'access', 'data altruism', 'public sector body' and 'secure processing environment', pursuant to Article 2, <i>points</i> (1), (8), (10), (11) and (14) of <i>[Data</i> <i>Governance Act</i> <i>Governance Act</i> <i>COM/2020/767</i> <i>final] Regulation (EU)</i> 2022/868; 	 (c) the definitions of 'data', 'access', 'data altruism', 'public sector body' and 'secure processing environment', pursuant to Article 2 (1), (8), (10(13), (16), (117) and (1420) of [Data Governance Act COM/2020/767 final] Regulation (EU) 2022/868; 	
	Article	2(1), point (d)			

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
110	Commission Proposal(d) the definitions of 'making available on the market', 'placing on the market', 'placing on the market', 'market surveillance', 'market surveillance authority', 'non-compliance', 'manufacturer', 'importer', 'distributor', 'economic operator', 'corrective action', 'risk', 'recall' and	EP Mandate(d) the definitions of 'making available on the market', 'placing on the market', 'market surveillance', 'market surveillance authority', 'non-compliance', 'manufacturer', 'importer', 'distributor', 'economic operator', 'corrective action', 'risk', 'recall' and	Council Mandate(d) the definitions of 'making available on the market', 'placing on the market', 'placing on the market', 'market surveillance', 'market surveillance authority', 'non-compliance', 'manufacturer', 'importer', 'distributor', 'economic operator', 'corrective action', 'risk', 'recall' and	Draft Agreement
	 'withdrawal', pursuant to Article 2 (1), (2), (3), (4), (7), (8), (9), (10), (13), (16), (18), (22) and (23) of the Regulation (EU) 2019/1020; 	 'withdrawal', pursuant to Article 2 (1), (2), (3), (4), (7), (8), (9), (10), (13), (16) (18), (22) and (23) of the Regulation (EU) 2019/1020; 	 'withdrawal', pursuant to Article 2 (1), (2), (3), (4), (7), (8), (9), (10), (13), (16), (18), (22) and (23) of the Regulation (EU) 2019/1020; 	

	Commission Prop	osal		EP Mandate	Council Mandate	Draft Agreement
		Article 2	2(1), point (e)			
111	(e) the definitions of 'medical device', 'inte purpose', 'instructions use', 'performance', 'h institution' and 'comm specifications', pursua Article 2 (1), (12), (14) (22), (36) and (71) of t Regulation (EU) 2017/	a for nealth non nt to), the		(e) the definitions of 'medical device', 'intended purpose', 'instructions for use', 'performance', 'health institution' and 'common specifications', pursuant to Article 2 (1), (12), (14), (22), (36) and (71) of the Regulation (EU) 2017/745;	(e) the definitions of 'medical device', 'intended purpose', 'instructions for use', 'performance', 'health institution' and 'common specifications', pursuant to Article 2 (1), (12), (14), (22), (36) and (71) of the Regulation (EU) 2017/745;	
		Article 2	2(1), point (f)			
112	(f) the definitions of 'electronic identification	on',		(f) the definitions of 'electronic identification',	(f) the definitions of 'electronic identification',	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	'electronic identification means' and 'person identification data' pursuant to Article 3 (1), (2) and (3) of the Regulation (EU) No 910/2014.		'electronic identification means' and 'person identification data' pursuant to Article 3 (1), (2) and (3) of the Regulation (EU) No 910/2014.	'electronic identification means' and 'person identification data' pursuant to Article 3 (1), (2) and (3) of the Regulation (EU) No 910/2014-;	
	Article	e 2(1), point (g)			
112a				(g) the definition of 'contracting authorities' pursuant to Article 2(1)(1) of the Directive 2014/24/EU;	
	Article	e 2(1), point (h)		<u>.</u>	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
112b				(h) the definition of 'public health' pursuant to Article 38(c) of the Regulation (EC) No 1338/2008.	
	Article	2(2)			
113	2. In addition, for the purposes of this Regulation the following definitions shall apply:		2. In addition, for the purposes of this Regulation the following definitions shall apply:	2. In addition, for the purposes of this Regulation the following definitions shall apply:	
	Article	2(2), point (a)		·	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
114	(a) 'personal electronic health data' means data concerning health and genetic data as defined in Regulation (EU) 2016/679, as well as data referring to determinants of health, or data processed in relation to the provision of healthcare services, processed in an electronic form;		(a) 'personal electronic health data' means data concerning health and genetic data as defined in Regulation (EU) 2016/679, <i>as well as data referring to</i> <i>determinants of health, or</i> <i>data processed in relation</i> <i>to the provision of</i> <i>healthcare services,that are</i> processed in an electronic form;	(a) 'personal electronic health data' means personal data concerning health and personal genetic data as defined in Regulation (EU) 2016/679, as well as data referring to determinants of health, or data processed in relation to the provision of healthcare servicesArticle 4 , (13) and (15) of Regulation (EU) 2016/679 , processed in an electronic form;	
	Article	e 2(2), point (b)			

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	(b) 'non-personal	(b) 'non-personal electronic	(b) ' non-	
	electronic health data'	health data' means data	personal anonymous	
	means data concerning	concerning health and	electronic health data'	
	health and genetic data in	aggregated genetic data in	means data	
	electronic format that falls	electronic format that falls	concerningrelated to	
	outside the definition of	outside the definition of	health, processed in an	
	personal data provided in	personal data provided in	electronic form, which	
	Article 4(1) of Regulation	Article 4 (1)<u>4</u>, point (1), of	does not relate to an	
115	(EU) 2016/679;	Regulation (EU) 2016/679;	identified or identifiable	
		where personal and non-	natural person or data	
		personal data in a data set	concerning health	
		are inextricably linked, the	processed in a such	
		entire dataset shall be	manner that the data	
		processed as personal	subject is not or no longer	
		electronic health data;	identifiableand genetic	
			data in electronic format	
			that falls outside the	
			definition of personal data	
			provided in Article 4(1) of	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				Regulation (EU) 2016/679;	
	Article	e 2(2), point (c)			
116	(c) 'electronic health data' means personal or non- personal electronic health data;		(c) 'electronic health data' means personal or non- personal electronic health data;	(c) 'electronic health data' means personal electronic health data or anonymous or non-personal electronic health data;	
	Article	e 2(2), point (d)			
117	(d) 'primary use ofelectronic health data'means the processing of		(d) 'primary use ofelectronic health data'means the processing of	(d) 'primary use ofelectronic health data'means the processing of	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	personal electronic health data for the provision of health services to assess, maintain or restore the state of health of the natural person to whom that data relates, including the prescription, dispensation and provision of medicinal products and medical devices, as well as for relevant social security, administrative or reimbursement services;		<i>personal</i> electronic health data for the provision of health services to assess, maintain or restore the state of health of the natural person to whom that data relates, including the prescription, dispensation and provision of medicinal products and medical devices, as well as for relevant social security, administrative or reimbursement services;	personal electronic health data for the provision of health services healthcare to assess, maintain or restore the state of health of the natural person to whom that data relates, including the prescription, dispensation and provision of medicinal products and medical devices, as well as for relevant social security, administrative or reimbursement services;	
	Article	2(2), point (e)			
118	(e) 'secondary use of		(e) 'secondary use of	(e) 'secondary use of	

Com	mission Proposal		EP Mandate	Council Mandate	Draft Agreement			
electron	nic health data'		electronic health data'	electronic health data'				
means	the processing of		means the processing of	means the processing of				
electron	nic health data for		electronic health data for	electronic health data for				
purpose	es set out in Chapter		purposes set out in Chapter	purposes set out in Chapter				
IV of th	nis Regulation. The		IV of this Regulation. The	HVArticle 34 of this				
data us	ed may include		data used may include	Regulation. The data used				
persona	al electronic health		personal electronic health	may include personal				
data ini	itially collected in		data initially collected in the	electronic health data				
the con	text of primary use,		context of primary use, but	initially collected in the				
but also	o electronic health		also electronic health data	context of primary use, but				
data co	llected for the		collected for the purpose of	also electronic health data,				
purpose	e of the secondary		the secondary use Chapter	other than the initial				
use;			IV of this Regulation;	purposes for which they				
				were collected for the				
				purpose of the secondary				
				use;or produced.				
				~ A				
	Article 2(2), point (f)							

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
119	(f) 'interoperability' means the ability of organisations as well as software applications or devices from the same manufacturer or different manufacturers to interact towards mutually beneficial goals, involving the exchange of information and knowledge without changing the content of the data between these organisations, software applications or devices, through the processes they support;	(f) 'interoperability' means the ability of organisations as well as software applications or devices from the same manufacturer or different manufacturers to interact towards mutually beneficial goals, involving the exchange of information and knowledge without changing the content of the data between these organisations, software applications or devices, through the processes they support;	(f) 'interoperability' means the ability of organisations as well as software applications or devices from the same manufacturer or different manufacturers to interact towards mutually beneficial goals, involving the exchange of information and knowledge without changing the content of the data between these organisations, software applications or devices, through the processes they support;	
	Article 2(2), point (g)			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
120	(g) 'European electronic health record exchange format' means a structured, commonly used and machine-readable format that allows transmission of personal electronic health data between different software applications, devices and healthcare providers;		(g) 'European electronic health record exchange format' means a structured, commonly used and machine-readable format that allows transmission of personal electronic health data between different software applications, devices and healthcare providers;	(g) <u>'European electronic</u> health record exchange format' means a structured, commonly used and machine-readable format that allows transmission of personal electronic health data between different software applications, devices and healthcare providers;	
	Article	2(2), point (h)			
121	(h) 'registration of electronic health data'		(h) 'registration of electronic health data'	(h) 'registration of electronic health data'	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	means the recording of health data in an electronic format, through manual entry of data, through the collection of data by a device, or through the conversion of non- electronic health data into an electronic format, to be processed in an EHR system or a wellness application;		means the recording of health data in an electronic format, through manual entry of data, through the collection of data by a device, or through the conversion of non- electronic health data into an electronic format, to be processed in an EHR system or a wellness application;	means the recording of health data in an electronic format, through manual entry of data, through the collection of data by a device, or through the conversion of non- electronic health data into an electronic format, to be processed in an EHR system or a wellness application;	
	Article	e 2(2), point (i)			
122	(i) 'electronic health data access service' means an online service, such as a		(i) 'electronic health data access service' means an online service, such as a	(i) 'electronic health data access service' means an online service, such as a	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	portal or a mobile application, that enables natural persons not acting in their professional role to access their own electronic health data or electronic health data of those natural persons whose electronic health data they are legally authorised to access;		portal or a mobile application, that enables natural persons not acting in their professional role to access their own electronic health data or electronic health data of those natural persons whose electronic health data they are legally authorised to access;	portal or a mobile application, that enables natural persons not acting in their professional role to access their own electronic health data or electronic health data of those natural persons whose electronic health data they are legally authorised to access;	
	Article	2(2), point (j)			
123	(j) 'health professional access service' means a service, supported by an EHR system, that enables health professionals to		(j) 'health professional access service' means a service, supported by an EHR system, that enables health professionals to	(j) 'health professional access service' means a service, supported by an EHR system, that enables health professionals to	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	access data of natural persons under their treatment;		access data of natural persons under their treatment <u>care</u> ;	access data of natural persons under their treatment;	
	Article	2(2), point (k)			
124	(k) 'data recipient' means a natural or legal person that receives data from another controller in the context of the primary use of electronic health data;		 (k) '<u>health</u> data recipient' means a natural or legal person that receives data from another controller<u>recipient as</u> defined in Article 4, point (9), of Regulation (EU) 2016/679, in the context of the primary use of electronic health data; 	(k) 'data recipient' means a natural or legal person that receives data from another controller in the context of the primary use of electronic health data;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	e 2(2), point (l)			
125	(1) 'telemedicine' means the provision of healthcare services, including remote care and online pharmacies, through the use of information and communication technologies, in situations where the health professional and the patient (or several health professionals) are not in the same location;		(1) 'telemedicine' means the provision of healthcare services, including remote care <i>and online pharmacies,</i> through the use of information and communication technologies, in situations where the health professional and the patient (or several health professionals) are not in the same location;	(1) 'telemedicine' means the provision of healthcare services, including remote care and online pharmacies, through the use of information and communication technologies, in situations where the health professional and the patient (or several health professionals) are not in the same location;	
	Article	le 2(2), point (m)			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
126	(m) 'EHR' (electronic health record) means a collection of electronic health data related to a natural person and collected in the health system, processed for healthcare purposes;		(m) 'EHR' (electronic health record) means a collection of electronic health data related to a natural person and collected in the health system, processed for <i>the purpose</i> of the provision of healthcare <i>purposesservices</i> ;	(m) 'EHR' (electronic health record) means a collection of personal electronic health data related to a natural person and collected in the health system, processed for the provision of healthcare purposes ;	
	Article	2(2), point (n)			
127	(n) 'EHR system'(electronic health record system) means any		(n) 'EHR system'(electronic health record system) means any	(n) 'EHR system'(electronic health record system) means any system	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
appliance or software	applianceproduct	where the appliance or	
intended by the	<u>(hardware</u> or software <u>)</u>	software allows to store,	
manufacturer to be used for	primarily intended by the	intermediate, export,	
storing, intermediating,	manufacturer to be used for	import, convert, edit or	
importing, exporting,	storing, intermediating,	view personal electronic	
converting, editing or	importing, exporting,	health data that belongs to	
viewing electronic health	converting, editing or	the priority categories of	
records;	viewing electronic health	personal electronic health	
	records between health	data as referred to in	
	professionals or that can be	Article 5(1) of this	
	reasonably expected by the	Regulation and is intended	
	manufacturer to be used	by the manufacturer to be	
	<u>for those purposes;</u>	used for storing,	
		intermediating, importing,	
		exporting, converting,	
		editing or viewing	
		electronic by healthcare	
		providers in providing	
		patient care or by patient	
		to access to their health	
		records data;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	2(2), point (na)			
127a				(na) 'putting into service' means the first use, for its intended purpose, in the Union, of an EHR system covered by this Regulation;	
	Article	2(2), point (nb)			
127b				(nb) 'software component' or 'component' means a	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				discrete part of software which provides specific functionality or performs specific functions or procedures and which can operate independently or in conjunction with other components. Components are designed to be reusable and to integrate seamlessly with other components within a larger software system;	
	Article	2(2), point (nc)			
127c				(nc) 'European interoperability	

Commission Prop	oosal	EP Mandate	Council Mandate	Draft Agreement			
			component for EHR systems' (or 'the interoperability component') means a software component of the EHR system which provides and receives personal electronic health data referred to in Article 5 in the format referred to in Article 6 of this Regulation; The European interoperability component is independent of the European logging component;				
	Article 2(2), point (nd)						

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
127d		EP Mandate	(nd) 'European logging component for EHR systems' (or 'the logging component') means a software component of the EHR system which provides logging information relating to accesses of health professionals or other individuals to personal electronic health data referred to in Article 5, in the format defined in Annex II.3.4 of this Regulation; The European logging component is independent of the European interoperability	Draft Agreement

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				component;	
	Article	2(2), point (ne)	_	-	
127e				(ne) 'harmonised components of EHR systems' means the European interoperability component for EHR systems and the European logging component for EHR systems;	
	Article	2(2), point (o)			
128					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	(o) 'wellness application' means any appliance or software intended by the manufacturer to be used by a natural person for processing electronic health data for other purposes than healthcare, such as well- being and pursuing healthy life-styles;		deleted	(o) 'wellness application' means any appliance or software intended by the manufacturer to be used by a natural person for processing electronic health data for other purposes than healthcare, such as well- being and pursuing healthy life-styles;	
	Article	2(2), point (p)			
129	(p) 'CE marking of conformity' means a marking by which the manufacturer indicates that the EHR system is in		(p) 'CE marking of conformity' means a marking by which the manufacturer indicates that the EHR system is in	(p) 'CE marking of conformity' means a marking by which the manufacturer indicates that the EHR system is in	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	conformity with the applicable requirements set out in this Regulation and other applicable Union legislation providing for its affixing;		conformity with the applicable requirements set out in this Regulation and other applicable Union legislation providing for its affixing;	conformity with the applicable requirements set out in this Regulation and other applicable Union legislation providing for its affixing pursuant to Regulation (EC) No 765/2008 ;	
	Article	2(2), point (pa)			
129a				(pa) 'risk' means the combination of the degree of severity of a harm and the probability of an occurrence of a hazard causing the harm to health, safety and	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				information security;	
	Article	2(2), point (q)			
130	(q) 'serious incident' means any malfunction or deterioration in the characteristics or performance of an EHR system made available on the market that directly or indirectly leads, might have led or might lead to any of the following:		(q) 'serious incident' means any malfunction or deterioration in the characteristics or performance of an EHR system made available on the market that directly or indirectly leads, <i>might</i> <i>havehas</i> led or <i>mightis</i> <i>likely to</i> lead to any of the following:	(q) 'serious incident' means any malfunction or deterioration in the characteristics or performance of an EHR system made available on the market that directly or indirectly leads, might have led or might lead to any of the following:	

	Commission Prop	osal		EP Mandate	Council Mandate	Draft Agreement
		Article 2(2),	point (q)(i)			
131	(i) the death of a natur person or serious dama a natural person's heal	age to hth;		(i) the death of a natural person or serious damage to a natural person's health <u>or</u> <u>rights</u> ;	(i) the death of a natural person or serious damage to a natural person's health;	
		Article 2(2),	point (q)(ii)			
132	(ii) a serious disruption the management and operation of critical infrastructure in the he sector;			(ii) a serious disruption of the management and operation of critical infrastructure in the health sector;	(ii) a serious disruption of the management and operation of critical infrastructure in the health sector;	

	Commission Propos	osal	EP Mandate	Council Mandate	Draft Agreement		
	A	Article 2(2), point (r)					
133	(r) 'national contact poin for digital health' means organisational and techn gateway for the provisio cross-border digital healt information services for primary use of electronic health data, under the responsibility of the Member States;	is an nical on of ilth r	(r) 'national contact point for digital health' means an organisational and technical gateway for the provision of cross-border digital health information services for primary use of electronic health data, under the responsibility of the Member States;	(r) <u><u></u>'national contact point for digital health' means an organisational and technical gateway for the provision of cross border digital health information services for primary use of electronic health data, under the responsibility of the <u>Member States;</u></u>			
	Article 2(2), point (s)						
134	(s) 'central platform for	pr	(s) 'central platform for	(s) 'central platform for			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	digital health' means an interoperability platform providing services to support and facilitate the exchange of electronic health data between national contact points for digital health;		digital health' means an interoperability platform providing services to support and facilitate the exchange of electronic health data between national contact points for digital health;	digital health' means an interoperability platform providing services to support and facilitate the exchange of electronic health data between national contact points for digital health;	
	Article	e 2(2), point (t)			
135	(t) 'MyHealth@EU' means the cross-border infrastructure for primary use of electronic health data formed by the combination of national contact points for digital health and the		(t) 'MyHealth@EU' means the cross-border infrastructure for primary use of electronic health data formed by the combination of national contact points for digital health and the	(t) <u>'MyHealth@EU' means</u> the cross-border infrastructure for primary use of electronic health data formed by the combination of national contact points for digital health and the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	central platform for digital health;		central platform for digital health;	central platform for digital health;	
	Article	2(2), point (u)			
136	(u) 'national contact point for secondary use of electronic health data' means an organisational and technical gateway enabling the cross-border secondary use of electronic health data, under the responsibility of the Member States;		(u) 'national contact point for secondary use of electronic health data' means an organisational and technical gateway enabling the cross-border secondary use of electronic health data, under the responsibility of the Member States;	(u) 'national contact point for secondary use of electronic health data' means an organisational and technical gateway enabling the cross border secondary use of electronic health data, under the responsibility of the Member States;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	2(2), point (v)			
137	(v) 'central platform for secondary use of electronic health data' means an interoperability platform established by the Commission, providing services to support and facilitate the exchange of information between national contact points for secondary use of electronic health data;		(v) 'central platform for secondary use of electronic health data' means an interoperability platform established by the Commission, providing services to support and facilitate the exchange of information between national contact points for secondary use of electronic health data;	(v) 'central platform for secondary use of electronic health data' means an interoperability platform established by the Commission, providing services to support and facilitate the exchange of information between national contact points for secondary use of electronic health data;	
	Article	2(2), point (x)		1	
138					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	(x) 'HealthData@EU' means the infrastructure connecting national contact points for secondary use of electronic health data and the central platform;		(x) 'HealthData@EU' means the infrastructure connecting national contact points for secondary use of electronic health data and the central platform;	(x) 'HealthData@EU' means the infrastructure connecting national contact points for secondary use of electronic health data and the central platform;	
	Article	e 2(2), point (qa)			
138a				(qa) 'care' means a professional service the purpose of which is to address the specific needs of a person who, on account of impairment or other physical or mental conditions requires assistance to carry out	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				essential activities of daily living in order to support their personal autonomy.	
	Article	2(2), point (y)			
139	(y) 'data holder' means any natural or legal person, which is an entity or a body in the health or care sector, or performing research in relation to these sectors, as well as Union institutions, bodies, offices and agencies who has the right or obligation, in accordance with this Regulation, applicable Union law or		(y) ' <u>health</u> data holder' means any natural or legal person, which is an entity or a body in the health, <u>social</u> <u>security</u> or care <u>sector or in</u> <u>the reimbursement services</u> sector, or <u>performingperforms</u> research in relation to these sectors, as well as Union institutions, bodies, offices and agencies <u>who has the</u>	(y)(xb) 'health data holder' means any natural or legal person, which is an entity or apublic authority, agency or other body in the health or care sector, or performing research in relation to thesehealthcare or the care sectors; as well as Union institutions, bodies, offices and agencies who has the right or	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
national legislation	right or obligation, and	obligation, in accordance	
implementing Union law, or	which, in accordance with	with this Regulation,	
in the case of non-personal	this Regulation, applicable	applicable Union law or	
data, through control of the	Union law or national	national legislation	
technical design of a	legislation implementing	implementing Union law, or	
product and related	Union law , <i>or in the case of</i>	in the case of non-personal	
services, the ability to make	non-personal data, through	data, through control of the	
available, including to	control of the technical	technical design of a	
register, provide, restrict	design of a product and	product and related	
access or exchange certain	related services,	services, the ability to make	
data;		available, including to	
	<u>(i) is a controller as set out</u>	register, provide, restrict	
	<u>in Regulation (EU)</u>	access or exchange certain	
	<u>2016/679 and has the right</u>	data; any natural or legal	
	<u>or obligation, in</u>	person developing	
	<u>accordance with this</u>	products or services	
	Regulation, applicable	intended for the health,	
	<u>Union law or national</u>	healthcare or care sectors;	
	legislation implementing	developing or	
	Union law, to process	manufacturing wellness	
	<u>personal electronic health</u>	applications; performing	
		Tr	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			data; or (ii) has the ability to make available, including to register, provide, restrict access or exchange certain datanon-personal electronic health data, through control of the technical design of a product and related services;	research in relation to the health, healthcare or care sectors; or acting as a mortality registry; as well as any Union institution, body, office or agency; who has either:	
	Article	2(2), point (a)			
139a				(a) the right or obligation, in accordance with applicable Union law or	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			national legislation, to process personal electronic health data for the provision of healthcare or care or for public health, reimbursement, research, innovation, policy making, official statistics, patient safety or regulatory purposes, in its capacity as a controller or joint controller; or	
_	Article 2(2), point (b)			
139b			(b) the ability to make available, including to	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			register, provide, restrict access or exchange anonymous electronic health data, through control of the technical design of a product and related services.	
	Article 2(2), point (ya)			
139c			(ya) 'health data intermediation entity' means a legal person able to make available, including to register, provide, process, restrict access or exchange electronic health data	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				provided by data holders for secondary use.	
	Article	2(2), point (z)			
140	(z) 'data user' means a natural or legal person who has lawful access to personal or non-personal electronic health data for secondary use;		(z) ' <u>health</u> data user' means a natural or legal person <u>, as well as a Union</u> institution, body, office or agency, which has been granted_who has-lawful access, in accordance with this Regulation, to-to personal or non-personal electronic health data for secondary use <u>pursuant to a</u> data permit or a health data request;	(z) 'health data user' means a natural or legal person who has lawful access to-personal or non- personal- electronic health data for secondary use based on a data permit or a data request pursuant to this Regulation;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	2(2), point (za)			
140a			(za) 'health data applicant' means any natural or legal person with a demonstrable professional link to the areas of health care, public health or medical research and that submits an application for health data;		
	Article	2(2), point (aa)			
141					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	(aa) 'data permit' means an administrative decision issued to a data user by a health data access body or data holder to process the electronic health data specified in the data permit for the secondary use purposes specified in the data permit based on conditions laid down in this Regulation;		(aa) 'health data permit' means an administrative decision issued to a data user by a health data access body or data holder to process the electronic health data specified in the data permit for the secondary use purposes specified in the data permit based on conditions laid down in this Regulation;	(aa) ² data permit' means an administrative decision issued to a health data user by a health data access body or a single health data holder to process thecertain electronic health data specified in the data permit for thespecific secondary use purposes specified in the data permit -based on conditions laid down in Chapter IV of this Regulation;	
Article 2(2), point (ab)					
142	(ab) 'dataset' means a		(ab) 'dataset' means a	(ab) 'dataset' means a	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	structured collection of electronic health data;		structured collection of electronic health data;	structured collection of electronic health data;	
	Article	e 2(2), point (aba)			
142a				(aba) 'datasets of high impact for the secondary use of electronic health data' means datasets the re-use of which is associated with important benefits because of their relevance for health research;	
	Article	e 2(2), point (ac)			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
143	(ac) 'dataset catalogue' means a collection of datasets descriptions, which is arranged in a systematic manner and consists of a user-oriented public part, where information concerning individual dataset parameters is accessible by electronic means through an online portal;		(ac) 'dataset catalogue' means a collection of datasets descriptions, which is arranged in a systematic manner and consists of a user-oriented public part, where information concerning individual dataset parameters is accessible by electronic means through an online portal;	(ac) 'dataset catalogue' means a collection of datasets descriptions, which is arranged in a systematic manner and consists of a user-oriented public part, where information concerning individual dataset parameters is accessible by electronic means through an online portal;	
	Article	e 2(2), point (ad)			
144	(ad) 'data quality' means		(ad) 'data quality' means	(ad) 'data quality' means	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	the degree to which characteristics of electronic health data are suitable for secondary use;		the degree to which characteristics of electronic health data are suitable for secondary use;	the degree to which characteristics the elements of electronic health data are assessed and considered suitable for their intended primary and secondary use;	
	Article	2(2), point (ae)			
145	(ae) 'data quality and utility label' means a graphic diagram, including a scale, describing the data quality and conditions of use of a dataset.		(ae) 'data quality and utility label' means a graphic diagram, including a scale, describing the data quality and conditions of use of a dataset.	(ae) 'data quality and utility label' means a graphic diagram, including a scale, describing the data quality and conditions of use of a dataset.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement		
	Article	e 2(2), point (aea)	·				
145a			(aea) 'wellness application' means any appliance or software intended by the manufacturer to be used by a natural person for processing electronic health data specifically for providing information on, managing, maintaining or improving the health of individual persons, or the delivery of care.				
	Chapter II						

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
146	Chapter II Primary use of electronic health data		Chapter II Primary use of electronic health data	Chapter II Primary use of electronic health data	
	Section	n 1			
147	Section 1 Access to and transmission of personal electronic health data for primary use		Section 1 Access to and transmission of personal electronic health data for primary use	Section 1 Access to and transmission of personal electronic health data for primary use	
	Article	2A			
147a					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				Article 2A Registration of personal electronic health data	
				[MOVED FROM ARTICLE 7]	
	Article	2a(1)			
147b				1. Member States shall ensure that, where data is processed in electronic format for the provision of healthcare, healthcare providers shall register	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			the relevant personal health data falling fully or partially under at least the priority categories referred to in Article 5 in the electronic format in an EHR system. [MOVED FROM ARTICLE 7(1) AND AMENDED]	
	Article 2a(1a)			
147c			1a. Where they process data in an electronic format,	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				healthcare providers shall ensure that the personal electronic health data of the natural persons they treat are updated with information related to the healthcare provided. [MOVED FROM ARTICLE 4(1)(b) AND AMENDED]	
	Article	2a(2)			
147d				2. Where personal electronic health data is registered in a Member	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				State of treatment that is not the Member State of affiliation of the person concerned, the Member State of treatment shall ensure that the registration is performed under the identification data of the natural person in the Member State of affiliation.	
	Article	2a(3)			
147e					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				3. The Commission shall, by means of implementing acts, determine data quality requirements, including semantics, uniformity, consistency of data registration, accuracy and completeness, for the registration of personal electronic health data in EHR system as relevant.	
	Article	2a(3c)			
147f				Those implementing acts shall be adopted in accordance with the	

		Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
					examination procedure referred to in Article 68(2).	
					[MOVED FROM ARTICLE 7(3) AND AMENDED]	
		Article	3			
14	48	Article 3 Rights of natural persons in relation to the primary use of their personal electronic health data		Article 3 Rights of natural persons in relation to the primary use of their personal electronic health data	Article 3 Rights of natural persons in relation to the primary use of their personal electronic health data	

	Commission Prop	oosal		EP Mandate	Council Mandate	Draft Agreement
		Article	3(1)			
149	1. Natural persons sh have the right to access their personal electron health data processed context of primary us electronic health data immediately, free of c and in an easily reada consolidated and access form.	ss nic in the e of , charge ble,		1. Natural persons shall have the right to access their personal electronic health data processed in the context of primary use of electronic health data, immediately, free of charge and in an easily readable, consolidated and accessible form.	 1. Natural persons shall have the right to access their personal electronic health data processed in the context of primary use of electronic health data, immediately, free of charge and in an easily readable, consolidated and accessible form. [MOVED TO ARTICLE 8A, SEE AMENDMENTS IN THAT ARTICLE] 	

	Commission Prop	posal		EP Mandate	Council Mandate	Draft Agreement
		Article 3(2	2)			
150	2. Natural persons sh have the right to recein electronic copy, in the European electronic here referred to in Article of least their electronic here data in the priority categories referred to Article 5.	ive an e nealth nat 6, of at nealth		2. Natural persons shall have the right to receive an electronic copy, in the European electronic health record exchange format referred to in Article 6, of at least their electronic health data, or at the request of the natural person, a printed copy thereof, in accordance with _in the priority categories referred to in Article 515(3) of Regulation (EU) 2016/679.	 2. Natural persons shall have the right to receive an electronic copy, in the European electronic health record exchange format referred to in Article 6, of at least their electronic health data in the priority categories referred to in Article 5. [MOVED TO ARTICLE 8A, SEE AMENDMENTS IN THAT ARTICLE] 	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	e 3(2a)			
150a			2a. The rights referred to in paragraphs 1 and 2 shall be deemed complementary to and be without prejudice to the rights and obligations established by Article 15 of Regulation (EU) 2016/679.		
	Article	2 3(3)			
151	3. In accordance withArticle 23 of Regulation(EU) 2016/679, Member		 3. In accordance with Article ²³23(1), point (i), of Regulation (EU) 	3. In accordance with Article 23 of Regulation (EU) 2016/679, Member	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
States may restrict the	2016/679, Member States	States may restrict the scope	
scope of this right whenever	may restrict the scope of	of this right whenever	
necessary for the protection	rights referred to in this	necessary for the protection	
of the natural person based	Articlethis right whenever	of the natural person based	
on patient safety and ethics	necessary for the protection	on patient safety and ethics	
by delaying their access to	of the natural person based	by delaying their access to	
their personal electronic	on patient safety and ethics	their personal electronic	
health data for a limited	by delaying their access to	health data for a limited	
period of time until a health	their personal electronic	period of time until a health	
professional can properly	health data for a limited	professional can properly	
communicate and explain to	period of time until a health	communicate and explain to	
the natural person	professional can properly	the natural person	
information that can have a	communicate and explain to	information that can have a	
significant impact on his or	the natural person	significant impact on his or	
her health.	information that can have a	her health.	
	significant impact on		
	hishim or her-health.		
		[MOVED ARTICLE 8A, SEE	
		AMENDMENTS IN THAT	
		ARTICLE]	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	2 3(4)			
	4. Where the personal			4. Where the personal	
	health data have not been registered electronically		deleted	health data have not been registered electronically	
	prior to the application of this Regulation, Member			prior to the application of this Regulation, Member	
152	States may require that such data is made available in			States may require that such data is made available in	
	electronic format pursuant to this Article. This shall			electronic format pursuant to this Article. This shall not affect the obligation to	
	not affect the obligation to make personal electronic health data registered after			make personal electronic health data registered after	
	the application of this Regulation available in			the application of this Regulation available in	
	electronic format pursuant			electronic format pursuant	

	Commission Prope	osal		EP Mandate	Council Mandate	Draft Agreement
	to this Article.				to this Article.	
					DELETED	
		Article	3(5), first subparagraph			
153	5. Member States shal	1:		5. Member States shall:	5. Member States shall:	
		Article	3(5), first subparagraph, point	(a)		
154	(a) establish one or mo electronic health data access services at natio			(a) establish one or more electronic health data access services at national,	(a) establish one or more electronic health data access services at national,	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	regional or local level enabling the exercise of rights referred to in paragraphs 1 and 2;		regional or local level enabling the exercise of rights referred to in <i>paragraphs 1 and 2<u>this</u></i> <u>Article</u> ;	regional or local level enabling the exercise of rights referred to in paragraphs 1 and 2;	
	Article	3(5), first subparagraph, point	(b)		
155	(b) establish one or more proxy services enabling a natural person to authorise other natural persons of their choice to access their electronic health data on their behalf.		(b) establish one or more proxy services enabling a natural person to <i>legally</i> authorise other natural persons of their choice to access their electronic health data on their behalf <i>for a specified or</i> <i>indeterminate period and if</i> <i>needed, for a specific</i>	(b) establish one or more proxy services enabling a natural person to authorise other natural persons of their choice to access their electronic health data on their behalf.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			purpose only, or enabling legal representatives of patients to access electronic health data of the natural persons whose affairs they administer, in accordance with national law.		
	Article	e 3(5), second subparagraph			
156	The proxy services shall provide authorisations free of charge, electronically or on paper. They shall enable guardians or other representatives to be authorised, either		The proxy services shall provide authorisations <u>in a</u> <u>transparent and easily</u> <u>understandable way</u> , free of charge, electronically or on paper. <u>Natural persons and</u> <u>those acting on their behalf</u>	The proxy services shall provide authorisations free of charge, electronically or on paper. They shall enable guardians or other representatives to be authorised, either	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
automatically or upon request, to access electronic health data of the natural persons whose affairs they administer. Member States may provide that authorisations do not apply whenever necessary for reasons related to the protection of the natural person, and in particular based on patient safety and ethics. The proxy services shall be interoperable among Member States.	shall be informed about their authorisation rights, how to exercise them, and what they can expect from the authorisation process. The electronic health data access services as well as the proxy services They shall enable guardians or otherbe easily accessible for persons with disabilities, vulnerable groups or persons with low digital literacy.	automatically or upon request, to access electronic health data of the natural persons whose affairs they administer. Member States may provide that authorisations do not apply whenever necessary for reasons related to the protection of the natural person, and in particular based on patient safety and ethics. The proxy services shall be interoperable among Member States.	
	<i>The proxy services shall</i> <i>enable legal</i> representatives <i>of patients</i> to be authorised,	[MOVED TO A NEW ARTICLE 8G SEE AMENDMENTS IN THAT	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	either automatically or upon	ARTICLE]	
	request, to access electronic		
	health data of the natural		
	persons whose affairs they		
	administer either for a		
	specific purpose and time		
	period or without limitation		
	for the purpose of such		
	administration. Member		
	States may provide that		
	authorisations do not apply		
	whenever necessary for		
	reasons related to the		
	protection of the natural		
	person, and in particular		
	based on patient safety and		
	ethics. The proxy services		
	shall be interoperable		
	among Member States.		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			The proxy services shall provide an easy complaint mechanism with a contact point designated to inform individuals of a way to seek redress or remedy if they believe that their authorisation rights have been violated.		
	Article	3(5a)			
156a			5a. In addition to the electronic services referred to in this Article, Member States shall also establish easily accessible support services for natural		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			persons with adequately trained staff dedicated to assisting them with exercising their rights referred to in this Article.		
	Article	3(6)			
157	6. Natural persons may insert their electronic health data in their own EHR or in that of natural persons whose health information they can access, through electronic health data access services or applications linked to these services. That information		6. Natural persons may insert their electronic health data in their own EHR or in that of natural persons whose health information they can access, through electronic health data access services <i>orand</i> applications linked to these services. That information shall be	6. Natural persons may insert their electronic health data in their own EHR or in that of natural persons whose health information they can access, through electronic health data access services or applications linked to these services. That information shall be	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	shall be marked as inserted by the natural person or by his or her representative.		marked as inserted by the natural person or by <i>his or</i> <i>her representative</i> <u>their</u> <i>legal representative and as</i> <i>non-validated. That</i> <i>information shall only be</i> <i>considered as a clinical</i> <i>fact if validated by a health</i> <i>professional. Without</i> <i>prejudice to the right to</i> <i>insert data, health</i> <i>professionals shall not be</i> <i>obliged to validate any</i> <i>inserted data in the EHR</i> .	marked as inserted by the natural person or by his or her representative. [MOVED TO A NEW ARTICLE 8B, SEE AMENDMENTS IN THAT ARTICLE]	
	Article	3(6a)			
157a			<u>6a.</u> Natural persons shall		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			have the right to download their electronic health data from their own EHR or the data of natural persons whose health information they can access through electronic health data access services and applications linked to these services.		
	Article	3(7)			
158	 7. Member States shall ensure that, when exercising the right to rectification under Article 16 of Regulation (EU) 		7. Member States shall ensure that <u>electronic</u> <u>health data services</u> <u>referred to in paragraph 5,</u> <u>point (a), of this Article</u>	7. Member States shall ensure that, when exercising the right to rectification under Article 16 of Regulation (EU) 2016/679,	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
2016/679, natural persons can easily request rectification online through the electronic health data access services referred to in paragraph 5, point (a), of this Article.	allow for the possibility fornatural persons to easilyrequest rectification oftheir personal data onlineas a way to exercise their ;when exercising theright torectification under Article16 of Regulation (EU)2016/679;2016/679;Natural personscan easily requestrectification online throughthe electronicshall not havethe possibility of directlychanging data inserted byhealth data access servicesreferred to in paragraph 5;point (a), of thisArticleprofessionals. Suchrectifications of clinicalfacts shall be validated,without undue delay, by a	natural persons can easily request rectification online through the electronic health data access services referred to in paragraph 5, point (a), of this Article. [MOVED TO A NEW ARTICLE 8C, SEE AMENDMENTS IN THAT ARTICLE]	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			registered healthcare professional with a relevant specialisation who is responsible for the natural person's treatment. The original data holder shall be responsible for the rectification.		
	Article	3(8), first subparagraph			
159	8. Natural persons shall have the right to give access to or request a data holder from the health or social security sector to transmit their electronic health data to a data recipient of their		8. Natural persons shall have the right to <i>give access</i> <i>to or</i> -request a <i>health</i> data holder from the health or social security sector <i>or</i> <i>reimbursement services</i> , to transmit <i>all or part of</i> their	8. Natural persons shall have the right to give access to or request a data holder from the health or social security sector to transmit their electronic health data to a data recipient of their	

Commis	ssion Proposal	EP Mandate	Council Mandate	Draft Agreement
social secu immediate and withou the data ho manufactu	m the health or urity sector, ely, free of charge at hindrance from older or from the urers of the sed by that holder.	electronic health data to ahealthdata recipient oftheir choice from the healthor social security sector orreimbursement services,immediately, free of chargeand without hindrance fromthe data holder or from themanufacturers of thesystems used by that holder.The health data recipientshall be clearly identifiedby the natural persons tothe health data holder andtheir affiliation to thehealth or social securitysector shall bedemonstrated. Health dataholders and theirprocessors shall complywith the request and shall	choice from the health or social security sector, immediately, free of charge and without hindrance from the data holder or from the manufacturers of the systems used by that holder. [MOVED TO A NEW ARTICLE 8D(1), SEE AMENDMENTS IN THAT ARTICLE]	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			<u>transmit the data in the</u> <u>format provided for in</u> <u>Article 5.</u>		
	Article	3(8), second subparagraph			
160	Natural persons shall have the right that, where the data holder and the data recipient are located in different Member States and such electronic health data belongs to the categories referred to in Article 5, the data holder shall transmit the data in the European electronic health record exchange format		Natural persons shall have the right that, where the <i>health</i> data holder and the <i>health</i> data recipient are located in different Member States and such electronic health data belongs to the categories referred to in Article 5, the <i>health</i> data holder shall transmit the data in the European electronic health record	Natural persons shall have the right that, where the data holder and the data recipient are located in different Member States and such electronic health data belongs to the categories referred to in Article 5, the data holder shall transmit the data in the European electronic health record exchange format referred to	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	referred to in Article 6 and the data recipient shall read and accept it.		exchange format referred to in Article 6 and the <i>health</i> data recipient shall read and accept it.	in Article 6 and the data recipient shall read and accept it. [MOVED TO A NEW ARTICLE 8D(2), SEE AMENDMENTS IN THAT ARTICLE]	
	Article	3(8), third subparagraph			
161	By way of derogation from Article 9 of Regulation [] [Data Act COM/2022/68 final], the data recipient shall not be required to		By way of derogation from Article 9 of Regulation [] [Data Act COM/2022/68 final], the <u>health</u> data recipient shall not be	By way of derogation from Article 9 of Regulation [] [Data Act COM/2022/68 final], the data recipient shall not be required to	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	compensate the data holder for making electronic heath data available.		required to compensate the health data holder for making electronic heathhealth data available. A health data holder, a health data recipient or a third party shall not directly or indirectly charge data subjects a fee, compensation or costs for sharing data or accessing it.	compensate the data holder for making electronic heath data available. [MOVED TO ARTICLE 9A]	
	Article	3(8), fourth subparagraph			
162	Natural persons shall have the right that, where priority categories of personal		Natural persons shall have the right that, where priority categories of personal	Natural persons shall have the right that, where priority categories of personal	

Commission Proposal		EP Mandate	Council Mandate	Draft Agreement		
electronic health data referred to in Article 5 are transmitted or made available by the natural person according to the European electronic health record exchange format referred to in Article 6, such data shall be read and accepted by other healthcare providers.		electronic health data referred to in Article 5 are transmitted or made available by the natural person according to the European electronic health record exchange format referred to in Article 6, such data shall be read and accepted by other healthcare providers.	electronic health data referred to in Article 5 are transmitted or made available by the natural person according to the European electronic health record exchange format referred to in Article 6, such data shall be read and accepted by other healthcare providers. [MOVED TO A NEW ARTICLE 8D(4), SEE AMENDMENTS IN THAT ARTICLE]			
Article 3(9)						

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
163	9. Notwithstanding Article 6(1), point (d), of Regulation (EU) 2016/679, natural persons shall have the right to restrict access of health professionals to all or part of their electronic health data. Member States shall establish the rules and specific safeguards regarding such restriction mechanisms.	9. Notwithstanding Without prejudice to Article 6(1), point (d), of Regulation (EU) 2016/679, natural persons shall have the right to restrict access of specific health professionals or categories of health professionals to all or part of their electronic health data. When restricting the information, natural persons shall be made aware that restricting access may impact the provision of healthcare provided to them. Such restrictions shall apply also for cross-border transfers	9: Notwithstanding Article 6(1), point (d), of Regulation (EU) 2016/679, natural persons shall have the right to restrict access of health professionals to all or part of their electronic health data. Member States shall establish the rules and specific safeguards regarding such restriction mechanisms. [MOVED TO A NEW ARTICLE 7E, SEE AMENDMENTS IN THAT ARTICLE]	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	of electronic health data.		
	The fact that a restriction		
	has been made by the		
	natural person shall not be		
	visible to healthcare		
	<u>providers.</u>		
	Member States shall		
	establish the rules and		
	specific safeguards		
	regarding such restriction		
	mechanisms. Those rules		
	shall include the possibility		
	of modifying restrictions		
	and of restricting access to		
	anyone except the health		
	professional who inserted		
	<u>the electronic health data.</u>		
	Those rules shall also		
	<u>establish the conditions of</u>		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			medical liability as a consequence of applying restrictions to electronic health data. The Commission shall establish guidelines regarding the implementation of this paragraph.		
	Article	3(10)			
164	10. Natural persons shall have the right to obtain information on the healthcare providers and health professionals that have accessed their electronic health data in the		10. Natural persons shall have the right to obtain information, <i>including</i> <i>through automatic</i> <i>notifications</i> , on the healthcare providers and health professionals that	10. Natural persons shall have the right to obtain information on the healthcare providers and health professionals that have accessed their electronic health data in the	

Commission Pro	oposal	EP Mandate	Council Mandate	Draft Agreement
context of healthcar information shall be provided immediate free of charge throu electronic health day access services.	e ely and gh	have accessed theirelectronic health data,including access providedin accordance with Article4(4), and on the substanceof the accessed data.Natural persons shall havethe possibility of disablingthose notifications. Inorder to demonstratecompliance with this right,all relevant entities shallmaintain a system ofautomated recording for atleast three years showingwho and when hasaccessed electronic healthdata in the context ofhealthcare. The informationshall be providedimmediately and free of	context of healthcare. The information shall be provided immediately and free of charge through electronic health data access services. [MOVED TO A NEW ARTICLE 7E, SEE AMENDMENTS IN THAT ARTICLE]	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			charge through electronic health data access services. <u>Member States may</u> provide for restrictions to this right in exceptional circumstances, where there are factual indications that disclosure would endanger the vital interests or rights of the health professional or the care of the natural person.		
	Article	3(11)			
165	11. The supervisory authority or authorities responsible for monitoring		11. The supervisory authority or authorities responsible for monitoring	11. The supervisory authority or authorities responsible for monitoring	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
the application of	the application of	the application of	
Regulation (EU) 2016/679	Regulation (EU) 2016/679	Regulation (EU) 2016/679	
shall also be responsible for	shall also be responsible for	shall also be responsible for	
monitoring the application	monitoring the application	monitoring the application	
of this Article, in	of this Article, in	of this Article, in	
accordance with the	accordance with the	accordance with the	
relevant provisions in	relevant provisions in	relevant provisions in	
Chapters VI, VII and VIII	Chapters VI, VII and VIII	Chapters VI, VII and VIII	
of Regulation (EU)	of Regulation (EU)	of Regulation (EU)	
2016/679. They shall be	2016/679. <i>They shall be</i>	2016/679. They shall be	
competent to impose	competent to impose	competent to impose	
administrative fines up to	administrative fines up to	administrative fines up to	
the amount referred to in	the amount referred to in	the amount referred to in	
Article 83(5) of that	Article 83(5) of that	Article 83(5) of that	
Regulation. Those	Regulation. Those	Regulation. Those	
supervisory authorities and	supervisory authorities and	supervisory authorities and	
the digital health authorities	the digital health	the digital health authorities	
referred to in Article 10 of	authorities referred to in	referred to in Article 10 of	
this Regulation shall, where	Article 10 of this Regulation	this Regulation shall, where	
relevant, cooperate in the	shall, where relevant,	relevant, cooperate in the	
enforcement of this	cooperate in the	enforcement of this	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Regulation, within the remit of their respective competences.		enforcement of this Regulation, within the remit of their respective competences.	Regulation, within the remit of their respective competences. [MOVED TO ARTICLE 11A, SEE AMENDMENTS IN THAT ARTICLE]	
	Article	3(12)			
166	12. The Commission shall, by means of implementing acts, determine the requirements concerning the technical implementation of the		12. The Commission shall, by means of implementing acts, determine the requirements concerning the technical implementation of the rights set out in this	12. The Commission shall, by means of implementing acts, determine the requirements concerning the technical implementation of the rights set out in this	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	rights set out in this Article. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2).		Article, <i>including technical</i> <i>and organisational</i> <i>measures to ensure the</i> <i>process of authentication</i> <i>of the authorised person</i> <i>referred to in paragraph 5,</i> <i>point (b), of this Article.</i> Those implementing acts shall be adopted in accordance with the <i>advisoryexamination</i> procedure referred to in Article <u>68(2)68(2a)</u> .	Article. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2). [MOVED TO A NEW ARTICLE 8D(4), SEE AMENDMENTS IN THAT ARTICLE]	
	Article	3(12a)			
166a			<u>12a.</u> <u>Member States,</u> <u>including regional and</u>		

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	local authorities, shall		
	<u>provide easily</u>		
	<u>understandable</u>		
	information to natural		
	persons in relation to the		
	use of the electronic health		
	records and primary use of		
	their personal electronic		
	<u>health data laid down in</u>		
	this Article. Such guidance		
	shall take into account		
	<u>different user groups,</u>		
	including persons with		
	disabilities and vulnerable		
	<u>groups, without</u>		
	compromising the quality		
	and the scope of the		
	information.		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	4			
167	Article 4 Access by health professionals to personal electronic health data		Article 4 Access by health professionals to personal electronic health data	Article 4 Access by health professionals to personal electronic health data	
	Article	4(-1)			
167a			-1. Access to EHR for primary use shall be strictly limited to healthcare providers.		

	Commission Proposa	al	EP Mandate	Council Mandate	Draft Agreement
	Ar	rticle 4(1)		·	
168	health professionals shall:		 Where they process data in an electronic format, health professionals shall: 	 Where they process data in an electronic format, health professionals shall: 	
	Ar	rticle 4(1), point (a)			
169	(a) have access to the electronic health data of natural persons under the treatment, irrespective of the Member State of affiliation and the Member State of treatment;		 (a) have access, based on the data minimisation and purpose limitation principles, to the electronic health data of natural persons under their treatment and exclusively for the purpose of that 	(a) have access to the electronic health data of natural persons under their treatment, irrespective of the Member State of affiliation and the Member State of treatment;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			<i>treatment, including</i> <i>relevant administration</i> , irrespective of the Member State of affiliation and the Member State of treatment, <i>in accordance with Article</i> 9(2), <i>point (h), of</i> <i>Regulation 2016/679</i> ;	[MOVED TO A NEW ARTICLE 7A(1), SEE AMENDMENTS IN THAT ARTICLE]	
	Article	4(1), point (b)			
170	(b) ensure that the personal electronic health data of the natural persons they treat are updated with information related to the health services provided.		(b) ensure that the personal electronic health data of the natural persons they treat are updated with information related to the health services provided.	(b) ensure that the personal electronic health data of the natural persons they treat are updated with information related to the health services provided.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				[MOVED TO A NEW ARTICLE 2A(1A), SEE AMENDMENTS IN THAT ARTICLE]	
	Article	e 4(2)			
171	2. In line with the data minimisation principle provided for in Regulation (EU) 2016/679, Member States may establish rules providing for the categories of personal electronic health data required by		2. In line with the data minimisation principleand purpose limitation principles provided for in Regulation (EU) 2016/679, Member States mayshall establish rules providing for the categories of personal	2. In line with the data minimisation principle provided for in Regulation (EU) 2016/679, Member States may establish rules providing for the categories of personal electronic health data required by different	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	different health professions. Such rules shall not be based on the source of electronic health data.		electronic health data required by different categories of health professions or different healthcare tasks. Such rules shall not be based on the source of electronic health data.	health professions. Such rules shall not be based on the source of electronic health data. [MOVED TO A NEW ARTICLE 7A(2), SEE AMENDMENTS IN THAT ARTICLE]	
	Article	4(2a)			
171a			2a. In the case of treatment in a Member State other than the <u>Member State of</u>		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			affiliation, the rules referred to in paragraphs 1a and 2 of the Member States of treatment shall apply.		
	Article	e 4(2b)			
171b			2b. <u>The Commission shall</u> issue guidelines for the implementation of paragraphs 1, 2 and 2a, including time limitations for the access by health professionals to electronic health data of natural persons.		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	e 4(3)			<u> </u>
	3. Member States shall		3. Member States <i>and</i> ,	3. Member States shall	
	ensure that access to at least		where appropriate, local or	ensure that access to at least	
	the priority categories of		<u>regional authorities</u> shall	the priority categories of	
	electronic health data		ensure that access to at least	electronic health data	
	referred to in Article 5 is		the priority categories of	referred to in Article 5 is	
	made available to health		electronic health data	made available to health	
172	professionals through health		referred to in Article 5 is	professionals through health	
	professional access		made available to health	professional access services.	
	services. Health		professionals, <i>including for</i>	Health professionals who	
	professionals who are in		<u>cross-border care,</u> through	are in possession of	
	possession of recognised		health professional access	recognised electronic	
	electronic identification		services, where the	identification means shall	
	means shall have the right		processing of health data is	have the right to use those	
	to use those health		necessary and for the	health professional access	
	professional access		purposes of Article 9(2),	services, free of charge.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
S	services, free of charge.		point (h), of Regulation 2016/679. Health professionals who are in possession of recognised electronic identification means shall have the right to use those health professional access services, free of charge. The electronic health data in the electronic health records shall be structured in a user-friendly manner to allow for easy use by health professionals.	[MOVED TO ARTICLE 7B SEE AMENDMENTS IN THAT ARTICLE]	
	Articl	le 4(3a)			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
172a			3a. Member States shall establish policies aimed at providing health professionals with the digital skills, competences, infrastructures and tools required to fulfil the obligations set out in paragraph 1.		
	Article 4(4	(4)			
173	4. Where access to electronic health data has been restricted by the natural person, the		4. Where access to electronic health data has been restricted by the natural person, the	4. Where access to electronic health data has been restricted by the natural person, the	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
healthcare provider or	healthcare provider or	healthcare provider or	
health professionals shall	health professionals shall	health professionals shall	
not be informed of the	not be informed of the	not be informed of the	
content of the electronic	restricted content of the	content of the electronic	
health data without prior	electronic health data	health data without prior	
authorisation by the natural	without prior authorisation	authorisation by the natural	
person, including where the	<i>by the natural person,</i>	person, including where the	
provider or professional is	including where the	provider or professional is	
informed of the existence	provider or professional is	informed of the existence	
and nature of the restricted	informed of the existence	and nature of the restricted	
electronic health data. In	and nature of the restricted	electronic health data. In	
cases where processing is	electronic health	cases where processing is	
necessary in order to protect	data explicit consent	necessary in order to protect	
the vital interests of the data	pursuant to Article 9(2),	the vital interests of the data	
subject or of another natural	point (a), of Regulation	subject or of another natural	
person, the healthcare	(EU) 2016/679 by the	person, the healthcare	
provider or health	<u>natural person</u> . In cases	provider or health	
professional may get access	where processing is	professional may get access	
to the restricted electronic	necessary in order to protect	to the restricted electronic	
health data. Following such	the vital interests of the data	health data. Following such	
access, the healthcare	subject or of another natural	access, the healthcare	

Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
provider or health professional shall inform the data holder and the natural person concerned or his/her guardians that access to electronic health data had been granted. Member States' law may add additional safeguards.		person, the healthcare provider or health professional may get access to the restricted electronic health data. Following such access, the healthcare provider or health professional shall inform the data holder and the natural person concerned or his/her guardians that access to electronic health data had been granted. Member States' law may add additional safeguards.	provider or health professional shall inform the data holder and the natural person concerned or his/her guardians that access to electronic health data had been granted. Member States' law may add additional safeguards. [MOVED TO A NEW ARTICLE 7A(3), SEE AMENDMENTS IN THAT ARTICLE]	
Article	5			

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
174	Article 5 Priority categories of personal electronic health data for primary use Article 5(1), first subparagraph	Article 5 Priority categories of personal electronic health data for primary use	Article 5 Priority categories of personal electronic health data for primary use	
			1	
175	1. Where data is processed in electronic format, Member States shall implement access to and exchange of personal electronic health data for primary use fully or partially falling under the	1. Where data is processed in electronic format, Member States shall implement access to and exchange of personal electronic health data for primary use fully or partially falling under the	1. For the purposes of this Chapter, where data is processed in electronic format, Member States shall implement access to and exchangethe priority categories of personal electronic health data for	

	Commission Prop	osal		EP Mandate	Council Mandate	Draft Agreement
	following categories:			following categories <u>making use of the</u> <u>International</u> <u>Classification of Diseases</u> (ICD) codes, where <u>applicable</u> :	primary use fully or partially falling undershall be the following: categories:	
		Article	5(1), first subparagraph, point	(a)		
176	76 (a) patient summaries;		(a) patient summaries;	(a) patient summaries;		
		Article	5(1), first subparagraph, point	(b)		
177	(b) electronic prescrip	otions;		(b) electronic prescriptions;	(b) electronic prescriptions;	

	Commission Prop	osal		EP Mandate	Council Mandate	Draft Agreement
		Article	5(1), first subparagraph, point	(c)		
178	(c) electronic dispensations;			(c) electronic dispensations;	(c) electronic dispensations;	
		Article	5(1), first subparagraph, point	(d)		
179	(d) medical images as image reports;	nd		(d) medical images and image reports;	(d) medical images and related image reports;	
	Article 5(1), first subparagraph, point (e)					

	Commission Proposa	1	EP Mandate	Council Mandate	Draft Agreement			
180	(e) laboratory results;		(e) laboratory results, <u>medical test results and</u> <u>other complementary and</u> <u>diagnostic results</u> ;	(e) laboratory results and related laboratory reports;				
	Art	icle 5(1), first subparagraph, point	(f)					
181	(f) discharge reports.		(f) <u>patient</u> discharge reports- <u>;</u>	(f) hospital discharge reports.				
	Article 5(1), first subparagraph, point (fa)							
181a			(fa) medical directives of					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			the natural persons and information about consent for substances of human origin and organ donations.		
	Article	e 5(1), second subparagraph			
182	The main characteristics of the categories of electronic health data in the first subparagraph shall be as set out in Annex I.		The main characteristics of the categories of electronic health data in the first subparagraph shall be as set out in Annex I <u>and limited</u> to those categories.	The main characteristics of the priority categories of personal electronic health data-in the first subparagraph- shall be as set out in Annex I.	
	Article	e 5(1), third subparagraph			

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
183	Access to and exchange of electronic health data for primary use may be enabled for other categories of personal electronic health data available in the EHR of natural persons.	EP MandateMember States may provide for access to and exchange of electronic health data for primary use may be enabled for other categories of personal electronic health data available in the EHR of natural persons.	Council Mandate I.A. Access to and exchange of Member States may provide by virtue of national law that additional categories of personal electronic health data shall be accessed and exchanged for primary use pursuant to this Chapter. The Commission may, by means of implementing acts, lay down cross- border specifications for these data categories pursuant to Article 6(1A) and Article 12(8)may be enabled for other categories of personal electronic health data available in the EHR of	Draft Agreement

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				natural persons.	
	Article	5(2)			
	 2. The Commission is empowered to adopt delegated acts in accordance with Article 67 to amend the list of priority 		 2. The Commission is empowered to adopt delegated acts in accordance with Article 67 to amend <i>the list of priority</i> 	 2. The Commission is empowered to adopt delegated acts in accordance with Article 67 to amend the list of priority categories 	
184	categories of electronic health data in paragraph 1. Such delegated acts may		categories of electronic health data in paragraph 1. Such delegated acts may	of electronic health data in paragraph 1. Such delegated acts may also amend Annex	
	also amend Annex I by adding, modifying or removing the main characteristics of the priority categories of electronic health data and		<i>also amend</i> Annex I by adding, modifying or removing the main characteristics of the priority categories of electronic health data, <i>as</i>	I by adding, modifying or removing the main characteristics of the priority categories of personal electronic health data and indicating, where	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	indicating, where relevant, deferred application date. The categories of electronic health data added through such delegated acts shall satisfy the following criteria:		Iaid down in paragraph 1 and indicating, where relevant, deferred application date. The categories of electronic health data added through such delegated acts shall satisfy the following criteria:	relevant, deferred application date. The categories of electronic health data added through such delegated acts as referred to in paragraph 1. The amendments shall satisfy the following cumulative criteria:	
	Article	5(2), point (a)			
185	(a) the category is relevant for health services provided to natural persons;		deleted	(a) the categorycharacteristic is relevant for health services healthcare provided to natural persons;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	e 5(2), point (b)			
186	(b) according to the most recent information, the category is used in a significant number of EHR systems used in Member States;		deleted	(b) according to the most recent information, the category the characteristic as modified is used in the majority of Member States according to the most recent information-a significant number of EHR systems used in Member States;	
	Article	e 5(2), point (c)			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
187	(c) international standards exist for the category that have been examined for the possibility of their application in the Union.		deleted	(c) international standards exist for the category that have been examined for the possibility of their application in the Unionthe changes are aimed to adapt the priority categories to the technical evolution and international standards.	
	Article	6			
188	Article 6 European electronic health		Article 6 European electronic health	Article 6 European electronic health	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	record exchange format		record exchange format	record exchange format	
	Article	6(1)			
	1. The Commission shall, by means of implementing		1. The Commission shall, by means of implementing	1. The Commission shall, by means of implementing	
	acts, lay down the technical specifications for the priority categories of		acts, lay down the technical specifications for the priority categories of	acts, lay down the technical specifications for the priority categories of	
189	personal electronic health data referred to in Article 5, setting out the European		personal electronic health data referred to in Article 5, setting out the European	personal electronic health data referred to in Article 55(1) , setting out the	
	electronic health record exchange format. The format shall include the		electronic health record exchange format, <i>taking</i> <i>into account its</i>	European electronic health record exchange format.	
	following elements:		Recommendation (EU) 2019/243. The format shall include the following	commonly used, machine- readable and allow transmission of personal	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			elements:	electronic health data between different software applications, devices and healthcare providers. The format should support transmission of structured and unstructured health data. The format shall include the following elements:	
	Article	6(1), point (a)			
190	 (a) datasets containing electronic health data and defining structures, such as data fields and data groups for the content 		 (a) <i>harmonised</i> datasets containing electronic health data and defining structures, such as <i>minimum</i> data fields and data groups for 	(a) datasets containing electronic health data and defining structures, such as data fields and data groups for the content	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	representation of clinical content and other parts of the electronic health data;		the content representation of clinical content and other parts of the electronic health <u>data, which can be</u> <u>enlarged to include</u> <u>disease-specific</u> data;	representation of clinical content and other parts of the electronic health data;	
	Arti	icle 6(1), point (b)			
191	(b) coding systems and values to be used in datase containing electronic healt data;		(b) coding systems and values to be used in datasets containing electronic health data;	(b) coding systems and values to be used in datasets containing electronic health data;	
	Arti	icle 6(1), point (c)			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
192	(c) technical specifications for the exchange of electronic health data, including its content representation, standards and profiles.		(c) technical <i>interoperability</i> specifications for the exchange of electronic health data, including its content representation, standards and profiles, <i>and</i> <i>for the translation of</i> <i>electronic health data</i> .	(c) technical specifications for the exchange of electronic health data, including its content representation, standards and profiles.	
	Article 6(-	(-1)(2)			
192a	2. Those implementing acts shall be adopted in accordance with the advisory procedure referred			2. Those implementing acts shall be adopted in accordance with the advisory examination	

ment	Draft Agreemer	Council Mandate	EP Mandate	al	Commission Proposal	
		procedure referred to in		oer	to in Article 68(2). Member	
		Article 68(2). Member			States shall ensure that	
		States shall ensure that			where the priority	
		where the priority			categories of personal	
		categories of personal			electronic health data	
		electronic health data		e	referred to in Article 5 are	
		referred to in Article 5 are			provided by a natural	
		provided by a natural			person directly or	
		person directly or		:e	transmitted to a healthcare	
		transmitted to a healthcare			provider by automatic	
		provider by automatic			means in the format	
		means in the format referred		ι,	referred to in paragraph 1,	
		to in paragraph 1, such data		ıd	such data shall be read and	
		shall be read and accepted			accepted by the data	
		by the data recipient.			recipient.	
	l	[MOVED FROM ARTICLE			Moved reference text	
		6(2)]				
	l					
		transmitted to a healthcare provider by automatic means in the format referred to in paragraph 1, such data shall be read and accepted by the data recipient.		l,	provider by automatic means in the format referred to in paragraph 1, such data shall be read and accepted by the data recipient.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				[FIRST SENTENCE MOVED TO PARA 1 IN THIS ARTICLE. SECOND SENTENCE MOVED AND AMENDED IN PARA 3 IN THIS ARTICLE] Moved from row 193 [193 - 192a]	
	Article	6(1a)			
192b			<u>1a.</u> The Commission shall		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			ensure that those implementing acts contain the latest versions of healthcare coding systems and nomenclatures and that they are updated regularly in order to keep up with the revisions of the healthcare coding systems and nomenclatures.		
	Article	6(-1a)			
192c				-1a. The Commission may, by means of implementing acts, lay down technical specifications that extend	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				the European electronic health record exchange format to additional categories of electronic health data referred to in Article 5(1A). Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 68(2).	
	Article	6(2)			
193	2. Those implementing acts shall be adopted in accordance with the advisory procedure referred		2. Those implementing acts shall be adopted in accordance with the <i>advisory</i> <u>examination</u>	Moved to row 192a [193 - 192a]	

Commission Proposal		EP Mandate	Council Mandate	Draft Agreement			
 to in Article 68(2). Member States shall ensure that where the priority categories of personal electronic health data referred to in Article 5 are provided by a natural person directly or transmitted to a healthcare provider by automatic 		procedure referred to in Article 68(2). Member States shall ensure that where the priority categories of personal electronic health data referred to in Article 5 are provided by a natural person directly or transmitted to a healthcare					
means in the format referred to in paragraph 1, such data shall be read and accepted by the data recipient.		provider by automatic means in the format referred to in paragraph 1, such data shall be read and accepted by the data recipient68(2a).					
Article	Article 6(3)						

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
194	Commission Proposal 3. Member States shall ensure that the priority categories of personal electronic health data referred to in Article 5 are issued in the format referred to in paragraph 1 and such data shall be read and accepted by the data recipient.	EP Mandate 3. Member States shall ensure that the priority categories of personal electronic health data referred to in Article 5 are issued in the format referred to in paragraph 1 <i>across the</i> <i>continuum of care</i> and such data shall be read and accepted by the data recipient.	Council Mandate3. Member States shall ensure that the priority categories of personal electronic health data referred to in Article 5 are issued in the European electronic health record exchange format referred to in paragraph 1. Where-and such data shall be read and accepted byare transmitted by automatic means for primary use the receiving provider shall accept the format of the data recipientand be able to read it.	Draft Agreement

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	27	·		
195	Article 7 Registration of personal electronic health data		Article 7 Registration of personal electronic health data	Article 7 Registration of personal electronic health data [MOVED TO THE NEW ARTICLE 2A]	
	Article	2 7(1)			
196	1. Member States shall ensure that, where data is processed in electronic		 Member States shall ensure that, where <u>health</u> data is processed-<u>in</u> 	1. Member States shall ensure that, where data is processed in electronic	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	format, health professionals systematically register the relevant health data falling under at least the priority categories referred to in Article 5 concerning the health services provided by them to natural persons, in		<i>electronic format</i> , health professionals- <i>systematically</i> register the relevant health data falling under at least the priority categories referred to in Article 5 concerning the health services provided by them	format, health professionals systematically register the relevant health data falling under at least the priority categories referred to in Article 5 concerning the health services provided by them to natural persons, in	
	the electronic format in an EHR system.		to natural persons, in the electronic format in an EHR system.	the electronic format in an EHR system. [MOVED TO ARTICLE 2A(1) SEE AMENDMENTS IN THAT ARTICLE]	
	Article	7(1a)			·
196a					

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Ia.Member States mayprovide for natural personsto have the right to objectto the registration of theirpersonal health data in anEHR system.		
	If a Member State provides for such a right, it shall establish the rules and specific safeguards regarding such objection mechanisms.		
	Plenary AM 555		

Commission Pro	posal	EP Mandate	Council Mandate	Draft Agreement
	Article 7(2)			
 2. Where electronic data of a natural persoregistered in a Membrostate of affiliation of person, the Member of treatment shall ensitiate that the registration i performed under the identification data of natural person in the Member State of affiliation of affiliation data of a state of a state of affiliation data of a state of a state	on is ber Aember That State sure s person The	2. Where electronic health data of a natural person is registered in a Member State that is not the Member State of affiliation of that person, the Member State of treatment shall ensure that the registration is performed under the person identification data of the natural person in the Member State of affiliation.	2. Where electronic health data of a natural person is registered in a Member State that is not the Member State of affiliation of that person, the Member State of treatment shall ensure that the registration is performed under the person identification data of the natural person in the Member State of affiliation.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				IN THAT ARTICLE]	
	Article	7(3), first subparagraph			
198	3. The Commission shall, by means of implementing acts, determine the requirements for the registration of electronic health data by healthcare providers and natural persons, as relevant. Those implementing acts shall establish the following:		3. The Commission shall, by means of implementing acts, determine the adopt delegated acts in accordance with Article 67 to supplement this Regulation by determining the data quality requirements for the electronic registration of electronic health data by healthcare providers and natural persons, as relevant. Those implementing acts	3. The Commission shall, by means of implementing acts, determine the requirements for the registration of electronic health data by healthcare providers and natural persons, as relevant. Those implementing acts shall establish the following:	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			shall establish the f ollowing:		
	Article	27(3), first subparagraph, point	(a)		
199	(a) categories of healthcare providers that are to register health data electronically;		deleted	(a) categories of healthcare providers that are to register health data electronically;	
	Article	e 7(3), first subparagraph, point	(b)		
200	(b) categories of health data that are to be registered systematically in electronic format by healthcare		deleted	(b) categories of health data that are to be registered systematically in electronic format by healthcare	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	providers referred to in point (a);			providers referred to in point (a);	
	Article	7(3), first subparagraph, point	- (c)		
201	(c) data quality requirements pertaining to the electronic registration of health data.		deleted	(c) data quality requirements pertaining to the electronic registration of health data.	
	Article	7(3), second subparagraph			
202	Those implementing acts shall be adopted in accordance with the		Those implementing acts When health data are registered or updated,	Those implementing acts shall be adopted in accordance with the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	advisory procedure referred to in Article 68(2).		electronic health recordsshall be adopted inaccordance with theadvisory procedure referredadvisory procedure referredto in Article 68(2)identifythe health professional,time and health careprovider that carried outthe registration or theupdate. Member States mayprovide for other aspects ofdata registration to berecorded.	advisory procedure referred to in Article 68(2).). [MOVED FROM ARTICLE 2A (3) SEE AMENDMENTS IN THAT ARTICLE]	
	Article	7(3a)			
202a			<u>3a.</u> <u>Where the personal</u> <u>health data have not been</u>		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			registered electronically prior to the application of this Regulation, Member States may require that such data be made available in electronic format pursuant to this Article. This shall not affect the obligation to make personal electronic health data, registered after the application of this Regulation, available in electronic format, pursuant to this Article.		
	Article	e 7A			
202b					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				Article 7A Access by health professionals to personal electronic health data	
	Article	7a, first paragraph			
202c				1. Member States shall ensure that where health professionals process personal health data in an electronic format, they	

Commission Proposal		EP Mandate	Council Mandate	Draft Agreement		
			shall have access to the personal electronic health data of natural persons under their treatment, through the health professional access services referred to in Article 7B, irrespective of the Member State of affiliation and the Member State of treatment.			
			[MOVED FROM ARTICLE 4(1)(a)]			
Article 7a, 1A.						

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
202d				1A. Where the Member States of affiliation of the natural person under treatment and the Member States of treatment differ, cross- border access to the electronic health data of the natural person under treatment shall be provided through the infrastructure referred to in Article 12.	
	Article	e 7a, 2.			
202e					

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		2. The access referred to in paragraphs 1 and 1A shall include at least the priority categories in Article 5. In line with the principles provided for in Article 5 of the Regulation (EU) 2016/679, Member States may also establish rules providing for the categories of personal electronic health data accessible by different health professionals. Such rules shall take into account the possibility of restrictions imposed in according to Article 8E.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				[MOVED FROM ARTICLE 4(2) AND AMENDED]	
	Articl	e 7a, 3.			
202f				3. Where access to electronic health data has been restricted by the natural person pursuant to Article 8E, the healthcare provider or health professional shall not be informed of the content of the electronic health data without prior authorisation by the natural person. The	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		healthcare provider or	
		health professional shall	
		be informed exclusively	
		about the existence of	
		restricted electronic	
		health data. In cases	
		where processing is	
		necessary in order to	
		protect the vital interests	
		of the data subject or of	
		another natural person as	
		referred to in Article	
		9(2)(c) of the Regulation	
		(EU) 2016/679, the	
		healthcare provider or	
		health professional may	
		get access to the restricted	
		electronic health data.	
		Such events shall be	
		logged in a clear and	
		understandable format	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				and shall be easily accessible for the natural persons. Member States' law may set out additional safeguards.	
				[MOVED FROM ARTICLE 4(4) AND AMENDED]	
	Article	7b	F		
202g				Article 7B Health professional access services	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	7b, first paragraph			
202h				For the provision of healthcare, Member States shall ensure that access to the priority categories of electronic health data referred to in Article 5 is made available to health professionals through health professional access services. Those services shall be accessible only to health professionals who are in possession of electronic identification means recognised pursuant to Article 6 of	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				Regulation (EU) No 910/2014 or other electronic identification means compliant with common specifications referred to in Article 23 and the access shall be free of charge. [MOVED FROM ARTICLE 4(3) AND AMENDED]	
	Article	8			
203	Article 8 Telemedicine in the context		Article 8 Telemedicine in the context	Article 8 Telemedicine in the context	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	of cross-border healthcare		of cross-border healthcare	of cross-border healthcare	
	Article	e 8, first paragraph	L	I	
204	Where a Member State accepts the provision of telemedicine services, it shall, under the same conditions, accept the provision of the services of the same type by healthcare providers located in other Member States.		Where a Member State accepts the provision of telemedicine services, it shall, under the same conditions <i>and in a non-</i> <i>discriminatory manner</i> , accept the provision of the services of the same type by healthcare providers located in other Member States, <i>without prejudice to the</i> <i>same rights and obligations</i> <i>to access and register</i> <i>electronic health data</i> .	Where a Member State accepts the provision of telemedicine services, it shall, under the same conditions, accept the provision of the services of the same type by healthcare providers located in other Member States.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	8A			
204a				Article 8A Right of natural persons to access their personal electronic health data	
	Article	8a(1)		L	
204b				1. Natural persons shall have the right to access their personal electronic health data, at a minimum	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		data that belongs in the priority categories in Article 5, processed for the provision of healthcare through the electronic health data access services referred to in Article 8G. The access shall be provided immediately after the personal electronic health data has been registered in an EHR system, adhering to technological practicability, free of charge and in an easily readable, consolidated and accessible form.	
		[MOVED FROM ARTICLE	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				3(1) AND AMENDED]	
	Article	e 8a(2)			
204c				2. Natural persons shall have the right to receive an electronic copy, free of charge, through the electronic health data access services referred to in Article 8G, in the European electronic health record exchange format referred to in Article 6, of at least their personal electronic health data in the priority categories referred to in	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				Article 5. [MOVED FROM ARTICLE 3(2) AMENDED]	
	Article	8a(3)			
204d				3. In accordance with Article 23 of Regulation (EU) 2016/679, Member States may restrict the scope of the rights referred to in paragraphs 1 and 2, in particular whenever necessary for the protection of the	

Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			natural person based on patient safety and ethics by delaying their access to their personal electronic health data for a limited period of time until a health professional can properly communicate and explain to the natural person information that can have a significant impact on their health.	
Artic	e 8B			

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
204e			Article 8B Right of natural persons to insert information in their own EHR	
	Article 8b(1)			
204f			Member States law may provide that natural persons or their representatives as referred to in Article 8G(2) have the right to insert information in their own EHR through	

Commis	sion Proposal	EP Mandate	Council Mandate	Draft Agreement
			electronic health data access services or applications linked to these services as referred to in Article 8G. That information shall in such cases be clearly distinguishable as inserted by the natural person or	
			by his or her representative. Natural persons shall not have the possibility to directly alter the electronic health data and related information inserted by health professionals.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				3(6)]	
	Article	8C			
204g				Article 8C Right of natural persons to rectification	
	Article	8c(1)			
204h				When exercising the right to rectification under Article 16 of Regulation (EU) 2016/679,	

Commis	sion Proposal		EP Mandate	Council Mandate	Draft Agreement
				natural persons shall be able to easily request, online through the electronic health data access services referred to in Article 8G, the controller of the personal electronic health data, to rectify their personal electronic health data.	
	Article	e 8c(2)			
204i					

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			Member States law may also enable natural persons to exercise other rights pursuant to Chapter III of Regulation (EU) 2016/679 online through the electronic health data access services referred to in Article 8G.	
	Article 8D			
204j			Article 8D Right to data portability for natural persons	

	Commission Proposa	al	EP Mandate	Council Mandate	Draft Agreement
	Art	ticle 8d(1)			
204k				1. Natural persons shall have the right to give access to or request a healthcare provider to transmit, all or part of their electronic health data that belongs to the priority categories as referred to in Article 5 to another provider of their choice from the healthcare sector, without delay, free of charge and without hindrance from the transmitting provider or from the manufacturers of the systems used by that	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				provider. [MOVED FROM ARTICLE 3(8) SUBPARA 1] [MOD.PU.16.rev1]	
	Article	e 8d(2)			
2041				2. Natural persons shall have the right that, where healthcare providers are located in different Member States and such electronic health data belongs to the priority categories referred to in	

Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			Article 5, the transmitting provider transmits the data in the European electronic health record exchange format referred to in Article 6 through the cross border infrastructure as referred to in Article 12. The receiving healthcare provider shall accept such data and shall be able to read it. [MOVED FROM ARTICLE 3(8) SUBPARA 2]	
Article 80	d(3)			

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
204 m			3. Where natural persons have received an electronic copy of their priority categories of personal electronic health data as referred to in Article 8A(2), they shall be able to transmit that data to healthcare providers of their choice in the European electronic health record exchange format referred to in Article 6 The receiving provider shall accept such data and be able to read it, as appropriate.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				[MOVED FROM ARTICLE 3(8) SUBPARA 4] [MOD.PU.16.rev1]	
	Article	8d(4)			
204n				4. The Commission shall, by means of implementing acts, determine the requirements concerning the technical implementation of the rights set out in this Article. Those implementing acts shall be adopted in accordance with the examination	

	Commission Propos	sal	EP Mandate	Council Mandate	Draft Agreement
				procedure referred to in Article 68(2).	
				[MOVED FROM ARTICLE 3(12)]	
	Α	Article 8E			
2040				Article 8E Right to restrict access and information on access	
	Article 8e(1), first subparagraph				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement		
204p				1. Natural persons shall have the right to restrict access of health professionals and healthcare providers to their personal electronic health data referred to in Article 8A. Member States laws may provide that such restriction of access may be derogated under the same conditions as those laid down in Article 7A(3).			
	Article 8e(1)						

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
204q				Member States shall establish the rules and specific safeguards regarding such restriction mechanisms, including the restriction of this right in a justified and proportionate manner.	
	Article	8e(2)			
204r					

Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			2. Natural persons shall have the right to obtain information on any access to their personal electronic health data through the health professional access service made in the context of healthcare. The information shall be provided without delay and free of charge through electronic health data access services. The information shall include, at least, the following:	
Article	8e(2a)			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
204s				(a) the healthcare provider or other individuals who accessed the personal electronic health data;	
	Article	8e(2), third subparagraph			
204t				(b) the date and time of access;	
	Article	8e(2), fourth subparagraph			
204u					

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			(c) the personal electronic health data that was accessed.	
			[MOVED FROM ARTICLE 3(10)]	
	Article 8a(3)			
204v			3. The Commission shall, by means of implementing acts, determine the requirements for the technical implementation of the rights set out in this Article. Those	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				implementing acts shall be adopted in accordance with the examination procedure referred to in Article 68(2).	
	Article	2 8F			
204 w				Article 8F Right of natural person to object	
	Article	e 8f(1)			
204x					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				1. Member States laws may provide that natural persons have the right to object to the access to their personal electronic health data registered in an EHR system through the electronic health data access services referred to in Articles 7B and 8G. In such cases, Member States should ensure that the exercise of this right is reversible.	
	Article	8f(1)			
204y				If a Member State	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Commission Proposal	EP Mandate	provides for such a right, it shall establish the rules and specific safeguards regarding such objection mechanism. In particular, Member States may allow for the possibility of the healthcare provider or health professional to get access to the personal electronic health data in cases where processing is necessary in order to protect the vital interests of the data subject or of another natural person as referred to in Article 9(2)(c) of the Regulation (EU) 2016/679, even if the	Draft Agreement
		patient has exercised the right to object.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	8f(2)			
204z				2. With regard to cross- border access to personal electronic health data referred to in Article 5, Member States laws may provide for natural persons to have the right to object to their personal electronic health data being made available for cross-border access and exchange through the cross-border infrastructure as referred to in Article 12.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	8f(2)			
204a a				If a Member State provides for such a right, it shall establish the rules and specific safeguards regarding such objection mechanism.	
	Article	8G			
204a b				Article 8G Electronic health data	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				access services for natural persons and their representatives	
	Article	8g(1)			
204a c				1. Member States shall ensure that one or more electronic health data access services at national, regional or local level are established, enabling natural persons access to their personal electronic health data and the exercise of rights referred to in Articles 8A to 8F.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				[MOVED FROM ARTICLE 3(5)(a)]	
	Article	8g(2)			
204a d				2. Member States shall ensure that one or more proxy services are established as a functionality of health data access services enabling natural persons to:	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	e 8g(2), point (a)			
204a e				(a) authorise other natural persons of their choice to access their personal electronic health data, or part thereof, on their behalf; and;	
	Article	e 8g(2), point (b)			
204a f				(b) have access to the personal electronic health data of natural persons whose affairs they administer as legal	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				guardians	
	Article	8g(second subparagraph)			
204a g				in an equivalent manner as they access their personal electronic health data and to manage those authorisations.	
	Article	8g(second subparagraph)			
204a h				The proxy services shall provide authorisations free of charge,	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				electronically or on paper.	
	Article	8g(second subparagraph)			
204a i				Member States shall establish rules regarding such authorisations, actions of guardians and representatives. The proxy services shall be interoperable among Member States. [MOVED FROM ARTICLE 3(5)(b) AND SUBPARA 2]	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	8g(5), second subparagraph	1		
204a j				2a. For the purposes of paragraph 2, the Commission shall, by means of implementing acts, lay down the technical specifications to ensure the interoperability of the proxy services of the Member States. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 68(2).	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement		
	Article	8g(3)					
204a k				3. The access to the electronic health data services as referred to in paragraph 1 shall be free of charge for the natural persons and their representatives.			
	Article 9						
205	Article 9		Article 9	Article 9			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Identification management		Identification management	Identification management	
	Article	9(1)			
206	1. Where a natural person uses telemedicine services or personal health data access services referred to in Article 3(5), point (a), that natural person shall have the right to identify electronically using any electronic identification means which is recognised pursuant to Article 6 of Regulation (EU) No 910/2014.		1. Where a natural person or a health professional uses, uses telemedicine services or personal health data access services referred to in Article 3(5), point (a), Article 4(3) and where applicable, Article 8 that natural person or health professional shall have the right to identify electronically using any electronic identification means which is recognised	1. Where a natural person uses telemedicine services or-personal health data access services referred to in Article 3(5), point (a)8G, that natural person shall have the right to identify electronically using any electronic identification means which is recognised pursuant to Article 6 of Regulation (EU) No 910/2014. Member States may provide	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			pursuant to Article 6 of Regulation (EU) No 910/2014 <u>, including eID</u> schemes where such systems are offered.	complementary mechanisms to ensure appropriate identity matching in cross-border situations.	
	Article	9(2)			
207	2. The Commission shall, by means of implementing acts, determine the requirements for the interoperable, cross-border identification and authentication mechanism for natural persons and health professionals, in accordance with Regulation		2. The Commission shall, by means of implementing acts, determine adopt delegated acts in accordance with Article 67 to supplement this Regulation by determining the requirements for the interoperable, cross-border identification and	2. The Commission shall, by means of implementing acts, determine the requirements for the interoperable, cross-border identification and authentication mechanism for natural persons and health professionals , in accordance with Regulation	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	(EU) No 910/2014 as amended by [COM(2021) 281 final]. The mechanism shall facilitate the transferability of electronic health data in a cross-border context. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2).		authentication mechanism for natural persons and health professionals, in accordance with Regulation (EU) No 910/2014- <i>as</i> <i>amended by [COM(2021)</i> <i>281 final]</i> . The mechanism shall facilitate the transferability of electronic health data in a cross-border context. <i>Those</i> <i>implementing acts shall be</i> <i>adopted in accordance with</i> <i>the advisory procedure</i> <i>referred to in Article 68(2).</i>	(EU) No 910/2014 as amended by [COM(2021) 281 final]. The mechanism shall facilitate the transferability of personal electronic health data in a cross-border context. Those implementing acts shall be adopted in accordance with the advisory examination procedure referred to in Article 68(2).	
	Article	9(3)			
208					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	3. The Commission shall implement services required by the interoperable, cross- border identification and authentication mechanism referred to in paragraph 2 of this Article at Union level, as part of the cross-border digital health infrastructure referred to in Article 12(3).		3. The Commission <u>, in</u> <i>cooperation with Member</i> <i>States</i> , shall implement services required by the interoperable, cross-border identification and authentication mechanism referred to in paragraph 2 of this Article at Union level, as part of the cross-border digital health infrastructure referred to in Article 12(3).	3. The Commission shall implement services required by the interoperable, cross- border identification and authentication mechanism referred to in paragraph 2 of this Article at Union level, as part of the cross-border digital health- infrastructure referred to in Article 12(3).	
	Article	9(4)			
209	4. The digital health authorities and the Commission shall		4. <i>The digital</i> <i>healthMember States</i> ' <u>competent</u> authorities and	4. The digital health authorities-Member States and the Commission shall	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	implement the cross-border identification and authentication mechanism at Union and Member States' level, respectively.		the Commission shall implement the cross-border identification and authentication mechanism at Union and Member States' level, respectively, in accordance with Regulation (EU) No 910/2014.	implement the cross-border identification and authentication mechanism at Union and Member States' and Union -level, respectively.	
	Article	9A			
209a				Article 9A Compensation for making personal electronic health data available	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	9a(1)			
209b				By way of derogation from Article 9 of Regulation [] [Data Act COM/2022/68 final], where personal electronic health data is transmitted in accordance with Article 8D, the receiving provider shall not be required to compensate the transmitting provider for making electronic heath data available.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				[MOVED FROM ARTICLE 3(8) SUBPARA 3]	
	Section	n 1a			
209c				Section 1a Governance for primary use of electronic health data	
	Article	10			
210	Article 10 Digital health authority		Article 10 Digital health authority	Article 10 Digital health authority	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	10(1)			
	1. Each Member State shall		1. Each Member State shall	1. Each Member State shall	
	designate a digital health		designate a digital health	designate one or more-a	
	authority responsible for the		authority responsible for the	digital health	
	implementation and		implementation and	authorityauthorities	
	enforcement of this Chapter		enforcement of this Chapter	responsible for the	
	at national level. The		at national level. The	implementation and	
211	Member State shall		Member State shall	enforcement of this Chapter	
	communicate the identity of		communicate the identity of	at national level. The	
	the digital health authority		the digital health authority	Member State shall	
	to the Commission by the		to the Commission by the	communicate the inform	
	date of application of this		date of application of this	the Commission of the	
	Regulation. Where a		Regulation. Where a	identity of the digital health	
	designated digital health		designated digital health	authority to the	
	authority is an entity		authority is an entity	Commission by the date of	
	consisting of multiple		consisting of multiple	application of this	

Commission Proposal		EP Mandate	Council Mandate	Draft Agreement			
organisations, the Member State shall communicate to the Commission a description of the separation of tasks between the organisations. The Commission shall make this information publicly available.		organisations, the Member State shall communicate to the Commission a description of the separation of tasks between the organisations. The Commission shall make this information publicly available.	Regulation. Where a Member State designated more than one digital health authority is an entity consistingand where the digital health authority consists of multiple organisations, the Member State shall communicate to the Commission a description of the separation of tasks between the organisations. The Commission shall make this information publicly available.				
Article 10(2)							

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
212	2. Each digital health authority shall be entrusted with the following tasks:	2. Each digital health authority shall be entrusted with the following tasks <i>and powers</i> :	2. Each The digital health authority shall be entrusted with the following tasks:	
	Article 10(2), point (a)		·	
213	(a) ensure the implementation of the rights and obligations provided for in Chapters II and III by adopting necessary national, regional or local technical solutions and by establishing relevant rules and mechanisms;	 (a) ensure the implementation of the rights and obligations provided for in Chapters II and III by adopting necessary national, regional or local technical solutions and by establishing relevant rules and mechanisms; 	(a) ensure the implementation of the rights and obligations provided for in Chapters II and III by adopting necessary national, regional or local technical solutions and by establishing relevant rules and mechanisms;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	10(2), point (b)			
	(b) ensure that complete and up to date information		(b) ensure that complete and up to date information	(b) ensure that complete and up to date information	
	about the implementation of rights and obligations provided for in in Chapters		about the implementation of rights and obligations provided for in in Chapters	about the implementation of rights and obligations provided for in in Chapters	
214	II and III is made readily available to natural persons, health professionals and healthcare providers;		II and III is made readily available to natural persons, health professionals and healthcare providers <u>and</u>	II and III is made readily available to natural persons, health professionals and healthcare providers;	
			<u>that appropriate training</u> <u>initiatives are undertaken</u> <u>at the local, regional and</u> <u>national level</u> ;		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Articl	e 10(2), point (c)		·	
215	(c) in the implementation of technical solutions referred to in point (a), enforce their compliance with Chapter II, III and Annex II;		(c) in the implementation of technical solutions referred to in point (a), enforce their compliance with Chapter II, III and Annex II;	(c) in the implementation of technical solutions referred to in point (a), enforce their compliance with Chapter II, III and Annex II;	
	Articl	e 10(2), point (d)			
216	(d) contribute, at Union level, to the development of technical solutions enabling natural persons and health professionals to exercise		(d) contribute, at Union level, to the development of technical solutions enabling natural persons and health professionals to exercise	(d) contribute, at Union level, to the development of technical solutions enabling natural persons and health professionals to exercise	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	their rights and obligations set out in this Chapter;		their rights and obligations set out in this Chapter;	their rights and obligations set out in this Chapter;	
	Article	e 10(2), point (e)			
217	 (e) facilitate for persons with disabilities to exercise their rights listed in Article 3 of this Regulation in accordance with Directive (EU) 2019/882 of the European Parliament and of the Council¹. 1. Directive (EU) 2019/882 of the European Parliament and of the Council of 17 April 2019 on the 		 (e) facilitate for persons with disabilities to exercise their rights listed in Article 3 of this Regulation in accordance with Directive (EU) 2019/882 of the European Parliament and of the Council¹. 1. Directive (EU) 2019/882 of the European Parliament and of the Council of 17 April 2019 on the 	 (e) facilitate for persons with disabilities to exercise their rights listed in Article 3 of this Regulation in accordance with Directive (EU) 2019/882 of the European Parliament and of the Council¹. 1. Directive (EU) 2019/882 of the European Parliament and of the Council of 17 April 2019 on the 	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	accessibility requirements for products and services (Text with EEA relevance) (OJ L 151, 7.6.2019, p. 70)		accessibility requirements for products and services (Text with EEA relevance) (OJ L 151, 7.6.2019, p. 70)	accessibility requirements for products and services (Text with EEA relevance) (OJ L 151, 7.6.2019, p. 70)	
	Artio	cle 10(2), point (f)			
218	(f) supervise the national contact points for digital health and cooperate with other digital health authorities and the Commission on further development of MyHealth@EU;		(f) supervise the national contact points for digital health and cooperate with other digital health authorities and the Commission on further development of MyHealth@EU;	(f) supervise the national contact points for digital health and cooperate with other digital health authorities and the Commission on further development of MyHealth@EU;	
	Arti	cle 10(2), point (g)			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
219	(g) ensure the implementation, at national level, of the European electronic health record exchange format, in cooperation with national authorities and stakeholders;		(g) ensure the implementation, at national level, of the European electronic health record exchange format, in cooperation with national authorities and stakeholders;	(g) ensure the implementation, at national level, of the European electronic health record exchange format, in cooperation with national authorities and stakeholders;	
	Article	10(2), point (h)			
220	(h) contribute, at Union level, to the development of the European electronic health record exchange format and to the		 (h) contribute, at Union level, and, where relevant, in cooperation at local and regional level within the Member States, to the 	 (h) contribute, at Union level, to the development of the European electronic health record exchange format and to the 	

Commission Proposal		EP Mandate	Council Mandate	Draft Agreement		
elaboration of common specifications addressing interoperability, security, safety or fundamental right concerns in accordance with Article 23 and of the specifications of the EU		development of the European electronic health record exchange format and to the elaboration of common specifications addressing <i>quality</i> , interoperability, security,	elaboration of common specifications addressing interoperability, security, safety or fundamental right concerns in accordance with Article 23 and of the specifications of the EU database for EHP systems			
database for EHR systems and wellness applications referred to in Article 32;		safety, <i>ease of use</i> , <i>accessibility, non</i> - <i>discrimination</i> or fundamental right concerns in accordance with Article 23 and of the specifications of the EU database for EHR systems and wellness applications referred to in Article 32;	database for EHR systems and wellness applications referred to in Article 32;			
Article 10(2), point (i)						

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
221	(i) where applicable, perform market surveillance activities in accordance with Article 28, while ensuring that any conflict of interest is avoided;		(i) where applicable, perform market surveillance activities in accordance with Article 28, while ensuring that any conflict of interest is avoided;	(i) where applicable, perform market surveillance activities in accordance with Article 28, while ensuring that any conflict of interest is avoided;	
	Article	10(2), point (j)			
222	(j) build national capacity for implementing interoperability and security of the primary use of electronic health data and participate in information exchanges and capacity		(j) build national capacity for implementing interoperability and security of the primary use of electronic health data and participate in information exchanges and capacity	(j) build national capacity for implementing interoperability and security of the primary use of electronic health data and participate in information exchanges and capacity	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	building activities at Union		building activities at Union	building activities at Union	
	level;		level;	level;	
	Article	e 10(2), point (k)			
	(k) offer, in compliance		(k) offer, in compliance	(k) offer, in compliance	
	with national legislation,		with national legislation,	with national legislation,	
	telemedicine services and		telemedicine services and	telemedicine services and	
	ensure that such services		ensure that such services are	ensure that such services are	
	are easy to use, accessible		easy to use, accessible and	easy to use, accessible to	
223	to different groups of		equitable to different	different groups of natural	
	natural persons and health		groups of natural persons	persons and health	
	professionals, including		and health professionals,	professionals, including	
	natural persons with		including natural persons	natural persons with	
	disabilities, do not		with disabilities, do not	disabilities, do not	
	discriminate and offer the		discriminate<mark>under the same</mark>	discriminate and offer the	
	possibility of choosing		non-discriminatory	possibility of choosing	
	between in person and		conditions and offer the	between in person and	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	digital services;		possibility of choosing between in person and digital services;	digital services;	
	Article	10(2), point (l)			
224	(1) cooperate with market surveillance authorities, participate in the activities related to handling of risks posed by EHR systems and of serious incidents and supervise the implementation of corrective actions in accordance with Article 29;		(1) cooperate with market surveillance authorities, participate in the activities related to handling of risks posed by EHR systems and of serious incidents and supervise the implementation of corrective actions in accordance with Article 29;	(1) cooperate with market surveillance authorities, participate in the activities related to handling of risks posed by EHR systems and of serious incidents and supervise the implementation of corrective actions in accordance with Article 29;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			I do not see any changes in EP or Council text		
	Article	e 10(2), point (m)			
225	(m) cooperate with other relevant entities and bodies at national or Union level, to ensure interoperability, data portability and security of electronic health data, as well as with stakeholders representatives, including patients' representatives, healthcare providers, health professionals, industry associations;		(m) cooperate with other relevant entities and bodies at <i>local, regional,</i> national or Union level, to ensure interoperability, data portability and security of electronic health data, <i>as</i> <i>well as with stakeholders</i> <i>representatives, including</i> <i>patients' representatives,</i> <i>healthcare providers, health</i> <i>professionals, industry</i>	(m) cooperate with other relevant entities and bodies at national or Union level, to ensure interoperability, data portability and security of electronic health data, as well as with stakeholders representatives, including patients' representatives, healthcare providers, health professionals , and industry associations;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			associations;		
	Article	10(2), point (n)			
	(n) cooperate with		(n) cooperate with	(n) cooperate with	
	supervisory authorities in		supervisory authorities in	supervisory authorities in	
	accordance with Regulation		accordance with Regulation	accordance with Regulation	
	(EU) 910/2014, Regulation		(EU) 910/2014, Regulation	(EU) 910/2014, Regulation	
	(EU) 2016/679 and		(EU) 2016/679 and	(EU) 2016/679 and ,	
226	Directive (EU) 2016/1148		Directive (EU) 2016/1148	Directive (EU) 2016/1148	
226	of the European Parliament		of the European Parliament	of the European Parliament	
	and of the Council ¹ with		and of the Council ¹ with	and of the Council ⁴	
	other relevant authorities,		other relevant authorities,	2022/2555 and with other	
	including those competent		including those competent	relevant authorities,	
	for cybersecurity, electronic		for cybersecurity, electronic	including those competent	
	identification, the European		identification, the European	for cybersecurity, electronic	
	Artificial Intelligence		Artificial Intelligence	identification, the European	
	Board, the Medical Device		Board, the Medical Device	Artificial Intelligence	

Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
Coordination Group, the European Data Innovation Board and the competent authorities under Regulation [] [Data Act COM/2022/68 final]; 1. Directive (EU) 2016/1148 of the European Parliament and of the Council of 6 July 2016 concerning measures for a high common level of security of network and information systems across the Union (OJ L 194, 19.7.2016, p. 1).		Coordination Group, the European Data Innovation Board and the competent authorities under Regulation [] [Data Act COM/2022/68 final]; 	Board, the Medical Device Coordination Group, the European Data Innovation Board and the competent authorities under Regulation [] [Data Act COM/2022/68 final];; 	
Article	e 10(2), point (o)			

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	(o) draw up, in	(o) draw up, in	(o) draw up, in	
	collaboration where	collaboration where	collaboration where	
	relevant with market	relevant with market	relevant with market	
	surveillance authorities, an	surveillance authorities, a	n surveillance authorities, an	
	annual activity report,	annual activity report,	annual activity report,	
	which shall contain a	which shall contain a	which shall contain a	
	comprehensive overview of	comprehensive overview	of comprehensive overview of	
	its activities. The report	its activities. The report	its activities. The report	
227	shall be transmitted to the	shall be transmitted to the	shall be transmitted to the	
	Commission. The annual	Commission. The annual	Commission. The annual	
	activity report shall follow a	activity report shall follow	w a activity report shall follow a	
	structure that is agreed at	structure that is agreed at	structure that is agreed at	
	Union level within EHDS	Union level within EHDS	Union level within EHDS	
	Board, to support	Board, to support	Board, to support	
	benchmarking pursuant to	benchmarking pursuant to	benchmarking pursuant to	
	Article 59. The report shall	Article 59. The report sha	Il Article 59. The report shall	
	contain at least information	contain at least information	on contain at least information	
	concerning:	concerning:	concerning:	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				[LETTER O MOVED TO ARTICLE 10A, SEE AMENDMENTS IN THAT ARTICLE]	
	Article	10(2), point (o)(i)			
228	(i) measures taken to implement this Regulation;		(i) measures taken to implement this Regulation;	(i) measures taken to implement this Regulation;	
	Article	10(2), point (o)(ii)			
229					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement		
	(ii) percentage of natural persons having access to different data categories of their electronic health records;		(ii) percentage of natural persons having access to different data categories of their electronic health records;	(ii) percentage of natural persons having access to different data categories of their electronic health records;			
	Article	e 10(2), point (o)(iii)					
230	(iii) information on the handling of requests from natural persons on the exercise of their rights pursuant to this Regulation;		(iii) information on the handling of requests from natural persons on the exercise of their rights pursuant to this Regulation;	(iii) information on the handling of requests from natural persons on the exercise of their rights pursuant to this Regulation;			
	Article 10(2), point (o)(iv)						

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
231	(iv) number of healthcare providers of different types, including pharmacies, hospitals and other points of care, connected to MyHealth@EU calculated a) in absolute terms, b) as share of all healthcare providers of the same type and c) as share of natural persons that can use the services;	(iv) number of healthcare providers of different types, including pharmacies, hospitals and other points of care, connected to MyHealth@EU calculated a) in absolute terms, b) as share of all healthcare providers of the same type and c) as share of natural persons that can use the services;	including pharmacies,	
	Article 10(2), r	oint (o)(v)	·	
232	(v) volumes of electronic	(v) volumes of electronic	(v) volumes of electronic	

	Commission Proposal	1	EP Mandate	Council Mandate	Draft Agreement		
	health data of different categories shared across borders through MyHealth@EU;		health data of different categories shared across borders through MyHealth@EU;	health data of different categories shared across borders through MyHealth@EU;			
	Arti	icle 10(2), point (o)(vi)					
233	(vi) level of natural persor satisfaction with MyHealth@EU services;	n	(vi) level of natural person satisfaction with MyHealth@EU services;	(vi) level of natural person satisfaction with MyHealth@EU services;			
	Article 10(2), point (o)(vii)						
234	(vii) number of certified EHR systems and labelled		(vii) number of certified EHR systems and labelled	(vii) number of certified EHR systems and labelled			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	wellness applications enrolled in the EU database;		wellness applications enrolled in the EU database;	wellness applications enrolled in the EU database;	
	Article	e 10(2), point (o)(viii)			
235	(viii) number of non- compliance cases with the mandatory requirements;		(viii) number of non- compliance cases with the mandatory requirements;	(viii) number of non- compliance cases with the mandatory requirements;	
	Article	e 10(2), point (o)(ix)			
236	(ix) a description of its activities carried out in relation to engagement with and consultation of relevant		(ix) a description of its activities carried out in relation to engagement with and consultation of relevant	(ix) a description of its activities carried out in relation to engagement with and consultation of relevant	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	stakeholders, including representatives of natural persons, patient organisations, health professionals, researchers, and ethical committees;	:	stakeholders, including representatives of natural persons, patient organisations, health professionals, researchers, and ethical committees;	stakeholders, including representatives of natural persons, patient organisations, health professionals, researchers, and ethical committees;	
	Article 10(2),	point (o)(x)			
237	(x) information on cooperation with other competent bodies in particular in the area of data protection, cybersecurity, and artificial intelligence.		(x) information on cooperation with other competent bodies in particular in the area of data protection, cybersecurity, and artificial intelligence.	(x) information on cooperation with other competent bodies in particular in the area of data protection, cybersecurity, and artificial intelligence.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	10(3)			
238	3. The Commission is empowered to adopt delegated acts in accordance with Article 67 to supplement this Regulation by entrusting the digital health authorities with additional tasks necessary to carry out the missions conferred on them by this Regulation and to modify the content of the annual report.		deleted	3. The Commission is empowered to adopt delegated acts in accordance with Article 67 to supplement this Regulation by entrusting the digital health authorities with additional tasks necessary to carry out the missions conferred on them by this Regulation and to modify the content of the annual report.	
	Article	10(3a)			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
238a			<u>3a.</u> <u>The digital health</u> <u>authorities and the data</u> <u>protection authorities shall</u> <u>consult each other and</u> <u>cooperate in the</u> <u>enforcement of this</u> <u>Regulation, within the</u> <u>remit of their respective</u> <u>competences.</u>		
	Article 10((4)			
239	4. Each Member State shall ensure that each digital health authority is provided with the human, technical		4. Each Member State shall ensure that each digital health authority is provided with the human, technical	4. Each Member State shall ensure that each digital health authority is provided with the human, technical	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	and financial resources, premises and infrastructure		and financial resources, premises and infrastructure	and financial resources, premises and infrastructure	
	necessary for the effective		necessary for the effective	necessary for the effective	
	performance of its tasks and		performance of its tasks and	performance of its tasks and	
	exercise of its powers.		exercise of its powers.	exercise of its powers.	
	Article	10(5)			
240	5. In the performance of its tasks, the digital health authority shall actively cooperate with stakeholders' representatives, including patients' representatives. Members of the digital health authority shall avoid any conflicts of interest.		5. In the performance of its tasks, the digital health authorityMembers of the digital health authority shall avoid any conflicts of interest. Members shall not have financial or other interests in industries or economic activities which could affect their	5. In the performance of its tasks, the digital health authority shall actively cooperate with stakeholders ² representatives, including patients' representatives. Members of the digital health authority shall avoid any conflicts of interest.	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	impartiality. They shall		
	<u>undertake to act in the</u>		
	public interest and in an	[SEE ALSO ARTICLE	
	<u>independent manner, and</u>	10(2)(m)]	
	shall actively cooperate		
	with stakeholders'		
	representatives, including		
	patients' representatives.		
	Members of the digital		
	health authority<mark>make an</mark>		
	annual declaration of their		
	<u>financial interests. All</u>		
	indirect interests which		
	could relate to such		
	industries or economic		
	<u>activities</u> shall avoid any		
	conflicts<u>be</u> entered in a		
	register available to the		
	public, upon request. The		
	Commission may adopt		
	guidance on what is likely		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			<i>to constitute a conflict</i> of interest <i>together with the</i> <i>procedure to be followed in</i> <i>such cases</i> .		
	Article	e 10(5a)			
240a			5a. In the performance of their tasks, the digital health authorities shall actively cooperate and consult with relevant stakeholders' representatives, including patients' representatives, health care providers and health professionals' representatives, including		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			health professional associations, consumer organisations and industry associations. Stakeholders shall declare any conflict of interest.		
	Article	e 10A			
240b				Article 10A Reporting by digital health authority	
	Article	e 10a(1), first subparagraph			

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
240c	Commission Proposal	EP Mandate	1. The digital health authority shall publish a biennial activity report, which shall contain a comprehensive overview of its activities. If a Member State designates more than one digital health authority, one of them shall be responsible for the report and request necessary information from the other digital health authorities. The	Draft Agreement
			shall follow a structure that is agreed at Union	
			level within EHDS Board. The report shall contain at	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				least information concerning: It appears in the wrong order but is ok on the structure and when exporting	
	Article	10a(1), second subparagraph			
240d				(a) measures taken to implement this Regulation;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	10a(1), third subparagraph			
240e				(b) percentage of natural persons having access to different data categories of their electronic health records;	
	Article	10a(1), fourth subparagraph			
240f				(c) formation on the handling of requests from natural persons on the exercise of their rights pursuant to this Regulation;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	10a(1), fifth subparagraph			
240g				(d) number of healthcare providers of different types, including pharmacies, hospitals and other points of care, connected to MyHealth@EU calculated a) in absolute terms, b) as share of all healthcare providers of the same type and c) as share of natural persons that can use the services;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	e 10a(1), sixth subparagraph	·	·	
240h				(e) volumes of electronic health data of different categories shared across borders through MyHealth@EU;	
	Article	e 10a(1), seventh subparagraph			
240i				[MOVED FROM ARTICLE 10(2)(0)]	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement	
	Article	10a(2)				
240j				2. The report shall be drawn up in collaboration with market surveillance authorities as referred to in Article 28 of this Regulation, where relevant. [FROM ARTICLE 10(2)(0)]		
	Article 10a(3)					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
240k				3. The report shall be sent to the Commission and the EHDS Board within 6 months after the end date of the 2 years reporting period. [FROM ARTICLE 10A(1) AND AMENDED]	
	Article	2 11			
241	Article 11 Right to lodge a complaint		Article 11 Right to lodge a complaint	Article 11 Right to lodge a complaint	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	with a digital health authority		with a digital health authority	with a digital health authority	
	Article	2 11(1)			
242	1. Without prejudice to any other administrative or judicial remedy, natural and legal persons shall have the right to lodge a complaint, individually or, where relevant, collectively, with the digital health authority. Where the complaint concerns the rights of natural persons pursuant to Article 3 of this Regulation, the digital health authority		1. Without prejudice to any other administrative or judicial remedy, natural and legal persons shall have the right to lodge a complaint, individually or, where relevant, collectively, with the digital health authority, where their rights laid down in this Regulation are affected. Where the complaint concerns the rights of natural persons	1. Without prejudice to any other administrative or judicial remedy, natural and legal persons shall have the right to lodge a complaint, individually or, where relevant, collectively, with the digital health authority, related to the provisions in this Chapter . Where the complaint concerns the rights of natural persons pursuant to Article	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
shall inform the supervisory	pursuant to Article 3 of this	3Articles 8A to 8F of this	
authorities under	Regulation or Regulation	Regulation, the digital	
Regulation (EU) 2016/679.	(EU) 2016/679, the digital	health authority shall	
	health authority shall inform	informtransmit the	
	the send a copy of the	complaint to the	
	complaint to and consult	supervisory authorities	
	with the competent	under Regulation (EU)	
	supervisory <i>authority under</i>	2016/679 and shall consult	
	Regulation (EU) 2016/679	and cooperate with them	
	<u>in order to facilitate its</u>	in the handling of such	
	assessment and	complaints.	
	investigation. The decision		
	<u>of the digital health</u>		
	authority shall not		
	<u>prejudice any measures</u>		
	<u>taken by the data</u>		
	protection authorities,		
	which shall be competent		
	to treat the complaint in		
	<u>separate proceedings,</u>		
	<u>pursuant to their tasks and</u>		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			<i>powers</i> under Regulation (EU) 2016/679.		
	Article	11(2)	<u> </u>		
243	2. The digital health authority with which the complaint has been lodged shall inform the complainant of the progress of the proceedings and of the decision taken.		2. The digital health authority with which the complaint has been lodged shall inform the complainant of the progress of the proceedings and of the decision taken <u></u> . <i>including, where</i> <i>applicable, that the</i> <i>complaint was referred to</i> <i>the relevant supervisory</i> <i>authority under Regulation</i> <i>(EU) 2016/679, and that</i>	2. The competent digital health authority with which the complaint has been lodged shall inform the complainant, in accordance with national law , of the progress of the proceedings and of the decision taken.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			the supervisory authority will, from that moment on, be the sole point of contact for the complainant in that matter.		
	Article	11(3)			
244	3. Digital health authorities shall cooperate to handle and resolve complaints, including by exchanging all relevant information by electronic means, without undue delay.		3. Digital health authorities shall cooperate to handle and resolve complaints, including by exchanging all relevant information by electronic means, without undue delay.	3. Digital health authorities in different Member States shall cooperate to handle and resolve complaints related to the cross-border exchange and access to personal electronic health data, including by exchanging all relevant information by	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				electronic means, without undue delay.	
	Article	e 11(3a)			
244a			3a. Each digital health authority shall facilitate submitting complaints, in particular by providing a complaint submission form which can also be completed electronically, without excluding the possibility of using other means of communication.		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Artic	le 11a	·	·	
244b			<u>Article 11a</u> <u>Right to an effective</u> <u>judicial remedy against a</u> <u>digital health authority</u>		
	Artic	le 11a(1)			
244c			1. Without prejudice to any other administrative or non-judicial remedy, each natural or legal person shall have the right to an effective judicial remedy against a legally binding		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			decision of a digital health authority concerning them.		
	Article	e 11a(2)			
244d			2. Without prejudice to any other administrative or non-judicial remedy, each natural or legal person shall have the right to an effective judicial remedy where the digital health authority which is competent pursuant to Article 10 does not handle a complaint or does not inform the natural or legal person within three months		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			about the progress or outcome of the complaint lodged pursuant to Article 11.		
	Artic	le 11a(3)	L		
244e			3. Proceedings against a digital health authority shall be brought before the courts of the Member States where the digital health authority is established.		
	Artic	le 11A			

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
244f			Article 11A Relationship with data protection supervisory authorities	
	Article 11a(1)			
244g			1. The supervisory authority or authorities responsible for monitoring and enforcement of Regulation (EU) 2016/679 shall also be competent for monitoring and enforcement of the	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Commission Proposal	EP Mandate	application of Articles 8A to 8F, in accordance with the relevant provisions of Regulation (EU) 2016/679. They shall be competent to impose administrative fines up to the amount referred to in Article 83(5) of that Regulation. Those supervisory authorities and the digital health	Draft Agreement
		authorities referred to in Article 10 of this Regulation shall, where relevant, cooperate in the enforcement of this Regulation, within the remit of their respective competences.	

	Commission Proposa	1l	EP Mandate	Council Mandate	Draft Agreement
				[MOVED FROM ARTICLE 3(11)]	
	Sec	ction 2			
245	Section 2 Cross-border infrastructure for primary use of electronic health da		Section 2 Cross-border infrastructure for primary use of electronic health data	Section 2 Cross-border infrastructure for primary use of personal electronic health data	
	Art	ticle 12			
246	Article 12		Article 12	Article 12	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	MyHealth@EU		MyHealth@EU	MyHealth@EU	
	Article	12(1)	-	-	
247	1. The Commission shall establish a central platform for digital health to provide services to support and facilitate the exchange of electronic health data between national contact points for digital health of the Member States.		1. The Commission shall establish a central platform for digital health to provide services to support and facilitate the exchange of electronic health data between national contact points for digital health of the Member States.	1. The Commission shall establish a central and interoperability platform for digital health, MyHealth@EU , to provide services to support and facilitate the exchange of personal electronic health data between national contact points for digital health of the Member States.	

	Commission Proposal	ıl	EP Mandate	Council Mandate	Draft Agreement
	Arti	ticle 12(2)			
	2. Each Member State sha	all	2. Each Member State shall	2. Each Member State shall	
	designate one national contact point for digital health to ensure the		designate one national contact point for digital health to ensure the	designate one national contact point for digital health. The national	
	connection to all other national contact points for digital health and to the	r	connection to all other national contact points for digital health and to the	contact point shall be an organisational and technical gateway for the	
248	central platform for digital health. Where a designated	ed	central platform for digital health. Where a designated	provision of cross-border digital health information	
	national contact point is an entity consisting of multipl organisations responsible	ple	national contact point is an entity consisting of multiple organisations responsible	services in the context of healthcare of personal electronic health data,	
	for implementing different services, the Member State shall communicate to the		for implementing different services, the Member State shall communicate to the	enabling and ensuring to ensure the connection to all other national contact points	
	Commission a description of the separation of tasks	1	Commission a description of the separation of tasks	for digital health and to the central platform for digital	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
between the organisations.	between the organisations.	health in cross-border	
The national contact point	The national contact point	infrastructure	
for digital health shall be	for digital health shall be	MyHealth@EU. Where a	
considered an authorised	considered an authorised	designated national contact	
participant in the	participant in the	point is an entity consisting	
infrastructure. Each	infrastructure. Each	of multiple organisations	
Member State shall	Member State shall	responsible for	
communicate the identity of	communicate the identity of	implementing different	
its national contact point to	its national contact point to	services, the Member State	
the Commission by [the	the Commission by [the	shall communicate to the	
date of application of this	date of application of this	Commission a description	
Regulation]. Such contact	Regulation]. Such contact	of the separation of tasks	
point may be established	point may be established	between the organisations.	
within the digital health	within the digital health	The national contact point	
authority established by	authority established by	for digital health shall be	
Article 10 of this	Article 10 of this	considered an authorised	
Regulation. Member States	Regulation. Member States	participant in the	
shall communicate to the	shall communicate to the	infrastructure. Each	
Commission any	Commission any	Member State shall	
subsequent modification of	subsequent modification of	communicate inform of the	
the identity of those contact	the identity of those contact	identity of its national	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
points. The Commission and the Member States shall make this information publicly available.	points. The Commission and the Member States shall make this information publicly available.	contact point to the Commission by [the date of application of this Regulation]. Such contact point may be established within the digital health authority established by Article 10 of this Regulation. Member States shall communicate to inform the Commission of any subsequent modification of the identity of those contact points. The Commission and the Member States shall make this information publicly available.	

	Commission Prop	oosal		EP Mandate	Council Mandate	Draft Agreement
		Article 12(3)			
	3. Each national cont	act		3. Each national contact	3. Each national contact	
	point for digital health	h shall		point for digital health shall	point for digital health shall	
	enable the exchange of	of the		enable the exchange of the	enable the exchange of the	
	personal electronic he	alth		personal electronic health	personal electronic health	
	data referred to in Art	ticle 5		data referred to in Article 5	data referred to in Article 5	
	with all other national	1		with all other national	with all5(1) with national	
	contact points. The			contact points. The	contact points in other	
249	exchange shall be bas	sed on		exchange shall be based on	national contact	
	the European electron	nic		the European electronic	pointsMember States	
	health record exchang	ge		health record exchange	through MyHealth@EU.	
	format.			format.	The exchange shall be	
					based on the European	
					electronic health record	
					exchange format. National	
					contact point for digital	
					health may enable the	
					exchange of additional	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			categories of electronic health data referred to in Article 5(1A) insofar as Member State law has provided for these additional categories of personal electronic health to be accessed and exchanged, according to Article 5(1A).	
	Article 12(4)			
250	4. The Commission shall, by means of implementing acts, adopt the necessary measures for the technical development of	4. The Commission shall, by means of implementing acts, adopt the necessary measures for the technical development of	4. The Commission shall, by means of implementing acts, adopt the necessary measures for the technical development of	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
MyHealth@EU, detailed	MyHealth@EU, detailed	MyHealth@EU, detailed	
rules concerning the	rules concerning the	rules concerning the	
security, confidentiality and	security, confidentiality and	security, confidentiality and	
protection of electronic	protection of electronic	protection of personal	
health data and the	health data and the	electronic health data and	
conditions and compliance	conditions and compliance	the conditions and	
checks necessary to join	checks necessary to join and	compliance checks	
and remain connected to	remain connected to	necessary to join and	
MyHealth@EU and	MyHealth@EU and	remain connected to	
conditions for temporary or	conditions for temporary or	MyHealth@EU and	
definitive exclusion from	definitive exclusion from	conditions for temporary or	
MyHealth@EU. Those	MyHealth@EU. Those	definitive exclusion from	
implementing acts shall be	implementing acts shall be	MyHealth@EU. Those	
adopted in accordance with	adopted in accordance with	implementing acts shall be	
the advisory procedure	the advisoryexamination	adopted in accordance with	
referred to in Article 68(2).	procedure referred to in	the advisoryexamination	
	Article 68(2)68(2a). The	procedure referred to in	
	implementing act shall	Article 68(2).	
	include the target		
	implementation dates,		
	<u>including for cross border</u>		

Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
		health datainteroperability, inconsultation with theEHDS board. TheEuropean Union Agencyfor Cyber Security(ENISA) shall be consultedand closely involved in allsteps of the examinationprocedure. Any measuresadopted shall meet thehighest technical standardsin terms of security,confidentiality andprotection of electronichealth data.		
Article	2 12(5)	·	·	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
251	5. Member States shall ensure connection of all healthcare providers to their national contact points for digital health and shall ensure that those connected are enabled to perform two- way exchange of electronic health data with the national contact point for digital health.		5. Member States shall ensure connection of all healthcare providers to their national contact points for digital health and shall ensure that those connected are enabled to perform two- way exchange of electronic health data with the national contact point for digital health.	5. Member States shall ensure connection of all healthcare providers to their national contact points for digital health. Member States -and-shall ensure that those connectedconnected healthcare providers are enabled to perform two-way exchange of electronic health data with the national contact point for digital health.	
	Article	2 12(6)			

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	6. Member States shall	6. Member States shall	6. Member States shall	
	ensure that pharmacies	ensure that pharmacies	ensure that pharmacies	
	operating on their	operating on their	operating on their	
	territories, including online	territories, including online	territories , including online	
	pharmacies, are enabled to	pharmacies, are enabled to	pharmacies, are enabled to	
	dispense electronic	dispense electronic	dispense electronic	
	prescriptions issued by	prescriptions issued by	prescriptions issued by	
	other Member States, under	other Member States, under	other Member States, under	
252	the conditions laid down in	the conditions laid down in	the conditions laid down in	
	Article 11 of Directive	Article 11 of Directive	Article 11 of Directive	
	2011/24/EU. The	2011/24/EU. The	2011/24/EU. The	
	pharmacies shall access and	pharmacies shall access and	pharmacies shall access and	
	accept electronic	accept electronic	accept electronic	
	prescriptions transmitted to	prescriptions transmitted to	prescriptions transmitted to	
	them from other Member	them from other Member	them from other Member	
	States through	States through	States through	
	MyHealth@EU. Following	MyHealth@EU <u>, provided</u>	MyHealth@EU. Following	
	dispensation of medicinal	that the requirements in	dispensation of medicinal	
	products based on an	<u>Article 11 of Directive</u>	products based on an	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	electronic prescription from another Member State, pharmacies shall report the dispensation to the Member State that issued the prescription, through MyHealth@EU.		2011/24/EU are fulfilled. Following dispensation of medicinal products based on an electronic prescription from another Member State, pharmacies shall report the dispensation to the Member State that issued the prescription, through MyHealth@EU.	electronic prescription from another Member State, pharmacies shall report the dispensation to the Member State that issued the prescription, through MyHealth@EU.	
	Article	12(7)			
253	7. The national contact points for digital health shall act as joint controllers of the electronic health data communicated through		7. The national contact points for digital health shall act as joint controllers of the electronic health data communicated through	7. The national contact points for digital health shall act as joint controllers of the personal electronic health data	

	Commission Proposal	J	EP Mandate	Council Mandate	Draft Agreement
	'MyHealth@EU' for the processing operations in which they are involved. The Commission shall act as processor.	process which t	alth@EU' for the ing operations in ney are involved. mmission shall act essor.	communicated through 'MyHealth@EU' for the processing operations in which they are involved. The Commission shall act as processor.	
	Article 12(8)				
254	8. The Commission shall, by means of implementing acts, allocate responsibilities among controllers and as regards the processor referred to in paragraph 7 of this Article, in accordance with Chapter IV of Regulation (EU)	by mean acts, all respons controll the proc paragra	Commission shall, ns of implementing ocate ibilities among ers and as regards ressor referred to in ph 7 of this Article, dance with Chapter	8. By means of implementing acts, the Commission shall , by means of implementing acts, allocate responsibilities among controllers and as regards lay down the rules regarding the	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
2016/679. Those	Regulation Regulations	requirements of	
implementing acts shall be	(EU) 2016/679 <u>and</u>	cybersecurity, technical	
adopted in accordance with	<u>2018/1725</u> . Those	interoperability, semantic	
the advisory procedure	implementing acts shall be	interoperability,	
referred to in Article 68(2).	adopted in accordance with	operations and service	
	the advisory procedure	management in relation to	
	referred to in Article 68(2).	the processing by the	
		processor referred to in	
		paragraph 7 of this Article	
		and its responsibilities	
		towards the controllers, in	
		accordance with Chapter IV	
		of Regulation (EU)	
		2016/679 and of	
		Regulation (EU)	
		2018/1725. Those	
		implementing acts shall be	
		adopted in accordance with	
		the advisoryexamination	
		procedure referred to in	
		Article 68(2).	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	12(9)			
	9. The approval for		9. The approval for	9. The national contact	
	individual authorised		individual authorised	points referred to in	
	participants to join		participants to join	paragraph 2 shall be	
	MyHealth@EU for		MyHealth@EU for	authorised participants in	
	different services, or to		different services, or to	MyHealth@EU, provided	
	disconnect a participant		disconnect a participant	that they fulfil the	
255	shall be issued by the Joint		shall be issued by the Joint	conditions to join and to	
	Controllership group, based		Controllership group, based	remain connected to	
	on the results of the		on the results of the	MyHealth@EU as laid	
	compliance checks.		compliance checks.	down pursuant to	
				paragraph 4. The approval	
				for individual authorised	
				participants to join	
				MyHealth@EU for	
				different services, or to	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		disconnect a participant	
		shall be issued by the Joint	
		Controllership	
		groupCommission , based	
		on the results of the	
		compliance checks	
		performed by the	
		Commission.	
		Subject to the outcome of	
		the compliance check, the	
		Commission shall, by	
		means of implementing	
		act, take decisions to	
		connect individual	
		authorised participants to	
		join the infrastructure or	
		to disconnect them. These	
		implementing acts shall be	
		adopted in accordance	
		with the examination	
		procedure referred to in	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				Article 68(2).	
	Article	2 13			
256	Article 13 Supplementary cross-border digital health services and infrastructures		Article 13 Supplementary cross-border digital health services and infrastructures	Article 13 Supplementary cross-border digital health services and infrastructures	
	Article	2 13(1)			
257	 Member States may provide through MyHealth@EU 		 Member States may provide through MyHealth@EU 	 Member States may provide through MyHealth@EU 	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
supplementary services that	supplementary services that	supplementary services that	
facilitate telemedicine,	facilitate telemedicine,	facilitate telemedicine,	
mobile health, access by	mobile health, access by	mobile health, access by	
natural persons to their	natural persons to their	natural persons to their	
translated health data,	translated health data,	translated health data,	
exchange or verification of	exchange or verification of	exchange or verification of	
health-related certificates,	health-related certificates,	health-related certificates,	
including vaccination card	including vaccination card	including vaccination card	
services supporting public	services supporting public	services supporting public	
health and public health	health and public health	health and public health	
monitoring or digital health	monitoring or digital health	monitoring or digital health	
systems, services and	systems, services and	systems, services and	
interoperable applications,	interoperable applications,	interoperable applications,	
with a view to achieving a	with a view to achieving a	with a view to achieving a	
high level of trust and	high level of trust and	high level of trust and	
security, enhancing	security, enhancing	security, enhancing	
continuity of care and	continuity of care and	continuity of care and	
ensuring access to safe and	ensuring access to safe and	ensuring access to safe and	
high-quality healthcare. The	high-quality healthcare. The	high-quality healthcare. The	
Commission shall, by	Commission shall, by	Commission shall, by	
means of implementing	means of implementing	means of implementing	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	acts, set out the technical aspects of such provision. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2).		acts, set out the technical aspects of such provision. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2).	acts, set out the technical aspects of such provisionservices . Those implementing acts shall be adopted in accordance with the advisory examination procedure referred to in Article 68(2).	
	Article	2 13(2)	<u> </u>	<u> </u>	
258	2. The Commission and Member States may facilitate the exchange of electronic health data with other infrastructures, such as the Clinical Patient Management System or		2. The Commission and Member States may facilitate the exchange of electronic health data with other infrastructures, such as the Clinical Patient Management System or	2. The Commission and Member States may facilitate the exchange of personal electronic health data with other infrastructures, such as the Clinical Patient	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
commission Proposal other services or infrastructures in the health, care or social security fields which may become authorised participants to MyHealth@EU. The Commission shall, by means of implementing acts, set out the technical aspects of such exchanges. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2). The connection of another infrastructure to the central platform for digital health shall be subject to a decision of the joint controllership group for	EP Mandateother services orinfrastructures in the health,care or social security fieldswhich may becomeauthorised participants toMyHealth@EU. TheCommission shall, bymeans of implementingacts, set out the technicalaspects of such exchanges.Those implementing actsshall be adopted inaccordance with theadvisory procedure referredto in Article 68(2). Theconnection of anotherinfrastructure to the centralplatform for digital healthshall be subject to adecision of the jointcontrollership group for	Council MandateManagement System orother services orinfrastructures in the health,care or social security fieldswhich may becomeauthorised participants toMyHealth@EU. TheCommission shall, bymeans of implementingacts, set out the technicalaspects of such exchanges.Those implementing actsshall be adopted inaccordance with theadvisory examinationprocedure referred to inArticle 68(2).The connection of anotherinfrastructure to the centralplatform for digital health,	Draft Agreement
		as well as its	

Commission Proposal		EP Mandate	Council Mandate	Draft Agreement		
MyHealth@EU referred to in Article 66.		MyHealth@EU referred to in Article 66.	disconnection, shall be subject to a decision, by means of implementing acts, of the joint controllership group for MyHealth@EUCommissio n, based on the result of the compliance checks of the technical aspects of such exchanges as referred to in subparagraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 6668(2).			
Article 13(3), first subparagraph						

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
health data exchange.		requirements of	
Before adopting such an		MyHealth@EU for the	
implementing act, a		purposes of the electronic	
compliance check of the		health data exchange.	
national contact point of the		Before adopting such an	
third country or of the		implementing act, a	
system established at an		compliance check of the	
international level shall be		national contact point of the	
performed under the control		third country or of the	
of the Commission.		system established at an	
		international levelmay	
		become an authorised	
		participant in	
		MyHealth@EU provided	
		that they fulfil the	
		requirements of	
		MyHealth@EU for the	
		purposes of the personal	
		electronic health data	
		exchange as referred to in	
		Article 12, that the	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		transfer stemming from	
		such connection complies	
		with the rules in Chapter	
		V of Regulation (EU)	
		2016/679, and that the	
		requirements concerning	
		legal, organizational,	
		operational, semantic,	
		technical and	
		cybersecurity measures	
		are equivalent to those	
		applicable to Member	
		States in the operation of	
		MyHealth@EU services.	
		The requirements in	
		subparagraph 1 shall be	
		performed under the control	
		of verified through	
		compliance check	
		performed by the	
		Commission.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	13(3), second subparagraph			
	The implementing acts referred to in the first		deleted	The implementing acts referred to in the first	
	subparagraph of this paragraph shall be adopted in accordance with the procedure referred to in		ucrereu	subparagraph of this paragraph shall be adopted in accordance with the procedure referred to in	
260	Article 68. The connection of the national contact point of the third country or of			Article 68. The connection of Based on the outcome of the compliance check, the	
	the system established at an international level to the central platform for digital			Commission may, by means of implementing act, take the decision to	
	health, as well as the decision to be disconnected shall be subject to a			connect as well as to disconnect the national contact point of the third	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
decision of the joint		country or of the system	
controllership group for		established at an	
MyHealth@EU referred to		international level to the	
in Article 66.		central platform for digital	
		health, as well as the	
		decision to be	
		disconnectedMyHealth@E	
		U. Member States	
		national security interests	
		shall be taken into	
		account. These	
		implementing acts shall be	
		subject to a decision of the	
		joint controllership group	
		for MyHealth@EUadopted	
		in accordance with the	
		examination procedure	
		referred to in Article	
		66 68(2).	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement	
	Articl	e 13(3), third subparagraph	·			
261	The Commission shall make the list of implementing acts adopted pursuant to this paragraph publicly available.		deleted	The Commission shall makemaintain the list of implementing acts adopted national contact points of a third country or of systems established at an international level connected to MyHealth@EU pursuant to this paragraph and shall make it publicly available.		
	CHAPTER III					
262						

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	CHAPTER III		CHAPTER III	CHAPTER III	
	EHR systems and wellness applications		EHR systems and wellness applications	EHR systems and wellness applications	
	Section	n 1			
263	Section 1 General provisions for EHR systems		Section 1 General provisions for EHR systems	Section 1 Scope and general provisions for EHR systems	
	Article	13A			
263a				Article 13A	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				EHR harmonised components	
	Article	e 13a(1)			
263b				1. EHR systems shall include a 'European interoperability component for EHR systems' and a 'European logging component for EHR systems' (the 'harmonised components'), in accordance with the provisions laid down in this Chapter.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				[MOVED FROM ARTICLE 14(1)]	
	Article	e 13a(2)			
263c				2. This Chapter shall not apply to general purpose software used in a healthcare environment. [MOVED FROM ARTICLE 14(2)]	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	13B			
263d				Article 13B Placing on the market and putting into service [MOVED FROM ARTICLE 15]	
	Article	13b(1)			
263e				 EHR systems as referred to in Article 13A(1) may be placed on 	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				the market or put into service only if they comply with the provisions laid down in this Chapter.	
				[MOVED FROM ARTICLE 15(1)]	
	Article	e 13b(2)			
263f				2. EHR systems that are manufactured and used within health institutions established in the Union and EHR systems offered as a service within the	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		meaning of Article 1(1),	
		point (b), of Directive	
		(EU) 2015/1535 of the	
		European Parliament and	
		of the Council ¹ to a	
		natural or legal person	
		established in the Union	
		shall be considered as	
		having been put into	
		service.	
		1. [1] Directive (EU)	
		2015/1535 of the European Parliament and of the Council	
		of 9 September 2015 laying	
		down a procedure for the	
		provision of information in the	
		field of technical regulations and	
		of rules on Information Society	
		services (OJ L 241, 17.9.2015, p.	
		1).	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				[MOVED FROM ARTICLE 15(2)]	
	Article	13b(3)			
263g				3. Member States may not, for considerations relating to aspects concerning the harmonised components regulated by this Regulation, prohibit or restrict the placing on the market of EHR systems which comply with this	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				Regulation.	
	Article	14			
264	Article 14 Interplay with legislation governing medical devices and AI systems		Article 14 Interplay with legislation governing medical devices and AI systems	Article 14 Interplay with legislation governing medical devices, in vitro diagnostic medical devices and AI systems	
	Article	14(1)			
265	1. EHR systems intended by their manufacturer for		1. EHR systems intended by their manufacturer for	1. EHR systems intended by their manufacturer for	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	primary use of priority categories of electronic health data referred to in Article 5 shall be subject to the provisions laid down in this Chapter.		primary use of priority categories of electronic health data referred to in Article 5 shall be subject to the provisions laid down in this Chapter.	primary use of priority categories of electronic health data referred to in Article 5 shall be subject to the provisions laid down in this Chapter. [MOVED TO THE NEW ARTICLE 13A(1)]	
	Article	14(2)			
266	2. This Chapter shall not apply to general software used in a healthcare environment.		2. This Chapter shall not apply to general software used in a healthcare environment <u>that it is not</u>	2. This Chapter shall not apply to general software used in a healthcare environment.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			<u>interoperable with EHR</u> <u>systems</u> .	[MOVED TO THE NEW ARTICLE 13A(2)]	
	Article	14(3)			
267	3. Manufacturers of medical devices as defined in Article 2(1) of Regulation (EU) 2017/745 that claim interoperability of those medical devices with EHR systems shall prove compliance with the essential requirements on interoperability laid down in Section 2 of Annex II of		3. Manufacturers of medical devices as defined in Article 2(1) of Regulation (EU) 2017/745 that claim interoperability of those medical devices with EHR systems shall prove compliance with the essential requirements on interoperability laid down in Section 2 of Annex II of	31 . Manufacturers of medical devices as defined in Article 2(1) of Regulation (EU) 2017/745 and manufacturers of in vitro diagnostic medical devices as defined in Article 2(2) of Regulation (EU) 2017/746 that claim interoperability of those medical devices with the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	this Regulation. Article 23 of this Chapter shall be applicable to those medical devices.		this Regulation. Article 23 of this Chapter shall be applicable to those medical devices.	harmonised components of EHR systems shall prove compliance with the essential requirements on the European interoperability component	
				for EHR systems and the European logging component for EHR systems, laid down in Section 2 of Annex II of this Regulation. Article 23 of this Chapter shall be applicable to those medical devices.	
268	Article	14(4)			

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
4. Providers of high-risk AI	4. <i>Notwithstanding the</i>	42. Providers of high-risk	
systems as defined in	obligations laid down in	AI systems as defined in	
Article 6 of Regulation []	Regulation [AI act	Article 6 of Regulation []	
[AI act COM/2021/206	<u>COM/2021/206 final],</u>	[AI act COM/2021/206	
final], which does not fall	providers of high-risk AI	final], which does not fall	
within the scope of	systems as defined in	within the scope of	
Regulation (EU) 2017/745,	Article 6 of Regulation []	Regulation (EU) 2017/745,	
that claim interoperability	[AI act COM/2021/206	that claim interoperability	
of those AI systems with	final], which does do not fall	of those AI systems with	
EHR systems will need to	within the scope of	the harmonised	
prove compliance with the	Regulation (EU) 2017/745,	components of EHR	
essential requirements on	that claim interoperability	systems will need to prove	
interoperability laid down	of those AI systems with	compliance with the	
in Section 2 of Annex II of	EHR systems will need to	essential requirements on	
this Regulation. Article 23	prove compliance with the	the European	
of this Chapter shall be	essential requirements on	interoperability component	
applicable to those high-	interoperability laid down	for EHR systems and the	
risk AI systems.	in Section 2 of Annex II of	European logging	
	this Regulation. Article 23	component for EHR	
	of this Chapter shall be	systems, as further laid	
	applicable to those high-risk	down in Section 2 of Annex	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			AI systems.	II of this Regulation. Article 23 of this Chapter shall be applicable to those high-risk AI systems.	
	Article	2 14(5)			
269	5. Member States may maintain or define specific rules for the procurement, reimbursement or financing of EHR systems in the context of the organisation, delivery or financing of healthcare services.		5. Member States may maintain or define specific rules for the procurement, reimbursement or financing of EHR systems in the context of the organisation, delivery or financing of healthcare services.	5. Member States may maintain or define specific rules for the procurement, reimbursement or financing of EHR systems in the context of the organisation, delivery or financing of healthcare services.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				ARTICLE 16A]	
	Article	15			
270	Article 15 Placing on the market and putting into service		Article 15 Placing on the market and putting into service	Article 15 Placing on the market and putting into service [MOVED TO ARTICLE 13B(1)]	
	Article	15(1)			
271					

	Commission Proposal	EP Mandate Council Mandate Draft Agreement
	1. EHR systems may be placed on the market or put into service only if they comply with the provisions laid down in this Chapter.	1. EHR systems may be placed on the market or put into service only if they comply with the provisions laid down in <u>Section 3 of</u> this Chapter <u>and in Annex</u> 1. EHR systems may be placed on the market or put into service only if they comply with the provisions laid down in <u>Section 3 of</u> this Chapter <u>and in Annex</u>
	Article 15(2)	
27.	2. EHR systems that are manufactured and used within health institutions established in the Union and EHR systems offered as a service within the meaning of Article 1(1), point (b), of Directive (EU)	2. EHR systems that are manufactured and used2. EHR systems that are manufactured and usedwithin health institutionswithin health institutionsestablished in the Union andestablished in the Union andEHR systems offered as a service within the meaningervice within the meaningof Article 1(1), point (b), of Directive (EU) 2015/1535of Article 1(1), point (b), of

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
2015/1535 of the European Parliament and of the Council ¹ to a natural or legal person established in the Union shall be considered as having been put into service. 1. Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (OJ L 241, 17.9.2015, p. 1).	of the European Parliament and of the Council ¹ to a natural or legal person established in the Union shall be considered as having been put into service. 1. Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (OJ L 241, 17.9.2015, p. 1).	of the European Parliament and of the Council ⁺ to a natural or legal person established in the Union shall be considered as having been put into service. 	
		[MOVED TO ARTICLE 13B(2)]	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	16			
273	Article 16 Claims		Article 16 Claims	Article 16 Claims	
	Article	16, first paragraph			
274	In the information sheet, instructions for use or other information accompanying EHR systems, and in the advertising of EHR systems, it shall be		In the information sheet, instructions for use or other information accompanying EHR systems, and in the advertising of EHR systems, it shall be	In the information sheet, instructions for use or other information accompanying EHR systems, and in the advertising of EHR systems, it shall be	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	prohibited to use text, names, trademarks, pictures and figurative or other signs that may mislead the user with regard to its intended purpose, interoperability and security by:		prohibited to use text, names, trademarks, pictures and figurative or other signs that may mislead the <i>professional user as</i> <i>defined under Regulation</i> (<i>EU</i>) 2018/1807 ₄₅₆₇ with regard to its intended purpose, interoperability and security by:	prohibited to use text, names, trademarks, pictures and figurative or other signs that may mislead the user with regard to its intended purpose, interoperability and security by:	
	Article 16, first para				
275	(a) ascribing functions and properties to the EHR system which it does not have;		(a) ascribing functions and properties to the EHR system which it does not have;	(a) ascribing functions and properties to the EHR system which it does not have;	

	Commission Propo	osal		EP Mandate	Council Mandate	Draft Agreement
	<i>F</i>	Article	16, first paragraph, point (b)			
276	 (b) failing to inform the user of likely limitations related to interoperability or security features of the EHR system in relation to its intended purpose; 			(b) failing to inform the <i>professional</i> user of likely limitations related to interoperability or security features of the EHR system in relation to its intended purpose;	(b) failing to inform the user of likely limitations related to interoperability or security features of the EHR system in relation to its intended purpose;	
	Article 16, first paragraph, point (c)					
277	(c) suggesting uses for EHR system other than			(c) suggesting uses for the EHR system other than	(c) suggesting uses for the EHR system other than	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	those stated in the technical documentation to form part of the intended purpose.		those stated in the technical documentation to form part of the intended purpose.	those stated in the technical documentation to form part of the intended purpose.	
	Article	e 16A			
277a				Article 16A Procurement, reimbursement and financing of EHR systems	
	Article	e 16a, first paragraph			
277b				Member States may	

Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			maintain or define requirements for the procurement, reimbursement or financing of EHR systems in the context of the organisation, delivery or financing of healthcare services provided that such requirements are compliant with Union law and do not affect the harmonised components. [MOVED FROM ARTICLE 14(5)]	
Sectio	n 2			

	Commission Proposa	al	EP Mandate	Council Mandate	Draft Agreement
278	Section 2 Obligations of economic operators with regard to EHR systems		Section 2 Obligations of economic operators with regard to EHR systems	Section 2 Obligations of economic operators with regard to EHR systems	
	Art	ticle 17		I	
279	Article 17 Obligations of manufacturers of EHR systems		Article 17 Obligations of manufacturers of EHR systems	Article 17 Obligations of manufacturers of EHR systems	
	Art	ticle 17(1)			
280					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	1. Manufacturers of EHR systems shall:		1. Manufacturers of EHR systems shall:	1. Manufacturers of EHR systems shall with regard to the harmonised components referred to in Article 13A(1):	
	Article	17(1), point (a)			
281	(a) ensure that their EHR systems are in conformity with the essential requirements laid down in Annex II and with the common specifications in accordance with Article 23;		(a) <i>ensure thatobtain for</i> their EHR systems <i>are ina</i> <i>certificate of compliance</i> <i>from an independent third-</i> <i>party body to attest their</i> conformity with the essential requirements laid down in Annex II and with the common specifications in accordance with Article	(a) ensure that these harmonised components of their EHR systems are in conformity with the essential requirements laid down in Annex II and with the common specifications in accordance with Article 23;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			23;		
	Article	e 17(1), point (ab)			
281a				(ab) ensure that these components of their EHR systems are not impeded or negatively affected by other components of the same EHR system;	
	Article	e 17(1), point (b)			
282	(b) draw up the technical documentation of their		(b) draw up the technical documentation of their EHR	(b) draw up the technical documentation of their EHR	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	EHR systems in accordance with Article 24;		systems in accordance with Article 24 <u>before placing</u> <u>their systems on the</u> <u>market, and subsequently</u> <u>keep them up to date</u> ;	systems for these harmonised components in accordance with Article 24;	
	Article	17(1), point (c)			
283	(c) ensure that their EHR systems are accompanied, free of charge for the user, by the information sheet provided for in Article 25 and clear and complete instructions for use;		(c) ensure that their EHR systems are accompanied, free of charge for the user, by the information sheet provided for in Article 25 and clear and complete instructions for use <i>including in accessible</i> <i>formats for vulnerable</i> <i>groups and persons with</i>	(c) ensure that these harmonised components of their EHR systems are accompanied, free of charge for the user, by the information sheet provided for in Article 25 and clear and complete instructions for use;	

	Commission Prop	osal		EP Mandate	Council Mandate	Draft Agreement
				<u>disabilities;</u>		
		Article	17(1), point (d)			
284	(d) draw up an EU declaration of conform referred to in Article 2			(d) <i>draw up an EU</i> <i>declaration of</i> <i>conformitycarry out the</i> <i>relevant conformity</i> <i>assessment procedures</i> as referred to in Article <u>2627a</u> <i>and Annex IVa</i> ;	(d) draw up an EU declaration of conformity as referred to in Article 26;	
		Article	17(1), point (da)			
284a				(da) draw up the EU		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			declaration of conformity in accordance with Article 26;		
	Articl	e 17(1), point (e)			
285	(e) affix the CE marking in accordance with Article 27;		(e) affix the CE marking in accordance with Article 27 after the conformity assessment procedure has been completed;	(e) affix the CE marking for those harmonised components in accordance with Article 27;	
	Articl	e 17(1), point (ea)			
285a			(ea) indicate the name,		

Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
		registered trade name or registered trade mark, and the postal address and website, e-mail address or other digital contact at which they can be contacted, on the front office of the EHR system; the address shall indicate a		
		single point at which the manufacturer can be contacted and. the contact details shall be in a language that is easily understood by users and market surveillance authorities;		
Article	e 17(1), point (f)			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
286	(f) comply with the registration obligations in Article 32;		(f) comply with the registration obligations in Article 32;	(f) comply with the registration obligations for these harmonised components in Article 32;	
	Article	17(1), point (g)			
287	(g) take without undue delay any necessary corrective action in respect of their EHR systems which are not in conformity with the essential requirements laid down in Annex II, or recall or withdraw such systems;		(g) take without undue delay any necessary corrective action in respect of their EHR systems whichimmediately, where manufacturers consider or have reasons to believe that such systems are not or no longer in conformity with	(g) take without undue delay any necessary corrective action in respect of these harmonised components of their EHR systems which are not in conformity with the essential requirements laid down in Annex II, or recall	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			the essential requirements laid down in Annex II, or recall or withdraw such systems; the manufacturers shall then inform the national authorities of the Member States in which they made their EHR systems available or put them into service of the non-conformity and of any corrective action taken;	or withdraw such systems;	
	Article	17(1), point (h)			
288	(h) inform the distributors of their EHR systems and, where applicable, the		(h) <i>immediately</i> inform the distributors of their EHR systems and, where	(h) inform the distributors of their EHR systems and, where applicable, the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	authorised representative and importers of any corrective action, recall or withdrawal;		applicable, the authorised representative and importers of <u>the non-conformity and</u> <u>of</u> any corrective action, recall or withdrawal <u>of that</u> <u>system</u> ;	authorised representative, importers and the users and importers of any mandatory preventive maintenance and its frequency, corrective action, recall or withdrawal in relation to these harmonised components;	
	Article	17(1), point (i)			
289	 (i) inform the market surveillance authorities of the Member States in which they made their EHR systems available or put them into service of the 		deleted	 (i) inform the market surveillance authorities of the Member States in which they made their EHR systems available or put them into service of the 	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	non-conformity and of any corrective action taken;			non-conformity and of any corrective action taken, including the timetable for implementation, when those harmonised components of their EHR system have been brought into conformity and been recalled or withdrawn;	
	Article	17(1), point (j)			
290	(j) upon request of a market surveillance authority, provide it with all the information and documentation necessary to demonstrate the conformity		 (j) upon request of aprovide market surveillance authority, provide it authorities in the Member States with all the information and 	(j) upon request of a market surveillance authority, provide it with all the information and documentation necessary to demonstrate the conformity	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	of their EHR system with the essential requirements laid down in Annex II.		documentation <i>in paper or</i> <i>digital format</i> , necessary to demonstrate the conformity of <i>theirthe</i> EHR system <i>which they have placed on</i> <i>the market or put into</i> <i>service</i> with the essential requirements laid down in Annex II <i>and Article 27a in</i> <i>the official language of the</i> <i>Member State</i> .	of these harmonised components of their EHR system with the essential requirements laid down in Annex II.	
	Article	17(1), point (k)			
291	(k) cooperate with market surveillance authorities, at their request, on any action taken to bring their EHR		(k) cooperate with market surveillance authorities, at their request, on any action taken to bring their EHR	(k) cooperate with market surveillance authorities, at their request, on any action taken to bring these	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	systems in conformity with the essential requirements laid down in Annex II.		systems <u>which they have</u> <u>placed on the market or put</u> <u>into service</u> in conformity with the essential requirements laid down in Annex II <u>and Article 27a in</u> <u>the official language of the</u> <u>Member State</u> .	harmonised components of their EHR systems in conformity with the essential requirements laid down in Annex II.	
	Article	17(1), point (ka)			
291a			(ka) establish channels of complaint and keep a register of complaints, of non-conforming EHR systems, and keep distributors informed of any such monitoring.		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	17(2)			
	2. Manufacturers of EHR		2. Manufacturers of EHR	2. Manufacturers of EHR	
	systems shall ensure that		systems shall ensure that	systems shall ensure that	
	procedures are in place to		procedures are in place to	procedures are in place to	
	ensure that the design,		ensure that the design,	ensure that the design,	
	development and		development and	development and	
	deployment of an EHR		deployment of an EHR	deployment of the	
292	system continues to comply		system continues to comply	components of an EHR	
	with the essential		with the essential	system defined in Article	
	requirements laid down in		requirements laid down in	2(2)(nc)-(nd) continues to	
	Annex II and the common		Annex II and the common	comply with the essential	
	specifications referred to in		specifications referred to in	requirements laid down in	
	Article 23. Changes in EHR		Article 23 for EHR systems	Annex II and the common	
	system design or		<u>to remain in conformity</u>	specifications referred to in	
	characteristics shall be		with this Regulation.	Article 23 Changes in	
	adequately taken into		Changes in EHR system	EHR system design or	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
account and reflected in the technical documentation.	design or characteristics and changes in the technical standards and the technical specifications referred to in Annex II and III by reference to which the conformity of the EHR system is declared shall be adequately taken into account and reflected in the technical documentation.	characteristics with regard to these harmonised components shall be adequately taken into account and reflected in the technical documentation.	
	Manufacturers shall establish reporting channels and ensure their accessibility to allow users to submit complaints, and shall keep a register of complaints, of non- conforming EHR systems		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			and EHR system recalls.		
	Artic	cle 17(3)			
	3. Manufacturers of EHR		3. Manufacturers of EHR	3. Manufacturers of EHR	
	systems shall keep the		systems shall keep the	systems shall keep the	
	technical documentation		technical documentation	technical documentation	
	and the EU declaration of		and the EU declaration of	and the EU declaration of	
	conformity for 10 years		conformity <i>at the disposal</i>	conformity for 10 years	
293	after the last EHR system		<u>of the market surveillance</u>	after the last components of	
293	covered by the EU		<u>authorities for at least</u> for	the EHR system defined in	
	declaration of conformity		10 years after the last EHR	Article 2(2)(nc)-(nd)	
	has been placed on the		system covered by the EU	covered by the EU	
	market.		declaration of conformity	declaration of conformity	
			has been placed on the	hashave been placed on the	
			market. The source code or	market.	
			the programming logic		
			<u>included in the technical</u>		

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	documentation shall, upon		
	<u>a reasoned request, be</u>		
	made available to the		
	competent national		
	authorities, if that source		
	<u>code or programming logic</u>		
	<u>is necessary in order for</u>		
	them to be able to check		
	<u>compliance with the</u>		
	<u>essential requirements set</u>		
	<u>out in Annex II. The</u>		
	personnel of competent		
	<u>national authorities shall</u>		
	<u>observe professional</u>		
	secrecy with regard to all		
	information obtained in		
	<u>carrying out the conformity</u>		
	<u>assessment activities in</u>		
	accordance with Annexes		
	IVa, except in relation to		
	the competent authorities		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			of the Member State in which their activities are carried out. Proprietary rights, intellectual property rights and trade secrets shall be protected. Manufacturers shall establish reporting channels and ensure their accessibility to allow users to submit complaints, keep a register of complaints, of non-conforming EHR systems and EHR systems recalls.		
	Articl	e 17(3a)			
293a					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			3a. <u>A manufacturer of</u> <u>EHR systems established</u> <u>outside the Union shall</u> <u>ensure that its authorised</u> <u>representative has the</u> <u>necessary documentation</u> <u>readily available in order to</u> <u>fulfil the tasks referred to</u> <u>in Article 18(2).</u>		
	Article	17(3b)		I	
293b			<u>3b. Manufacturers shall,</u> <u>further to a reasoned</u> <u>request from a market</u> <u>surveillance authority,</u> <u>provide it with all the</u> <u>information and</u>		

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	documentation, in paper or		
	electronic form, necessary		
	to demonstrate the		
	<u>conformity of the EHR</u>		
	<u>system with the essential</u>		
	<u>requirements set out in</u>		
	Annex II and the common		
	specifications referred to in		
	Article 23, in a language		
	<u>which can be easily</u>		
	understood by that		
	<u>authority. They shall</u>		
	<u>cooperate with that</u>		
	<u>authority, at its request, on</u>		
	<u>any measures taken to</u>		
	<u>eliminate the risks posed by</u>		
	the EHR system, which		
	<u>they have placed on the</u>		
	<u>market or put into service.</u>		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	17(3c)		·	
293c			3c. Liability rules under Directive 85/374/EEC, shall apply to manufacturers of EHR systems without prejudice to more protective measures under national law.		
	Article	18			
294	Article 18 Authorised representatives		Article 18 Authorised representatives	Article 18 Authorised representatives	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	e 18(1)			
295	1. Prior to making an EHR system available on the Union market, a manufacturer of an EHR system established outside of the Union shall, by written mandate, appoint an authorised representative which is established in the Union.		1. Prior to making an EHR system available on the Union market, a manufacturer of an EHR system established outside of the Union shall, by written mandate, appoint an authorised representative which is established in the Union.	1. Prior to making an EHR system available on the Union market, a manufacturer of an EHR system established outside of the Union shall, by written mandate, appoint an authorised representative which is established in the Union.	
	Article	e 18(2)			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
296	2. An authorised representative shall perform the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to do at least the following:		2. An authorised representative shall perform the tasks specified in the mandate <i>received</i> <i>fromagreed with</i> the manufacturer. The mandate shall allow the authorised representative to do at least the following:	2. An authorised representative shall perform the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to do at least the following:	
	Article	18(2), point (a)			
297	(a) keep the EU declaration of conformity and the technical documentation at the disposal of market		(a) keep the EU declaration of conformity and the technical documentation at the disposal of <i>the Member</i>	(a) keep the EU declaration of conformity and the technical documentation at the disposal of market	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	surveillance authorities for the period referred to in Article 17(3);		<u>State</u> market surveillance authorities for the period referred to in Article 17(3);	surveillance authorities for the period referred to in Article 17(3);	
	Article	18(2), point (b)			
298	(b) further to a reasoned request from a market surveillance authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of an EHR system with the essential requirements laid down in Annex II;		(b) further to a reasoned request from a market surveillance <i>authority</i> , <i>provide that</i> <i>authorityprovide</i> <i>authorities of the Member</i> <i>States concerned a copy of</i> <i>the mandate</i> with all the information and documentation necessary to demonstrate the conformity of an EHR system with the	(b) further to a reasoned request from a market surveillance authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of an EHR system with the essential requirements laid down in Annex II as well as the common specifications in accordance with Article	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			essential requirements laid down in Annex II;	23;	
	Article	e 18(2), point (ba)			
298a			(ba) immediately inform the manufacturer if the authorised representative has a reason to believe that an EHR system is no longer in conformity with the essential requirements laid down in Annex II;		
	Article	e 18(2), point (bb)			

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
298b		(bb) immediately inform the manufacturer about complaints received by consumers and professional users;		
	Article 18(2), point	(c)		
299	(c) cooperate with the market surveillance authorities, at their request, on any corrective action taken in relation to the EHR systems covered by their mandate.	(c) cooperate with the market surveillance authorities <i>in the Member</i> <i>State</i> , at their request, on any corrective action taken in relation to the EHR systems covered by their mandate.	(c) cooperate with the market surveillance authorities, at their request, on any corrective action taken in relation to the components of the EHR systems defined in Article 2(2)(nc)-(nd) covered by	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				their mandate.	
	Article	18(2), point (d)		-	
299a				(d) terminate the mandate if the manufacturer acts contrary to its obligations under this Regulation.	
	Article	18(2), point (e)	L		
299b				(e) ensure that the technical documentation can be made available to	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				those authorities, upon request.	
				[[MOVED FROM ARTICLE 19(6)]]	
	Article	18(2a)			
299c			2a. In the event of a change of the authorised representative, the detailed arrangements for the change shall address at least the following aspects: (a) the date of termination of the mandate of the		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			outgoing authorised representative and the date of the beginning of the mandate of the incoming authorised representative;(b) the transfer of documents, including confidentiality aspects and property rights.		
	Article	19			
300	Article 19 Obligations of importers		Article 19 Obligations of importers	Article 19 Obligations of importers	
	Article	19(1)	·	·	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
301	1. Importers shall place on the Union market only EHR systems which are in conformity with the essential requirements laid down in Annex II.		1. Importers shall place on the Union market only EHR systems which are in conformity with the essential requirements laid down in Annex II.	1. Importers shall place on the Union market only EHR systems which are in conformity with the essential requirements in relation to the harmonised components of EHR systems as laid down in Annex II as well as the common specifications in accordance with Article 23.	
	Article	19(2)	L		
302	2. Before making an EHR		2. Before making an EHR	2. Before making an EHR	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	system available on the market, importers shall ensure that:		system available on the market, importers shall ensure that:	system available on the market, importers shall ensure that:	
	Article	19(2), point (a)			
303	(a) the manufacturer has drawn up the technical documentation and the EU declaration of conformity;		(a) the manufacturer has drawn up the technical documentation and obtained a certificate of compliance from an independent third body to attest to the relevant conformity assessment procedure referred to in Article 27a and drawn up the EU declaration of conformity <u>in accordance</u>	(a) the manufacturer has drawn up the technical documentation and the EU declaration of conformity;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			with Article 26; and drawn up the technical documentation, in accordance with Article 24, before placing their system on the market;		
	Article	e 19(2), point (aa)			
303a			(aa) the manufacturer is identified and an authorised representative in accordance with Article 18 has been appointed;		
	Article	e 19(2), point (b)			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
304	(b) the EHR system bears the CE marking of conformity;		(b) the EHR system bears the CE marking of conformity <u>referred to in</u> <u>Article 27 after the</u> <u>conformity assessment</u> <u>procedure has been</u> <u>completed</u> ;	(b) the EHR system bears the CE marking of conformity;	
	Article	19(2), point (c)			
305	(c) the EHR system is accompanied by the information sheet referred to in Article 25 and appropriate instructions for use.		(c) the EHR system is accompanied by the information sheet referred to in Article 25 <i>with clear</i> <i>and completeand</i> <i>appropriate</i> instructions for	(c) the EHR system is accompanied by the information sheet referred to in Article 25 and appropriate instructions for use, including	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			use <u>including in accessible</u> <u>formats</u> .	maintenance actions.	
	Article	2 19(3)			
306	3. Importers shall indicate their name, registered trade name or registered trade mark and the address at which they can be contacted in a document accompanying the EHR system.		3. Importers shall indicate their name, registered trade name or registered trade mark and the <i>postal</i> address <i>and website, e-mail address</i> <i>or other digital contact</i> at which they can be contacted in a document accompanying the EHR system. <i>The address shall</i> <i>indicate a single point at</i> <i>which the manufacturer</i> <i>can be contacted. The</i>	3. Importers shall indicate their name, registered trade name or registered trade mark and the address at which they can be contacted in a document accompanying the EHR system.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			contact details shall be in a language easily understood by users and the market surveillance authorities. They shall ensure that any additional label does not obscure any information on the label provided by the manufacturer.		
	Article	19(4)			
307	4. Importers shall ensure that, while an EHR system is under their responsibility, the EHR system is not altered in such a way that its conformity with the		4. Importers shall ensure that, while an EHR system is under their responsibility, the EHR system is not altered in such a way that its conformity with the	4. Importers shall ensure that, while an EHR system is under their responsibility, the EHR system is not altered in such a way that its conformity with the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	essential requirements laid		essential requirements laid	essential requirements laid	
	down in Annex II is		down in Annex II <u>and</u>	down in Annex II is	
	jeopardised.		Article 27a is jeopardised.	jeopardised.	
	Article	19(5)		l	
	5. Where an importer		5. Where an importer	5. Where an importer	
	considers or has reason to		considers or has reason to	considers or has reason to	
	believe that an EHR system		believe that an EHR system	believe that an EHR system	
	is not in conformity with		is not <u>or no longer</u> in	is not in conformity with	
308	the essential requirements		conformity with the	the essential requirements in	
500	in Annex II, it shall not		essential requirements in	Annex II, it shall not make	
	make that system available		Annex II and Article 27a, it	that system available on the	
	on the market until that		shall not make that system	market until that system has	
	system has been brought		available on the market, or	been brought into	
	into conformity. The		<u>shall recall it or withdraw</u>	conformity. The importer	
	importer shall inform		<u>it if was already available</u>	shall inform without undue	
	without undue delay the		<u>on the market,</u> until that	delay the manufacturer of	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
manufacturer of such EHR	system has been brought	such EHR system, the	
system and the market	into conformity. The	users and the market	
surveillance authorities of	importer shall inform	surveillance authorities of	
the Member State in which	without undue	the Member State in which	
it made the EHR system	delay immediately the	it made the EHR system	
available, to that effect.	manufacturer of such EHR	available on the market	
	system and the market	where this situation	
	surveillance authorities of	occurs, to that effect.	
	the Member State in which		
	it made the EHR system		
	available, to that effect.		
	<u>giving details, in</u>		
	particular, of the non-		
	<u>conformity and of any</u>		
	<u>corrective measures, recall</u>		
	<u>or withdrawal of that</u>		
	system taken. Where an		
	importer considers or has		
	reason to believe that an		
	EHR system presents a risk		
	<u>to the health or safety of</u>		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			natural persons, it shall immediately inform the market surveillance authority of the Member State in which the importer is established, as well as the manufacturer and where applicable, the authorised representative.		
	Article	19(6)			
309	6. Importers shall keep a copy of the EU declaration of conformity at the disposal of the market surveillance authorities for the period referred to in		6. Importers shall keep a copy of the EU declaration of conformity at the disposal of the market surveillance authorities for the period referred to in	6. Importers shall keep a copy of the EU declaration of conformity at the disposal of the market surveillance authorities for the period referred to in	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 17(3) and ensure that the technical documentation can be made available to those authorities, upon request.		Article 17(3) and ensure that the technical documentation can be made available to those authorities, upon request.	Article 17(3) and ensure that the technical documentation can be made available to those authorities, upon request. [[MOVED TO ARTICLE 18(2)(e)]]	
	Article	19(7)			
310	7. Importers shall, further to a reasoned request from a market surveillance authority, provide it with all the information and		 7. Importers shall, further to a reasoned request from a market surveillance authority, authorities of Member States concerned 	7. Importers shall, further to a reasoned request from a market surveillance authority, provide it with all the information and	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
documentation necessary to	provide it with all the	documentation necessary to	
demonstrate the conformity	information and	demonstrate the conformity	
of an EHR system in the	documentation <i>in paper or</i>	of harmonised	
official language of the	digital format necessary to	components of an EHR	
Member State where the	demonstrate the conformity	system in the official	
market surveillance	of an EHR system. <i>They</i>	language of the Member	
authority is located. They	shall cooperate with that	State where the market	
shall cooperate with that	authority, at its request,	surveillance authority is	
authority, at its request, on	and with the manufacturer	located. They shall	
any action taken to bring	and, where applicable, with	cooperate with that	
their EHR systems in	the manufacturer's	authority, at its request, on	
conformity with the	authorised representative	any action taken to bring	
essential requirements laid	in the official language of	their EHR systems in	
down in Annex II.	the Member State where the	conformity with the	
	market surveillance	essential requirements in	
	authority is located. They	relation to those	
	shall cooperate with that	components as laid down	
	authority, at its request, on	in Annex II.	
	any action taken to bring		
	their EHR systems in		
	conformity with the		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			essential requirements laid down in Annex II <u>, and</u> <u>Article 27a, or to ensure</u> <u>that their EHR systems are</u> <u>withdrawn or recalled</u> .		
	Article	19(7a)			
310a			7a. <u>Manufacturers shall</u> <u>establish reporting</u> <u>channels and ensure their</u> <u>accessibility to allow users</u> <u>to submit complaints, keep</u> <u>a register of complaints, of</u> <u>non-conforming EHR</u> <u>systems and EHR systems</u> <u>recalls. Importers shall</u> <u>verify whether the</u>		

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	established channels of		
	<u>complaint referred to in</u>		
	Article 17(2) are publicly		
	available allowing them to		
	submit complaints and		
	<u>communicate any risk</u>		
	related to their health and		
	<u>safety or to other aspects of</u>		
	public interest protection		
	and of any serious incident		
	involving an EHR system.		
	<u>If such channels are not</u>		
	<u>available, the importer</u>		
	<u>shall provide for them,</u>		
	taking into account the		
	accessibility needs of		
	vulnerable groups and		
	<u>persons with disabilities.</u>		

	Commission Prop	osal		EP Mandate	Council Mandate	Draft Agreement
		Article	19(7b)			
310b				7b. Importers shallinvestigate complaints andinformation on incidentsinformation on incidentsinvolving an EHR systemthey made available on themarket and file thosecomplaints, as well as ofsystem recalls and anycorrective measures takento bring the EHR systeminto conformity, in theregister referred to inArticle 17(3d) or in theirown internal register.Importers shall keep themanufacturer, distributorsand, where relevant,		

	Commission Prop	osal		EP Mandate	Council Mandate	Draft Agreement
				authorised representatives informed in a timely manner of the investigation performed and of the results of the investigation.		
		Article	20			
311	Article 20 Obligations of distrib	outors		Article 20 Obligations of distributors	Article 20 Obligations of distributors	
	Article 20(1)					
312	1. Before making an I	EHR		1. Before making an EHR	1. Before making an EHR	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	system available on the market, distributors shall verify that:	system available on the market, distributors shall verify that:	system available on the market, distributors shall verify that: with regard to the harmonised components of EHR systems	
	Article 20(1), poin	(a)		
313	(a) the manufacturer has drawn up the EU declaration of conformity;	(a) the manufacturer has obtained a certificate of compliance from an independent third body to attest to the relevant conformity assessment procedure referred to in Article 27a and has drawn up the EU declaration of	(a) the manufacturer has drawn up the EU declaration of conformity;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			conformity <u>, in accordance</u> with Article 26, and the technical documentation, in accordance with Article 24, before placing their system on the market;		
	Article	20(1), point (b)			
314	(b) the EHR system bears the CE marking of conformity;		(b) the EHR system bears the CE marking of conformity <u>referred to in</u> <u>Article 27 after the</u> <u>conformity assessment</u> <u>procedure has been</u> <u>completed</u> ;	(b) the EHR system bears the CE marking of conformity;	

	Commission Prop	posal	EP Mandate	Council Mandate	Draft Agreement
		Article 20(1), point (c)			
315	(c) the EHR system i accompanied by the information sheet refe to in Article 25 and appropriate instructio use;	erred	(c) the EHR system is accompanied by the information sheet referred to in Article 25 <u>with clear</u> <u>and complete</u> and <u>complete</u> instructions for use <u>in accessible formats</u> ;	(c) the EHR system is accompanied by the information sheet referred to in Article 25 and appropriate instructions for use;	
		Article 20(1), point (d)			
316	(d) where applicable, importer has complied the requirements set of Article 19(3).	d with	(d) where applicable, the importer has complied with the requirements set out in Article 19(3).	(d) where applicable, the importer has complied with the requirements set out in Article 19(3).	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement		
	Article	e 20(2)					
317	2. Distributors shall ensure that, while an EHR system is under their responsibility, the EHR system is not altered in such a way that its conformity with the essential requirements laid down in Annex II is jeopardised.		2. Distributors shall ensure that, while an EHR system is under their responsibility, the EHR system is not altered in such a way that its conformity with the essential requirements laid down in Annex II <i>and</i> <i>Article 27a</i> is jeopardised.	2. Distributors shall ensure that, while an EHR system is under their responsibility, the EHR system is not altered in such a way that its conformity with the essential requirements with regards to the EHR harmonised components laid down in Annex II is jeopardised.			
	Article 20(3)						

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
318	3. Where a distributor considers or has reason to believe that an EHR system is not in conformity with the essential requirements laid down in Annex II, it shall not make the EHR system available on the market until it has been brought into conformity. Furthermore, the distributor shall inform without undue delay the manufacturer or the importer, as well as the market surveillance authorities of the Member states where the EHR system has been made available on the market, to	3. Where a distributor considers or has reason to believe that an EHR system is not in conformity with the essential requirements laid down in Annex II <u>and</u> <u>Article 27a</u> , it shall not make the EHR system available on the market, <u>or</u> <u>shall recall it or withdraw</u> it if was already available on the market, until it has been brought into conformity. Furthermore, the distributor shall inform without undue delayimmediately the manufacturer or the importer, as well as the	3. Where a distributor considers or has reason to believe that an EHR system is not in conformity with the essential requirements laid down in Annex II, it shall not make the EHR system available on the market until it has been brought into conformity with the harmonised components of EHR systems. Furthermore, the distributor shall inform without undue delay the manufacturer or the importer and the users, as well as the market surveillance authorities of	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Commission Proposal that effect.	market surveillance authorities of the Member states where the EHR system has been made available on the market, to that effect. <u>Where a</u> <u>distributor considers or has</u> <u>reason to believe that an</u> <u>EHR system presents a risk</u> <u>to the health or safety of</u>	Council Mandate the Member states where the EHR system has been made available on the market, to that effect.	Draft Agreement
	natural persons, it shall immediately inform the market surveillance authority of the Member State in which the distributor is established, as well as the manufacturer, the importer and where applicable, the authorised representative.		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	20(4)			
	4. Distributors shall,		4. Distributors shall, further	4. Distributors shall, further	
	further to a reasoned		to a reasoned request from a	to a reasoned request from a	
	request from a market		market surveillance	market surveillance	
	surveillance authority,		authority, provide it with all	authority, provide it with all	
	provide it with all the		the information and	the information and	
	information and		documentation necessary to	documentation necessary to	
319	documentation necessary to		demonstrate the conformity	demonstrate the conformity	
	demonstrate the conformity		of an EHR system. They	of an EHR system with	
	of an EHR system. They		shall cooperate with that	regard to the harmonised	
	shall cooperate with that		authority, at its request, and	components of EHR	
	authority, at its request, on		<u>with the manufacturer, the</u>	systems. They shall	
	any action taken to bring		importer and, where	cooperate with that	
	their EHR systems in		applicable, with the	authority, at its request, on	
	conformity with the		<u>manufacturer's authorised</u>	any action taken to bring	
	essential requirements laid		representative on any action	their EHR systems in	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	down in Annex II.		taken to bring <i>theirthe</i> EHR systems in conformity with the essential requirements laid down in Annex II or to withdraw or recall it.	conformity with the essential requirements laid down in Annex II in relation to those two components.	
	Article	21		1	
320	Article 21 Cases in which obligations of manufacturers of an EHR system apply to importers and distributors		Article 21 Cases in which obligations of manufacturers of an EHR system apply to <i>importers</i> <i>and distributors economic</i> <i>operators</i>	Article 21 Cases in which obligations of manufacturers of an EHR system apply to importers and distributors	
	Article	e 21, first paragraph			

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	An importer or distributor	An importer or distributor	An importer or a distributor	
	shall be considered a manufacturer for the	shall be considered a manufacturer <mark>If any</mark>	shall be considered a manufacturer for the	
	purposes of this Regulation and shall be subject to the obligations laid down in	<u>economic operator other</u> <u>than the manufacturer</u> makes modifications to the	purposes of this Regulation and shall be subject to the obligations laid down in	
	Article 17, where they made an EHR system	<u>EHR system whilst</u> deploying or using it,	Article 17, where they made an EHR system available on	
321	available on the market under their own name or	which lead to changes in the intended purpose and	the market under their own name or trademark or	
	trademark or modify an EHR system already placed	<u>deployment</u> <u>recommendations</u> for the	modify an EHR system already placed on the	
	on the market in such a way that conformity with the applicable requirements	purposes of this Regulation and shall be subject <u>EHR</u> system as declared by the	market in such a way that conformity with the applicable requirements	
	may be affected.	manufacturer, in any case of any malfunctioning or	may be affected.	
		<i>deterioration in</i> <i>performance quality due</i> to		

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	the obligations laid down in		
	Article 17, where they made		
	<mark>an<mark>changes made by the</mark></mark>		
	<u>economic operator during</u>		
	<u>deployment or use of the</u>		
	EHR system available on		
	the market under their own		
	name or trademark or		
	modify an EHR system		
	already placed on the		
	market in such a way that		
	conformity with the		
	applicable requirements		
	may be affected<mark>contrary to</mark>		
	the manufacturer's		
	recommendations for		
	<u>technical deployment of the</u>		
	system or purpose of its		
	use, the economic operator		
	<u>shall be considered a</u>		
	manufacturer for the		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement			
			purposes of this Regulation and shall be subject to the obligations laid down in Article 17.					
	Artic	e 22						
322	Article 22 Identification of economic operators		Article 22 Identification of economic operators	Article 22 Identification of economic operators				
	Article 22, first paragraph							
323	Economic operators shall,		Economic operators shall,	Economic operators shall,				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement		
	on request, identify the following to the market surveillance authorities, for 10 years after the last EHR system covered by the EU declaration of conformity has been placed on the market:		on request, identify the following to the market surveillance authorities, for 10 years after the last EHR system covered by the EU declaration of conformity has been placed on the market:	on request, identify the following to the market surveillance authorities, for 10 years after the last EHR system covered by the EU declaration of conformity has been placed on the market:			
	Article	22, first paragraph, point (a)					
324	(a) any economic operator who has supplied them with an EHR system;		(a) any economic operator who has supplied them with an EHR system;	(a) any economic operator who has supplied them with an EHR system;			
	Article 22, first paragraph, point (b)						

	Commission Proposal	1	EP Mandate	Council Mandate	Draft Agreement			
325	(b) any economic operator to whom they have supplie an EHR system.		(b) any economic operator to whom they have supplied an EHR system.	(b) any economic operator to whom they have supplied an EHR system.				
	Sect	ction 3						
326	Section 3 Conformity of the EHR system		Section 3 Conformity of the EHR system Assessment	Section 3 Conformity of the EHR system				
	Article 23							
327	Article 23		Article 23	Article 23				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Common specifications		Common specifications	Common specifications	
	Article	23(1), first subparagraph			
328	 The Commission shall, by means of implementing acts, adopt common specifications in respect of the essential requirements set out in Annex II, including a time limit for implementing those common specifications. Where relevant, the common specifications shall take into account the specificities of medical devices and high risk AI 		1. The Commission shall, by means of implementing acts, adopt common specifications in respect of the essential requirements set out in Annex II, including a <u>common</u> <u>template document and a</u> time limit for implementing those common specifications. Where relevant, the common specifications shall take into account the specificities <u>and</u>	1. The Commission shall, by means of implementing acts, adopt common specifications in respect of the essential requirements set out in Annex II, including a time limit for implementing those common specifications. Those common specifications shall be based on existing harmonised standards for the harmonised	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
systems referred to in	verify compatibility with	components of EHR	
paragraphs 3 and 4 of	sectoral legislation and	systems, where applicable.	
Article 14.	harmonised standards of	Where relevant, the	
	medical devices and high	common specifications shall	
	risk AI systems referred to	take into account the	
	in paragraphs 3 and 4 of	specificities and verify	
	Article 14, <i>including the</i>	compatibility with	
	state-of-the art standards	sectorial legislation and	
	for health informatics and	harmonised standards of	
	the European electronic	medical devices and high	
	health record exchange	risk AI systems referred to	
	<u>format</u> .	in paragraphs 3 and 41 and	
		2 of Article 14, including	
		the state-of-the-art	
		standards for health	
		informatics and the	
		European electronic	
		health record exchange	
		format.	

	Commission Proposa	վ	EP Mandate	Council Mandate	Draft Agreement
	Art	ticle 23(1), second subparagraph			
329	Those implementing acts shall be adopted in accordance with the advisory procedure referre to in Article 68(2).		Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2) <u>after</u> <u>consultation with the</u> <u>EHDS board and the</u> <u>Advisory Forum</u> .	Those implementing acts shall be adopted in accordance with the advisory examination procedure referred to in Article 68(2).	
	Art	ticle 23(2)			
330	 The common specifications referred to i paragraph 1 shall include 		 The common specifications referred to in paragraph 1 shall include 	2. The common specifications referred to in paragraph 1 shall include	

	Commission Prop	oosal	EP Mandate	Council Mandate	Draft Agreement
	the following element	ts:	the following elements:	the following elements:	
		Article 23(2), point (a)			
33	1 (a) scope;		(a) scope;	(a) scope;	
		Article 23(2), point (b)			
33	(b) applicability to different categories of systems or functions included in them;	fEHR	(b) applicability to different categories of EHR systems or functions included in them;	(b) applicability to different categories of EHR systems or functions included in them;	

	Commission Prop	oosal		EP Mandate	Council Mandate	Draft Agreement
		Article	23(2), point (c)		·	
333	(c) version;			(c) version;	(c) version;	
		Article	23(2), point (d)			
334	(d) validity period;			(d) validity period;	(d) validity period;	
		Article	23(2), point (e)			
335	(e) normative part;			(e) normative part;	(e) normative part;	

	Commission Prop	posal		EP Mandate	Council Mandate	Draft Agreement
		Article	23(2), point (f)			
336	(f) explanatory part, including any relevan implementation guide			(f) explanatory part, including any relevant implementation guidelines.	(f) explanatory part, including any relevant implementation guidelines.	
		Article	23(3)			
337	3. The common specifications may in- elements related to th following:			3. The common specifications may include elements related to the following:	3. The common specifications may include elements related to the following:	
	1	Article 2	23(3), point (a)		1	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
338	(a) datasets containing electronic health data and defining structures, such as data fields and data groups for the representation of clinical content and other parts of the electronic health data;		(a) datasets containing electronic health data and defining structures, such as data fields and data groups for the representation of clinical content and other parts of the electronic health data;	(a) datasets containing electronic health data and defining structures, such as data fields and data groups for the representation of clinical content and other parts of the electronic health data;	
	Article	23(3), point (b)			
339	(b) coding systems and values to be used in datasets containing electronic health data;		(b) coding systems and values to be used in datasets containing electronic health data;	(b) coding systems and values to be used in datasets containing electronic health data, taking due account of both the future	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				harmonisation of terminologies and their compatibility with existing national terminologies;	
	Artio	cle 23(3), point (c)			
340	(c) other requirements related to data quality, such as the completeness and accuracy of electronic health data;	1	(c) other requirements related to data quality, such as the completeness and accuracy of electronic health data;	(c) other requirements related to data quality, such as the completeness and accuracy of electronic health data;	
	Artio	cle 23(3), point (d)			
341					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	(d) technical specifications, standards and profiles for the exchange of electronic health data;		(d) technical specifications, standards and profiles for the exchange of electronic health data;	(d) technical specifications, standards and profiles for the exchange of electronic health data;	
	Article	e 23(3), point (e)			
342	(e) requirements and principles related to security, confidentiality, integrity, patient safety and protection of electronic health data;		(e) requirements and principles related to security, confidentiality, integrity, patient safety and protection of electronic health data;	(e) requirements and principles related to security, confidentiality, integrity, patient safety and protection of electronic health data;	
	Article	e 23(3), point (f)	I		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
343	(f) specifications and requirements related to identification management and the use of electronic identification.	(f) specifications and requirements related to identification management and the use of electronic identification.	(f) specifications and requirements related to identification management and the use of electronic identification.	
	Article 23(4)			
344	4. EHR systems, medical devices and high risk AI systems referred to in Article 14 that are in conformity with the common specifications referred to in paragraph 1 shall be considered to be in	4. EHR systems, medical devices and high risk AI systems referred to in Article 14 that are in conformity with the common specifications referred to in paragraph 1 shall be considered to be in	4. EHR systems, medical devices, in vitro diagnostic medical devices and high risk AI systems referred to in ArticleArticles 13A and 14 that are in conformity with the common specifications referred to in	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	conformity with the essential requirements covered by those specifications or parts thereof, set out in Annex II covered by those common specifications or the relevant parts of those common specifications.		conformity with the essential requirements covered by those specifications or parts thereof, set out in Annex II covered by those common specifications or the relevant parts of those common specifications.	paragraph 1 shall be considered to be in conformity with the essential requirements covered by those specifications or parts thereof, set out in Annex II covered by those common specifications or the relevant parts of those common specifications.	
	Article	23(4a)			
344a			4a. Where common specifications have an impact on data protection requirements for EHR		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			systems, they shall be subject to consultation with the European Data Protection Board (EDPB) and the European Data Protection Supervisor (EDPS) before their adoption, pursuant to Article 42(2) of Regulation (EU) 2018/1725.		
	Article	23(5)			
345	5. Where common specifications covering interoperability and security requirements of EHR systems affect medical		5. Where common specifications covering interoperability and security requirements of EHR systems affect medical	5. Where common specifications covering interoperability and security requirements of EHR systems affect medical	

Commission Proposal	 EP Mandate	Council Mandate	Draft Agreement
devices or high-risk AI	devices or high-risk AI	devices, in vitro diagnostic	
systems falling under other	systems falling under other	medical devices or high-	
acts, such as Regulations	acts, such as Regulations	risk AI systems falling	
(EU) 2017/745 or [] [AI	(EU) 2017/745 or [] [AI	under other acts, such as	
Act COM/2021/206 final],	Act COM/2021/206 final],	Regulations (EU) 2017/745	
the adoption of those	the adoption of those	and (EU) 2017/746 or []	
common specifications may	common specifications	[AI Act COM/2021/206	
be preceded by a	mayshall be preceded by a	final], the Commission	
consultation with the	consultation with the	shall ensure that the	
Medical Devices	Medical Devices	adoption of those common	
Coordination Group	Coordination Group	specifications shall have	
(MDCG) referred to in	(MDCG) referred to in	been may be preceded by a	
Article 103 of Regulation	Article 103 of Regulation	consultation with the	
(EU) 2017/745 or the	(EU) 2017/745 or the	Medical Devices	
European Artificial	European Artificial	Coordination Group	
Intelligence Board referred	Intelligence Board referred	(MDCG) referred to in	
to in Article 56 of	to in Article 56 of	Article 103 of Regulation	
Regulation [] [AI Act	Regulation [] [AI Act	(EU) 2017/745 or the	
COM/2021/206 final], as	COM/2021/206 final], as	European Artificial	
applicable.	applicable <u>, as well as the</u>	Intelligence Board referred	
	EDPB referred to in Article	to in Article 56 of	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		<u>68 of Regulation (EU)</u> 2016/679	Regulation [] [AI Act COM/2021/206 final], as applicable.	
	Article 23(6)			
346	6. Where common specifications covering interoperability and security requirements of medical devices or high-risk AI systems falling under other acts such as Regulation (EU) 2017/745 or	6. Where common specifications covering interoperability and security requirements of medical devices or high-risk AI systems falling under other acts such as Regulation (EU) 2017/745 or	6. Where common specifications covering interoperability and security requirements of medical devices, in vitro diagnostic medical devices or high- risk AI systems falling under other acts such as	
	Regulation [] [AI Act COM/2021/206 final], impact EHR systems, the adoption of those common	Regulation [] [AI Act COM/2021/206 final], impact EHR systems, the adoption of those common	RegulationRegulations (EU) 2017/745 and (EU) 2017/746 or Regulation [] [AI Act	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	specifications shall be preceded by a consultation with the EHDS Board, especially its subgroup for Chapters II and III of this Regulation.		specifications shall be preceded by a consultation with the EHDS Board, especially its subgroup for Chapters II and III of this Regulation, <i>and, where</i> <i>applicable, the EDPB</i> <i>referred to in Article 68 of</i> <i>Regulation (EU) 2016/679</i> .	COM/2021/206 final], impact EHR systems, the Commission shall ensure that the adoption of those common specifications shall behave been preceded by a consultation with the EHDS Board, especially its subgroup for Chapters II and III of this Regulation.	
	Article	24			
347	Article 24 Technical documentation		Article 24 Technical documentation	Article 24 Technical documentation	

	Commission Prop	oosal		EP Mandate	Council Mandate	Draft Agreement
		Article	24(1)			
348	1. The technical documentation shall t drawn up before the E system is placed on th market or put into ser and shall be kept up-t date.	EHR ne vice		1. <i>The technical</i> <i>documentationManufacture</i> <i>rs</i> shall <i>be drawn updraw</i> <i>up technical</i> <i>documentation</i> before the EHR system is placed on the market or put into service and shall be kept up- to-date.	1. The technical documentation shall be drawn up before the EHR system is placed on the market or put into service and shall be kept up-to-date.	
		Article	24(2)			
349	2. The technical documentation shall b	oe		2. The technical documentation shall be	2. The technical documentation shall be	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
drawn up in such a way as	drawn up in such a way as	drawn up in such a way as	
to demonstrate that the	to demonstrate that the EHR	to demonstrate that the EHR	
EHR system complies with	system complies with the	system complies with the	
the essential requirements	essential requirements laid	essential requirements laid	
laid down in Annex II and	down in Annex II and	down in Annex II and	
provide market surveillance	provide market surveillance	provide market surveillance	
authorities with all the	authorities with all the	authorities with all the	
necessary information to	necessary information to	necessary information to	
assess the conformity of the	assess the conformity of the	assess the conformity of the	
EHR system with those	EHR system with those	EHR system with those	
requirements. It shall	requirements. It shall	requirements. It shall	
contain, at a minimum, the	contain, at a minimum, the	contain, at a minimum, the	
elements set out in Annex	elements set out in Annex	elements set out in Annex	
III.	III. Where the system or	III.	
	any part of it complies with		
	European standards or		
	common specifications, the		
	list of the relevant		
	European standards and		
	common specifications		
	<u>shall also be indicated.</u>		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	24(2a)			
349a			2a. <u>To ensure conformity,</u> a single unified template for technical documentation shall be provided by the Commission.		
	Article	24(3)			
350	3. The technical documentation shall be drawn up in one of the		3. The technical documentation shall be drawn up in <i>one of</i> the	3. The technical documentation shall be drawn up in one of the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	official languages of the Union. Following a reasoned request from the market surveillance authority of a Member State, the manufacturer shall provide a translation of the relevant parts of the technical documentation into the official language of that Member State.		official <i>languages</i> language of the <i>UnionMember State</i> <i>concerned</i> . Following a reasoned request from the market surveillance authority of a Member State, the manufacturer shall provide a translation of the relevant parts of the technical documentation into the official language of that Member State.	official languages of the Union. Following a reasoned request from the market surveillance authority of a Member State, the manufacturer shall provide a translation of the relevant parts of the technical documentation into the official language of that Member State.	
	Article	24(4)			
351	4. When a market surveillance authority requests the technical		4. When a market surveillance authority requests the technical	4. When a market surveillance authority requests the technical	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
documentation or a	documentation or a	documentation or a	
translation of parts thereof	translation of parts thereof	translation of parts thereof	
from a manufacturer, it	from a manufacturer, it shall	from a manufacturer, it shall	
shall set a deadline of 30	set a deadline of 30 days for	set a deadline of 30 days for	
days for receipt of such	receipt of such	receipt of such	
documentation or	documentation or	documentation or	
translation, unless a shorter	translation, unless a shorter	translation, unless a shorter	
deadline is justified because	deadline is justified because	deadline is justified because	
of a serious and immediate	of a serious and immediate	of a serious and immediate	
risk. If the manufacturer	risk. If the manufacturer	risk. If the manufacturer	
does not comply with the	does not comply with the	does not comply with the	
requirements of paragraphs	requirements of paragraphs	requirements of paragraphs	
1, 2 and 3, the market	1, 2 and 3, the market	1, 2 and 3, the market	
surveillance authority may	surveillance authority may	surveillance authority may	
require it to have a test	require it to have a test	require it to have a test	
performed by an	performed by an	performed by an	
independent body at its own	independent body at its own	independent body at its own	
expense within a specified	expense within a specified	expense within a specified	
period in order to verify the	period in order to verify the	period in order to verify the	
conformity with the	conformity with the	conformity with the	
essential requirements laid	essential requirements laid	essential requirements laid	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	down in Annex II and the common specifications referred to in Article 23.		down in Annex II and the common specifications referred to in Article 23.	down in Annex II and the common specifications referred to in Article 23.	
	Article	25			
352	Article 25 Information sheet accompanying the EHR system		Article 25 Information sheet accompanying the EHR system	Article 25 Information sheet accompanying the EHR system	
	Article	25(1)			
353	1. EHR systems shall be		1. EHR systems shall be	1. The harmonised	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	accompanied by an information sheet that includes concise, complete, correct and clear information that is relevant, accessible and comprehensible to users.		accompanied by an information sheet that includes concise, complete, correct and clear information that is relevant, accessible and comprehensible to <i>professional</i> users.	components of EHR systems shall be accompanied by an information sheet that includes concise, complete, correct and clear information that is relevant, accessible and comprehensible to users.	
	Article	25(2)			
354	2. The information sheet referred to in paragraph 1 shall specify:		2. The information sheet referred to in paragraph 1 shall specify:	2. The information sheet referred to in paragraph 1 shall specify:	

	Commission Prop	osal		EP Mandate	Council Mandate	Draft Agreement		
		Article	25(2), point (a)					
355	(a) the identity, regist trade name or register trademark, and the co details of the manufac and, where applicable authorised representat	ed ntact cturer , of its		(a) the identity, registered trade name or registered trademark, and the contact details of the manufacturer <i>including the postal and e-</i> <i>mail address and the</i> <i>telephone number</i> and, where applicable, of its authorised representative;	(a) the identity, registered trade name or registered trademark, and the contact details of the manufacturer and, where applicable, of its authorised representative;			
	Article 25(2), point (aa)							
355a				(aa) If the EHR system is not accompanied by the				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			information sheet referred to in this Article and by clear and complete instructions for use in accessible formats for persons with disabilities, the manufacturer of the EHR system concerned, its authorised representative and all other relevant economic operators shall be required to add to the EHR system that information sheet and those instructions for use.		
	Artic	le 25(2), point (b)			
356					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	(b) the name and version of the EHR system and date of its release;		(b) the name and version of the EHR system and date of its release;	(b) the name and version of the EHR system and date of its release;	
	Article	25(2), point (c)			
357	(c) its intended purpose;		(c) its intended purpose;	(c) its intended purpose;	
	Article	e 25(2), point (d)			
358	(d) the categories of electronic health data that the EHR system has been designed to process;		(d) the categories of electronic health data that the EHR system has been designed to process;	(d) the categories of electronic health data that the EHR system has been designed to process;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	25(2), point (e)			
359	(e) the standards, formats and specifications and versions thereof supported by the EHR system.		(e) the standards, formats and specifications and versions thereof supported by the EHR system.	(e) the standards, formats and specifications and versions thereof supported by the EHR system.	
	Article	25(3)			
360	3. The Commission is empowered to adopt delegated acts in accordance with Article 67 to supplement this		3. The Commission is empowered to adopt delegated acts in accordance with Article 67 to supplement this Regulation	3. The Commission is empowered to adopt delegated acts in accordance with Article 67 to supplement this Regulation	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Regulation by allowing		by allowing manufacturers	by allowing As an	
	manufacturers to enter the		to enter the information	alternative to supplying	
	information referred to in		referred to in paragraph 2	the information sheet	
	paragraph 2 into the EU		into the EU database of	referred to in paragraph 1	
	database of EHR systems		EHR systems and wellness	with the EHR system,	
	and wellness applications		applications referred to in	manufacturers tomay enter	
	referred to in Article 32, as		Article 32, as an alternative	the information referred to	
	an alternative to supplying		to supplying the	in paragraph 2 into the EU	
	the information sheet		information sheet referred	database of EHR systems	
	referred to in paragraph 1		to in paragraph 1 with the	and wellness applications	
	with the EHR system.		EHR system.	referred to in Article 32 , as	
				an alternative to supplying	
				the information sheet	
				referred to in paragraph 1	
				with the EHR system.	
	Article	26	I		
361					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 26		Article 26	Article 26	
	EU declaration of conformity		EU declaration of conformity	EU declaration of conformity	
	Article	26(1)			
362	1. The EU declaration of conformity shall state that the manufacturer of the EHR system has demonstrated that the essential requirements laid down in Annex II have been fulfilled.		1. The EU declaration of conformity shall state that the manufacturer of the EHR system has demonstrated that the essential requirements laid down in Annex II have been fulfilled.	1. The EU declaration of conformity shall state that the manufacturer of the EHR system has demonstrated that the essential requirements laid down in Annex II have been fulfilled.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	the identification of the Union legislation to which the declaration relates.		the identification of the Union legislation to which the declaration relates.	the identification of the Union legislation to which the declaration relates.	
	Article 2	26(3)			
364	3. The EU declaration of conformity shall, as a minimum, contain the information set out in Annex IV and shall be translated into one or more official Union languages determined by the Member State(s) in which the EHR system is made available.		3. The EU declaration of conformity shall, as a minimum, contain the information set out in Annex IV and shall be translated into one or more official Union languages determined by the Member State(s) in which the EHR system is made available. <u>Manufacturers shall</u> provide a translation of the	3. The EU declaration of conformity shall , as a minimum, contain the information set out in Annex IV and shall be translated into one or more official Union languages determined by the Member State(s) in which the EHR system is made available.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			relevant parts of the technical documentation into the official language of the Member States where they have placed products on the market.		
	Article	26(3a)			
364a			3a. Digital EU declarations of conformity shall be made accessible online for the expected lifetime of the EHR system and in any event for at least 10 years after the placing on the market or the putting into service of		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			<u>the EHR system.</u>		
	Artio	cle 26(4)			
365	4. By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for the conformity of the EHR system.		4. By drawing up the EU declaration of conformity , the manufacturer] shall assume responsibility for the <i>conformity_compliance</i> of the EHR system <i>with the</i> <i>requirements laid down in</i> <i>this Regulation</i> .	4. By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for the conformity of the EHR system when it is placed on the market or put into service.	
	Artio	cle 26(4a)			
365a					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			4a. The Commission is empowered to adopt delegated acts in accordance with Article 67 in order to amend the minimum content of the EU declaration of conformity set out in Annex IV.		
	Article	26(4b)			
365b			<u>4b.</u> <u>The Commission shall</u> <u>publish a standard</u> <u>uniformed template for the</u> <u>EU declaration of</u> <u>conformity and make it</u> <u>available in a digital</u>		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			<u>format in all the official</u> <u>Union languages.</u>		
_	Article	26A			
365c				Article 26A European digital testing environment	
	Article	26a(1)			
365d				1. The Commission shall set up and operate a European digital testing	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				environment to support the assessment of harmonised components of EHR systems	
	Article	26a(2)			
365e				2. Member States may set up digital testing environment to support the assessment of harmonised components of EHR systems. Such environments shall comply with the common specifications for digital testing environments laid down pursuant paragraph	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			4 and shall be communicated to the Commission.	
	Article 26a(3)			
365f			3. Manufacturers shall use the testing environments mentioned in paragraphs 1 and 2 as a supporting element for the assessment of harmonised components of EHR systems. The results of the test shall be included in the documentation referred to in Article 24. The conformity to this	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				regulation shall be presumed in respect of the elements tested with positive results.	
	Article	26a(4)	L		
365g				4. The Commission shall, by means of implementing acts, lay down the common specifications for digital testing environments. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 68(2).	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Articl	e 27			
366	Article 27 CE marking	e 27(1)	Article 27 CE marking	Article 27 CE marking	
367	1. The CE marking shall be affixed visibly, legibly and indelibly to the accompanying documents of the EHR system and, where applicable, to the		1. The CE marking shall be affixed visibly, legibly and indelibly to the accompanying documents of the EHR system and, where applicable, to the	1. The CE marking shall be affixed visibly, legibly and indelibly to the accompanying documents of the EHR system and, where applicable, to the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	packaging.		packaging.	packaging.	
	Article	27(1a)			
367a			<u>1a.</u> <u>The CE marking shall</u> <u>be affixed before making</u> <u>the EHR system available</u> <u>on the market.</u>		
	Article	27(2)			
368	2. The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC)		 2. The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) 	2. The CE marking shall be subject to the general principles set out in Article30 of Regulation (EC)	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	765/2008 of the European Parliament and of the Council ¹ . 1. Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30).		765/2008 of the European Parliament and of the Council ¹ .	765/2008 of the European Parliament and of the Council ¹ .	
	Article	27(2a)			
368a			<u>2a.</u> <u>Where EHR systems</u> <u>are subject to other Union</u>		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			law in respect of aspects not covered by this Regulation, which also requires the affixing of the CE marking, the CE marking shall indicate that the systems also fulfil the requirements of that other law.		
	Article	27(2b)			
368b			2b. <u>Member States shall</u> <u>build upon existing</u> <u>mechanisms to ensure</u> <u>correct application of the</u> <u>regime governing the CE</u> <u>marking and shall take</u>		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			appropriate action in the event of improper use of that marking.		
	Article	27a			
368c			<u>Article 27a</u> <u>Conformity assessment for</u> <u>EHR systems</u>		
	Article	27a(1)			
368d			1. In order to certify the conformity of an EHR		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			system with this Regulation, prior to placing an EHR system on the market, the manufacturer, its authorised representative, or any economic operator referred to in Article 21 shall apply for a conformity assessment procedure.		
	Article	27a(2)			
368e			2. Notified bodies shall take into account the specific interests and needs of SMEs when setting the		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement		
			fees for conformity assessment and reduce those fees proportionately to their specific interests and needs.				
	Article	27a(3), first subparagraph					
368f			2. <u>The conformity</u> assessment procedure shall require the notified body to assess:				
	Article 27a(3), first subparagraph, point (a)						
368g							

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement		
			(a) whether the EHR system is in conformity with the requirements laid down in Annex II;				
	Article	e 27a(3), first subparagraph, po	int (b)				
368h			(b) whether the EHR system is in conformity with the requirements laid down in Regulation (EU) / [(Cyber Resilience Act COM/2022/457];				
	Article 27a(3), first subparagraph, point (c)						

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
368i			(<u>c)</u> whether the technical documentation is available and complete;		
	Article	27a(3), first subparagraph, poi	int (d)		
368j			(d) whether the technical design of an EHR system meets the applicable requirements of this Regulation as provided for in an EU type examination procedure laid down in Annex IVa;		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	27a(3), second subparagraph	·	·	
368k			The EU type-examination is the part of a conformity assessment procedure in which a notified body examines the technical design of an EHR system and verifies and attests that the technical design of the EHR system meets the applicable requirements of this Regulation.		
	Article	27a(3), third subparagraph			
3681					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			Only after an Union wide approval has been issued, may the CE marking be affixed, together with an identification number.		
	Articl	e 27A			
368 m				Article 27A National requirements and reporting to the Commission	
	Articl	e 27a(1)			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
368n				1. Member States may introduce national requirements for EHR systems and provisions on their conformity assessment in relation to aspects other than the harmonised components of EHR systems.	
	Article	27a(2)			
3680				2. National requirements or provisions on assessment referred to in paragraph 1 shall not	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				impede or adversely interact with the harmonised components of EHR systems.	
	Article	27a(3)			
368p				3. When Member States adopt regulations in accordance with paragraph 1, they shall inform thereabout the Commission.	
	Article	27aa			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
368q			<u>Article 27aa</u> <u>General principles of the</u> <u>CE marking</u>		
	Article	27aa, first subparagraph			
368r			<u>The CE marking shall be</u> <u>subject to the general</u> <u>principles set out in Article</u> <u>30 of Regulation (EC) No</u> <u>765/2008.</u>		
	Article	27b		·	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
368s			<u>Article 27b</u> <u>Notification</u>		
	Article	27b, first subparagraph			
368t			<u>Member States shall</u> <u>notify the Commission and</u> <u>the other Member States of</u> <u>conformity assessment</u> <u>bodies authorised to carry</u> <u>out conformity assessments</u> <u>in accordance with this</u> <u>Regulation.</u>		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Artic	le 27c			
368u			<u>Article 27c</u> <u>Notifying authorities</u>		
	Artic	le 27c(1)			
368v			1. <u>Member States shall</u> designate a notifying authority that shall be responsible for setting up and carrying out the necessary procedures for the assessment and notification of conformity assessment bodies and the		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			monitoring of notified bodies, including compliance with Article 27h.		
	Arti	cle 27c(2)			
368 w			2. Member States may decide that the assessment and monitoring referred to in paragraph 1 shall be carried out by a national accreditation body within the meaning of and in accordance with Regulation (EC) No 765/2008.		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	e 27c(3)			
368x			3. Where the notifying authority delegates or otherwise entrusts the assessment, notification or monitoring referred to in paragraph 1 of this Article to a body, which is not a governmental entity that body shall be a legal entity and shall comply mutatis mutandis with the requirements laid down in Article 27e. In addition,		
			<u>that body shall have</u> arrangements to cover		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement		
			<u>liabilities arising out of its</u> <u>activities.</u>				
	Article	27c(4)					
368y			4. The notifying authority shall take full responsibility for the tasks performed by the body referred to in paragraph 3				
	Article 27d						
368z			<u>Article 27d</u>				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement		
			<u>Requirements relating to</u> <u>notifying authorities</u>				
	Article	27d(1)					
368a a			1. <u>A notifying authority</u> shall be established in such a way that no conflict of interest with conformity assessment bodies occurs.				
	Article 27d(2)						
368a b			2. <u>A notifying authority</u>				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			<u>shall be organised and</u> <u>operated so as to safeguard</u> <u>the objectivity and</u> <u>impartiality of its activities.</u>		
	Article	27d(3)			
368a c			3. <u>A notifying authority</u> shall be organised in such a way that each decision relating to notification of a conformity assessment body is taken by competent persons other than those who carried out the assessment of the EHR system.		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement		
	Article	e 27d(4)					
368a d			4. <u>A notifying authority</u> shall not offer or provide any activities that conformity assessment bodies perform, or consultancy services on a commercial or competitive basis.				
	Article 27d(5)						
368a e			5. <u>A notifying authority</u>				

	Commission Proposa	ıl	EP Mandate	Council Mandate	Draft Agreement
			<u>shall safeguard the</u> <u>confidentiality of the</u> information it obtains.		
	Art	ticle 27d(6)			
368a f			6. <u>A notifying authority</u> shall have a sufficient number of competent personnel at its disposal for the proper performance of its tasks.		
	Art	ticle 27e			
368a					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
g			<u>Article 27e</u> <u>Information obligation on</u> <u>notifying authorities</u>		
	Article	27e(1)			
368a h			<u>Member States shall</u> <u>inform the Commission of</u> <u>their procedures for the</u> <u>assessment and notification</u> <u>of conformity assessment</u> <u>bodies and the monitoring</u> <u>of notified bodies, and of</u> <u>any changes thereto. The</u> <u>Commission shall make</u> <u>that information publicly</u> <u>available.</u>		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	27f			
368a i			<u>Article 27f</u> <u>Requirements relating to</u> <u>notified bodies</u>		
	Article	27f(1)			
368a j			1. For the purposes of notification, a conformity assessment body shall meet the requirements laid down in paragraphs 2 to 11.		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	27f(2)			
368a k			2. <u>A conformity</u> assessment body shall be established under the national law of a Member State and have legal personality.		
	Article	27f(3)			
368a 1			<u>3.</u> <u>A conformity</u> assessment body shall be a third-party body		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			<u>independent of the</u> <u>organisation or the EHR</u> <u>system it assesses.</u>		
	Article	27f(4)			
368a m			4. <u>A conformity</u> <u>assessment body, its top-</u> <u>level management and the</u> <u>personnel responsible for</u> <u>carrying out the conformity</u> <u>assessment tasks shall not</u> <u>be the designer,</u> <u>manufacturer, supplier,</u> <u>installer, purchaser, owner,</u> <u>user or maintainer of an</u> <u>EHR system, that they</u> <u>assess, or the</u>		

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	representative of any of		
	those parties. A conformity		
	assessment body, its top-		
	level management and the		
	<u>personnel responsible for</u>		
	carrying out the conformity		
	<u>assessment tasks shall not</u>		
	<u>be directly involved in the</u>		
	<u>design, manufacture,</u>		
	<u>marketing, installation, use</u>		
	<u>or maintenance of EHR</u>		
	<u>systems, or represent the</u>		
	<u>parties engaged in those</u>		
	<u>activities. They shall not</u>		
	<u>engage in any activity that</u>		
	<u>may conflict with their</u>		
	<u>independence of judgement</u>		
	<u>or integrity in relation to</u>		
	<u>conformity assessment</u>		
	<u>activities for which they are</u>		
	<u>notified. This shall in</u>		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			particular apply to consultancy services. A conformity assessment body shall ensure that the activities of its subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of its conformity assessment activities.		
	Article	27f(5)			
368a n			5. <u>A conformity</u> assessment body and its personnel shall carry out the conformity assessment activities with the highest		

Commission Pro	pposal	EP Mandate	Council Mandate	Draft Agreement
		degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence its judgement or the results of its conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.		
	Article 27g(6)			
368a				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
0			<u>6.</u> <u>The personnel</u> <u>responsible for carrying</u> <u>out conformity assessment</u> <u>tasks shall have the</u> <u>following:</u>		
	Article	27g(6), point (a)			
368a p			(a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified;		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	27g(6), point (b)			
368a q			(b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;		
	Article	27g(6), point (c)			
368a r			(c) appropriate knowledge and understanding of the applicable harmonised standards and common specifications referred to in		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			this Regulation, and of the relevant provisions of Union harmonisation legislation and of national legislation;		
	Artic	le 27g(6), point (d)			
368a s			(d) the ability to draw up certificates, records and reports demonstrating that conformity assessments have been carried out.		
	Artic	le 27g(7)	·	·	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
368a t			7. <u>A conformity</u> assessment body shall take out liability insurance unless liability is assumed by the Member State in accordance with national law, or the Member State itself is directly responsible for the conformity assessment.		
	Article	27g(8)			
368a u			<u>8.</u> <u>The personnel of a</u> <u>conformity assessment</u> <u>body shall observe</u>		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement	
			professional secrecy with regard to all information obtained in carrying out the conformity assessment activities in accordance with Annexes IVa, except in relation to the competent authorities of the Member State in which its activities are carried out. Proprietary rights, intellectual property rights and trade secrets shall be protected.			
	Article 27g(9)					
368a v			<u>9.</u> <u>A conformity</u> assessment body shall			

Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
		participate in, or ensure that its personnel responsible for carrying out the conformity assessment activities are informed of, the relevant standardisation activities and the activities of the notified body coordination group established under Article 27r and shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group.		
Article	27f(6), first subparagraph			

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
368a w		6.A conformityassessment body shall becapable of carrying out allthe conformity assessmentactivities mentioned inAnnexes IVa in relation towhich it has been notified,whether those tasks arecarried out by theconformity assessmentbody itself or on its behalfand under itsresponsibility. At all times,and for each conformityassessment procedure andeach kind of a EHR systemfor which it has beennotified, a conformity		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			<u>at its disposal the</u> <u>necessary:</u>		
	Article	27f(6), first subparagraph, poi	nt (a)		
368a x			(a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment activities;		
	Article	27f(6), first subparagraph, poi	nt (b)	-	
368a у			(b) descriptions of		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			procedures in accordance with which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures;		
	Article	27f(6), first subparagraph, poi	nt (c)		
368a z			(c) appropriate policies and procedures to distinguish between activities that it carries out as a notified body and other activities;		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	27f(6), first subparagraph, poi	nt (d)		
368b a			(d) procedures for the performance of conformity assessment activities which take due account of the size of an undertaking, the sector in which it operates, its structure and the degree of complexity of the technology in question.		
	Article	27f(6), second subparagraph			
368b b			<u>A conformity assessment</u> body shall have the means		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and shall have access to all necessary equipment or facilities.		
	Article	27f(8), first subparagraph			
368b c			8. The impartiality of a conformity assessment body, its top-level management and the personnel responsible for carrying out the conformity		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			<u>assessment activities shall</u> <u>be guaranteed.</u>		
	Article	27f(8), second subparagraph			
368b d			The remuneration of the top-level management and the personnel responsible for carrying out the conformity assessment activities shall not depend on the number of conformity assessments carried out or on the results of those assessments.		

	Commission Prop	posal	EP Mandate	Council Mandate	Draft Agreement
		Article 27g			
368b e			<u>Article 27g</u> <u>Presumption of conformity</u> <u>of notified bodies</u>		
		Article 27g(1)			
368b f			Where a conformity assessment body demonstrates its conformity with the criteria laid down in the relevant harmonised standards the references of which have been published in the Official Journal of		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			the European Union, it shall be presumed to comply with the requirements set out in Article 27g in so far as the applicable harmonised standards cover those requirements.		
	Article	27h			
368b g			<u>Article 27h</u> <u>Use of subcontractors and</u> <u>subsidiaries by notified</u> <u>bodies</u>		

	Commission Prop	oosal		EP Mandate	Council Mandate	Draft Agreement
	·	Article	27h(1)			
368b h				1. Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in Article 27fand shall inform the notifying authority accordingly.		
		Article	27h(2)	·		
368b						

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
i			2. <u>A notified body shall</u> take full responsibility for the tasks performed by subcontractors or subsidiaries wherever those are established.		
	Article	27h(3)			
368b j			3. Activities may be subcontracted or carried out by a subsidiary only with the agreement of the client.		
	Article	27h(4)			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
368b k			4. <u>A notified body shall</u> <u>keep at the disposal of the</u> <u>notifying authority the</u> <u>relevant documents</u> <u>concerning the assessment</u> <u>of the qualifications of the</u> <u>subcontractor or the</u> <u>subsidiary and the work</u> <u>carried out by them under</u> <u>Annex IVa.</u>		
	Article	27i			
368b 1			<u>Article 27i</u> <u>Application for notification</u>		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	e 27i(1)			
368b m			1. <u>A conformity</u> assessment body shall submit an application for notification to the notifying authority of the Member State in which it is established.		
	Article 27i(2)				
368b n			2. <u>The application for</u> notification shall be		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			accompanied by a description of the conformity assessment activities, of the conformity assessment procedures set out in Annex IVa as well as by an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article 27f.		
	Article	27i(3)			
368b 0			<u>3.</u> Where the conformity		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			assessment body concerned cannot provide an accreditation certificate as referred to in paragraph 2, it shall provide the notifying authority with all the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Article 27f.		
	Artic	le 27j			
368b p			<u>Article 27j</u>		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			Notification procedure		
	Arti	cle 27j(1)			
368b q			1. <u>A notifying authority</u> shall notify only conformity assessment bodies which have satisfied the requirements laid down in Article 27f.		
	Arti	cle 27j(2)			
368b r			2. The notifying authority		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			shall send a notification to the Commission and the other Member States of each conformity assessment body referred to in paragraph 1, using the electronic notification tool developed and managed by the Commission.		
	Article	27j(3)		1	
368b s			3. <u>The notification</u> <u>referred to in paragraph 2</u> <u>shall include the following:</u>		

	Commission Proposal	1	EP Mandate	Council Mandate	Draft Agreement
	Arti	cle 27j(3), point (a)			
368b t			(a) full details of the conformity assessment activities to be performed;		
	Arti	cle 27j(3), point (b)			
368b u			(b) the relevant attestation of competence.		
	Arti	cle 27j(4)			
368b					

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
V		4. Where a notification is not based on an accreditation certificate referred to in Article 27i(2), the notifying authority shall provide the Commission and the other Member States with documentary evidence which attests to the conformity assessment body's competence and the arrangements in place to ensure that that body will be monitored regularly and will continue to satisfy the requirements laid down in Article 27f.		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Artic	le 27j(5), first subparagraph			
368b w			5. The conformity assessment body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within two weeks of the validation of the notification where it includes an accreditation certificate referred to in Article 27i(2), or within two months of the notification where it includes documentary evidence referred to in		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			paragraph 4 of this Article.		
	Article	27j(5), second subparagraph			
368b x			<u>Only such a body shall be</u> <u>considered a notified body</u> <u>for the purposes of this</u> <u>Regulation.</u>		
	Article	27j(6)			
368b y			<u>6.</u> <u>The notifying authority</u> <u>shall notify the</u> <u>Commission and the other</u> <u>Member States of any</u>		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			<u>subsequent relevant</u> <u>changes to the notification</u> <u>referred to in paragraph 2.</u>		
	Article	27k			
368b z			<u>Article 27k</u> <u>Identification numbers and</u> <u>lists of notified bodies</u>		
	Article	e 27k(1)			
368c a			<u>1.</u> <u>The Commission shall</u> assign an identification		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			number to a notified body. It shall assign a single such number even where the body is notified under several Union acts.		
	Article	27k(2)			
368c b			2. The Commission shall make publicly available the list of notified bodies including the identification numbers that have been assigned to them and the conformity assessment activities for which they have been notified. The Commission shall ensure		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			<u>that the list is kept up to</u> <u>date.</u>		
	Article	271			
368c c			<u>Article 271</u> <u>Changes to notification</u>		
	Article	271(1)		L	
368c d			1. Where a notifying authority has ascertained or has been informed that a notified body no longer		

Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
Commission Proposal		meets the requirements laiddown in Article 27f, or thatit is failing to fulfil itsobligations as set out inArticle 27n, the notifyingauthority shall restrict,suspend or withdraw thenotification, asappropriate, depending onthe seriousness of thefailure to meet thoserequirements or fulfil thoseobligations. It shallimmediately inform the	Council Mandate	Draft Agreement
		<u>Commission and the other</u> <u>Member States</u> <u>accordingly.</u>		
Article	e 27l(2)			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement		
368c e			2. In the event of restriction, suspension or withdrawal of notification, or where the notified body has ceased its activity, the notifying authority shall take appropriate steps to ensure that the files of that body are either processed by another notified body or kept available for the responsible notifying and market surveillance authorities at their request.				
	Article 27m						

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
368c f			<u>Article 27m</u> <u>Challenge of the</u> <u>competence of notified</u> <u>bodies</u>		
	Article	27m(1)			
368c g			1. <u>The Commission shall</u> <u>investigate all cases where</u> <u>it has doubts, or a doubt is</u> <u>brought to its attention,</u> <u>regarding the competence</u> <u>of a notified body or the</u> <u>continued fulfilment by a</u> <u>notified body of the</u>		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			requirements and responsibilities to which it is subject.		
	Article	27m(2)			
368c h			2. The notifying authority shall provide the Commission, on request, with all information relating to the basis for the notification or the maintenance of the competence of the notified body concerned.		

	Commission Proposa	ો	EP Mandate	Council Mandate	Draft Agreement
	Art	ticle 27m(3)			
368c i			3. <u>The Commission shall</u> <u>ensure that all sensitive</u> <u>information obtained in the</u> <u>course of its investigations</u> <u>is treated confidentially.</u>		
	Art	ticle 27m(4), first subparagraph			
368c j			4. Where the Commission ascertains that a notified body does not meet or no longer meetsthe requirements for its notification, it shall adopt		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			an implementing act requesting the notifying authority to take the necessary corrective measures, including the withdrawal of the notification if necessary.		
	Article	27m(4), second subparagraph			
368c k			<u>That implementing act</u> <u>shall be adopted in</u> <u>accordance with the</u> <u>advisory procedure</u> <u>referred to in Article 68(2).</u>		

	Commission Prop	posal	EP Mandate	Council Mandate	Draft Agreement
		Article 27n	· · · ·		
368c 1			<u>Article 27n</u> <u>Operational obligations of</u> <u>notified bodies</u>		
		Article 27n(1)			
368c m			1. <u>A notified body shall</u> carry out conformity assessments in accordance with the conformity assessment procedures set out in Article 27a.		

	Commission Proj	oposal	EP Mandate	Council Mandate	Draft Agreement
	1	Article 27n(2)			
368c n			2. <u>A notified body shall</u> perform its activities in a proportionate manner, avoiding an unnecessary burden for economic operators, and taking due account of the size of an undertaking, the structure of the undertaking, the degree of complexity of the EHR system in question. In so doing, the notified body shall nevertheless respect the degree of rigour and the level of protection required for the compliance of the EHR		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			<u>system with the</u> requirements of this <u>Regulation.</u>		
	Article	27n(3)			
368c 0			3. Where a notified body finds that the harmonised standards or common specifications referred in this Regulation have not been met by a manufacturer, it shall require the manufacturer to take appropriate corrective actions and shall not issue an EU type- examination certificate.		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Articl	e 27n(4), first subparagraph			
368c p			4. Where, in the course of the monitoring of conformity following the issuance of a certificate of conformity or the adoption of an approval decision, a notified body finds that a EHR system no longer complies, it shall require the manufacturer to take appropriate corrective measures and shall suspend or withdraw the		
			<u>certificate of conformity or</u> <u>the approval decision, if</u>		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			<u>necessary.</u>		
	Article	e 27n(4), second subparagraph			
368c q			Where corrective measures are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw any certificates of conformity or approval decisions, as appropriate.		
	Article	270			
368c					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
r			<u>Article 270</u> <u>Appeals against decisions</u> <u>of notified bodies</u>		
	Arti	cle 27o, first subparagraph			
368c s			<u>A notified body shall</u> <u>ensure that a transparent</u> <u>and accessible appeals</u> <u>procedure against its</u> <u>decisions is available.</u>		
	Arti	cle 27p			
368c					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
t			<u>Article 27p</u> <u>Information obligation on</u> <u>notified bodies</u>		
	Article	27p(1)			
368c u			<u>1.</u> <u>A notified body shall</u> <u>inform the notifying</u> <u>authority of the following:</u>		
	Article	27p(1), point (a)			
368c v			(a) any refusal, restriction, suspension or withdrawal		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			<u>of a certificate of</u> <u>conformity or approval</u> <u>decision;</u>		
	Article	27p(1), point (b)		1	
368c w			(b) any circumstances affecting the scope of, or the conditions for, its notification;		
	Article	27p(1), point (c)			
368c x			<u>(c)</u> any request for information which it has		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			<u>received from market</u> <u>surveillance authorities</u> <u>regarding its conformity</u> <u>assessment activities;</u>		
	Article	27p(1), point (d)			
368c y			(d) upon request, any conformity assessment activities performed within the scope of its notification and any other activity performed, including cross-border activities and subcontracting.		

	Commission Prop	posal	EP Mandate	Council Mandate	Draft Agreement
		Article 27q			
368c z			<u>Article 27q</u> <u>Coordination of notified</u> <u>bodies</u>		
		Article 27q, first subparagraph			
368d a			<u>The Commission shall</u> <u>ensure that appropriate</u> <u>coordination and</u> <u>cooperation between</u> <u>notified bodies are put in</u> <u>place and properly</u> <u>operated in the form of a</u> <u>sectoral group of notified</u>		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			<u>bodies.</u>		
	Article	e 27q, second subparagraph			
368d b			<u>Notified bodies shall</u> <u>participate in the work of</u> <u>that group, directly or by</u> <u>means of designated</u> <u>representatives.</u>		
	Article	27r	I	I	
368d c			<u>Article 27r</u> <u>Exchange of experience</u>		

	Commission Proposal	ıl	EP Mandate	Council Mandate	Draft Agreement	
	Arti	ticle 27r, first subparagraph				
368d d			<u>The Commission shall</u> provide for the organisation of exchange of experience between the Member States' national authorities responsible for notification policy.			
	Section 4					
369	Section 4 Market surveillance of EHR		Section 4 Market surveillance of EHR	Section 4 Market surveillance of EHR		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	systems		systems	systems	
	Article	28			
370	Article 28 Market surveillance authorities		Article 28 Market surveillance authorities	Article 28 Market surveillance authorities	
	Article	28(1)			
371	 Regulation (EU) 2019/1020 shall apply to EHR systems covered by Chapter III of this 		 Regulation (EU) 2019/1020 shall apply to EHR systems covered by Chapter III of this 	 Regulation (EU) 2019/1020 shall apply to EHR systems in relation to the harmonised 	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Regulation.	Regulation.	components of EHR systems covered by Chapter III of this Regulation.	
	Article 28(2)			
37:	2. Member States shall designate the market surveillance authority or authorities responsible for the implementation of this Chapter. They shall entrust their market surveillance authorities with the powers, resources, equipment and knowledge necessary for the proper performance of their tasks pursuant to this	2. Member States shall designate the market surveillance authority or authorities responsible for the implementation of this Chapter. They shall entrust their market surveillance authorities with the <u>necessary</u> powers, <u>financial</u> resources, equipment, <u>technical expertise</u> , <u>adequate staffing</u> , and	2. Member States shall designate the market surveillance authority or authorities responsible for the implementation of this Chapter. They shall entrust their market surveillance authorities with the powers, resources, equipment and knowledge necessary for the proper performance of their tasks pursuant to this	

Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
Commission Proposal Regulation. Member States shall communicate the identity of the market surveillance authorities to the Commission which shall publish a list of those authorities.		EP Mandate knowledge necessary for the proper performance of their tasks pursuant to this Regulation. Member States shall communicate the identity of the market surveillance authorities to the Commission which shall publish a list of those authorities.	Council MandateRegulation. Marketsurveillance authoritiesshall take the measuresreferred to in Article 16 ofRegulation (EU)2019/1020 to enforce thisChapter. Member Statesshall communicate theidentity of the marketsurveillance authorities tothe Commission which shallpublish a list of thoseauthorities TheCommission and theMember States shall makethis information publicly	Draft Agreement
Article	e 28(2a)		available.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
372a			2a. Staff of market surveillance authorities shall have no direct or indirect economic, financial or personal conflicts of interest that might be considered prejudicial to their independence and, in particular, they shall not be in a situation that may, directly or indirectly, affect the impartiality of their professional conduct.		
	Article	e 28(2b)			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
372b			2b. Pursuant to paragraph 2 of this Article, Member States shall determine and publish the selection procedure for market surveillance authorities. They shall ensure that the procedure is transparent and does not allow for conflicts of interest.		
	Article	28(3)			
373	3. Market surveillance authorities designated pursuant to this Article may		3. Market surveillance authorities designated pursuant to this Article may	3. Market surveillance authorities designated pursuant to this Article may	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	be the digital health authorities designated pursuant to Article 10. Where a digital health authority carries out tasks of market surveillance authority, any conflict of interest shall be avoided.		be the digital health authorities designated pursuant to Article 10. Where a digital health authority carries out tasks of market surveillance authority, any conflict of interest shall be avoided.	be the digital health authorities designated pursuant to Article 10. Where a digital health authority carries out tasks of market surveillance authority, Member States shall ensure that any conflict of interest-shall be is avoided.	
	Article	28(4)			
374	4. Market surveillance authorities shall report to the Commission on a regular basis the outcomes of relevant market		4. Market surveillance authorities shall report to the Commission on a regular basis the outcomes of relevant market	4. Market surveillance authorities shall report to the Commission on a regular yearly basis the outcomes of relevant market	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	surveillance activities.		surveillance activities.	surveillance activities.	
	Article	28(4a)			
374a			4a. Market surveillance authorities shall immediately inform notified bodies about manufacturers of EHR systems that no longer comply with the requirements on the declaration of conformity.		
	Article	28(4b)			

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
374b	Commission Proposal	EP Mandate4b. When a manufactureror, pursuant to Article 21,another economic operatorfails to cooperate withmarket surveillanceauthorities or if theinformation anddocumentation provided isincomplete or incorrect,market surveillanceauthorities shall take allappropriate measures toprohibit or restrict therelevant EHR system frombeing available on themarket until themanufacturer cooperatesor provides complete andcorrect information, or to	Council Mandate	Draft Agreement

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			<u>withdraw it from the</u> <u>market or to recall.</u>		
	Article	28(5)			
375	5. The market surveillance authorities of the Member States shall cooperate with each other and with the Commission. The Commission shall provide for the organisation of exchanges of information necessary to that effect.		5. The market surveillance authorities of the Member States shall cooperate with each other and with the Commission. The Commission shall provide for the organisation of exchanges of information necessary to that effect.	5. The market surveillance authorities of the Member States shall cooperate with each other and with the Commission. The Commission shall provide for the organisation of exchanges of information necessary to that effect.	
	Article	28(6)			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
376	6. For medical devices or high-risk AI systems referred to in Article 14 (3) and (4), the responsible authorities for market surveillance shall be those referred to in Article 93 of Regulation (EU) 2017/745 or Article 59 of Regulation [] [AI act COM/2021/206 final], as applicable.		6. For medical devices or high-risk AI systems referred to in Article 14 (3) and (4), the responsible authorities for market surveillance shall be those referred to in Article 93 of Regulation (EU) 2017/745 or Article 59 of Regulation [] [AI act COM/2021/206 final], as applicable.	6. For medical devices, in vitro diagnostic medical devices or high-risk AI systems referred to in Article 14 (3) and (4), the responsible authorities for market surveillance shall be those referred to in Article 93 of Regulation (EU) 2017/745, Article 88 of Regulation (EU) 2017/746 or Article 59 of Regulation [] [AI act COM/2021/206 final], as applicable.	
	Article	29			

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
377	Article 29 Handling of risks posed by EHR systems and of serious incidents Article 29(1)	Article 29 Handling of risks posed by EHR systems and of serious incidents	Article 29 Handling of risks posed by EHR systems and of serious incidents	
378	1. Where a market surveillance authority finds that an EHR system presents a risk to the health or safety of natural persons or to other aspects of public interest protection, it shall require the manufacturer of	1. Where a market surveillance authority <i>findsof one Member State</i> <i>has a reason to believe</i> that an EHR system presents a risk to the health <u>, safety or</u> <i>rights-or safety</i> of natural persons- <i>or to other aspects</i>	 Where a market surveillance authority finds that an any of the harmonised components of EHR systemsEHR system presents a risk to the health or safety of natural persons, to the security of 	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
the EHR system concerned,	of public interest	the EHR system or to other	
its authorised representative	protection,<mark>, to the</mark>	aspects of public interest	
and all other relevant	protection of personal data	protection, it shall require	
economic operators to take	it shall <i>require the</i>	the manufacturer of the	
all appropriate measures to	manufacturer of<mark>carry out</mark>	EHR system concerned, its	
ensure that the EHR system	an evaluation in relation to	authorised representative	
concerned no longer	the EHR system concerned,	and all other relevant	
presents that risk when	<u>covering all relevant</u>	economic operators to take	
placed on the market to	<u>requirements laid down in</u>	all appropriate measures to	
withdraw the EHR system	<u>this regulation.</u> Its	ensure that the EHR system	
from the market or to recall	authorised	concerned no longer	
it within a reasonable	representative<mark>representativ</mark>	presents that risk when	
period.	es and all other relevant	placed on the market. The	
	economic operators to shall	measures may include	
	cooperate as necessary	withdrawal of to withdraw	
	with the market	the EHR system from the	
	<u>surveillance authorities for</u>	market or to recall it within	
	<u>that purpose and</u> take all	a reasonable period.	
	appropriate measures to		
	ensure that the EHR system		
	concerned no longer		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			presents that risk when placed on the market to withdraw the EHR system from the market or to recall it within a reasonable period. The market surveillance authorities shall inform the relevant notified body accordingly.		
	Article	29(1a)			
378a			<u>1a.</u> Where the market surveillance authorities consider that non-		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			compliance is not restricted to their national territory, they shall inform the Commission and the other Member States of the results of the evaluation and of the actions which they have required the economic operator to take.		
	Article	29(1b)			
378b			<u>1b.</u> <u>Where a market</u> <u>surveillance authority</u> <u>considers or has reason to</u> <u>believe that an EHR system</u> <u>has caused damage to the</u> <u>health or safety of natural</u>		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			persons or to other aspects of public interest protection, it shall immediately provide information and documentation, as applicable, to the affected person or user and, as appropriate, other third parties affected by the damage caused to the person or user, without prejudice to data protection rules.		
	Article	29(2)			
379	2. The economic operator		2. The economic operator	2. The economic operator	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	referred to in paragraph 1 shall ensure that corrective action is taken in respect of all the EHR systems concerned that it has placed on market throughout the Union.		referred to in paragraph 1 shall ensure that corrective action is taken in respect of all the EHR systems concerned that it has placed on market throughout the Union.	referred to in paragraph 1 shall ensure that corrective action is taken in respect of all the EHR systems with regard to the harmonised components concerned that it has placed on market	
	Article	29(3)		throughout the Union.	
380	3. The market surveillance authority shall immediately inform the Commission and the market surveillance authorities of other Member States of the measures ordered pursuant to		3. The market surveillance authority, <i>or</i> , <i>where</i> <i>applicable, the supervisory</i> <i>authority under Regulation</i> <i>(EU) 2016/679</i> , shall immediately inform the Commission and the market	3. The market surveillance authority shall immediately inform the Commission and the market surveillance authorities of other Member States of the measures ordered pursuant to	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
paragraph 1. That	surveillance authorities, or,	paragraph 1. That	
information shall include all	<u>if applicable, the</u>	information shall include all	
available details, in	supervisory authorities	available details, in	
particular the data	under Regulation (EU)	particular the data necessary	
necessary for the	2016/679, of other Member	for the identification of the	
identification of the EHR	States of the measures	EHR system concerned, the	
system concerned, the	ordered pursuant to	origin and the supply chain	
origin and the supply chain	paragraph 1. That	of the EHR system, the	
of the EHR system, the	information shall include all	nature of the risk involved	
nature of the risk involved	available details, in	and the nature and duration	
and the nature and duration	particular the data necessary	of the national measures	
of the national measures	for the identification of the	taken.	
taken.	EHR system concerned, the		
	origin and the supply chain		
	of the EHR system, the		
	nature of the risk involved		
	and the nature and duration		
	of the national measures		
	taken.		

	Commission Prop	posal		EP Mandate	Council Mandate	Draft Agreement
		Article 29(3a)			
380a				3a. Where a finding of a market surveillance authority, or a serious incident it is informed of, concerns personal data protection, the market surveillance authority shall immediately inform and cooperate with the relevant supervisory authorities under Regulation (EU) 2016/679.		
		Article 29(4),	first subparagraph		·	
381						

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
4. Manufacturers of EHR	4. Manufacturers of EHR	4. Manufacturers of EHR	
systems placed on the	systems placed on the	systems placed on the	
market shall report any	market shall report any	market or put into service	
serious incident involving	serious incident involving	shall report any serious	
an EHR system to the	an EHR system to the	incident involving an EHR	
market surveillance	market surveillance	system to the market	
authorities of the Member	authorities, or, in cases	surveillance authorities of	
States where such serious	involving personal data,	the Member States where	
incident occurred and the	the supervisory authorities	such serious incident	
corrective actions taken or	under Regulation (EU)	occurred and to the market	
envisaged by the	<u>2016/679</u> of the Member	surveillance authorities of	
manufacturer.	States where such serious	the Member States where	
	incident occurred and the	such EHR systems is	
	corrective actions taken or	placed on the market or	
	envisaged by the	put into service. The	
	manufacturer.	report shall also contain a	
		description of the	
		corrective actions taken or	
		envisaged by the	
		manufacturer. Member	
		States may provide for	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				users of EHR systems placed on the market or put into service to report such incidents.	
	Article	29(4), second subparagraph			
382	Such notification shall be made, without prejudice to incident notification requirements under Directive (EU) 2016/1148, immediately after the manufacturer has established a causal link between the EHR system and the serious incident or the reasonable likelihood of		Such notification shall be made, without prejudice to incident notification requirements under Directive (EU) 2016/1148, immediately after the manufacturer has established a causal link between the EHR system and the serious incident or the reasonable likelihood of	Such notification shall be made, without prejudice to incident notification requirements under Directive (EU) 2016/11482022/2555 , immediately after the manufacturer has established a causal link between the EHR system and the serious incident or	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	such a link, and, in any event, not later than 15 days after the manufacturer becomes aware of the serious incident involving the EHR system.	such a link, and, in any event, not later than <u>157</u> days after the manufacturer becomes aware of the serious incident involving the EHR system.	the reasonable likelihood of such a link, and, in any event, not later than 153 days after the manufacturer becomes aware of the serious incident involving the EHR system.	
	Article 29(5)			
383	5. The market surveillance authorities referred to in paragraph 4 shall inform the other market surveillance authorities, without delay, of the serious incident and the corrective action taken or envisaged by the	5. The <i>market surveillance</i> authorities referred to in paragraph 4 shall inform the other <i>market surveillance</i> authorities, without delay, of the serious incident and the corrective action taken or envisaged by the	5. The market surveillance authorities referred to in paragraph 4 shall inform the other market surveillance authorities, without delay, of the serious incident and the corrective action taken or envisaged by the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	manufacturer or required of		manufacturer or required of	manufacturer or required of	
	it to minimise the risk of		it to minimise the risk of	it to minimise the risk of	
	recurrence of the serious		recurrence of the serious	recurrence of the serious	
	incident.		incident.	incident.	
	Article	29(6)			
	6. Where the tasks of the		6. Where the tasks of the	6. Where the tasks of the	
	market surveillance		market surveillance	market surveillance	
	authority are not performed		authority are not performed	authority are not performed	
	by the digital health		by the digital health	by the digital health	
384	authority, it shall cooperate		authority, it shall cooperate	authority, it shall cooperate	
	with the digital health		with the digital health	with the digital health	
	authority. It shall inform the		authority. It shall inform the	authority. It shall inform the	
	digital health authority of		digital health authority of	digital health authority of	
	any serious incidents and of		any serious incidents and of	any serious incidents and of	
	EHR systems presenting a		EHR systems presenting a	EHR systems in relation to	
	risk, including risks related		risk, including risks related	the harmonised	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	to interoperability, security and patient safety, and of any corrective action, recall or withdrawal of such EHR systems.		to interoperability, security and patient safety, and of any corrective action, recall or withdrawal of such EHR systems.	components of EHR systems presenting a risk, including risks related to interoperability, security and patient safety, and of any corrective action, recall or withdrawal of such EHR systems.	
	Article	29(7)			
384a				7. Where the market surveillance authority becomes aware that the risk or the incident can entail a personal data breach, as defined in Article 4(12) of Regulation	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				(EU) 2016/679 which is to be notified pursuant to Article 33 of that Regulation, they shall, without undue delay, inform the supervisory authorities as referred to in Article 55 or 56 of that Regulation.	
	Article	29(8)			
384b				8. For incidents putting at risk patient safety or information security, the market surveillance authorities may take immediate actions and	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				require immediate corrective actions.	
	Article	30			
385	Article 30 Handling of non- compliance			Article 30 Handling of non- compliance	
	Article	30(1)			
386	 Where a market surveillance authority makes one of the following 		 Where a market surveillance authority makes one, <i>inter alia</i>, of the 	 Where a market surveillance authority makes one of the following 	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	findings, it shall require the manufacturer of the EHR system concerned, its authorised representative and all other relevant economic operators to put an end to the non- compliance concerned:		following findings, it shall require the manufacturer of the EHR system concerned, its authorised representative and all other relevant economic operators to <i>put</i> <i>an end to the non-</i> <i>compliance concernedbring</i> <i>the EHR system into</i> <i>conformity</i> :	findings, it shall require the manufacturer of the EHR system concerned, its authorised representative and all other relevant economic operators, within a deadline it establishes, to take appropriate measures to put an end to the non-compliance concerned:	
	Article	e 30(1), point (a)			
387	(a) the EHR system is not in conformity with essential requirements laid down in Annex II;		(a) the EHR system is not in conformity with essential requirements laid down in Annex II <u>and with the</u>	(a) the harmonised components of EHR systems EHR system is not in conformity with the	

	Commission Proposa	ો	EP Mandate	Council Mandate	Draft Agreement
			<u>common specifications in</u> <u>accordance with Article 23</u> ;	essential requirements laid down in Annex II;	
	Art	ticle 30(1), point (b)			
388	(b) the technical documentation is either no available or not complete;		(b) the technical documentation is <i>either not</i> <i>availablenot available, not</i> <u>complete</u> or not <u>completein</u> <u>accordance with Article 24</u> ;	(b) the technical documentation is either not available or not complete;	
	Art	ticle 30(1), point (c)			
389	(c) the EU declaration of conformity has not been		(c) the EU declaration of conformity has not been	(c) the EU declaration of conformity has not been	

	Commission Propose	al	EP Mandate	Council Mandate	Draft Agreement
	drawn up or has not been drawn up correctly;		drawn up or has not been drawn up correctly <u>as</u> <u>referred to in Article 26</u> ;	drawn up with regard to the harmonised components of EHR systems or has not been drawn up correctly;	
	Ar	ticle 30(1), point (d)			
390	(d) the CE marking has been affixed in violation Article 27 or has not beer affixed.		(d) the CE marking has been affixed in violation of Article 27 or has not been affixed.	(d) the CE marking has been affixed in violation of Article 27 or has not been affixed.	
	Ar	ticle 30(1), point (da)			
390a					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			(da) the registration obligations of Article 32 have not been fulfilled.		
	Article	e 30(1a)			
390b			Ia.Where, in the course of the evaluation referred to in the first subparagraph, the market surveillance authorities find that theEHR system does not comply with therequirements laid down in this Regulation, they shall 		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			corrective action to bring the EHR system into compliance with those requirements, to withdraw the EHR system from the market, or to recall it within a reasonable period.		
	Article	30(1b), first subparagraph			
390c			<u>1b.</u> <u>Where the relevant</u> <u>economic operator does not</u> <u>take adequate corrective</u> <u>action within the period</u> <u>referred to in Article 29(1),</u> <u>second subparagraph, the</u> <u>market surveillance</u> <u>authorities shall take all</u>		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			appropriate provisional measures to prohibit or restrict the EHR system being made available on their national market, to withdraw the EHR system from that market or to recall it.		
	Article	30(1b), second subparagraph			
390d			<u>The market surveillance</u> <u>authorities shall inform the</u> <u>Commission and the other</u> <u>Member States, without</u> <u>delay, of those measures.</u>		

	Commission Prope	osal		EP Mandate	Council Mandate	Draft Agreement
		Article	30(1c)			
390e				Ic. The informationreferred to in paragraph1b, second subparagraph,shall include all availabledetails, in particular thedata necessary for theidentification of thenoncompliant EHR system,the origin of that EHRsystem, the nature of thenon-compliance allegedand the risk involved, thenature and duration of thenational measures takenand the arguments putforward by the relevanteconomic operator. In		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			particular, the market surveillance authorities shall indicate whether the noncompliance is due to any of the following:		
	Article	e 30(1c), point (a)			
390f			(a) failure of the EHR system to meet the requirements relating to the essential requirements set out in Annex II;		
	Article	e 30(1c), point (b)		·	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
390g			(b) shortcomings in the harmonised standards referred to in Article 23;		
	Article	e 30(1c), point (c)			
390h			(c) shortcomings in the technical specifications referred to in Article 23.		
	Article	e 30(1d)			
390i			<u>1d.</u> <u>Member States other</u>		

	Commission Proposal	1	EP Mandate	Council Mandate	Draft Agreement
			than the Member State initiating the procedure under this Article shall without delay inform the Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of the EHR system concerned, and, in the event of disagreement with the adopted national measure, of their objections.		
390j	Arti	icle 30(1e)			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			1e. Where, within three months of receipt of the information referred to in paragraph 1b, second subparagraph, no objection has been raised by either a Member State or the Commission in respect of a provisional measure taken by a Member State, that measure shall be deemed justified.		
	Article	30(2)			
391	2. Where the non- compliance referred to in paragraph 1 persists, the		2. Where the non- compliance referred to in paragraph 1 persists, the	2. Where the non- compliance referred to in paragraph 1 persists, the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Member State concerned shall take all appropriate measures to restrict or prohibit the EHR system being placed on the market or ensure that it is recalled or withdrawn from the market.		Member State concerned shall take all appropriate measures to restrict or prohibit the EHR system being placed on the market or ensure that it is recalled or withdrawn from the market.	Member State-market surveillance authority concerned shall take all appropriate measures to restrict or prohibit the EHR system being placed on the market or ensure that it is recalled or withdrawn from the market.	
	Article	: 30a			
391a			<u>Article 30a</u> <u>Union safeguard procedure</u>		
	Article	30a(1)			

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
391b		1.Where, on completionof the procedure set out inArticle 29(2) and Article30(1a), objections areraised against a measuretaken by a Member State,or where the Commissionconsiders a nationalmeasure to be contrary toUnion law, theCommission shall withoutdelay enter intoconsultation with theMember States and therelevant economic operatoror operators and shallevaluate the nationalmeasure. On the basis ofthe results of that		

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	evaluation, the		
	Commission shall adopt an		
	implementing act in the		
	<u>form of a decision</u>		
	determining whether the		
	<u>national measure is</u>		
	justified or not. The		
	Commission shall address		
	its decision to all Member		
	States and shall		
	immediately communicate		
	<u>it to them and to the</u>		
	<u>relevant economic operator</u>		
	<u>or operators. That</u>		
	implementing act shall be		
	adopted in accordance with		
	the examination procedure		
	<u>referred to in Article</u>		
	<u>68(2a).</u>		

	Commission Propos	sal	EP Mandate	Council Mandate	Draft Agreement
	Α	Article 30a(2)			
391c			2. If the national measure is considered justified, all Member States shall take the necessary measures to ensure that the non- compliant EHR system is withdrawn from their market, and shall inform the Commission accordingly. If the national measure is considered unjustified, the Member State concerned shall withdraw that measure. Where the national measure is considered justified and the non-		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			compliance of the EHR system is attributed to shortcomings in the harmonised standards or technical specifications referred to in this Regulation, the Commission shall apply the procedure provided for in Article 11 of Regulation (EU) No 1025/2012.		
	Sectio	on 5			
392	Section 5 Other provisions on interoperability		Section 5 Other provisions on interoperability	Section 5 Other provisions on interoperability	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Artic	cle 31			
393	Article 31 Voluntary labelling of wellness applications		Article 31 <i>Voluntary</i> Labelling of wellness applications	Article 31 Voluntary -Labelling of wellness applications	
	Artic	cle 31(1)			
394	1. Where a manufacturer of a wellness application claims interoperability with an EHR system and therefore compliance with the essential requirements laid down in Annex II and common specifications in	h	1. Where a manufacturer of a wellness application claims interoperability with an EHR system and therefore compliance with the essential requirements laid down in Annex II and common specifications in	1. Where a manufacturer of a wellness application claims interoperability with an EHR system in relation to the harmonised components of EHR systems and therefore compliance with the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 23, such wellness application may be accompanied by a label, clearly indicating its compliance with those requirements. The label shall be issued by the manufacturer of the wellness application.		Article 23, such wellness application <i>mayshall</i> be accompanied by a label, clearly indicating its compliance with those requirements. The label shall be issued by the manufacturer of the wellness application <i>and</i> <i>the competent market</i> <i>surveillance authority shall</i> <i>be informed</i> .	essential requirements laid down in Annex II and common specifications in Article 23, such wellness application mayshall be accompanied by a label, clearly indicating its compliance with those requirements. The label shall be issued by the manufacturer of the wellness application.	
	Article	31(2)			
395	2. The label shall indicate the following information:		2. The label shall indicate the following information:	2. The label shall indicate the following information:	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	e 31(2), point (a)			
396	(a) categories of electronic health data for which compliance with essential requirements laid down in Annex II has been confirmed;		(a) categories of electronic health data for which compliance with essential requirements laid down in Annex II has been confirmed;	(a) categories of electronic health data for which compliance with essential requirements laid down in Annex II has been confirmed;	
	Article	e 31(2), point (b)			
397	(b) reference to common specifications to demonstrate compliance;		(b) reference to common specifications to demonstrate compliance;	(b) reference to common specifications to demonstrate compliance;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Artic	e 31(2), point (c)			
398	(c) validity period of the label.		(c) validity period of the label.	(c) validity period of the label.	
	Artic	e 31(3)			
399	3. The Commission may, by means of implementing acts, determine the format and content of the label. Those implementing acts shall be adopted in accordance with the		3. The Commission <i>mayshall</i> , by means of implementing acts, determine the format and content of the label. Those implementing acts shall be adopted in accordance with	3. The Commission may, by means of implementing acts, determine the format and content of the label. Those implementing acts shall be adopted in accordance with the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	advisory procedure referred to in Article 68(2).		the advisory procedure referred to in Article 68(2).	advisoryexamination procedure referred to in Article 68(2).	
	Article	31(4)			
400	4. The label shall be drawn-up in one or more official languages of the Union or languages determined by the Member State(s) in which the in which the wellness application is placed on the market.		4. The label shall be drawn- up in one or more official languages of the Union, <i>and</i> <i>in the language of or</i> <i>languages determined by</i> the Member State(s) <i>in</i> <i>which the</i> in which the wellness application is placed on the market.	4. The label shall be drawn- up in one or more official languages of the Union or languages determined by the Member State(s) in which the in which the wellness application is placed on the market or put into service.	

	Commission Prop	posal	EP Mandate	Council Mandate	Draft Agreement
		Article 31(5)			
401	5. The validity of the shall not exceed 5 year		5. The validity of the label shall not exceed 5 years.	5. The validity of the label shall not exceed 53 years.	
		Article 31(6)			
402	6. If the wellness application is embedd a device, the accompa label shall be placed of device. 2D barcodes r also be used to displa label.	anying on the may	6. If the wellness application is <u>an integral</u> <u>part of a device or</u> embedded in a device <u>after</u> <u>its putting into service</u> , the accompanying label shall be <u>shown in the application</u> <u>itself or placed on the</u> device <u>and in the case of</u>	 6. If the wellness application is embedded in a device, the accompanying label shall be placed on the device. Two-dimensional, 2D,2D barcodes may also be used to display the label. 	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			<i>software a digital label</i> . 2D barcodes may also be used to display the label.		
	Artio	cle 31(7)			
403	7. The market surveillance authorities shall check the compliance of wellness applications with the essential requirements laid down in Annex II.		7. The market surveillance authorities shall check the compliance of wellness applications with the essential requirements laid down in Annex II.	7. The market surveillance authorities shall check the compliance of wellness applications with the essential requirements laid down in Annex II.	
	Artio	cle 31(8)			
404					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	8. Each supplier of a wellness application, for which a label has been issued, shall ensure that the wellness application that is placed on the market or put into service is accompanied with the label for each individual unit, free of charge.		8. Each supplier of a wellness application, for which a label has been issued, shall ensure that the wellness application that is placed on the market or put into service is accompanied with the label for each individual unit, free of charge.	8. Each supplier of a wellness application, for which a label has been issued, shall ensure that the wellness application that is placed on the market or put into service is accompanied with the label for each individual unit, free of charge.	
	Article	31(9)			
405	9. Each distributor of a wellness application for which a label has been issued shall make the label available to customers at		9. Each distributor of a wellness application for which a label has been issued shall make the label available to customers at the	9. Each distributor of a wellness application for which a label has been issued shall make the label available to customers at the	

	Commission Prop	osal		EP Mandate	Council Mandate	Draft Agreement
	the point of sale in electronic form or, upo request, in physical for			point of sale in electronic form or, upon request, in physical form.	point of sale in electronic form or, upon request, in physical form.	
		Article	31(10)			
406	10. The requirements this Article shall not ap to wellness application which are high-risk AI systems as defined und Regulation [] [AI Ad COM/2021/206 final].	pply is der ct		deleted	<i>10.</i> The requirements of this Article shall not apply to wellness applications which are high-risk AI systems as defined under Regulation [] [AI Act COM/2021/206 final].	
		Article	31a		·	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
406a			<u>Article 31a</u> <u>Interoperability of wellness</u> <u>applications with EHR</u> <u>systems</u>		
	Article	31a(1)			
406b			1. Manufacturers of wellness applications may claim interoperability with an EHR system, after relevant conditions are met. When this is the case, the users of such wellness applications shall be duly		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			<u>informed about such</u> <u>interoperability and its</u> <u>effects.</u>		
	Article	e 31a(2)			
406c			2. The interoperability of wellness applications with EHR systems shall not mean automatic sharing or transmission of all or part of the health data from the wellness application with the EHR system. The sharing or transmission of such data shall only be possible following the consent of the natural		

Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
		person and in accordance with Article 3(6) of this Regulation and interoperability shall be limited exclusively to this end. The manufacturers of wellness applications claiming interoperability with an EHP system shall		
		with an EHR system shall ensure that the user is able to choose which categories of health data from the wellness application they want to insert in the EHR system and the circumstance for that		
Article	e 31a(3)	<u>sharing or transmission.</u>		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
406d			3. <u>Wellness applications</u> shall not be permitted to access the information in EHRs or extract or process information from it.		
	Sectio	n 6			
406e				Section 6 Registration of EHR system and wellness application	
	Article	2 32			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
407	Article 32 Registration of EHR systems and wellness applications		Article 32 Registration of EHR systems and wellness applications	Article 32 EU database for registration of EHR systems and wellness applications	
	Article	32(1)			
408	1. The Commission shall establish and maintain a publicly available database with information on EHR systems for which an EU declaration of conformity has been issued pursuant to Article 26 and wellness		1. The Commission shall establish and maintain a publicly available database with information on EHR systems for which an EU declaration of conformity has been issued pursuant to Article 26 <i>and</i> -wellness	1. The Commission shall establish and maintain a publicly available database with information on EHR systems for which an EU declaration of conformity has been issued pursuant to Article 26 and wellness	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	applications for which a		applications for which a	applications for which a	
	label has been issued		label has been issued	label has been issued	
	pursuant to Article 31.		pursuant to Article 3134.	pursuant to Article 31.	
	Article	32(2)			
	2. Before placing on the		2. Before placing on the	2. Before placing on the	
	market or putting into		market or putting into	market or putting into	
	service an EHR system		service an EHR system	service an EHR system	
	referred to in Article 14 or a		referred to in Article 14 or a	referred to in Article 14 or a	
409	wellness application		wellness application	wellness application	
409	referred to in Article 31, the		referred to in Article 31, the	referred to in Article 31, the	
	manufacturer of such EHR		manufacturer of such EHR	manufacturer of such EHR	
	system or wellness		system or wellness	system or wellness	
	application or, where		application or, where	application or, where	
	applicable, its authorised		applicable, its authorised	applicable, its authorised	
	representative shall register		representative shall register	representative shall register	
	the required data into the		the required data into the	the required data into the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	EU database referred to in		EU database referred to in	EU database referred to in	
	paragraph 1.		paragraph 1.	paragraph 1.	
	Article	32(3)			
-					
	3. Medical devices or high-		3. Medical devices or high-	3. Medical devices, in	
	risk AI systems referred to		risk AI systems referred to	vitro diagnostic medical	
	in paragraphs 3 and 4 of		in paragraphs 3 and 4 of	devices or high-risk AI	
	Article 14 of this		Article 14 of this	systems referred to in	
	Regulation shall be		Regulation shall <i>also</i> be	paragraphs 3 and 41 and 2	
410	registered in the database		registered in the database	of Article 14 of this	
	established pursuant to		established pursuant to	Regulation shall be	
	Regulations (EU) 2017/745		Regulations (EU) 2017/745	registered in the database	
	or [] [AI Act		or [] [AI Act	established pursuant to	
	COM/2021/206 final], as		COM/2021/206 final], as	Regulations (EU) 2017/745,	
	applicable.		applicable.	(EU) 2017/746 or [] [AI	
				Act COM/2021/206 final],	
				as applicable. In such	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			cases, the information shall also be forwarded to the EU database referred to in paragraph 1.	
	Article 32(4)			
411	4. The Commission is empowered to adopt delegated acts in accordance with Article 67 to determine the list of required data to be registered by the manufacturers of EHR systems and wellness applications pursuant to paragraph 2.	4. The Commission is empowered to adopt delegated acts in accordance with Article 67 to determine the list of required data to be registered by the manufacturers of EHR systems and wellness applications pursuant to paragraph 2.	4. The Commission is empowered to adopt delegated acts in accordance with Article 67 to determine the list of required data to be registered by the manufacturers of EHR systems and wellness applications pursuant to paragraph 2.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	СНАР	TER IV			
412	CHAPTER IV Secondary use of electronic health data		CHAPTER IV Secondary use of electronic health data	CHAPTER IV Secondary use of electronic health data	
	Sectio	on 1			
413	Section 1 General conditions with regard to the secondary use of electronic health data		Section 1 General conditions with regard to the secondary use of electronic health data	Section 1 General conditions with regard to the secondary use of electronic health data	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	32A			
413a				Article 32A Applicability to health data holders	
	Article	32, (1)			
413b				1. The following categories of health data holders shall be exempted from the obligations incumbent on health data holders laid down in this Chapter:	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	32, (1a)			
413c				(a) individual researchers and natural persons;	
	Article	32, (1b)			
413d				(b) legal persons that qualify as micro- enterprises as defined in Article 2 of the Annex to Commission Recommendation	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				2003/361/EC.	
	Article	32, (2)			
413e				2. Member States may, by virtue of national legislation, provide that the obligations of health data holders laid down in this Chapter shall apply to the health data holders referred to in paragraph 1 which fall under their jurisdiction.	
	Article	32, (3)			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
413f				3. Member States may provide, by virtue of national legislation, that the obligations of health data holders laid down in this Chapter shall not apply to health data holders in the care sector, which fall under their jurisdiction, in order to avoid a disproportionate burden on the entities pertaining to this sector.	
	Article	32, (4)			
413g					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				4. Member States may, by virtue of national legislation, provide that the duties of certain categories of data holders shall be fulfilled by health data intermediation entities.	
	Article	32, (5)			
413h				 5. National legislation defined under paragraphs 2, 3 and 4 of this Article shall be notified to the Commission by [date of applicability of chapter IV]. Any subsequent law 	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement		
				or amendment affecting them shall be notified to the Commission without delay.			
	Article	33					
414	Article 33 Minimum categories of electronic data for secondary use		Article 33 Minimum Categories of electronic health data for secondary use	Article 33 Minimum categories of electronic data for secondary use			
	Article 33(1)						
415							

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	1. Data holders shall make the following categories of electronic data available for secondary use in accordance with the provisions of this Chapter:		 Data holders This chapter shall makeapply to the following categories of electronic health data available for secondary use in accordance with the provisions of this Chapter: 	1. Health data holders shall make the following categories of electronic data available for secondary use in accordance with the provisions of this Chapter:	
	Article	: 33(1), point (a)			
416	(a) EHRs;		(a) <u>electronic health data</u> <u>from</u> EHRs;	(a) health data from EHRs processed in a structured form EHRs ;	
	Article	233(1), point (b)			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
417	(b) data impacting on health, including social, environmental behavioural determinants of health;		(b) data <u>on factors</u> impacting on health, including <u>socialsocio-</u> <u>economic</u> , environmental <u>and</u> behavioural determinants of health;	(b) data impacting on health, including on social, environmental and behavioural determinants of health ;	
	Article	33(1), point (ba)	L		
417a				(ba) aggregated data on healthcare needs, resources allocated to healthcare, the provision of and access to healthcare, healthcare expenditure and	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				financing;	
	Article	e 33(1), point (c)			
418	(c) relevant pathogen genomic data, impacting on human health;		(c) relevant pathogen genomic data, impacting on human health;	(c) relevant pathogen genomic- data, impacting on human health;	
	Article	e 33(1), point (d)			
419	(d) health-related administrative data, including claims and reimbursement data;		(d) <i>health-</i> <i>related</i> <u>healthcare-related</u> administrative data, including claims and	(d) health- relatedhealthcare-related administrative data, including insurance status, claims and reimbursement	

	Commission Propo	osal		EP Mandate	Council Mandate	Draft Agreement
				reimbursement data;	data and other administrative data relating to an individual's socioeconomic status, in a structured form;	
	F	Article	33(1), point (e)			
420	(e) human genetic, genomic and proteomic data;	2		(e) <u>extracts from</u> human genetic, genomic and proteomic data <u>, such as</u> <u>genetic markers</u> ;	(e) human genetic , genomic and proteomic and genomic data;	
	A	Article	33(1), point (ea)			
420a						

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				(ea) other human molecular data such as proteomic transcriptomic, epigenomic, metabolomic, lipidomic and other omic data;	
	Article	33(1), point (f)			
421	(f) person generated electronic health data, including medical devices, wellness applications or other digital health applications;		(f) <i>person<u>automatically</u></i> generated electronic health data, <i>including<u>via</u></i> medical devices , wellness <i>applications or other digital</i> <i>health applications</i> ;	(f) person generated electronic- health data , including through medical devices, wellness applications or other digital health applications;	

	Commission Propo	osal	EP Mandate	Council Mandate	Draft Agreement
	,	Article 33(1), point (fa)			
421a			<u>(fa)</u> data from wellness applications;		
	,	Article 33(1), point (g)			
422	(g) identification data related to health professionals involved the treatment of a natur person;	in	(g) identification data related to <i>healthcare</i> <i>providers and categories of</i> health professionals involved in the treatment of a natural person <u>or in</u> <i>research</i> ;	(g) identification data related to- data on professional status, specialisation and institution of health professionals involved in the treatment of a natural person;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	e 33(1), point (h)			
423	(h) population wide health data registries (public health registries);		(h) population wide health data registries (public health registries);	(h) population wide population-based health data registries (public health registries);	
	Article	e 33(1), point (i)			
424	 (i) electronic health data from medical registries for specific diseases; 		 (i) electronic health data from medical registries for specific diseases; 	 (i) electronic health data from medical registries for specific diseases and mortality registries ; 	

	Commission Propose	al	EP Mandate	Council Mandate	Draft Agreement
	Ar	rticle 33(1), point (j)			
425	(j) electronic health data from clinical trials;		(j) electronic health data from clinical trials <u>subject</u> to transparency provisions <u>under Union law</u> ;	(j) electronic health data from data from clinical trials and clinical trials investigations that have ended in accordance with Article 37(4) of Regulation (EU) 536/2014 and Article 77(5) of Regulation (EU) 2017/745, respectively;	
	Article 33(1), point (k)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
426	(k) electronic health data from medical devices and from registries for medicinal products and medical devices;		(k) electronic health data from medical devices and from registries for medicinal products and medical devices;	(k) electronic health data from medical devices and from registries for medicinal products and medical devices;	
	Article	33(1), point (ka)			
426a				(ka) data from registries for medicinal products and medical devices;	
	Article	33(1), point (l)	•	•	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
427	(l) research cohorts, questionnaires and surveys related to health;		(l) <u>data from</u> research cohorts, questionnaires and surveys related to health;	(1) data from research cohorts, questionnaires and surveys related to health, after the first publication of results ;	
	Article	e 33(1), point (m)			
428	(m) electronic health data from biobanks and dedicated databases;		(m) electronic health data from biobanks and dedicated databases;	(m) electronic health data from biobanks and dedicated associated databases;	
	Article	e 33(1), point (n)			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
429	 (n) electronic data related to insurance status, professional status, education, lifestyle, wellness and behaviour data relevant to health; 		deleted	(n) electronic-data related to-insurance status, professional status, education , lifestyle, wellness and behaviour data relevant to health;	
	Article	- 33(1), point (o)			
430	(o) electronic health data containing various improvements such as correction, annotation, enrichment received by the data holder following a processing based on a data		 (o) electronic health data containing various improvements such as correction, annotation, enrichment received by the data holder following a processing based on a data 	(o) electronic health data containing various improvements such as correction, annotation, enrichment received by the data holder following a processing based on a data	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	permit.		permit.	permit.	
				SEE PARA 9 IN THIS	
				ARTICLE]	
	Article	33(2)			
	2. The requirement in the		2. The <i>requirement in the</i>	2. The requirement in the	
	first subparagraph shall not		first subparagraph shall not	first subparagraph shall not	
	apply to data holders that		apply to data holders that	apply to data holders that	
431	qualify as micro enterprises		qualify as micro enterprises	qualify as micro enterprises	
	as defined in Article 2 of		as defined in Article 2 of the	as defined in Article 2 of	
	the Annex to Commission		Annex to Commission	the Annex to Commission	
	Recommendation		Recommendation	Recommendation	
	2003/361/EC ¹ .		2003/361/EC ⁴ Commission,	2003/361/EC¹.	
			after consulting the EDPB,		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	1. Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36).		EDPS and the Member States, shall adopt guidelines on measures to protect the personal data of health professionals involved in the treatment of natural persons.	1. Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36).	
			1. Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36).	[MOVED TO ARTICLE 35B(5) AND AMENDED]	
	Article	33(3)			
432	3. The electronic health data referred to in		3. The electronic health data referred to in paragraph	3. The electronic health data referred to in paragraph	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
paragraph 1 shall cover data	1 shall cover data processed	1 shall cover data processed	
processed for the provision	for the provision of health	for the provision of health	
of health or care or for	or care or for public health,	or care or for public health,	
public health, research,	research, innovation, policy	research, innovation, policy	
innovation, policy making,	making, official statistics,	making, official statistics,	
official statistics, patient	patient safety or regulatory	patient safety or regulatory	
safety or regulatory	purposes, collected by	purposes, collected by	
purposes, collected by	entities and bodies in the	entities and bodies in the	
entities and bodies in the	health or care sectors,	health or care sectors,	
health or care sectors,	including public and private	including public and private	
including public and private	providers of health or care,	providers of health or care,	
providers of health or care,	entities or bodies	entities or bodies	
entities or bodies	performing research in	performing research in	
performing research in	relation to these sectors, and	relation to these sectors, and	
relation to these sectors,	Union institutions, bodies,	Union institutions, bodies,	
and Union institutions,	offices and agencies.	offices and agencies.	
bodies, offices and			
agencies.			
		INTEGRATED IN ARTICLE	
		-	
		2(2)(y)]	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	33(4)			
433	4. Electronic health data entailing protected intellectual property and trade secrets from private enterprises shall be made available for secondary use. Where such data is made available for secondary use, all measures necessary to preserve the confidentiality of IP rights and trade secrets shall be taken.		deleted	4. Electronic health data entailing protected intellectual property and trade secrets from private enterprises shall be made available for secondary use. Where such data is made available for secondary use, all measures necessary to preserve the confidentiality of IP rights and trade secrets shall be taken.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				AND 35A(1)]	
	Article	33(5)			
434	5. Where the consent of the natural person is required by national law, health data access bodies shall rely on the obligations laid down in this Chapter to provide access to electronic health data.		5. Where the consentNatural persons shall have the right to opt- out of the natural person is required by national law, health data access bodiesprocessing of their electronic health data for secondary use. Member States shall rely on the obligations laid down in this Chapter to provide access to provide for an accessible and easily	 5. Where the consent of the natural person is required by national law, health data access bodies shall rely on the obligations laid down in this Chapter to provide access to electronic health data. [MOVED TO ARTICLE 37(5)] 	

Commission Propos	sal	EP Mandate	Council Mandate	Draft Agreement
		understandable opt-out mechanism, whereby natural persons shall be offered the possibility to explicitly express their wish not to have all or part of their personal electronic health data processed for some or all secondary use purposes. The exercise of this right to opt-out shall not affect the lawfulness of the processing that took place under Chapter IV before the individual opted- out.		
A	rticle 33(5a)			

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
434a		5a. Without prejudice to paragraph 5, electronic health data referred to under paragraph 1, points (e), (fa) and (m), shall only be made available for secondary use after obtaining the consent of the natural person. Such an opt-in mechanism shall be easily understandable and accessible and provided in a user-friendly format whereby data subjects are made aware of the sensitive nature of the data.		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Article 33(6)		1 1	
435	6. Where a public sector body obtains data in emergency situations as defined in Article 15, point (a) or (b) of the Regulation [] [Data Act COM/2022/68 final], in accordance with the rules laid down in that Regulation, it may be supported by a health data access body to provide technical support to process the data or combing it with other data for joint analysis.	6. Where a public sector body obtains data in emergency situations as defined in Article 15, point (a) or (b) of the Regulation [] [Data Act COM/2022/68 final], in accordance with the rules laid down in that Regulation, it may be supported by a health data access body to provide technical support to process the data or combing it with other data for joint analysis.	6. Where a public sector body obtains data in emergency situations as defined in Article 15, point (a) or (b) of the Regulation [] [Data Act COM/2022/68 final], in accordance with the rules laid down in that Regulation, it may be supported by a health data access body to provide technical support to process the data or combing it with other data for joint analysis.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				[MOVED TO ARTICLE 37(3B)]	
	Articl	e 33(7)		1	
436	7. The Commission is empowered to adopt delegated acts in accordance with Article 67 to amend the list in paragraph 1 to adapt it to the evolution of available electronic health data.		deleted	7. The Commission is empowered to adopt delegated acts in accordance with Article 67 to amend the list in paragraph 1 to adapt it to the evolution of available electronic health data.	
	Articl	e 33(8)		1	

 8. Health data access bodies may provide access to additional categories of electronic health data that they have been entrusted with pursuant to national law or based on voluntary cooperation with the relevant data holders at 		Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
national level, in particular to electronic health datathe relevant data holders at national level, in particular to electronic health dataheld by private entities in the health sector.to electronic health dataheld by crivate entities in the health sector.held by private entities in the health sector thatdditional categories of electronic health dataheld by crivate entities in the health sector thatdditional categories of electronic health datafor secondary use	437	8. Health data access bodies may provide access to additional categories of electronic health data that they have been entrusted with pursuant to national law or based on voluntary cooperation with the relevant data holders at national level, in particular to electronic health data held by private entities in	137 I 1 1 1 1 1 1 1		83. Health data access bodiesMember States may provide access to additional categories of electronic health data that they have been entrusted with pursuant to by virtue of national law or based on voluntary cooperation with the relevant data holders at national level, in particular to electronic health data held by private entities in the health sectorthat additional categories of electronic health data shall be made available	Draft Agreement

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				Regulation.	
	Article	33(9)	-	-	
437a				4. Member States may establish rules for the processing and use of electronic health data containing various improvements related to processing of electronic health data based on a data permit pursuant to Article 46, such as correction, annotation and enrichment.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				[DELETED IN ARTICLE 33(1)(o) AND AMENDED]	
	Article	233(5)			
437b				5. Member States may introduce stricter measures at a national level aimed at safeguarding the sensitivity and value of the data referred to in Article 33 (1) points (e) and (ea). Member States shall notify the Commission of those rules and measures and shall notify the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				Commission without delay of any subsequent amendment affecting them.	
	Article	e 33a			
437c			<u>Article 33a</u> <u>IP rights and trade secrets</u> <u>in secondary use</u>		
	Article	e 33a, first subparagraph			
437d			<u>Electronic health data</u>		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			entailing content protected by intellectual property rights, trade secrets or data covered by regulatory data protection shall be made available for secondary use. In those cases, the following procedure shall apply:		
	Article	33a, first subparagraph, point	(a)		
437e			(a) health data access bodies shall take measures necessary to preserve the confidentiality of such data and to ensure such rights are not infringed;		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Artic	le 33a, first subparagraph, point	(b)		
437f			(b) the Commission shall, after consultation with the EHDS Board, issue guidelines on the identification of commercially confidential information. The guidelines shall outline procedural steps and measures the health data access bodies may undertake to identify and		
			preserve the confidentiality of such information before providing data access to the		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			<u>health data users. The</u> guidance shall be made publicly available;		
	Article	33a, first subparagraph, point	(c)		
437g			(c) health data holders may, when requested to make available to health data access bodies relevant electronic health data pursuant to Article 41(1) which it considers to contain content protected by intellectual property rights, trade secrets or data covered by regulatory data protection, inform the data		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			access body that this is the case and indicate which parts of the datasets are concerned. The determination of which data contains intellectual property, trade secrets or data covered by regulatory data protection shall nevertheless rest with the health data access body;		
	Article	33a, first subparagraph, point	(d)		
437h			(d) <u>health data holders</u> and the health data users may conclude data sharing agreements, in order to		

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	share additional data		
	containing protected		
	content protected by		
	<u>intellectual property rights,</u>		
	<u>trade secrets or data</u>		
	<u>covered by regulatory data</u>		
	protection, that would		
	<u>otherwise be made</u>		
	<u>available under point (a).</u>		
	<u>Such agreements shall set</u>		
	out the relevant conditions		
	for the use of such data.		
	<u>The health data holder or</u>		
	<u>the health data user shall</u>		
	inform the health data		
	<u>access body of the</u>		
	<u>conclusion of such an</u>		
	<u>agreement. The</u>		
	<u>Commission shall, by</u>		
	implementing acts draw up		
	<u>templates with standard</u>		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			<u>clauses for such</u> <u>agreements. The</u> <u>implementing acts shall be</u> <u>adopted in accordance with</u> <u>the advisory procedure;</u>		
	Article	33a, first subparagraph, point	(e)		
437i			(e) should the health data access body deem any measures under point (a) to be insufficient to ensure the protection of IP rights, the confidentiality of trade secrets or the data covered by regulatory data protection for regulatory approval, it shall refuse the		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			granting of the relevant health data access permit to the health data user;		
	Article	33a, first subparagraph, point	(f)		
437j			(f) the decision of health data access bodies on the measures in point (a) or the refusal of the data in point (e) shall be binding. Health data holders and health data users shall have the right to lodge a complaint in accordance with Article 38a and to a judicial remedy in accordance with Article		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			<u>38b regarding such</u> <u>decisions.</u>		
	Article	2 34			
438	Article 34 Purposes for which electronic health data can be processed for secondary use		Article 34 Purposes for which electronic health data can be processed for secondary use	Article 34 Purposes for which electronic health data can be processed for secondary use	
	Article	2 34(1)			
439	1. Health data access		1. Health data access	1. Health data access	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	bodies shall only provide access to electronic health data referred to in Article 33 where the intended purpose of processing pursued by the applicant complies with:		bodies shall only provide access to electronic health data referred to in Article 33 to a health data user where the intended purpose of processing pursuedprocessing of the data by the applicant complies withdata user is necessary for one of the following purposes, and in accordance with Article 6(1), point (c), and Article 9(2), points (g) to (j), of Regulation (EU) 2016/679:	bodies shall only providegrant access for secondary use to electronic health data referred to in Article 33 where the intended purpose of processing pursued by the applicant complies withto a health data user for the following categories of purposes :	
	Article	34(1), point (a)		·	
440					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	(a) activities for reasons of public interest in the area of public and occupational health, such as protection against serious cross-border threats to health, public health surveillance or ensuring high levels of quality and safety of healthcare and of medicinal products or medical devices;		(a) activities for reasons of public interest in the area of public <i>and occupational</i> health, such as protection against serious cross-border threats to health, public health surveillance or ensuring high levels of quality and safety of healthcare and of medicinal products or medical devices;	(a) activities for reasons of public interest in the area of public and occupational health, such as activities for protection against serious cross-border threats to health, and public health surveillance or activities ensuring high levels of quality and safety of healthcare, including patient safety , and of medicinal products or medical devices;	
	Article 34(1	(1), point (b)			
441	(b) to support public sector		(b) to support public sector	(b) policy making and	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	bodies or Union institutions, agencies and bodies including regulatory authorities, in the health or care sector to carry out their tasks defined in their mandates;		bodies <i>orand</i> Union institutions, agencies and bodies- <i>including regulatory</i> <i>authorities</i> , in the health or care sector to carry out their tasks defined in their mandates <i>where processing</i> <i>is necessary for reasons of</i> <i>substantial public interest</i> <i>in the area of public</i> <i>health</i> ;	regulatory activities to support public sector bodies or Union institutions, agencies and bodies, including regulatory authorities, in the health or care sector to carry out their tasks defined in their mandates;	
	Article	34(1), point (c)			
442	(c) to produce national, multi-national and Union level official statistics related to health or care		(c) to produce national, multi-national and Union level official statistics <u>defined in Regulation (EU)</u>	(c) to produce statistics, such as national, multi- national and Union level official statistics related to	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
sectors;	<u>No 223/2009</u> ¹ related to	health or care sectors;	
	health or care sectors;		
	<u>1</u> . <u>Regulation (EC) No 223/2009</u>		
	of the European Parliament and of the Council of 11 March 2009		
	on European statistics and repealing Regulation (EC,		
	Euratom) No 1101/2008 of the		
	<u>European Parliament and of the</u> <u>Council on the transmission of</u>		
	<u>data subject to statistical</u> <u>confidentiality to the Statistical</u>		
	<u>Office of the European</u> <u>Communities, Council</u>		
	Regulation (EC) No 322/97 on		
	<u>Community Statistics, and</u> <u>Council Decision 89/382/EEC,</u>		
	<u>Euratom establishing a</u> <u>Committee on the Statistical</u>		
	Programmes of the European		
	<u>Communities (OJ L 87,</u> <u>31.3.2009, p. 164).</u>		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	34(1), point (d)			
443	(d) education or teaching activities in health or care sectors;		deleted	(d) education or teaching activities in health or care sectors at the level of vocational or higher education ;	
	Article	34(1), point (e)			
444	(e) scientific research related to health or care sectors;		(e) scientific research related to health or care sectors, <i>contributing to</i> <i>public health or health</i>	(e) scientific research related to health or care sectors;	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	technology assessment, or		
	<u>ensuring high levels of</u> quality and safety of health		
	care, of medicinal products		
	or of medical devices, with		
	the aim of benefitting the		
	<u>end-users, such as patients,</u>		
	health professionals and		
	<u>health administrators,</u>		
	<u>including:</u>		
	<u>(i) development and</u>		
	innovation activities for		
	products or services;		
	(ii) training, testing and		
	evaluating of algorithms,		
	including in medical		
	<u>devices, in-vitro diagnostic</u>		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			<u>medical devices, AI systems</u> <u>and digital health</u> <u>applications;</u>		
			<u>(iii) university and post-</u> <u>university teaching</u> <u>activities related to</u> <u>scientific research.</u>		
	Article	e 34(1), point (f)			
445	(f) development and innovation activities for products or services contributing to public health or social security, or ensuring high levels of		deleted	(f) development and innovation activities for products or services contributing to the public health or social security, or aimed at ensuring high	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	quality and safety of health care, of medicinal products or of medical devices;			levels of quality and safety of health carehealthcare, of medicinal products or of medical devices ; , in particular:	
	Article	34(1), point (i)			
445a				(i) activities for the development of medicinal products or services of medical devices;	
	Article	34(1), point (ii)			
445b					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				(ii) training, testing and evaluating activities of algorithms, including in medical devices, AI systems and digital health applications;	
	Article 34(1), J	oint (g)			
446	(g) training, testing and evaluating of algorithms, including in medical devices, AI systems and digital health applications, contributing to the public health or social security, or ensuring high levels of quality and safety of health		deleted	(g) training, testing and evaluating of algorithms, including in medical devices, AI systems and digital health applications, contributing to the public health or social security, or ensuring high levels of quality and safety of health	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	care, of medicinal products or of medical devices;			care, of medicinal products or of medical devices; moved to f(ii)	
	Article	34(1), point (h)			
447	(h) providing personalised healthcare consisting in assessing, maintaining or restoring the state of health of natural persons, based on the health data of other natural persons.		(h) <i>providing personalised</i> <i>healthcare consisting in</i> <i>assessing, maintaining or</i> <i>restoring the state of health</i> <i>of natural persons, based</i> <i>on the health data of other</i> <i>natural persons</i> <u>improving</u> <i>delivery of care, treatment</i> <i>optimisation and providing</i>	(h) providing personalised healthcare consisting in assessing, maintaining or restoring the state of health of natural persons, based on the electronic health data of other natural persons.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			personalised healthcare.		
	Article	e 34(2)			
	2. Access to electronic		2. Access to electronic	2. Access to electronic	
	health data referred to in		health data referred to in	health data referred to in	
	Article 33 where the		Article 33 where the	Article 33 where the	
	intended purpose of		intended purpose of	intended purpose of	
	processing pursued by the		processing pursued by the	processing pursued by the	
448	applicant fulfils one of the		applicant fulfils one of The	applicant fulfils one offor	
448	purposes referred to in		purposes referred to in	the purposes referred- to in	
	points (a) to (c) of		points (a) to (c) of	points (a) to (c) of	
	paragraph 1 shall only be		paragraph 1 shall o<i>nly be</i>	paragraph 1 shall only be	
	granted to public sector		granted to<mark>be reserved for</mark>	granted to 1is reserved for	
	bodies and Union		public sector bodies and	public sector bodies and	
	institutions, bodies, offices		Union institutions, bodies,	Union institutions, bodies,	
	and agencies exercising		offices and agencies	offices and agencies	
	their tasks conferred to		exercising their tasks	exercising their tasks	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	them by Union or national law, including where processing of data for carrying out these tasks is done by a third party on behalf of that public sector body or of Union institutions, agencies and bodies.		conferred to them by Union or national law, including where processing of data for carrying out these tasks is done by a third party on behalf of that public sector body or of Union institutions, agencies and bodies.	conferred to them by Union or national law, including where processing of data for carrying out these tasks is done by a third party on behalf of that public sector body or of Union institutions, agencies and bodies.	
	Article	2 34(3)	-	-	-
449	3. The access to privately held data for the purpose of preventing, responding to or assisting in the recovery from public emergencies shall be ensured in		3. The access to privately held data for the purpose of preventing, responding to or assisting in the recovery from public emergencies shall be ensured in	3. The access to privately held data for the purpose of preventing, responding to or assisting in the recovery from public emergencies shall be ensured in	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	accordance with Article 15 of the Regulation [] [Data Act COM/2022/68 final].		accordance with Article 15 of the Regulation [] [Data Act COM/2022/68 final].	accordance with Article 15 of the Regulation [] [Data Act COM/2022/68 final].	
	Article	34(4)			
450	4. Public sector bodies or Union institutions, agencies and bodies that obtain access to electronic health data entailing IP rights and trade secrets in the exercise of the tasks conferred to them by Union law or national law, shall take all specific measures necessary to preserve the confidentiality of such data.		deleted	4. Public sector bodies or Union institutions, agencies and bodies that obtain access to electronic health data entailing IP rights and trade secrets in the exercise of the tasks conferred to them by Union law or national law, shall take all specific measures necessary to preserve the confidentiality of such data.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement			
				[MOVED TO ARTICLE 35A(1) AND AMENDED]				
	Article	2 35						
451	Article 35 Prohibited secondary use of electronic health data		Article 35 Prohibited secondary use of electronic health data	Article 35 Prohibited secondary use of electronic health data				
	Article 35, first paragraph -1							
451a			-1. Secondary use of					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			electronic health data that is not covered by the data permit pursuant to Article 46 or data requests pursuant to Article 47 shall be prohibited.		
	Article	e 35, - first paragraph a			
451b			<u>-1a.</u> Any secondary use of electronic health data for purposes other than those referred to in Article 34 shall be prohibited.		
	Article	e 35, first paragraph			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
452	Commission Proposal Seeking access to and processing electronic health data obtained via a data permit issued pursuant to Article 46 for the following purposes shall be prohibited:		<i>EP</i> Mandate <i>I.</i> Seeking access to and processing electronic health data obtained via a data permit issued pursuant to Article 46 <i>or a data request</i> <i>granted pursuant to Article</i> <i>47</i> for the following purposes shall be prohibited:	Council Mandate Seeking access to and processingHealth data users shall be prohibited to access, processor use electronic health data obtained via aoutside the scope of the data permit issuedpursuant to Article 46 or data request pursuant to Article 46 for47. In particular, the following purposesprocessing and using the electronic health data shall be prohibited:	Draft Agreement
	Article	35, first paragraph, point (a)			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
453	(a) taking decisions detrimental to a natural person based on their electronic health data; in order to qualify as "decisions", they must produce legal effects or similarly significantly affect those natural persons;		(a) taking decisions detrimental to a natural person or group of natural persons based on their electronic health data; in order to qualify as "decisions", they must produce legal, economic or social effects or similarly significantly affect those natural persons;	(a) taking decisions detrimental to a natural person or a group of natural persons based on their electronic health data; in order to qualify as "decisions", they must produce legal, social or economical , effects or similarly significantly affect those natural persons;	
	Article	35, first paragraph, point (b)			
454	(b) taking decisions in relation to a natural person		(b) taking decisions in relation to a natural person	(b) taking decisions in relation to a natural person	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
or groups of natural persons	or groups of natural persons	or groups of natural persons	
to exclude them from the	in relation to job offers or	to exclude them from the	
benefit of an insurance	offering less favourable	benefit of an insurance	
contract or to modify their	<u>terms in the provision of</u>	contract, such as life	
contributions and insurance	goods or services,	assurance contract or a	
premiums;	including to exclude them	policy of health insurance	
	from the benefit of an	or health-related	
	insurance or credit contract	insurance, or to modify	
	or to modify their	their contributions or	
	contributions and insurance	premiums contract or to	
	premiums or conditions of	modify their contributions	
	loans, or taking any other	and insurance premiums;	
	decisions in relation to a		
	natural person or groups of		
	natural persons having the		
	effect of discriminating on		
	the basis of the health data		
	obtained;		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	35, first paragraph, point (ba)		·	
454a				(ba) activities potentially detrimental to natural persons related to employment, pension and banking, including mortgaging of properties;	
	Article	35, first paragraph, point (c)			
455	 (c) advertising or marketing activities towards health professionals, organisations in health or natural persons; 		(c) advertising or marketing activities <i>towards</i> <i>health professionals,</i> <i>organisations in health or</i> <i>natural persons</i> ;	(c) advertising or marketing activities towards health professionals, organisations in health or natural persons, with the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				exception of public health messaging by competent public sector bodies;	
	Article	35, first paragraph, point (d)			
456	(d) providing access to, or otherwise making available, the electronic health data to third parties not mentioned in the data permit;		(d) providing access to, or otherwise making available, the electronic health data to third parties not mentioned in the data permit;	 (d) providing access to, or otherwise making available, the electronic health data to third parties not mentioned in the data permit; [MOVE TO ARTICLE 35C(2)] 	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	e 35, first paragraph, point (e)			
457	(e) developing products or services that may harm individuals and societies at large, including, but not limited to illicit drugs, alcoholic beverages, tobacco products, or goods or services which are designed or modified in such a way that they contravene public order or morality.		(e) developing products or services that may harm individuals, <i>public health</i> <i>or-and</i> societies at large, including, but not limited to illicit drugs, alcoholic beverages, tobacco <i>and</i> <i>nicotine</i> products, <i>weaponry or productsor</i> <i>goods</i> or services which are designed or modified in such a way that they <u>create</u> <i>addiction or that they</i> contravene public order or morality-;	(e) developing products or services that may harm individuals and societies at large, including, but not limited to illicit drugs, alcoholic beverages, tobacco products, or goods or services, services , included those for automated processing , which are designed or modified in such a way that they contravene public order or morality. cause a risk for human health;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Artic	le 35, 1., point (ea)	·		
457a			(ea) automated individual decision-making, including profiling, in accordance with Article 22 of the Regulation (EU) 2016/679, whether solely on the basis of the datasets shared under this Regulation or in combination with other data.		
	Artic	le 35, first paragraph, point (f)			
457b				(f) activities in conflict	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				with ethical provisions pursuant to national law;	
	Article	: 35A			
457c				Article 35A Intellectual property rights and trade secrets	
	Article	35a, first paragraph			
457d				1. Where the health data access body or the Union data access service obtain	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		access to electronic health	
		data from health data	
		holders entailing	
		intellectual property	
		rights and/or trade secrets	
		in the exercise of the tasks	
		conferred to them by this	
		Regulation, they shall take	
		all specific measures,	
		including legal,	
		organisational, and	
		technical ones, necessary	
		to preserve the	
		confidentiality of such	
		data. If the health data	
		access body, by itself or in	
		cooperation with other	
		entities, is unable to	
		preserve the	
		confidentiality of	
		intellectual property	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement			
		rights or trade secrets, it shall refuse access to the health data user in that respect. The health data access body shall inform the health data user of this refusal and explain why it is not possible to provide access.				
		[MOVED FROM ARTICLE 34(4) AND AMENDED, SEE ALSO ARTICLE 37(1)(ii)]				
Article 35a, second paragraph						

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
457e				2. The health data access body or the Union data access service shall make the legal, organisational and technical measures taken to preserve the confidentiality of electronic health data entailing intellectual property rights or trade secrets referred to in paragraph 1 available to the data holder. Generic information about these measures may be made publicly available.	
	Article	35b			

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
457f			Article 35B Duties of health data holders Old Article 41	
	Article 35b, first paragraph			
457g			1. A health data holder is obliged to make the electronic health data under Article 33 they hold available upon request to the health data access	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				body according to a data permit pursuant to Article 46 or data request pursuant to Article 47.	
	Article	2 35b, (1aa)			
457h				1aa. Where such electronic health data entail intellectual property rights or trade secrets the health data holder shall inform the health data access body of such intellectual property rights and trade secrets when communicating to the health data access	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		body the dataset	
		descriptions pursuant to	
		Article 35B(2) for the	
		datasets it holds, or at the	
		latest following a request	
		received from the health	
		data access body. If the	
		requested electronic	
		health data is protected by	
		intellectual property	
		rights and/or trade	
		secrets, the health data	
		holder shall justify to the	
		health access body why	
		the data needs specific	
		protection.	
		[MOVED FROM ARTICLES	
		41(1) AND 33(4) AND	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				AMENDED]	
	Article	35b, (1a)	I		
457i				1a. The health data holder shall put the requested electronic health data referred to in paragraph 1 at the disposal of the health data access body within a reasonable time of up to 3 months determined by the health data access body. In justified cases, such as in complex and burdensome request, the health data access body	

	Commission Proposal	EP Mandate	Council Mandate Draft Agree	ement
			may extend this period by up to 3 additional months.	
			[MOVED FROM ARTICLE 41(4) AND AMENDED]	
	Article 35b, (1b)			
457j			1b. The health data holder shall fulfil its obligations towards natural persons laid down in Article 35D.	

	Commission Prope	oosal	EP Mandate	Council Mandate	Draft Agreement
		Article 35b, (2)	·		
457k				2. The health data holder shall communicate to the health data access body a description of the dataset it holds in accordance with Article 55. The health data holder shall, at a minimum, on an annual basis check that its dataset description in the national datasets catalogue is accurate and up to date. [MOVED FROM ARTICLE 41(2) AND AMENDED]	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	35b, (3.)			
4571				3. Where a data quality and utility label accompanies the dataset pursuant to Article 56, the health data holder shall provide sufficient documentation to the health data access body for that body to confirm the accuracy of the label.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	235b, (4)			
457 m				4. A health data holder shall cooperate with the health data access body when the body is carrying out its tasks. [SOME PARTS MOVED FROM ARTICLE 41(1)]	
	Article	235b, (5)	1		
457n					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				Old Art. 41(5) - [MOVED FROM ARTICLE 33(2)] [[THEN MOVED TO ARTICLE 33A AND AMENDED]]	
	Article	235c			
4570				Article 35C Duties of health data users	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Articl	e 35c, first paragraph			
457p				1. Health data users shall only access and process the electronic health data in accordance with a data permit pursuant to Article 46 or a data request pursuant to Article 47 . This includes a prohibition for health data users to try to re- identify the natural persons in the dataset made available to them or to process and use electronic health data outside the scope of the respectively data permit	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			pursuant to Article 46 or data request pursuant to Article 47, in particular the prohibited purposes pursuant to Article 35 or any other misuse of electronic health data. [MOVED FROM ARTICLE 46(7) AND ARTICLE 44(3)]	
	Article 35c, second paragraph			
457q			2. When processing electronic health data within the secure	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				processing environments referred to in Article 50, the health data users are prohibited to provide access to or otherwise making the electronic health data available to third parties not mentioned in the data permit.	
	Article	35c, third paragraph		1	
457r					

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		3. Health data users shall	
		make public the results or	
		output of the secondary	
		use of electronic health	
		data, including	
		information relevant for	
		the provision of	
		healthcare, within 18	
		months after the	
		completion of the	
		electronic health data	
		processing in the secure	
		environment or after	
		having received the	
		answer to the data request	
		referred to in Article 47.	
		This period may in	
		justified cases related to	
		the permitted purposes of	
		the processing of	
		electronic health data be	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		extended by the health	
		data access body, in	
		particular in cases where	
		the result is published in a	
		scientific journal or other	
		scientific publication.	
		Those results or output	
		shall only contain	
		anonymous data. The	
		health data users shall	
		inform the health data	
		access bodies from which	
		a data permit was	
		obtained and support	
		them to also make the	
		information related to the	
		results or output provided	
		by the health data users	
		public on health data	
		access bodies' websites.	
		Such publication on the	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		health data access bodies	
		website shall be without	
		prejudice to publication	
		rights in a scientific	
		journal or other scientific	
		publication. Whenever the	
		health data users have	
		used electronic health	
		data in accordance with	
		this Chapter, they shall	
		acknowledge the	
		electronic health data	
		sources and the fact that	
		electronic health data has	
		been obtained in the	
		context of the EHDS.	
		[MOVED FROM ARTICLE	
		- 46(11) AND AMENDED]	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	35c, fourth paragraph			
457s				4. Where required by Member State's law, the health data users shall inform the health data access body of any clinically significant findings that may influence the health status of the natural persons whose data are included in the dataset as referred to in Article 35G.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement	
				46(12) AND AMENDED]		
	Article	35c, fifth paragraph		_		
457t				5. The health data users shall cooperate with the health data access body when the health data access body is carrying out its tasks.		
	Article 35d					
457u				Article 35D		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				Information from the health data holder to natural persons	
	Article	35d, first paragraph			
457v				1. Where Member State law provides that health data holders, in addition to their information obligations under Regulation (EU) 2016/679 and Regulation (EU) 2018/1725, health data holders shall inform natural persons about their processing of personal electronic health	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				data pursuant to this Chapter, the information shall in particular include the following:	
	Article	35d, first paragraph, point (a)			
457 w				(a) the health data holder's obligation to make personal electronic health data available for secondary use to the health data access body upon request or, in situations referred to in Article 49, the health data holder's role pursuant to that Article;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	e 35d, first paragraph, point (b)			
457x				(b) the categories of personal electronic health data it holds that may be made available and the purposes for which those data may be processed pursuant to Article 34;	
	Article	e 35d, second paragraph			
457y				2. The information referred to in paragraph 1	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		shall be provided to the	
		natural persons in an	
		easily accessible,	
		intelligible and clearly	
		legible manner and within	
		the timeframe set out	
		respectively in Articles	
		13(1) and 14(3) of	
		Regulation (EU) 2016/679	
		or, where applicable	
		Articles 15(1) and 16(3) of	
		Regulation (EU)	
		2018/1725. Where the	
		health data holder has not	
		obtained the personal	
		electronic health data	
		from the natural person	
		concerned and if the	
		provision of information	
		to each person concerned	
		proves impossible or	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				would involve a disproportionate effort in the meaning of Article 14(5)(b) of Regulation (EU) 2016/679 or Article 16(5)(b) of Regulation (EU) 2018/1725 respectively, the health data holder shall take appropriate measures and at the minimum make the information referred to in paragraph 1 publicly available.	
	Article	35d, third paragraph			
457z				3. The information	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				referred to in paragraph 1 shall also be made publicly available.	
	Article	e 35d, fourth paragraph			
457a a					
	Article	e 35d, fifth paragraph			
457a b				4. Where a Member State has provided for the right to object pursuant to Article 35F,	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	35d, fifth paragraph, point (a)			
457a c				(a) if this right is to be exercised with the data holder, the data holder shall inform the data subject about the procedure to object.	
	Article	35d, fifth paragraph, point (b)			
457a d				(b) if this right is to be exercised with the health data access bodies or with	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				the health data intermediation entities, national legislation may define an obligation for the data holder or the health data intermediation entities to inform the data subject about the procedure to object.	
	Article	35e			
457a e				Article 35E Obligations of health data access bodies towards natural persons	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	35e, first paragraph			
457a f				1. Health data access bodies shall make publicly available and easily searchable through electronic means the conditions under which electronic health data is made available for secondary use. This shall include information concerning:	
	Article	35e, first paragraph, point (a)			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
457a g				(a) the legal basis under which access is granted;	
	Article	35e, first paragraph, point (b)			
457a h				(b) the technical and organisational measures taken to protect the rights of natural persons;	
	Article	35e, first paragraph, point (c)		_	
457a i				(c) the applicable rights	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				of natural persons in relation to secondary use of electronic health data;	
	Article	35e, first paragraph, point (d)			
457a j				(d) the arrangements for natural persons to exercise their rights in accordance with Chapter III of Regulation (EU) 2016/679;	
	Article	35e, first paragraph, point (e)			
457a					

	Commission Propos	sal	EP Mandate	Council Mandate	Draft Agreement
k				(e) the results or outcomes of the projects for which the electronic health data were used.	
	A	Article 35e, second paragraph			
457a 1					
	A	Article 35e, third paragraph			
457a m				2. If a Member State has provided for the right to object pursuant to Article	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				35F to be exercised at the health data access bodies, the relevant health data access bodies shall provide public information about the procedure to object and facilitate the exercise of this right. Paras 3 and 4 deleted in ST 14216/23	
	Articl	e 35f	L		
457a n				Article 35F Right to object to the	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			processing of personal electronic health data for secondary use	
	Article 35f, first paragraph			
457a o			1. Member States may provide, by way of national legislation, that natural persons falling under their jurisdiction shall have a specific right to object to the processing of their personal electronic health data for the purposes laid down in Article 34(1) under the conditions set out in	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement	
				paragraph 2.		
	Article	35f, second paragraph				
457a p				2. Where Member State law provides for the right to object referred to in paragraph 1, it shall lay down at least the following rules and specific safeguards:		
	Article 35f, second paragraph, point (a)					
457a q				(a) Natural persons may		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			exercise this right to object, at any time and without stating reasons, in a simple and accessible manner, including by electronic means;	
	Article 35f, second paragraph, point ((b)		
457a r			(b) Member State law shall lay down whether the right to object is to be exercised with either the health data access bodies, the health data intermediation entities, the health data holders or with more than one of	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				them;	
	Article	35f, second paragraph, point ((c)		
457a s				(c) After a natural person has exercised the right to object referred to in paragraph 1, the personal electronic health data related to the natural person shall not be made available for secondary use under a data permits pursuant to Article 46 or be processed for secondary use following a data request for electronic health data in a statistical	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				format pursuant to Article 47;	
	Article	35f, second paragraph, point ((d)		
457a t				(d) Member State law shall lay down the mechanisms to inform the applicant of, a data permit pursuant to Article 46 or a data request pursuant to Article 47 at the latest prior to the payment of any fees, about the anonymous statistics of natural persons who have exercised the right to object pursuant to this	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				article.	
	Article	35f, third paragraph			
457a u				3. Member States may restrict the right to object referred to in paragraph 1 under the conditions set out in Article 23 of Regulation (EU) 2016/679, especially for purposes related to public interest in the area of public and occupational health, such as activities for protection against serious cross- border threats to health, and public health	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				surveillance or activities ensuring high levels of quality and safety of healthcare, including patient safety, and of medicinal products or medical devices. In such case, Member States shall implement appropriate and effective measures to inform data subjects about restrictions to the right to object.	
	Article	35g	r		
457a v				Article 35G	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				Information of findings related to a natural person's health status	
	Article	35g, first paragraph			
457a w				Where Member States' law to which the health data access body is subject requires health data users to inform the health data access body of any clinically significant findings that may influence the health status of the natural persons whose data are included in the dataset pursuant to a	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		data permit the health data access body may, under the conditions laid down in national law, inform the natural person or his or her treating health professional about that finding. [FIRST SENTENCE MOVED FROM ARTICLE 46(12) AND SECOND SENTENCE MOVED FROM ARTICLE 38(3)]	
Section 2			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement		
458	Section 2 Governance and mechanisms for the secondary use of electronic health data		Section 2 Governance and mechanisms for the secondary use of electronic health data	Section 2 Governance and mechanisms for the secondary use of electronic health data			
	Article	36					
459	Article 36 Health data access bodies		Article 36 Health data access bodies	Article 36 Health data access bodies			
	Article 36(1)						
460							

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
1. Member States shall	1. Member States shall	1. Member States shall	
designate one or more	designate one or more	designate one or more	
health data access bodies	health data access bodies	health data access bodies	
responsible for granting	responsible for granting	responsible for granting	
access to electronic health	access to electronic health	access to electronic health	
data for secondary use.	data for secondary use<mark>the</mark>	data for secondary	
Member States may either	tasks and obligations	usecarrying out the tasks	
establish one or more new	referred to in Articles 37,	set out in Articles 37 and	
public sector bodies or rely	<u>38 and 39 of this</u>	39 . Member States may	
on existing public sector	<u>Regulation</u> . Member States	either establish one or more	
bodies or on internal	may either establish one or	new public sector bodies or	
services of public sector	more new public sector	rely on existing public	
bodies that fulfil the	bodies or rely on existing	sector bodies or on internal	
conditions set out in this	public sector bodies or on	services of public sector	
Article. Where a Member	internal services of public	bodies that fulfil the	
State designates several	sector bodies that fulfil the	conditions set out in this	
health data access bodies, it	conditions set out in this	Article. The tasks laid	
shall designate one health	Article.	down in Article 37 may be	
data access body to act as		divided between different	
coordinator, with		health data access bodies.	
responsibility for	Where a Member State	Where a Member State	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
coordinating requests with	designates several health	designates several health	
the other health data access	data access bodies, it shall	data access bodies, it shall	
bodies.	designate one health data	designate one health data	
	access body to act as	access body to act as	
	coordinator, with	coordinator, with	
	responsibility for	responsibility for	
	coordinating data access	coordinating requests tasks	
	applications and requests	with the other health data	
	with the other health data	access bodies both within	
	access bodies.	the Member State and	
		towards health data access	
		bodies in other Member	
	<u>Each health data access</u>	States.	
	body shall contribute to the		
	consistent application of		
	this Regulation throughout		
	the Union. For that		
	purpose, the health data		
	access bodies shall		
	cooperate with each other		
	and with the Commission,		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			and, for concerns regarding data protection, with the supervisory authorities under Regulation (EU) 2016/679 as well as with the EDPB and the EDPS.		
	Article	36(2)			
461	2. Member States shall ensure that each health data access body is provided with the human, technical and financial resources, premises and infrastructure necessary for the effective performance of its tasks and		2. Member States shall ensure that each health data access body is provided with the human <u>and</u> <u>financial resources</u> , <u>including necessary</u> <u>expertise, and ethics</u> <u>bodies, to support their</u>	2. Member States shall ensure that each health data access body is provided with the human, technical and financial resources, premises and infrastructure necessary for the effective performance of its tasks and	

Commission I	Proposal		EP Mandate	Council Mandate	Draft Agreement
the exercise of its	s powers.		tasks as provided for in Article 37(1), points (a) and (aa), and shall guarantee that all rights of natural persons under this Chapter are respected. Member States shall also ensure technical, technical and financial resources, premises and infrastructure necessary for the effective performance of its tasks and the exercise of its powers, in a timely manner.	the exercise of its powers.	
	Article	e 36(2a)			

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
461a		2a. Member States shall ensure that designated separate structures are set up within health data access bodies for the authorisation of the data permit, on the one hand, and for the reception and preparation of the data set, including anonymisation, pseudonymisation of the electronic health data and possible re-identification of natural persons for the purposes of Article 33(5) and 38(3), on the other hand.		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	36(3)			
462	3. In the performance of their tasks, health data access bodies shall actively cooperate with stakeholders' representatives, especially with representatives of patients, data holders and data users. Staff of health data access bodies shall avoid any conflicts of interest. Health data access bodies shall not be bound by any instructions, when making their decisions.		3. In the performance of their tasks, health data access bodies shall actively cooperate with <u>relevant</u> stakeholders' representatives, especially with representatives of patients, <u>consumers</u> , data holders and data users. <u>Staff</u> of health data access bodies shall avoid any conflicts of interest. Health data access bodies shall not be bound by any instructions, when making their decisions.	3. In the performance of their tasks, health data access bodies shall actively cooperate with stakeholders ² representatives, especially with representatives of patients, data holders and data users. Staff of health data access bodies shall avoid any conflictsconflict of interest. Health data access bodies shall not be bound by any instructions, when making their decisions.	

	Commission Prop	osal	EP Mandate	Council Mandate	Draft Agreement
		Article 36(3a)			
462a			3a.Each health dataaccess body shall act withcomplete independence inperforming its tasks andexercising its powers inaccordance with thisRegulation. The membersof the governance anddecision-making bodiesand staff of each healthdata access body shall, inthe performance of theirtasks and exercise of theirpowers in accordance withthis Regulation, remainfree from externalinfluence, whether direct		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			or indirect and shall neither seek nor take instructions from any natural or legal person. Members of the governance and decision- making bodies and staff of each health data access body shall refrain from any action incompatible with their duties and shall not, during their term of office, engage in any incompatible occupation, whether gainful or not.		
	Article	2 36(4)			
463					

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement				
4. Member States shall	4. Member States shall	4. Member States shall					
communicate to the	communicate to the	communicate toinform the					
Commission the identity of	Commission the identity of	Commission of the identity					
the health data access	the health data access	of the health data access					
bodies designated pursuant	bodies designated pursuant	bodies designated pursuant					
to paragraph 1 by the date	to paragraph 1 by the date	to paragraph 1 by the date					
of application of this	of application of this	of application of this					
Regulation. They shall also	Regulation. They shall also	Regulation. They shall also					
communicate to the	communicate to the	communicate toinform the					
Commission any	Commission any	Commission of any					
subsequent modification of	subsequent modification of	subsequent modification of					
the identity of those bodies.	the identity of those bodies.	the identity of those bodies.					
The Commission and the	The Commission and the	The Commission and the					
Member States shall make	Member States shall make	Member States shall make					
this information publicly	this information publicly	this information publicly					
available.	available.	available.					
Article 36a	Article 36a						

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
463a				Article 36A Union data access service	
	Article	36a(1)			
463b				1. The Commission shall exercise the tasks set out in Articles 37 and 39 concerning health data holders which are Union institutions, bodies, offices or agencies.	
	Article	36a(2)			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
463c				2. The Commission shall ensure that the necessary human, technical and financial resources, premises and infrastructure are allocated to the effective performance of these tasks and the exercise of its duties.	
	Article	36a(3)			
463d				3. Unless there is an explicit exclusion, references to the tasks and	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				duties of health data access bodies in this regulation shall also apply to the Commission, where data holders which are Union institutions, bodies, offices, or agencies are concerned.	
	Article	37			
464	Article 37 Tasks of health data access bodies	Т	Article 37 Fasks of health data access bodies	Article 37 Tasks of health data access bodies	
	Article	37(1)			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
465	1. Health data access bodies shall carry out the following tasks:		 Health data access bodies shall carry out the following tasks: 	 Health data access bodies shall carry out the following tasks: 	
	Article	a 37(1), point (a)			
466	 (a) decide on data access applications pursuant to Article 45, authorise and issue data permits pursuant to Article 46 to access electronic health data falling within their national remit for secondary use and decide on data requests in accordance with Chapter II 		(a) decide on data access applications pursuant to Article 45, <i>authorise and</i> <i>issue data permits pursuant</i> <i>to Article 46 to access</i> <i>electronic health data</i> <i>falling within their national</i> <i>remit for secondary use and</i> <i>decide on data requests in</i> <i>accordance with Chapter II</i>	(a) decide on data access applications pursuant to Article 45, authorise and issue data permits pursuant to Article 46 to access electronic health data falling within their national remit for secondary use and decide on data requests in accordance with Chapter II	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	of Regulation [] [Data Governance Act COM/2020/767 final] and this Chapter;		of Regulation [] [Data Governance Act COM/2020/767 final] and this Chapterincluding deciding on whether the data shall be made accessible in anonymised or pseudonymised form, based on its own thorough assessment of any reasons provided by the health data applicant pursuant to Article 45(2), point (d);	of Regulation [] [Data Governance Act COM/2020/767 final] and this Chapterpursuant to Article 47 in accordance with this Chapter and Chapter II of Regulation (EU) 2022/868 including;	
	Article	37(1), point (a)(i)			
466a				(i) process electronic health data referred to in	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		Article 33 such as the gathering, combination, preparation and compiling of necessary requested data from health data holders, the pseudonymisation or anonymisation of the data and the disclosure of those data for secondary use to health data users on the basis of a data permit or a data request;	
		[MOVED FROM ARTICLE 37(1)(d)] [MOD.SU.12.rev1]	

	Commission Propos	sal	EP Mandate	Council Mandate	Draft Agreement
	A	rticle 37(1), point (a)(ii)			
466b				(ii) take all measures necessary to preserve the confidentiality of IP rights and of trade secrets of electronic health data before those data are made available for secondary use pursuant to a data permit or a data request taking into account the relevant rights of both the health data holder and health data user;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				37(1)(d)]	
	Article	37(1), point (a)(iii)			
466c				(iii) provide access to electronic health data to health data users pursuant to a data permit in a secure processing environment in accordance with the requirements laid down in Article 50.	
	Article	37(1), point (aa)			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
466d			(aa) assess and issue data permits pursuant to Article 46 of this Regulation and assess data request pursuant to Article 47 of this Regulation to access electronic health data falling within their national remit for secondary use and decide on data requests in accordance with Chapter II of Regulation (EU)/ [] [Data Governance Act COM/2020/767 final] and this Chapter;		
	Article	e 37(1), point (ab)			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
466e			(ab) request electronic health data referred to in Article 33 from relevant health data holders pursuant to a data permit or a data request granted;		
	Article	e 37(1), point (ab)			
466f				(ab) monitor and supervise compliance with the requirements laid down in this Regulation by health data users and health data holders.	

	Commission Prope	osal		EP Mandate	Council Mandate	Draft Agreement
					[MOVED FROM ARTICLE 43(1)]	
		Article	37(1), point (b)		1	
467	(b) support public sect bodies in carrying out t tasks enshrined in their mandate, based on nati or Union law;	the r		(b) support public sector bodies in carrying out the tasks enshrined in their mandate, based on national or Union law;	(b) support public sector bodies in carrying out the tasks enshrined in their mandate, based on national or Union law;	
	Article 37(1), point (c)					
468						

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	(c) support Union institutions, bodies, offices and agencies in carrying out tasks enshrined in the mandate of Union institutions, bodies, offices and agencies, based on national or Union law;		(c) support Union institutions, bodies, offices and agencies in carrying out tasks enshrined in the mandate of Union institutions, bodies, offices and agencies, based on national or Union law;	(c) support Union institutions, bodies, offices and agencies in carrying out tasks enshrined in the mandate of Union institutions, bodies, offices and agencies, based on national or Union law;	
	Article	37(1), point (d)			
469	(d) process electronic health data for the purposes set out in Article 34, including the collection, combination, preparation and disclosure of those data for secondary use on the		 (d) process electronic health data for the purposes set out in Article 34, including the <i>collection</i>, <i>combination</i>, <i>preparation</i> combination, <i>preparation</i>, 	(d) process electronic health data for the purposes set out in Article 34, including the collection, combination, preparation and disclosure of those data for secondary use on the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	basis of a data permit;	37(1), point (e)	anonymisation and pseudonymisation and disclosure of those data for secondary use on the basis of a data permit, while also ensuring proper security of that data;	basis of a data permit; [MOVED TO ARTICLE 37(1)(a)(i) AND AMENDED]	
470	(e) process electronic health data from other relevant data holders based on a data permit or a data request for a purposes laid down in Article 34;		deleted	(e) process electronic health data from other relevant data holders based on a data permit or a data request for a purposes laid down in Article 34;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Articl	le 37(1), point (f)			
471	(f) take all measures necessary to preserve the confidentiality of IP rights and of trade secrets;		(f) take all measures necessary to preserve the confidentiality of IP rights and <u>regulatory data</u> <u>protection, and the</u> <u>confidentiality</u> of trade secrets <u>as provided for in</u> <u>Article 33a</u> ;	 (f) take all measures necessary to preserve the confidentiality of IP rights and of trade secrets; [MOVED TO ARTICLE 37(1)(a)(ii) AND AMENDED] 	
	Articl	le 37(1), point (g)			
472	(g) gather and compile or provide access to the		(g) gather and compile or provide access to the	(g) gather and compile or provide access to the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	necessary electronic health data from the various data holders whose electronic health data fall within the scope of this Regulation and put those data at the disposal of data users in a secure processing environment in accordance with the requirements laid down in Article 50;		necessarybased on a data permit, put the relevant electronic health data from the various data holders whose electronic health data fall within the scope of this Regulation and put those data at the disposal of data users in a secure processing environment in accordance with the requirements laid down in Article 50 and store the data for the period of the duration of the data permit;	necessary electronic health data from the various data holders whose electronic health data fall within the scope of this Regulation and put those data at the disposal of data users in a secure processing environment in accordance with the requirements laid down in Article 50; SEE ARTICLE 37(1)(a)(i)]	
	Article	37(1), point (h)	·	· 	
473					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	(h) contribute to data altruism activities in accordance with Article 40		(h) contribute to data altruism activities in accordance with Article 40;	(h) contribute to data altruism activities in accordance with Article 40;	
	Artic	le 37(1), point (i)	L		
474	(i) support the development of AI systems, the training, testing and validating of AI systems and the development of harmonised standards and guidelines under Regulation [] [AI Act COM/2021/206 final] for the training, testing and validation of AI systems in health;	1	deleted	(i) support the development of AI systems, the training, testing and validating of AI systems and the development of harmonised standards and guidelines under Regulation [] [AI Act COM/2021/206 final] for the training, testing and validation of AI systems in health;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	e 37(1), point (j)			
475	(j) cooperate with and supervise data holders to ensure the consistent and accurate implementation of the data quality and utility label set out in Article 56;		(j) cooperate with and supervise data holders to ensure the consistent and accurate implementation of the data quality and utility label set out in Article 56;	(j) cooperate with and supervise data holders to ensure the consistent and accurate implementation of the data quality and utility label set out in Article 56;	
	Article	e 37(1), point (ja)			
475a			(ja) support data holders that are small enterprises in accordance with		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			Commission <u>Recommendation</u> 2003/361/EC, in particular medical practioners and pharmacies, to comply with their obligations under <u>Article 41;</u>		
	Article 37(7(1), point (k)			
476	(k) maintain a management system to record and process data access applications, data requests and the data permits issued and data requests answered, providing at least information on the name of		 (k) maintain a management system to record and process data access applications, data requests, the decisions on those applications and the data permits issued and data requests answered, 	 (k) maintain a management system to record and process data access applications, data requests, the decisions on these and the data permits issued and data requests answered, providing at least 	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	the data applicant, the purpose of access the date of issuance, duration of the data permit and a description of the data application or the data request;		providing at least information on the name of the data applicant, the purpose of access the date of issuance, duration of the data permit and a description of the data application or the data request;	information on the name of the data applicant, the purpose of access the date of issuance, duration of the data permit and a description of the data application or the data request;	
	Article	e 37(1), point (I)	L		
477	(1) maintain a public information system to comply with the obligations laid down in Article 38;		(1) maintain a public information system to comply with the obligations laid down in Article 38;	(1) maintain a public information system to comply with the obligations laid down in Article 38;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				[MOVED TO LETTER Q(V) AND AMENDED]	
	Articl	e 37(1), point (m)	L	I	
478	(m) cooperate at Union and national level to lay down appropriate measures and requirements for accessing electronic health data in a secure processing environment;		(m) cooperate at Union and national level to lay down <i>appropriate measures and</i> <i>requirements</i> <u>common</u> <i>standards, technical</i> <i>requirements and</i> <i>appropriate measures</i> for accessing electronic health data in a secure processing environment;	(m) cooperate at Union and national level to lay down appropriate measures and requirements for accessing electronic health data in a secure processing environment;	

	Commission Prop	posal	EP Mandate	Council Mandate	Draft Agreement
		Article 37(1), point (n)			
479	(n) cooperate at Unio national level and pro advice to the Commis on techniques and bes practices for electroni health data use and management;	ovide ssion st	(n) cooperate at Union and national level and provide advice to the Commission on techniques and best practices for <i>electronic</i> <i>health datathe secondary</i> use and management <i>of</i> <i>electronic health data</i> ;	(n) cooperate at Union and national level and provide advice to the Commission on techniques and best practices for secondary use of electronic health data-use and management;	
		Article 37(1), point (o)			
480	(o) facilitate cross-bo access to electronic ho data for secondary use	ealth	(o) facilitate cross-border access to electronic health data for secondary use	(o) facilitate cross-border access to electronic health data for secondary use	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	hosted in other Member States through HealthData@EU and cooperate closely with each other and with the Commission.	hosted in other Member States through HealthData@EU and cooperate closely with each other and with the Commission.	hosted in other Member States through HealthData@EU and cooperate closely with each other and with the Commission.	
	Article 37(1), point (p)			
481	(p) send to the data holder free of charge, by the expiry of the data permit, a copy of the corrected, annotated or enriched dataset, as applicable, and a description of the operations performed on the original dataset;	(p) send to the data holder free of charge, by the expiry of the data permit, a copy of the corrected, annotated or enriched dataset, as applicable, and a description of the operations performed on the original dataset;	(p) send to the data holder free of charge, by the expiry of the data permit, a copy of the corrected, annotated or enriched dataset, as applicable, and a description of the operations performed on the original dataset;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	37(1), point (q)			
482	(q) make public, through electronic means:		(q) make public, through electronic means:	(q) make public, through electronic means:	
	Article	37(1), point (q)(i)			
483	(i) a national dataset catalogue that shall include details about the source and nature of electronic health data, in accordance with Articles 56 and 58, and the conditions for making		(i) a national dataset catalogue that shall include details about the source and nature of electronic health data, in accordance with Articles <u>55</u> , 56 and 58, and the conditions for making	(i) a-national- dataset catalogue that shall include details about the source and nature of electronic health data, in accordance with Articles 56 and 58, and the conditions for making	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	electronic health data available. The national dataset catalogue shall also be made available to single information points under Article 8 of Regulation [] [Data Governance Act COM/2020/767 final];		electronic health data available. The national dataset catalogue shall also be made available to single information points under Article 8 of Regulation [] [Data Governance Act COM/2020/767 final];	electronic health data available. The national dataset catalogue shall also be made available to single information points under referred to in Article 8-of Regulation [] [Data Governance Act COM/2020/767 final];55	
	Article	37(1), point (q)(ii)		[DELETED PARTS MOVED TO ARTICLE 55]	
484	(ii) all data permits,		(ii) all data permits,	(ii) all data access	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	requests and applications on their websites within 30 working days after issuance of the data permit or reply to a data request;		requests and applications on their websites within 30 working dayshealth data applications and requests without undue delay after issuance of the data permit or reply to a data request <u>their reception</u> ;	applications and data permits, requests and answers, including the rejected applications, on their websites within 30 working days after issuance of thedeciding on a data permit or reply to a data request;	
	Article	37(1), point (q)(iia)			
484a			(iia) all health data permits or requests granted as well as denied, together with a justification, within 30 working days of their issuance;		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	37(1), point (q)(iii)			
485	(iii) penalties applied pursuant to Article 43;		 (iii) penaltiesenforcement measures applied pursuant to Article 43 and administrative fines applied pursuant to Article 43a; 	(iii) penalties applied measures related to non- compliance pursuant to Article 43;	
	Article	- 37(1), point (q)(iv)			
486	(iv) results communicated by data users pursuant to Article 46(11);		(iv) results communicated by data users pursuant to Article 46(11);	 (iv) results communicated by health data users pursuant to Article 46(11)35C(3); 	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Articl	e 37(1), point (q)(v)			
486a				(v) an information system to comply with the obligations laid down in Article 35E; [MOVED FROM LETTER L AND AMENDED] [MOD.SU.12.rev1]	
	Articl	e 37(1), point (q)(vi)			
486b					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				(vi) information of the connection of a national contact point of a third country or an international organisation, as soon as it becomes an authorised participant in HealthData@EU, through electronic means, at minimum on an easily accessible website or web portal.	
	Article	37(1), point (r)			
487	(r) fulfil obligations towards natural persons		(r) fulfil obligations towards natural persons	 (r) fulfil obligations towards natural persons pursuant to Article 	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	pursuant to Article 38;		pursuant to Article 38;	38 Articles 35E to 35G;	
	Article	2 37(1), point (ra)			
487a			(ra) monitor and supervise compliance by data users and data holders with the requirements laid down in this Chapter; monitoring and supervision shall include regular audits on health data users regarding their processing of electronic health data in the secure processing environment;		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	e 37(1), point (s)			
488	(s) request from data users and data holders all the relevant information to verify the implementation of this Chapter;		(s) request from data users and data holders all the relevant information to verify the implementation of this Chapter;	(s) request from data users and data holders all the relevant information to verify the implementation of this Chapter;	
	Article	e 37(1), point (t)			
489	(t) fulfil any other tasks related to making available the secondary use of		(t) fulfil any other tasksrelated to making availablethe secondary use of	(t) fulfil any other tasksrelated to making availablethe secondary use of	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	electronic health data in the context of this Regulation.		electronic health data in the context of this Regulation.	electronic health data in the context of this Regulation.	
	Article	2 37(2)			
490	2. In the exercise of their tasks, health data access bodies shall:			2. In the exercise of their tasks, health data access bodies shall:	
	Article	e 37(2), point (a)			
491	 (a) cooperate with supervisory authorities under Regulation (EU) 2016/679 and Regulation 		 (a) cooperate with supervisory authorities under Regulation (EU) 2016/679 and Regulation 	 (a) cooperate with supervisory authorities under Regulation (EU) 2016/679 and Regulation 	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	(EU) 2018/1725 in relation to personal electronic health data and the EHDS Board;		(EU) 2018/1725-in relation to personal electronic health data and the EHDS Board;	(EU) 2018/1725 in relation to personal electronic health data and the EHDS Board;	
	Articl	le 37(2), point (aa)			
491a			(aa) immediately notify the relevant supervisory authorities under Regulation (EU) 2016/679 of any potential issue related to the processing of personal electronic health data for secondary use, and exchange any relevant information at their disposal to ensure application and		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			enforcement of this Regulation and relevant provisions of Regulation (EU) 2016/679 and this Regulation, including penalties;		
	Article	37(2), point (b)			
492	 (b) inform the relevant supervisory authorities under Regulation (EU) 2016/679 and Regulation (EU) 2018/1725 where a health data access body has imposed penalties or other measures pursuant to Article 43 in relation to 		 (b) inform the relevant supervisory authorities under Regulation (EU) 2016/679 and Regulation (EU) 2018/1725-where a health data access body has imposed penalties or other measures enforcement measures pursuant to 	 (b) inform the relevant supervisory authorities under Regulation (EU) 2016/679 and Regulation (EU) 2018/1725 where a health data access body has imposed penalties or other measures pursuant to Article 43 in relation to 	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	processing personal electronic health data and where such processing refers to an attempt to re- identify an individual or unlawful processing of personal electronic health data;		Article 43 or administrative fines pursuant to Article 4343a in relation to processing personal electronic health data and where such processing refers to an attempt to re- identify an individual or unlawful processing of personal electronic health data;	processing personal electronic health data and where such processing refers to an attempt to re- identify an individual orof any suspected unlawful processing of personal electronic health data;	
	Article	37(2), point (c)			
493	(c) cooperate with stakeholders, including patient organisations, representatives from natural		 (c) cooperate with <u>all</u> <u>relevant</u> stakeholders, including patient organisations, 	(c) cooperate with stakeholders, including patient organisations, representatives from natural	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	persons, health professionals, researchers, and ethical committees, where applicable in accordance with Union and national law;		representatives from natural persons, health professionals, researchers, and <i>ethicalethics</i> committees, where applicable in accordance with Union and national law;	persons, health professionals, researchers, and ethical committees, where applicable in accordance with Union-and or national law;	
	Article	37(2), point (d)	<u></u>		
494	(d) cooperate with other national competent bodies, including the national competent bodies supervising data altruism organisations under Regulation [] [Data		(d) cooperate with other national competent bodies, including the national competent bodies supervising data altruism organisations under Regulation [] [Data	(d) cooperate with other national competent bodies, including the national competent bodies supervising data altruism organisations under Regulation [] [Data	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Governance Act COM/2020/767 final], the competent authorities under Regulation [] [Data Act COM/2022/68 final] and the national competent authorities for Regulations (EU) 2017/745 and Regulation [] [AI Act COM/2021/206 final] .		Governance Act COM/2020/767 final], the competent authorities under Regulation [] [Data Act COM/2022/68 final] and the national competent authorities for Regulations (EU) 2017/745 and Regulation [] [AI Act COM/2021/206 final] .	Governance Act COM/2020/767 final](EU) 2022/868 , the competent authorities under Regulation [] [Data Act COM/2022/68 final] and the national competent authorities for Regulations (EU) 2017/745, (EU) 2017/746 and Regulation [] [AI Act COM/2021/206 final], where relevant	
	Article	37(3)			
495	3. The health data access bodies may provide		3. The health data access bodies may provide	3. The health data access bodies may provide	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	assistance to public sector bodies where those public sector bodies access electronic health data on the basis of Article 14 of Regulation [] [Data Act COM/2022/68 final].	37(3a)	assistance to public sector bodies where those public sector bodies access electronic health data on the basis of Article 14 of Regulation [] [Data Act COM/2022/68 final].	assistance to public sector bodies where those public sector bodies access electronic health data on the basis of Article 14 of Regulation [] [Data Act COM/2022/68 final].	
495a				3a. The health data access body may provide support to a public sector body where it obtains data in emergency situations as defined in Article 15, point (a) or (b) of the Regulation [] [Data Act	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				COM/2022/68 final], in accordance with the rules laid down in that Regulation, by providing technical support to process the data or combining it with other data for joint analysis.	
	Article	37(4)			
496	4. The Commission is empowered to adopt			4. The Commission is empowered to adopt	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	delegated acts in accordance with Article 67 to amend the list of tasks in paragraph 1 of this Article, to reflect the evolution of activities performed by health data access bodies.		deleted	delegated acts in accordance with Article 67 to amend the list of tasks in paragraph 1 of this Article, to reflect the evolution of activities performed by health data access bodies.	
	Article 37((5)			
496a				5. Notwithstanding national laws requesting the data subject's consent pursuant to Article 9(4) of Regulation (EU) 2016/679, health data access bodies shall rely on the obligations laid down in	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				this Chapter, when requesting and processing personal electronic health data from the health data holder and provide access to pseudonymised electronic health data to the health data user.	
	Article	2 38			
497	Article 38 Obligations of health data		Article 38 Obligations of health data	Article 38 Obligations of health data	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	access bodies towards natural persons		access bodies towards natural persons	access bodies towards natural persons	
	Article	38(1)			
498	1. Health data access bodies shall make publicly available and easily searchable the conditions under which electronic health data is made available for secondary use, with information concerning:		1. Health data access bodies shall make publicly available and easily searchable <i>and accessible</i> <i>for natural persons</i> the conditions under which electronic health data is made available for secondary use, with information concerning:	1. Health data access bodies shall make publicly available and easily searchable the conditions under which electronic health data is made available for secondary use, with information concerning:	

	Commission Proposal			EP Mandate	Council Mandate	Draft Agreement
		Article 38	(1), point (a)			
499	(a) the legal basis un which access is grante			 (a) the legal basis under which access is granted <u>to</u> the health data user; 	(a) the legal basis under which access is granted; [MOVED TO ARTICLE 35E(1) AND AMENDED]	
		Article 38	5(1), point (b)			
500	(b) the technical and organisational measur taken to protect the ri- natural persons;			(b) the technical and organisational measures taken to protect the rights of natural persons;	(b) the technical and organisational measures taken to protect the rights of natural persons;	

Commission Proposal			EP Mandate	Council Mandate	Draft Agreement
				[MOVED TO ARTICLE 35E(1) AND AMENDED]	
	Article	e 38(1), point (c)			
501	(c) the applicable rights of natural persons in relation to secondary use of electronic health data;		(c) the applicable rights of natural persons in relation to secondary use of electronic health data <u></u> <u>including the right to opt-</u> <u>out pursuant to Article</u> <u>33(5) and the right to opt-</u> <u>in pursuant to Article</u> <u>33(5a), and detailed</u> <u>information on how to</u>	 (c) the applicable rights of natural persons in relation to secondary use of electronic health data; [MOVED TO ARTICLE 35E(1) AND AMENDED] 	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			<u>exercise them;</u>		
	Article	e 38(1), point (d)			
502	(d) the arrangements for natural persons to exercise their rights in accordance with Chapter III of Regulation (EU) 2016/679;		(d) the <i>arrangementsmodalities</i> for natural persons to exercise their rights in accordance with Chapter III of Regulation (EU) 2016/679;	(d) the arrangements for natural persons to exercise their rights in accordance with Chapter III of Regulation (EU) 2016/679; [MOVED TO ARTICLE 35E(1) AND AMENDED]	
	Article	938(1), point (da)			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
502a			(da) the identity and the contact details of the health data access body;		
	Article	38(1), point (db)			
502b			(db) the record on who has been granted access to which sets of electronic health data and a justification regarding the purposes for processing them as referred to in Article 34(1);		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	e 38(1), point (e)			
503	(e) the results or outcomes of the projects for which the electronic health data were used.		(e) the results or outcomes of the projects for which the electronic health data were used.	(e) the results or outcomes of the projects for which the electronic health data were used. [MOVED TO ARTICLE 35E(1) AND AMENDED]	
	Article	38(2)			
504	 Health data access bodies shall not be obliged to provide the specific 		deleted	2. Health data access bodies shall not be obliged to provide the specific	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	information under Article 14 of Regulation (EU) 2016/679 to each natural person concerning the use of their data for projects subject to a data permit and shall provide general public information on all the data permits issued pursuant to Article 46.			information under Article 14 of Regulation (EU) 2016/679 to each natural person concerning the use of their data for projects subject to a data permit and shall provide general public information on all the data permits issued pursuant to Article 46. [SEE ARTICLE 35E]	
	Article	38(3)			
505	3. Where a health data access body is informed by		3. Where a health data access body is informed by	3. Where a health data access body is informed by	

C	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
may a na data info and hea	lata user of a finding that ay impact on the health of natural person, the health ta access body may form the natural person d his or her treating alth professional about at finding.	a healtha healthdata user of afinding that may impactomsignificant findingrelated tothe health of anatural person, as referredto in Article 41a(5) of thisRegulationthe health dataaccess body shall informthe treating healthprofessional with therelevant competence of thenatural person and if thathealth professional cannotbe found, and shall informthat finding. Naturalpersons shall have the rightto request not to beinformed of such findings.In accordance with Article23(1), point (i), of	a data user of a finding that may impact on the health of a natural person, the health data access body may inform the natural person and his or her treating health professional about that finding. [MOVED TO ARTICLE 35G AND AMENDED]	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Regulation (EU) 2016/679,		
	<u>Member States may restrict</u>		
	the scope of the obligation		
	to may inform the natural		
	person and his or her		
	t reating persons whenever		
	<u>necessary for the</u>		
	protection of the natural		
	<u>persons based on patient</u>		
	<u>safety and ethics, by</u>		
	<u>delaying the</u>		
	<u>communication of their</u>		
	<u>information until a</u> health		
	professional about that		
	f inding can communicate		
	<u>and explain to the natural</u>		
	persons information that		
	potentially can have an		
	<u>impact on them</u> .		

	Commission Proposa	al	EP Mandate	Council Mandate	Draft Agreement
	Ar	rticle 38(4)		·	
506	4. Member States shall regularly inform the publ at large about the role and benefits of health data access bodies.		4. Member States shall regularly inform the public at large about the role and benefits of health data access bodies.	4. Member States shall regularly inform the public at large about the role and benefits of health data access bodies.	
	Ar	rticle 38a			
506a			<u>Article 38a</u> <u>Right to lodge a complaint</u> <u>with a health data access</u> <u>body</u>		

	Commission Propos	sal	EP Mandate	Council Mandate	Draft Agreement
	A	Article 38a(1)			
506b			1. Without prejudice toany other administrative orjudicial remedy, naturaland legal persons shallhave the right to lodge acomplaint, individually or,where relevant, collectively,with the health data accessbody, where their rightslaid down in this Chapterare affected. Where thecomplaint concerns therights of natural personspursuant to Article 38(1),point (d), of thisRegulation, the health dataaccess body shall inform		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			and send a copy of the complaint to the competent supervisory authorities under Regulation (EU) 2016/679.		
	Article	e 38a(2)			
506c			2. <u>The health data access</u> <u>body with which the</u> <u>complaint has been lodged</u> <u>shall inform the</u> <u>complainant of the</u> <u>progress of the proceedings</u> <u>and of the decision taken.</u>		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	238a(3)	·		
506d			3. <u>Health data access</u> <u>bodies shall cooperate to</u> <u>handle and resolve</u> <u>complaints, including by</u> <u>exchanging all relevant</u> <u>information by electronic</u> <u>means, without undue</u> <u>delay.</u>		
	Article	238a(4)			
506e			<u>4.</u> Each health data access body shall facilitate submitting complaints, in		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			particular by providing a complaint submission form which can also be completed electronically, without excluding the possibility of using other means of communication.		
	Artic	le 38b			
506f			<u>Article 38b</u> <u>Right to an effective</u> <u>judicial remedy against a</u> <u>health data access body</u>		
	Artic	le 38b(1)			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
506g			1. Without prejudice to any other administrative or non-judicial remedy, each natural or legal person shall have the right to an effective judicial remedy against a legally binding decision of a health data access body concerning them.		
	Article	- 38b(2)			
506h			2. <u>Without prejudice to</u> any other administrative or non-judicial remedy, each		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			natural or legal person shall have the right to an effective judicial remedy where the health data access body which is competent pursuant to Article 37 does not handle a complaint or does not inform the natural or legal person within three months about the progress or outcome of the complaint lodged pursuant to Article 38a.		
	Article	38b(3)			
506i			<u>3.</u> <u>Proceedings against a</u>		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			<u>health data access body</u> <u>shall be brought before the</u> <u>courts of the Member</u> <u>States where the health</u> <u>data access body is</u> <u>established.</u>		
	Article	39			
507	Article 39 Reporting by health data access bodies		Article 39 Reporting by health data access bodies	Article 39 Reporting by health data access bodies	
	Article	39(1)			

	Commission Proposal	 EP Mandate	Council Mandate	Draft Agreement
508	1. Each health data access body shall publish an annual activity report which shall contain at least the following:	1. Each health data access body shall publish an annual activity report <u>and</u> <u>make it publicly available</u> <u>on its website</u> , which shall contain at least the following <u>categories of</u> <u>information</u> :	1. Each health data access body shall publish an annual a biennial activity report. If a Member States designates more than one health data access body, the coordinating body referred to in Article 37(1) shall be responsible for the report and request necessary information from the other health data access bodies. The activity report shall follow a structure agreed within EHDS Board. The activity report -which-shall contain at least the following:	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	39(1), point (a)			
	(a) information relating to		(a) information relating to	(a) information relating to	
	the data access applications		the data access applications	the data access applications	
	for electronic health data		<u>and data requests</u> for	for electronic health data	
	access submitted, such as		electronic health data access	access submitted, such as	
	the types of applicants,		submitted, such as the types	the types of applicants,	
	number of data permits		of applicants, number of	number of data permits	
509	granted or refused, purposes		data permits granted or	granted or refused,	
	of access and categories of		refused, purposes of access	categories of purposes of	
	electronic health data		and categories of electronic	access and categories of	
	accessed, and a summary of		health data accessed, and a	electronic health data	
	the results of the electronic		summary of the results of	accessed, and a summary of	
	health data uses, where		the electronic health data	the results of the electronic	
	applicable;		uses, where applicable;	health data uses, where	
				applicable;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	e 39(1), point (b)			
510	(b) a list of data permits involving access to electronic health data processed by the health data access body based on data altruism and a summary description of the general interests purposes pursued, where applicable, including the outcomes of the data permits granted;		(b) a list of data permits involving access to electronic health data processed by the health data access body based on data altruism and a summary description of the general interests purposes pursued, where applicable, including the outcomes of the data permits granted;	(b) a list of data permits involving access to electronic health data processed by the health data access body based on data altruism and a summary description of the general interests purposes pursued, where applicable, including the outcomes of the data permits granted;	
	Article	e 39(1), point (c)			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
511	(c) information on the fulfilment of regulatory and contractual commitments by data users and data holders, as well as penalties imposed;		(c) information on the fulfilment of regulatory and contractual commitments by data users and data holders, as well as <i>penaltics<u>the</u></i> <i>number and amount of</i> <i>administrative fines</i> imposed <i>by health data</i> <i>access bodies</i> ;	(c) information on the fulfilment of regulatory and contractual commitments by health data users and health data holders, as well as penalties imposed;	
	Article	39(1), point (d)			
512	(d) information on audits carried out on data users to ensure compliance of the processing with this		(d) information on audits carried out on data users to ensure compliance of the processing with within the	(d) information on audits carried out on health data users to ensure compliance of the processing with in	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Regulation,		secure processing environment as referred to in Article 50(3) of this Regulation ;	the secure processing environment pursuant to Article 50(1)(e) of this Regulation,	
	Article	e 39(1), point (e)	I		
513	(e) information on audits on compliance of secure processing environments with the defined standards, specifications and requirements;		(e) information on <i>internal</i> and third party audits on compliance of secure processing environments with the defined standards, specifications and requirements, as referred to in Article 50(3) of this Regulation;	(e) information on third party audits on compliance of secure processing environments with the defined standards, specifications and requirements pursuant to Article 50(3) of this Regulation; ;	

	Commission Proposal	I	EP Mandate	Council Mandate	Draft Agreement
	Artio	cle 39(1), point (f)			
514	(f) information on the handling of requests from natural persons on the exercise of their data protection rights;		(f) information on the handling of requests from natural persons on the exercise of their data protection rights;	(f) information on the handling of requests from natural persons on the exercise of their data protection rights;	
	Artio	cle 39(1), point (g)			
515	(g) a description of its activities carried out in relation to engagement with and consultation of relevan stakeholders, including representatives of natural		(g) a description of its activities carried out in relation to engagement with and consultation of relevant stakeholders, including representatives of natural	(g) a description of its activities carried out in relation to engagement with and consultation of relevant stakeholders, including representatives of natural	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	persons, patient organisations, health professionals, researchers, and ethical committees;		persons, patient organisations, health professionals, researchers, and ethical committees;	persons, patient organisations, health professionals, researchers, and ethical committees;	
	Article	e 39(1), point (h)			
516	(h) information on cooperation with other competent bodies in particular in the area of data protection, cybersecurity, data altruism, and artificial intelligence;		 (h) information on cooperation with other competent bodies in particular in the area of data protection, cybersecurity, data altruism, and artificial intelligence; 	(h) information on cooperation with other competent bodies in particular in the area of data protection, cybersecurity, data altruism, and artificial intelligence;	
	Article	e 39(1), point (i)			

	Commission Prop	osal	EP Mandate	Council Mandate	Draft Agreement		
517	(i) revenues from data permits and data reque		(i) revenues from data permits and data requests;	(i) revenues from data permits and data requests;			
		Article 39(1), point (j)					
518	(j) satisfaction from applicants requesting a to data;	access	deleted	(j) satisfaction from applicants requesting access to data;			
	Article 39(1), point (k)						
519	(k) average number o between application a		(k) average number of days between application and	(k) average number of working days between			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	access to data;		access to data;	application and access to data;	
	Article	e 39(1), point (l)			
520	(l) number of data quality labels issued, disaggregated per quality category;		 (1) number of data quality labels issued <u>by data</u> <u>holders</u>, disaggregated per quality category; 	(l) number of data quality labels issued, disaggregated per quality category;	
	Article	e 39(1), point (m)			
521	(m) number of peer- reviewed research publications, policy		(m) number of peer- reviewed research publications, policy	(m) number of peer- reviewed research publications, policy	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	documents, regulatory procedures using data accessed via the EHDS;		documents, regulatory procedures using data accessed via the EHDS;	documents, regulatory procedures using data accessed via the EHDS;	
	Article	e 39(1), point (n)			
522	(n) number of digital health products and services, including AI applications, developed using data accessed via EHDS.		 (n) number of digital health products and services, including AI applications, developed using data accessed via EHDS. 	 (n) number of digital health products and services, including AI applications, developed using data accessed via EHDS. 	
	Article	: 39(2)			
523	2. The report shall be		2. The report shall be	2. The report shall be	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	transmitted to the Commission.		transmitted to the Commission <u>, which shall</u> <u>make it publicly available</u> <u>on its website</u> .	transmitted sent to the Commission and the EHDS Board within 6 months after the end date of the 2 year reporting period.	
	Article	39(3)			
524	3. The Commission is empowered to adopt delegated acts in accordance with Article 67 to modify the content of the annual activity report.		3. The Commission is empowered to adopt delegated acts in accordance with Article 67 to <i>modify</i> <i>the content of the annual</i> <i>activity reportamend</i> <i>paragraph 1 of this Article</i> <i>by adding categories to</i> <i>those listed in that</i>	3. The Commission is empowered to adopt delegated acts in accordance with Article 67 to modify the content of the annual activity report.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			paragraph.		
	Article	40		-	
525	Article 40 Data altruism in health		Article 40 Data altruism in health	Article 40 Data altruism in health	
	Article	40(1)			
526	1. When processing personal electronic health data, data altruism organisations shall comply with the rules set out in		1. When processing personal electronic health data, <u>In addition to rules</u> regarding data altruism organisations shall comply	1. When processing personal electronic health data, data altruism organisations shall comply with the rules set out in	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Chapter IV of Regulation [] [Data Governance Act COM/2020/767 final]. Where data altruism organisations process personal electronic health data using a secure processing environment, such environments shall also comply with the requirements set out in Article 50 of this Regulation.	with the rules set outinestablished by Regulation(EU) 2022/868, where dataaltruism organisationsrecognised underChapterIV of Regulation [] [DataGovernance ActCOM/2020/767 final].Where data altruismorganisationsthatRegulation processpersonal electronic healthdata using a secureprocessing environment,such environments shallalso comply with therequirements set out inArticle 50 of thisRegulation.	Chapter IV of Regulation [] [Data Governance Act COM/2020/767 final]: Where data altruism organisations process personal electronic health data using a secure processing environment, such environments shall also comply with the requirements set out in Article 50 of this Regulation. MOVED TO ARTICLE 50(3A)	

	Commission Prop	osal		EP Mandate	Council Mandate	Draft Agreement
		Article	40(2)			
527	2. Health data access bodies shall support th competent authorities designated in accordar with Article 23 of Regulation [] [Data Governance Act COM/2020/767 final] monitoring of entities carrying out data altru activities.	nce in the		2. Health data access bodies shall support the competent authorities designated in accordance with Article 23 of Regulation [] [Data Governance Act COM/2020/767 final] (EU) 2022/868 in the monitoring of entities carrying out data altruism activities, where electronic health data are concerned.	2. Health data access bodies shall support the competent authorities designated in accordance with Article 23 of Regulation [] [Data Governance Act COM/2020/767 final] in the monitoring of entities carrying out data altruism activities.	
		Article	41			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
528	Article 41 Duties of data holders		Article 41 Duties of <u>health</u> data holders	Article 41 Duties of data holders	
	Article	41(1)			
529	1. Where a data holder is obliged to make electronic health data available under Article 33 or under other Union law or national legislation implementing Union law, it shall cooperate in good faith with the health data access		1. Where a data holder is obliged to makeHealth data holders shall make relevant electronic health data available-under Article 33 or under other Union law or national legislation implementing Union law, itavailable upon request to	1. Where a data holder is obliged to make electronic health data available under Article 33 or under other Union law or national legislation implementing Union law, it shall cooperate in good faith with the health data access	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	bodies, where relevant.		the health data access body pursuant to a data permit issued or data request granted by such a body. Health data holders shall cooperate in good faith with the health data access bodies, where relevant.	bodies, where relevant. MOVED TO ARTICLE 35B(1)	
	Article	41(1a)			
529a			1a. The requirement laid down in the first paragraph shall not apply to data holders that qualify as micro enterprises as defined in Article 2 of the Annex to Commission		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			<u>Recommendation</u> 2003/361/EC.		
	Article	e 41(1b)			
529b			1b.The health data holdershall put the electronichealth data at the disposalof the health data accessbody within three monthsof receiving the requestfrom the health data accessbody. In justified cases,after consultation with thehealth data holderconcerned, that period maybe extended by the healthdata access body for a		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			maximum of two months. <u>The health data access</u> <u>body may decide that the</u> <u>extension is to be shorter</u> <u>than two months.</u>		
	Article	e 41(1c)			
529c			1c. Paragraphs 1 and 1a of this Article constitute a legal obligation pursuant to Article 6(1), point (c), of this Regulation in combination with Article 9(2), points (g) (to (j), of Regulation 2016/679 for the health data holder to disclose personal electronic		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			<u>health data to the health</u> <u>data access body.</u>		
	Article	41(2)			
530	2. The data holder shall communicate to the health data access body a general description of the dataset it holds in accordance with Article 55.		2. The <i>health</i> data holder shall communicate to the health data access body a general description of the dataset it holds in accordance with Article 55.	 2. The data holder shall communicate to the health data access body a general description of the dataset it holds in accordance with Article 55. MOVED TO ARTICLE 35B(2) 	

	Commission Propo	osal	EP Mandate	Council Mandate	Draft Agreement			
	ļ	Article 41(3)						
531	3. Where a data quality utility label accompanie the dataset pursuant to Article 56, the data hold shall provide sufficient documentation to the he data access body for tha body to confirm the accuracy of the label.	es der ealth	3. Where a data quality and utility label accompanies the dataset pursuant to Article 56, the <i>health</i> data holder shall provide sufficient documentation to the health data access body for that body to confirm the accuracy of the label.	3. Where a data quality and utility label accompanies the dataset pursuant to Article 56, the data holder shall provide sufficient documentation to the health data access body for that body to confirm the accuracy of the label. MOVED TO ARTICLE 35B(3)				
	Article 41(4)							

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
532	4. The data holder shall put the electronic health data at the disposal of the health data access body within 2 months from receiving the request from the health data access body. In exceptional cases, that period may be extended by the health data access body for an additional period of 2 months.	deleted	4. The data holder shall put the electronic health data at the disposal of the health data access body within 2 months from receiving the request from the health data access body. In exceptional cases, that period may be extended by the health data access body for an additional period of 2 months. MOVED TO ARTICLE 35B(1A)	

	Commission Propos	osal	EP Mandate	Council Mandate	Draft Agreement		
	А	Article 41(5)					
533	5. Where a data holder received enriched datase following a processing based on a data permit, is shall make available the new dataset, unless it considers it unsuitable a notifies the health data access body in this respondent	ets it e and	5. Where a <i>health</i> data holder has received enriched datasets following a processing based on a data permit, it shall make available the new dataset, unless it considers it unsuitable and notifies the health data access body in this respect.	5. Where a data holder has received enriched datasets following a processing based on a data permit, it shall make available the new dataset, unless it considers it unsuitable and notifies the health data access body in this respect.			
	Article 41(6)						

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
534	6. Data holders of non- personal electronic health data shall ensure access to data through trusted open databases to ensure unrestricted access for all users and data storage and preservation. Trusted open public databases shall have in place a robust, transparent and sustainable governance and a transparent model of user access.		6. <i>Health</i> data holders of non-personal electronic health data shall ensure access to data through trusted open databases to ensure unrestricted access for all users and data storage and preservation. Trusted open public databases shall have in place a robust, transparent and sustainable governance and a transparent model of user access.	6. Data holders of non- personal electronic health data shall ensure access to data through trusted open databases to ensure unrestricted access for all users and data storage and preservation. Trusted open public databases shall have in place a robust, transparent and sustainable governance and a transparent model of user access.	
	Article	2 41(7)			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
535	7. The Commission is empowered to adopt delegated acts in accordance with Article 67 to amend the duties of the data holders in this Article, to reflect the evolution of activities performed by data holders.		deleted	7. The Commission is empowered to adopt delegated acts in accordance with Article 67 to amend the duties of the data holders in this Article, to reflect the evolution of activities performed by data holders.	
	Article	e 41a			
535a			<u>Article 41a</u> Duties of health data users		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement		
	Article	41a(1)					
535b			1. <u>Health data users may</u> access and process the electronic health data for secondary use referred to in Article 33 only in accordance with the data permit issued by the health data access body in accordance with Article 46 of this Regulation.				
	Article 41a(2)						

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
535c			2. Health data users shall not re-identify or seek to re-identify the natural persons to whom the electronic health data which they obtained based on the data permit or data request belong. Such conduct shall be considered a serious breach of this Regulation.		
	Article	41a(3)			
535d			<u>3. Health data users shall</u> make public the results or		

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	output of the secondary use		
	<u>of electronic health data,</u>		
	including information		
	<u>relevant for the provision</u>		
	<u>of healthcare, no later than</u>		
	<u>18 months after the</u>		
	<u>completion of the</u>		
	<u>electronic health data</u>		
	processing or after having		
	<u>received the answer to the</u>		
	data request referred to in		
	Article 47. Those results or		
	<u>output shall not contain</u>		
	<u>personal data. In justified</u>		
	<u>cases, especially cases</u>		
	<u>referred to in Article 34(1),</u>		
	<u>point (e), that period may</u>		
	<u>be extended by the relevant</u>		
	<u>health data access body,</u>		
	after consultation with the		
	<u>health data user. The</u>		

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	health data users shall		
	inform the health data		
	access bodies from which a		
	<u>data permit was obtained</u>		
	about the results or output		
	and provide them with		
	<u>necessary support in order</u>		
	<u>to make them public also</u>		
	<u>on health data access</u>		
	bodies' websites. The result		
	<u>shall also be made publicly</u>		
	<u>available in lay summaries.</u>		
	Whenever the health data		
	<u>users have used electronic</u>		
	<u>health data in accordance</u>		
	<u>with this Chapter, they</u>		
	<u>shall acknowledge the</u>		
	<u>electronic health data</u>		
	sources and the fact that		
	<u>electronic health data has</u>		
	<u>been obtained in the</u>		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			<u>context of the EHDS.</u>		
	Article	e 41a(4)			
535e			4. Without prejudice to paragraph 2, health data users shall inform the health data access body of any significant findings related to the health of the natural person whose data are included in the dataset.		
	Article	e 41a(5)			
535f					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			5. The ECDC and the EMA shall, in consultation and cooperation with relevant stakeholders, including representatives of patients, health professionals and researchers, create guidelines in order to help health data users to fulfil their obligation under paragraph 5, especially to determine whether their findings are clinically significant.		
	Artic	le 41a(6)			
535g					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			6. The ECDC and the EMA shall, in consultation and cooperation with relevant stakeholders, including representatives of patients, health professionals and researchers, create guidelines in order to help health data users to fulfil their obligation under paragraph 5, especially to determine whether their findings are clinically significant.		
	Artio	cle 42			
536					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 42		Article 42	Article 42	
	Fees		Fees	Fees	
	Article	42(1)		<u> </u>	
537	1. Health data access bodies and single data holders may charge fees for making electronic health data available for secondary use. Any fees shall include and be derived from the costs related to conducting the procedure for requests,		 Health data access bodies and single data holders may charge feesmay charge fees to health data users for making electronic health data available for secondary use. Any fees shall include and be derived from the 	1. Health data access bodies andor single health data holders referred to in Article 49 may charge fees for making electronic health data available for secondary use. AnySuch fees shall include and be derived from the costs related to	
	including for assessing a data application or a data request, granting, refusing		costs related to <u>the set up</u> , <u>combination, preparation</u> , <u>anonymisation</u> ,	the costs related to conducting the procedure for requests, including be in proportion to the cost of	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
or amending a data permit	pseudonymisation,	making the data available	
pursuant to Articles 45 and	<u>maintenance, tasks under</u>	and not restrict	
46 or providing an answer	Article 33a, making	competition. Such fees	
to a data request pursuant to	available or updating of the	shall cover all or part of	
Article 47, in accordance	dataset and conducting the	costs related to the	
with Article 6 of Regulation	procedure for requests,	procedure for assessing a	
[] [Data Governance Act	including for assessing a	data permit application or a	
COM/2020/767 final]	data application or a data	data request, granting,	
	request, granting, refusing	refusing or amending a data	
	or amending a data permit	permit pursuant to	
	pursuant to Articles 45 and	ArticlesArticle 45 and 46 or	
	46 or providing an answer	providing an answer to a	
	to a data request pursuant to	data request pursuant to	
	Article 47, in accordance	Article 47, in accordance	
	with Article 6 of Regulation	withas well as costs related	
	[] [Data Governance Act	to the gathering,	
	COM/2020/767 final] <u>. No</u>	preparation and	
	fees shall be charged to	provisioning of the	
	public sector bodies and	electronic health data.	
	Union institutions, offices,	This provision prevails	
	agencies and bodies when	over Article 6 of Regulation	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			making data available for the purposes referred to in Article 34(1), points (a), (b) and(c). No fees shall be charged to public sector bodies or Union institutions, offices, agencies and bodies with a legal mandate in the field of public health.	[] [Data Governance Act COM/2020/767 final](EU)2022/868 for health data holders and single data holders from the public sector. Reduced fees may be established by the Member States for certain types of data users located in the Union, such as university researchers or micro-enterprises.	
	Article	42(2)			
538	2. Where the data in question are not held by the data access body or a public		 In the case of health data holders, where the data in question are not held 	 2. Where the electronic health data in question are not held by the data access 	

Co	ommission Proposal	EP Mandate	Council Mandate	Draft Agreement
secto	tor body, the fees may	by the <i>health</i> data access	body or a public sectora	
also	o include compensation	body or a public sector	health data holder or a	
for p	part of the costs for	body <u><i>or a Union</i></u>	data intermediation entity	
colle	lecting the electronic	institution, office, agency	which is not a health data	
healt	lth data specifically	and body, the fees may also	access body, the fees	
unde	ler this Regulation in	include compensation for	charged pursuant to	
addi	lition to the fees that	part of<u>be</u> derived from the	paragraph 1 may also	
may	y be charged pursuant to	costs for	include compensation for	
para	agraph 1. The part of the	collectinggathering,	part of the costs for	
fees	s linked to the data	enriching, and preparing	collecting costs incurred	
hold	der's costs shall be paid	the electronic health data	by the health data holder	
to th	he data holder.	specifically under this	compiling and preparing	
		Regulation in addition to	the electronic health data	
		the fees that may be charged	specifically under this	
		pursuant to paragraph 1.	Regulation in addition to	
		The part of the fees linked	the fees that may be charged	
		to the <i>health</i> data holder's	pursuant to paragraph 1to	
		costs shall be paid to the	be made available for	
		<u>health</u> data holder.	secondary use. When the	
			health data holder is a	
			public sector body, Article	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				6 of Regulation (EU)2022/868 shall not apply. The part of the fees linked to the health data holder's costs shall be paid to the health data holder.	
	Article	e 42(3)			
539	3. The electronic health data referred to in Article 33(1), point (o), shall be made available to a new user free of charge or against a fee matching the compensation for the costs of the human and technical resources used to enrich the		3. The electronic health data referred to in Article 33(1), point (o), shall be made available to a new user free of charge or against a fee matching the compensation for the costs of the human and technical resources used to enrich the	3. The electronic health data referred to in Article 33(1), point (o), shall be made available to a new user free of charge or against a fee matching the compensation for the costs of the human and technical resources used to enrich the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	electronic health data. That		electronic health data. That	electronic health data. That	
	fee shall be paid to the		fee shall be paid to the	fee shall be paid to the	
	entity that enriched the		entity that enriched the	entity that enriched the	
	electronic health data.		electronic health data.	electronic health data.	
	Article	2 42(4)			
	4. Any fees charged to data		4. Any fees charged to	4. Any fees charged to data	
	users pursuant to this		<u>health</u> data users pursuant	users pursuant to this	
	Article by the health data		to this Article by the health	Article by the health data	
	access bodies or data		data access bodies or <i>health</i>	access bodies or data	
540	holders shall be transparent		data holders shall be	holders shall be transparent	
	and proportionate to the		transparent <mark>, <i>non</i>-</mark>	and proportionate to the	
	cost of collecting and		<u>discriminatory,</u> and	cost of collecting and	
	making electronic health		proportionate to the cost of	making electronic health	
	data available for secondary		collecting and making	data available for secondary	
	use, objectively justified		electronic health data	use, objectively justified	
	and shall not restrict		available for secondary use,	and shall not restrict	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
competition. The support	objectively justified and	competition. The support	
received by the data holder	shall not restrict	received by the data holder	
from donations, public	competition. The support	from donations, public	
national or Union funds, to	received by the <i>health</i> data	national or Union funds, to	
set up, develop or update tat	holder from donations,	set up, develop or update tat	
dataset shall be excluded	public national or Union	dataset shall be excluded	
from this calculation. The	funds, to set up, develop or	from this calculation. The	
specific interests and needs	update t<i>at</i> that dataset shall	specific interests and needs	
of SMEs, public bodies,	be excluded from this	of SMEs, public bodies,	
Union institutions, bodies,	calculation. The specific	Union institutions, bodies,	
offices and agencies	interests and needs of	offices and agencies	
involved in research, health	SMEs, public bodies, Union	involved in research, health	
policy or analysis,	institutions, bodies, offices	policy or analysis,	
educational institutions and	and agencies involved in	educational institutions and	
healthcare providers shall	research, health policy or	healthcare providers shall	
be taken into account when	analysis, <u>academic and</u>	be taken into account when	
setting the fees, by reducing	educational institutions,	setting the fees, by reducing	
those fees proportionately	<u>non-commercial entities</u>	those fees proportionately to	
to their size or budget.	and healthcare providers	their size or budget.	
	shall be taken into account		
	when setting the fees, by		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			reducing those fees proportionately to their size or budget.		
	Article	42(5)			
541	5. Where data holders and data users do not agree on the level of the fees within 1 month of the data permit being granted, the health data access body may set the fees in proportion to the cost of making available electronic health data for secondary use. Where the data holder or the data user disagree with the fee set out		5. Where <i>health</i> data holders and <i>health</i> data users do not agree on the level of the fees within 1 month of the data permit being granted, the health data access body may set the fees in proportion to the cost of making available electronic health data for secondary use. Where the <i>health</i> data holder or the	5. Where data holders and data users do not agree on the level of the fees within 1 month of the data permit being granted, the health data access body may set the fees in proportion to the cost of making available electronic health data for secondary use. Where the data holder or the data user disagree with the fee set out	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	by the health data access body, they shall have access to dispute settlement bodies set out in accordance with Article 10 of the Regulation [] [Data Act COM/2022/68 final].		<i>health</i> data user disagree with the fee set out by the health data access body, they shall have access to dispute settlement bodies set out in accordance with Article 10 of the Regulation [] [Data Act COM/2022/68 final].	by the health data access body, they shall have access to dispute settlement bodies set out in accordance with Article 10 of the Regulation [] [Data Act COM/2022/68 final].	
	Article	42(5a)			
541a				5a. Before issuing a data permit pursuant to Article 46 or providing an answer to a data request pursuant to Article 47, the health data access body shall	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				inform the applicant of the expected fees. The applicant shall be informed about the option to withdraw the application. If the applicant withdraw its application, the applicant shall only be charged the costs that have already been incurred.	
	Article 42(6	(6)			
542	6. The Commission may, by means of implementing acts, lay down principles and rules for the fee		6. The Commission <i>mayshall</i> , by means of implementing acts, lay down principles and rules	6. The Commission may, by means of implementing acts, lay down principles and rules for thein close	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement		
	policies and fee structures. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2).		for the fee policies and fee structures, <i>including</i> <i>deductions for the entities</i> <i>listed in paragraph 4,</i> <i>second sub-paragraph</i> . Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2).	cooperation with the EHDS Board, issue guidelines on fee policies and fee structures. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2) in order to support consistency and transparency between Member States.			
	Article 43						
543	Article 43 Penalties by health data		Article 43 Penalties <u>Enforcement</u> by	Article 43 Penalties Non-compliance			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	access bodies		health data access bodies	by health data access bodies holder and health data user	
	Article	43(1)			
544	1. Health data access bodies shall monitor and supervise compliance by data users and data holders with the requirements laid down in this Chapter.		deleted	 Health data access bodies shall monitor and supervise compliance by data users and data holders with the requirements laid down in this Chapter. [MOVED TO ARTICLE 37(1)(ab)] 	

	Commission Propos	sal		EP Mandate	Council Mandate	Draft Agreement
	A	rticle	43(2)			
	2. When requesting from	m		2. When requesting from	2. When requesting from	
	data users and data holde	ers		data users and data holders	data users and data holders	
	the information that is			the information that is	the information that is	
	necessary to verify			necessary carrying out its	necessary to verify	
	compliance with this			monitoring and supervisory	compliance with this	
	Chapter, the health data			to verify compliance	Chapter, thehealth data	
545	access bodies shall be			with this Chapter, <u>as</u>	access bodies perform	
	proportionate to the			referred to in Article 37(1),	their monitoring and	
	performance of the			point (ra), the health data	supervising tasks the	
	compliance verification			access bodies shall	bodies have the right to	
	task.			be <u>request information from</u>	request and receive from	
				health data holders and	health data access bodies	
				users that is proportionate	shall be proportionate to the	
				to for the performance of the	performance of the users	
				compliance verification	and health data holders all	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		task.	the necessary information to verify compliance verification taskwith this Chapter.	
	Article 43(3)			
546	3. Where health data access bodies find that a data user or data holder does not comply with the requirements of this Chapter, they shall immediately notify the data user or data holder of those findings and shall give it the opportunity to state its views within 2 months.	3. Where health data access bodies find that a <i>health</i> data user or <i>health</i> data holder does not comply with the requirements of this Chapter, they shall immediately notify the <i>health</i> data user or <i>health</i> data holder of those findings and shall give it the opportunity to state its	3. Where a health data access bodies find body finds that a health data user or a health data holder does not comply with the requirements of this Chapter, they it shall immediately notify the health data user or health data holder of those findings and take	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	views within 2 <i>months</i>4	appropriate measures.	
	<u>weeks.</u>	The health data access	
		body shall give itthe	
		concerned health data	
	Where the finding of non-	user or the health data	
	compliance concerns a	holder the opportunity to	
	possible breach of	state its views within a	
	Regulation (EU) 2016/679,	reasonable time 2 months .	
	the health data access body		
	<u>shall immediately inform</u>		
	the supervisory authorities		
	under Regulation (EU)		
	2016/679 and provide them		
	with all relevant		
	information at their		
	disposal concerning this		
	finding to ensure		
	application and		
	enforcement of the relevant		
	provisions of that		
	Regulation, including		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			<u>penalties</u> .		
	Article	2 43(4)			
	4. Health data access		4. Health data access	4. With regard to non-	
	bodies shall have the power		bodies shall have the power	compliance by a health	
	to revoke the data permit		to revoke the data permit	data user pursuant to a	
	issued pursuant to Article		issued pursuant to Article	data permit, health data	
	46 and stop the affected		46 and stop the affected	access bodies shall have the	
547	electronic health data		electronic health data	power to revoke the data	
347	processing operation carried		processing operation carried	permit issued pursuant to	
	out by the data user in order		out by the <u>health</u> data user	Article 46 and stop the	
	to ensure the cessation of		in order to ensure the	affected electronic health	
	the non-compliance referred		cessation of the non-	data processing operation	
	to in paragraph 3,		compliance referred to in	carried out by the health	
	immediately or within a		paragraph 3, immediately or	data user-in order to ensure	
	reasonable time limit, and		within a reasonable time	the cessation of the non-	
	shall take appropriate and		limit<u>without undue delay</u>,	compliance referred to in	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
proportionate measures	and shall take appropriate	paragraph 3, immediately	
aimed at ensuring	and proportionate measures	or within a reasonable time	
compliant processing by the	aimed at ensuring compliant	limit, and shall take	
data users. In this regard,	processing by the <i>health</i>	appropriate and	
the health data access	data users. In this regard,	proportionate measures	
bodies shall be able, where	the health data access	aimed at ensuring compliant	
appropriate, to revoke the	bodies shall be able, where	processing by the health	
data permit and to exclude	appropriate, to revoke the	data users In this regard,	
the data user from any	data permit and to exclude	the health data access	
access to electronic health	the <i>health</i> data user from	bodies shall also be able,	
data for a period of up to 5	any access to electronic	where appropriate,-to	
years.	health data for a period of	revoke the data permit and	
	up to 5 years.	to exclude or initiate	
		proceedings to exclude in	
		accordance with national	
		law the healththe data user	
		from any access to	
		electronic health data	
		within the EHDS in the	
		context of secondary use	
		for a period of up to 5 years.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	e 43(4a)			
547a				4a. Where a health data access body finds that a health data user is processing or using the electronic health data outside the scope of the data permit for the prohibited uses laid down in Article 35 or a health data user does not respect the health data access body's measures ensuring pseudonymisation, it shall immediately revoke the data permit issued.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	43(5)		<u> </u>	
	5. Where data holders		5. Where <u>health</u> data	5. With regard to non-	
	withhold the electronic		holders withhold the	compliance by a health	
	health data from health data		electronic health data from	data holder, where health	
	access bodies with the		health data access bodies	data holders withhold the	
	manifest intention of		with the manifest intention	electronic health data from	
	obstructing the use of		of obstructing the use of	health data access bodies	
548	electronic health data, or do		electronic health data, or do	with the manifest intention	
	not respect the deadlines set		not respect the deadlines set	of obstructing the use of	
	out in Article 41, the health		out in Article 41, the health	electronic health data, or do	
	data access body shall have		data access body shall have	not respect the deadlines set	
	the power to fine the data		the power to fine the <i>health</i>	out in Article 4135B(1a),	
	holder with fines for each		data holder with fines for	the health data access body	
	day of delay, which shall be		each day of delay, which	shall have the power to fine	
	transparent and		shall be transparent and	the health data holder with	
	proportionate. The amount		proportionate. The amount	finesperiodic penalty	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
of the fines shall be	of the fines shall be	payment in accordance	
established by the health	established by the health	with national law for each	
data access body. In case of	data access body. In case of	day of delay, which shall be	
repeated breaches by the	repeated breaches by the	transparent and	
data holder of the obligation	health data holder of the	proportionate. The amount	
of loyal cooperation with	obligation of loyal	of the fines shall be	
the health data access body,	cooperation with the health	established by the health	
that body can exclude the	data access body, that body	data access body. In case of	
data holder from	can exclude the <u>health</u> data	repeated breaches by the	
participation in the EHDS	holder from participation in	health data holder of the	
for a period of up to 5	the EHDS submitting data	obligation of loyal	
years. Where a data holder	access applications	cooperation with the health	
has been excluded from the	<i>pursuant to Chapter IV</i> for	data access body, that body	
participation in the EHDS	a period of up to 5 years.	can may exclude the data	
pursuant to this Article,	Where a data holder has	holder from participation in	
following manifest	been excluded from the	the EHDS for a period of up	
intention of obstructing the	participation in the EHDS,	to 5 years. Where aor	
secondary use of electronic	while still being obliged to	initiate proceedings to	
health data, it shall not have	make data accessible	exclude in accordance	
the right to provide access	pursuant to t<i>his Article,</i>	with national law the	
to health data in accordance	following manifest intention	health data holder has been	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	with Article 49.		of obstructing the secondary use of electronic health data, it shall not have the right to provide access to health data in accordance with Article 49 <u>Chapter IV, where</u> applicable.	excluded from thefrom participation in the EHDS pursuant to this Article, following manifest intention of obstructing the in the context of secondary use of electronic health data, it shall not have the right to provide access to health data in accordance with Article 49.for a period of up to 5 years.	
	Article	43(6)			
549	6. The health data access body shall communicate the measures imposed pursuant		6. The health data access body shall communicate the measures imposed pursuant	6. The health data access body shall communicate the measures imposed pursuant	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	to paragraph 4 and the reasons on which they are based to the data user or holder concerned, without delay, and shall lay down a reasonable period for the data user or holder to comply with those measures.		to <i>paragraphparagraphs</i> 4 and <u>5 and</u> the reasons on which they are based to the <i>health</i> data user or holder concerned, without delay, and shall lay down a reasonable period for the <i>health</i> data user or holder to comply with those measures.	to paragraph 4 and the reasons on which they are based to the health data user or holder concerned, without delay, and shall lay down a reasonable period for the health data user or holder to comply with those measures.	
	Article 4	13(7)			
550	7. Any penalties and measures imposed pursuant to paragraph 4 shall be made available to other health data access bodies.		7. Any <i>penalties</i> and <u>enforcement</u> measures imposed pursuant to paragraph 4 shall be <i>made</i> available <u>notified</u> to other	7. Any measures imposed by the health data access body - <u>penalties and</u> <u>measures imposed</u> pursuant to paragraph 4 shall be	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			health data access bodies <u>and made publicly</u> <u>available on the website of</u> <u>the EHDS Board</u> .	made available-notified to other health data access bodies, through the tool referred to in paragraph 8.	
	Article	e 43(7a)			
550a			7a.The health data accessbody shall ensure coherentenforcement based on theprovisions of thisRegulation and Regulation(EU) 2016/679 by takinginto account any decisionor investigation ongoing insupervisory authorities.		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	: 43(8)			
	8. The Commission may,		8. The Commission may,	8. The Commission	
	by means of implementing		by means of implementing	mayshall, by means of	
	act, set out the architecture		act, set out the architecture	implementing act, set out	
	of an IT tool aimed to		of an IT tool aimed to	the architecture of an IT	
	support and make		support and make	tool aimed to support and	
	transparent to other health		transparent to other health	make transparent to other	
551	data access bodies the		data access bodies the	health data access bodies	
	activities referred to in this		activities referred to in this	the activities measures	
	Article, especially penalties		Article, especially penalties	related to non-compliance	
	and exclusions. Those		and exclusions. Those	referred to in this Article,	
	implementing acts shall be		implementing acts shall be	especially penalties periodic	
	adopted in accordance with		adopted in accordance with	penalty payments,	
	the advisory procedure		the advisory procedure	revoking of data permits	
	referred to in Article 68(2).		referred to in Article 68(2).	and exclusions. Those	
				implementing acts shall be	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				adopted in accordance with the advisory examination procedure referred to in Article 68(2).	
	Article	e 43(9)			
552	9. Any natural or legal person affected by a decision of a health data access body shall have the right to an effective judicial remedy against such decision.		deleted	9. Any natural or legal person affected by a decision of a health data access body shall have the right to an effective judicial remedy against such decision.	
	Article	e 43(10)			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
553	10. The Commission may issues guidelines on penalties to be applied by the health data access bodies.		10. The Commission <i>may</i> <i>issuesshall issue</i> guidelines on <i>penaltiesenforcement</i> <i>measures</i> to be applied by the health data access bodies, <i>in accordance with</i> <i>the principles set out in</i> <i>Article 68a</i> .	10. The Commission may issuesissue guidelines, in close cooperation with EHDS Board, on periodic penalty payments and other measures-on penalties to be applied by the health data access bodies.	
	Article	43a			
553a			<u>Article 43a</u> <u>General conditions for the</u> <u>imposition of</u>		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			<u>administrative fines by</u> <u>health data access bodies</u>		
	Article	e 43a(1)			
553b			1. Each health data access body shall ensure that the imposition of administrative fines pursuant to this Article in respect of infringements referred to in paragraphs 4 and 5 shall in each individual case be effective, proportionate and dissuasive.		

	Commission Prop	oosal		EP Mandate	Council Mandate	Draft Agreement	
		Article	43a(2)				
553c				2. Administrative fines shall, depending on the circumstances of each individual case, be imposed in addition to, or instead of, measures referred to in Article 43(4) and (5). When deciding whether to impose an administrative fine and deciding on the amount of the administrative fine in each individual case due regard shall be given to the following:			
	Article 43a(2), point (a)						

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
553d			(a) the nature, gravity and duration of the infringement;		
	Article	e 43a(2), point (b)			
553e			(b) whether any penalties or administrative fines have already been applied by other competent authorities to the same infringing party for the same infringement;		

	Commission Propo	osal		EP Mandate	Council Mandate	Draft Agreement
	ļ	Article	43a(2), point (c)			
553f				(c) the intentional or negligent character of the infringement;		
	ļ	Article	43a(2), point (d)			
553g				(d) any action taken by the health data holder or health data user to mitigate the damage suffered by natural persons;		
	ļ	Article	43a(2), point (e)			

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
553h		(e) the degree of responsibility of the health data user, taking into account technical and organisational measures implemented by them pursuant to Article 45(2), points (e) and (f),and Article 45(4);		
	Article 43a(2), poi	nt (f)	-	
553i		(f) any relevant previous infringements by the health data holder or health data user;		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	43a(2), point (g)			
553j			(g) the degree of cooperation with the health data access body, in order to remedy the infringement and mitigate the possible adverse effects of the infringement;		
	Article	: 43a(2), point (h)			
553k			(h) the manner in which the infringement became		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			<u>known to the health data</u> <u>access body, in particular</u> <u>whether, and if so to what</u> <u>extent, the health data user</u> <u>notified the infringement;</u>		
	Article	43a(2), point (i)			
5531			(i) where measures referred to in Article 43(4) and (5) have previously been ordered against the controller or processor concerned with regard to the same subject-matter, compliance with those measures;		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	43a(2), point (j)			
553 m			(j) any other aggravating or mitigating factor applicable to the circumstances of the case, such as financial benefits gained, or losses avoided, directly or indirectly, from the infringement.		
	Article	e 43a(3)			
553n			<u>3.</u> If a health data holder		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			or health data user intentionally or negligently, for the same or linked health data permits or health data requests, infringes several provisions of this Regulation, the total amount of the administrative fine shall not exceed the amount specified for the gravest infringement.		
	Article	43a(4)			
5530			<u>4.</u> In accordance with paragraph 2, infringements of the obligations of the		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			health data holder or health data user pursuant to Article 41 and Article 41a(1), (4), (5) and (7) shall be subject to administrative fines of up to 10 000 000 EUR, or in the case of an undertaking, up to 2 % of the total worldwide annual turnover of the preceding financial year, whichever is higher.		
	Article	43a(5)			
553p			5. Infringements of the following provisions shall, in accordance with		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			paragraph 2, be subject to administrative fines of up to EUR 20 000 000, or in the case of an undertaking, of up to 4 % of the total worldwide annual turnover of the preceding financial year, whichever is higher;		
	Article	43a(5), point (a)			
553q			(a) health data users processing electronic health data obtained via a data permit issued in line with Article 46 for the purposes referred to in Article 35;		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	e 43a(5), point (b)			
553r			(b) health data users extracting personal health data outside the secure processing environment provided by the health data access body pursuant to Article 50;		
	Article	e 43a(5), point (c)			
553s			(c) <u>re-identifying or</u> seeking to re-identify the		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			natural persons to whom the electronic health data which they obtained based on the data permit or data request pursuant to Article 41a(3) belong;		
	Artic	cle 43a(5), point (d)			
553t			(d) non-compliance with enforcement measures by the health data access body pursuant to Article 43.		
	Artic	cle 43a(6)			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
553u			6. Without prejudice to the corrective powers of health data access bodies pursuant to Article 43, each Member State may lay down the rules on whether and to what extent administrative fines may be imposed on public authorities and bodies established in that Member State.		
	Article	2 43a(7)			
553v			<u>7.</u> The exercise by the		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			health data access body of its powers under this Article shall be subject to appropriate procedural safeguards in accordance with Union and Member State law, including effective judicial remedies and due process.		
	Article	43a(8)			
553 w			8. Where the legal system of the Member State does not provide for administrative fines, this Article may be applied in such a manner that the		

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	fine is initiated by the		
	competent health data		
	access body and imposed		
	by competent national		
	<u>courts, while ensuring that</u>		
	<u>those legal remedies are</u>		
	<u>effective and have an</u>		
	equivalent effect to the		
	<u>administrative fines</u>		
	<u>imposed by health data</u>		
	access bodies. In any event,		
	the fines imposed shall be		
	<u>effective, proportionate and</u>		
	<u>dissuasive. Those Member</u>		
	<u>States shall notify the</u>		
	Commission of the		
	provisions of their laws		
	which they adopt pursuant		
	to this paragraph by		
	[date of application of this		
	<u>Regulation] and, without</u>		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			<u>delay, any subsequent</u> <u>amendment law or</u> <u>amendment affecting them.</u>		
	Article	e 43A			
553x				Article 43A Relationship with data protection supervisory authorities	
	Article	e 43a(1)			
553y				The supervisory	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		authority or authorities	
		responsible for monitoring	
		and enforcement the	
		application of Regulation	
		(EU) 2016/679 or	
		Regulation (EU)	
		2018/1725 shall also be	
		responsible for monitoring	
		and enforcement the	
		processing of personal	
		electronic health data for	
		secondary use, in	
		accordance with the	
		relevant provisions of	
		Regulation (EU) 2016/679	
		or of Regulation (EU)	
		2018/1725 respectively.	
		They shall be competent	
		to impose administrative	
		fines up to the amount	
		referred to in Article 83	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				and 52 respectively of those Regulations. Those supervisory authorities and the health data access bodies referred to in Article 36 of this Regulation shall, where relevant, cooperate in the enforcement of this Regulation, within the remit of their respective competences.	
	Section	n 3			
554	Section 3 Data permit for the secondary use of electronic health data		Section 3 Data permit for the secondary use of electronic health data	Section 3 Data permit for the secondary use of Access to electronic health data for	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				secondary use	
	Article	44			
555	Article 44 Data minimisation and purpose limitation		Article 44 Data minimisation and purpose limitation	Article 44 Data minimisation and purpose limitation	
	Article	44(1)			
556	1. The health data access body shall ensure that access is only provided to requested electronic health		1. The health data access body shall ensure that access is only provided to requested electronic health	1. The health data access body shall ensure that access is only provided to requested electronic health	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	data relevant for the purpose of processing indicated in the data access application by the data user and in line with the data permit granted.		data <u>that are adequate</u> , relevant <u>for and limited to</u> <u>what is necessary in</u> <u>relation to</u> the purpose of processing indicated in the data access application by the data user and in line with the data permit granted.	data relevant for the purpose of processing indicated in the data access permit application by the health data user and in line with the data permit granted.	
	Article	2 44(2)			
557	2. The health data access bodies shall provide the electronic health data in an anonymised format, where the purpose of processing by the data user can be		2. The health data access bodies shall provide the electronic health data in an anonymised format, <i>in any</i> <i>event</i> where the purpose of processing by the <i>health</i>	2. The health data access bodies shall provide-the electronic health data in an anonymised or anonymised statistical format, where the purpose of processing by	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	achieved with such data, taking into account the information provided by the data user.		data user can be achieved with such data, taking into account the information provided by the <i>health</i> data user.	the health data user can be achieved with such data, taking into account the information provided by the health data user.	
	Article	44(3)			
558	3. Where the purpose of the data user's processing cannot be achieved with anonymised data, taking into account the information provided by the data user, the health data access bodies shall provide access to electronic health data in pseudonymised		3. Where the <i>purpose of the</i> <i>data user'shealth data user</i> <i>has sufficiently</i> <i>demonstrated that the</i> <i>purpose of</i> processing cannot be achieved with anonymised data <i>in line</i> <i>with Article 46(1c)</i> , taking into account the information provided by the <i>health data</i>	3. Where the purpose of the health data user's processing cannot be achieved with anonymised data, taking into account the information provided by the health data user, the health data access bodies shall provide access to electronic health data in	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
format. The information	<u>userthe-data user, the</u>	pseudonymised format. The	
necessary to reverse the	health data access bodies	information necessary to	
pseudonymisation shall be	shall provide access to	reverse the	
available only to the health	electronic health data in	pseudonymisation shall be	
data access body. Data	pseudonymised format. The	available only to the health	
users shall not re-identify	information necessary to	data access body . Data users	
the electronic health data	reverse the	shall not re-identify the	
provided to them in	pseudonymisation shall be	electronic health data	
pseudonymised format. The	available only to the health	provided to them in	
data user's failure to respect	data access body. <u><i>Health</i></u>	pseudonymised format. The	
the health data access	Data users shall not re-	data user's failure to respect	
body's measures ensuring	identify the electronic	the health data access	
pseudonymisation shall be	health data provided to	body's measures ensuring	
subject to appropriate	them in <i>anonymised or</i>	pseudonymisation shall be	
penalties.	pseudonymised formatThe	subject to appropriate	
	data user's failure to	penalties. or a body that	
	respect the health data	acts as trusted third party	
	access body's measures	in accordance with	
	ensuring pseudonymisation	national law.	
	shall be subject to		
	appropriate penalties.		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				[THIRD SENTENCE MOVED TO ARTICLE 35C(1). LAST SENTENCE SEE ARTICLE 43(4A)]	
	Article	44(3a)			
558a			3a. The health data user's failure to respect the health data access body's measures ensuring anonymisation and pseudonymisation shall be considered a particularly serious breach of this Regulation and shall be subject to effective,		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			<u>proportionate and</u> <u>dissuasive penalties.</u>		
	Article	44(3b)			
558b			<u>3b.</u> <u>The Commission shall,</u> <u>by means of implementing</u> <u>acts, set out the procedures</u> <u>and requirements, and</u> <u>provide technical tools, for</u> <u>a unified procedure for</u> <u>anonymising and</u> <u>pseudonymising the</u> <u>electronic health data.</u> <u>Those implementing acts</u> <u>shall be adopted in</u> <u>accordance with the</u> <u>advisory procedure</u>		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			<u>referred to in Article 68(2).</u>		
	Article	45			
559	Article 45 Data access applications		Article 45 Data access applications	Article 45 Data access applications	
	Article	45(1)			
560	1. Any natural or legal person may submit a data access application for the purposes referred to in Article 34.		 Any natural or legal person<u>Health data</u> <u>applicants</u> may submit a data access application for the purposes referred to in 	1. AnyA natural or legal person may submit a data access application for the purposes referred to in Article 34 to the health	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			Article 34.	data access body.	
	Article	2 45(2)			
561	2. The data access application shall include:		2. The data access application shall include:	2. The data access application shall include a data utilisation plan with the following information:	
	Article	e 45(2), point (-a)			
561a			(-a) the health data applicant's identity, description of professional functions and operations,		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			including the identity of the natural persons who will have access to electronic health data, if a data permit is granted; the list of natural persons can be updated and in that case it shall be notified to the health data access body;		
	Article	e 45(2), point (aa)			
561b				(aa) a description of the applicant's identity, professional function and activities, including the identity of the natural persons who will have	

	Commission Proposal	1	EP Mandate	Council Mandate	Draft Agreement		
				access to the electronic health data;			
	Arti	icle 45(2), point (a)					
562	(a) a detailed explanation of the intended use of the electronic health data, including for which of the purposes referred to in Article 34(1) access is sought;		(a) a detailed explanation of the intended use of the electronic health data , including for which of the purposes referred to in Article 34(1), access is <i>soughtnecessary</i> ;	(a) a-detailed explanation of the intended use and expected benefit related to the use of the electronic health data, including for which of the purposes referred to in Article 34(1) access is sought;			
	Article 45(2), point (aa)						

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
562a			(aa) a description of how the health data applicant is qualified vis-à-vis the intended purposes of data use, including professional qualifications to demonstrate appropriate expertise, consistent with ethical practice and applicable laws and regulations;		
	Article	45(2), point (ab)			
562b			(ab) an explanation of the expected benefits and how		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			<u>these benefits contribute to</u> <u>the purposes referred to in</u> <u>Article 34(1);</u>		
	Article	e 45(2), point (b)			
563	(b) a description of the requested electronic health data, their format and data sources, where possible, including geographical coverage where data is requested from several Member States;		(b) a description of the requested electronic health data, their <i>timeframe</i> , format and data sources, where possible, including geographical coverage where data is requested from several Member States;	(b) a description of the requested electronic health data, their format and data sources, where possible, including geographical coverage where data is requested from health data holder in several Member States or authorised participants in the cross- border infrastructure referred to in Article 52;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	e 45(2), point (c)			
564	(c) an indication whether electronic health data should be made available in an anonymised format;		(c) an <i>indication<u>explanation</u></i> whether electronic health data <i>should<u>needs to</u></i> be made available in <i>an</i> <i>anonymised</i> <i>pseudonymised</i> format <u>and</u> <i>why the envisaged purpose</i> <i>for processing cannot be</i> <i>pursued using anonymised</i> <i>data</i> ;	(c) an indication a description whether electronic health data need to should be made available in ana pseudonymised or anonymised format;	
	Article	e 45(2), point (d)			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
565	(d) where applicable, an explanation of the reasons for seeking access to electronic health data in a pseudonymised format;		(d) where applicable, an explanationa description of the reasons for seeking access to electronic health data in a pseudonymised formatsafeguards planned to prevent any other use or any misuse of the electronic health data;	(d) where applicable, an explanation of the reasons for seeking access to electronic health data in a pseudonymised format;	
	Article	e 45(2), point (e)	_	_	
566	(e) a description of the safeguards planned to prevent any other use of the electronic health data;		(e) a description of the safeguards <i>proportionate to</i> <i>the risks</i> , planned to <i>prevent any other</i>	(e) a description of the safeguards planned to prevent any other use misuse of the electronic	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			useprotect the rights and interests of the electronic health data holder;	health data, including re- identification of natural persons in the dataset;	
	Article	e 45(2), point (ea)			
566a				(ea) in case the applicant intends to bring datasets it already holds into the secure processing environment, a description of those datasets;	
	Article	e 45(2), point (f)	·		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
567	(f) a description of the safeguards planned to protect the rights and interests of the data holder and of the natural persons concerned;		(f) <u>for personal electronic</u> <u>health data</u> , a description of the safeguards <u>plannednecessary technical</u> <u>and organisational</u> <u>measures pursuant to</u> <u>Article 32 of Regulation</u> (EU) 2016/679; to protect the rights and interests of the <u>data holder and of</u> the <u>natural persons</u> <u>concerned, including to</u> <u>prevent any re-</u> <u>identification of</u> natural persons concerned<u>in the</u> <u>dataset</u> ;	(f) a description of the safeguards planned to protect the rights and interests of the health data holder and of the natural persons concerned;	
	Article	e 45(2), point (g)			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
568	(g) an estimation of the period during which the electronic health data is needed for processing;		(g) ama justified estimation of the period during which the electronic health data is needed for processing;	(g) an estimation indication of the period during which the electronic health data is needed for processing in a secure processing environment;	
	Artic	le 45(2), point (h)			
569	(h) a description of the tools and computing resources needed for a secure environment.		(h) a description of the tools and computing resources needed for a secure environment.	(h) a description of the tools and computing resources needed for a secure environment.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Artic	le 45(2), point (ha)			
569a			(ha) where applicable, information on the assessment of ethical aspects of the processing and details of any necessary ethics approval obtained by the competent ethics committee in line with national law, which may serve to replace their own ethics assessment;		
	Artic	le 45(2), point (hb)		-	
569b					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			(hb) a plan defining audiences and tools to provide information publicly on the results or outcomes of the access to the data in accordance with Article 46(11);		
	Article	e 45(2), point (hc)			
569c			(hc) a declaration that the intended uses of the data requested do not pose a risk of stigmatisation of or causing harm to the dignity of individuals or the groups to which the dataset		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			requested relates.		
	Article	45(2), point (i)			
569d				(i) information on the assessment of ethical aspects of the processing, where applicable and in line with national law. [MOVED FROM ARTICLE 45(4)(b)]	
	Article	45(3)			

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
570	3. Data users seeking access to electronic health data from more than one Member State shall submit a single application to one of the concerned health data access bodies of their choice which shall be responsible for sharing the request with other health data access bodies and authorised participants in HealthData@EU referred to in Article 52, which have been identified in the data access application. For	3. <u>Health data</u> <u>applicantsData users</u> seeking access to electronic health data from more than one Member State shall submit a single application to one of the concerned health data access bodies of their choice which shall be responsible for sharing the <u>request with application</u> <u>with the</u> other health data access bodies and authorised participants in HealthData@EU referred to in Article 52, which have been identified in the data	3. Data users seeking access to electronic health data from more than one Member State shall submit a single application to one of the concerned health data access bodies of their choice which shall be responsible for sharing the request with other health data access bodies and authorised participants in HealthData@EU referred to in Article 52, which have been identified in the data access application. For	
	requests to access electronic health data from more than one Member States, the	access application. <i>For</i> <i>requests to access</i>	requests to access electronic health data from more than one Member States, the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	health data access body shall notify the other relevant health data access bodies of the receipt of an application relevant to them within 15 days from the date of receipt of the data access application.		<i>electronic health data from</i> <i>more than one Member</i> <i>States In such a case</i> , the health data access body shall notify the other relevant health data access bodies of the receipt of an application relevant to them within 15 days from the date of receipt of the data access application.	health data access body shall notify the other relevant health data access bodies of the receipt of an application relevant to them within 15 days from the date of receipt of the data access application. [MOVED TO ARTICLE 45(5A) AND AMENDED]	
	Article	45(4)			
571	4. Where the applicant intends to access the		4. Where the <i>applicant</i> intendshealth data	43 . Where the applicant intends to seeks for access	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	personal electronic health data in a pseudonymised format, the following additional information shall be provided together with the data access application:		<i>applicants intend</i> to access the personal electronic health data in a pseudonymised format, the following additional information shall be provided together with the data access application:	the personal electronic health data in a pseudonymised format in a secure processing environment , the following additional information shall be provided together with the data access application:	
	Article	45(4), point (aa)		I	
571a				(aa) a detailed justification on the reasons why access to electronic health data in an anonymised form is not sufficient for the intended use;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				[MOVED FROM PARA 2(D)]	
	Article	45(4), point (a)			
572	(a) a description of how the processing would comply with Article 6(1) of Regulation (EU) 2016/679;		 (a) a description of how the processing would comply with <i>Article 6(1)</i> <i>ofapplicable Union and</i> <i>national law on data</i> <i>protection and privacy</i>, <i>notably</i> Regulation (EU) 2016/679; 	 (a) a description of how the processing would comply with Article 6(1) of Regulation (EU) 2016/679 or Articles 5(1) and 10(2) of Regulation (EU) 2018/1725; 	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Articl	e 45(4), point (ba)			
572a				(ba) a description of how the processing would comply with Chapter V of Regulations (EU) 2016/679 or (EU) 2018/1725 respectively, where applicable;	
	Articl	e 45(4), point (b)			
573	(b) information on the assessment of ethical aspects of the processing, where applicable and in line		deleted	(b) information on the assessment of ethical aspects of the processing, where applicable and in line	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	with national law.			with national law. [MOVED TO ARTICLE 45(2)(i)]	
	Article	45(4), point (c)			
573a				(c) a documented data protection impact assessment required by Article 35 of Regulation (EU) 2016/679 or Article 39 of Regulation (EU) 2018/1725, where applicable.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	45(5), first subparagraph		<u> </u>	<u> </u>
	5. For the implementation		5. For the implementation	54. For the implementation	
	of the tasks referred to in		of the tasks referred to in	of the tasks referred to in	
	Article 37(1), points (b) and		Article 37(1), points (b) and	Article 37(1), points (b) and	
	(c), the public sector bodies		(c), the public sector bodies	(c), The public sector bodies	
	and the Union institutions,		and the Union institutions,	and the Union institutions,	
	bodies, offices and agencies		bodies, offices and agencies	bodies, offices and agencies	
574	shall provide the same		shall provide the same	shall provide the same	
	information as requested		information as requested	information as requested	
	under Article 45(2), except		under Article 45(2), except	under Article 45(2) and	
	for point (g), where they		for point (g), where they	45(4) , except for point (g)	
	shall submit information		shall submit information	in 45(2), where they shall	
	concerning the period for		concerning the period for	submit information	
	which the data can be		which the data can be	concerning the period for	
	accessed, the frequency of		accessed, the frequency of	which the electronic health	
	that access or the frequency		that access or the frequency	data can be accessed, the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	of the data updates.		of the data updates.	frequency of that access or the frequency of the data updates.	
	Article	45(5), second subparagraph			
575	Where the public sector bodies and the Union institutions, bodies, offices and agencies intend to access the electronic health data in pseudonymised format, a description of how the processing would comply with Article 6(1) of Regulation (EU) 2016/679 or Article 5(1) of Regulation (EU)		deleted	Where the public sector bodies and the Union institutions, bodies, offices and agencies intend to access the electronic health data in pseudonymised format, a description of how the processing would comply with Article 6(1) of Regulation (EU) 2016/679 or Article 5(1) of Regulation (EU)	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	2018/1725, as applicable, shall also be provided.			2018/1725, as applicable, shall also be provided.	
	Article	45(5)			
575a				5. Where an applicant seeks access to electronic health data from health data holders established in different Member State or from other authorised participants in the cross- border infrastructure referred to in Article 52, the applicant shall submit a single data access application through the Health Data Access Body	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		of their main	
		establishment or through	
		the services provided by	
		the Commission in the	
		cross-border	
		infrastructure	
		HealthData@EU referred	
		to in Article 52. The	
		application shall be	
		automatically forwarded	
		to the authorised	
		participants identified in	
		the data access application	
		and to the Health Data	
		Access Bodies of the	
		Member States where the	
		data holders and the	
		authorised participants	
		identified in the data	
		access application have	
		their main establishment.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				MOVED FROM ARTICLE 45(3)	
	Article	2 45(6)			
576	6. The Commission may, by means of implementing acts, set out the templates for the data access application referred to in this Article, the data permit referred to in Article 46 and the data request referred to in Article 47. Those implementing acts shall be adopted in accordance with		6. The Commission <i>mayshall</i> , by means of implementing acts, set out the templates for the data access application referred to in this Article, the data permit referred to in Article 46 and the data request referred to in Article 47. Those implementing acts shall be adopted in	6. The Commission may, by means of implementing acts, set out the templates for the data access application referred to in this Article, the data permit referred to in Article 46 and the data request referred to in Article 47. Those implementing acts shall be adopted in accordance with	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	the procedure referred to in Article 68(2).	accordance with the procedure referred to in Article 68(2).	the procedure referred to in Article 68(2). [MOVED TO ARTICLE 47A]	
	Article 45(7)			
577	 7. The Commission is empowered to adopt delegated acts in accordance with Article 67 to amend the list of information in paragraphs 2, 4, 5 and 6 of this Article, to ensure the adequacy of 	7. The Commission is empowered to adopt delegated acts in accordance with Article 67 to amend the list of information in paragraphs 2, 4, 5 and 6 of this Article, to ensure the adequacy of the list for	7. The Commission is empowered to adopt delegated acts in accordance with Article 67 to amend the list of information in paragraphs 2, 4, 5 and 6 of this Article, to ensure the adequacy of the list for	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	the list for processing a data access application at national or cross-border level.		processing a data access application at national or cross-border level.	processing a data access application at national or eross-border level.	
	Articl	le 46	L		
578	Article 46 Data permit		Article 46 Data permit	Article 46 Data permit	
	Articl	le 46(1)			
579	 Health data access bodies shall assess if the 		 Health data access bodies shall assess if the 	-1. The health data access bodies shall assess if the	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
application fulfils one of the purposes listed in Article 34(1) of this Regulation, if the requested data is necessary for the purpose listed in the application and if the requirements in this Chapter are fulfilled by the applicant. If that is the case, the health data access body shall issue a data permit.	issue a data permit only when, after an assessment of the data access application, they find that it fulfils oneall of the purposes listed in Article 34(1) of this Regulation, iffollowing criteria: (a) the purpose described in the health data access application is one of the purposes listed in Article 34(1);	application fulfils one of the purposes listed in Article 34(1) of this Regulation, if the requested data is necessary for the purpose listed in the application and if the requirements in this Chapter are fulfilled by the applicant. If that is the case, the health data access body shall issue a data permit.decide to grant or refuse access to electronic health data on the basis of the following criteria:	
	(b) the requested data is necessary, <i>adequate and</i> <i>proportionate</i> for the purpose or <i>purposes</i> listed		

Comm	ssion Proposal	EP Mandate	Council Mandate	Draft Agreement
		in the <i>health data access</i> application <u>:</u>		
		(c) in the case of pseudonomised data, there is sufficient justification		
		<u>that the purpose cannot be</u> achieved with anonymised data;		
		(d) the processing complies with Article 6(1) and Article 9(2) of Regulation		
		(EU) 2016/679 in and if the requirements in this Chapter are fulfilled by the applicant. If that is the case, of access to pseudonymised		

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	<u>electronic health data;</u>		
	(e) the health data access		
	body shall issue a data		
	permitapplicant		
	<u>demonstrates sufficient</u>		
	<u>technical and</u>		
	organisational measures to		
	prevent any other use or		
	<u>misuse of the electronic</u> <u>health data and to protect</u>		
	the rights and interests of		
	the data holder and of the		
	natural persons concerned;		
	(f) the information on the		
	assessment of ethical		
	aspects of the processing,		
	<u>where applicable, is in line</u>		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			<u>with national law;</u> (g) all other requirements		
			in this Chapter are fulfilled by the health data applicant.		
	Article	46(-1), first subparagraph, poi	nt (a)		
579a				(a) the purpose described in the data permit application matches one or more of the purposes listed in Article 34(1) of this Regulation;	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Article 46(-1), first subparagraph, poi	int (b)		
579b			(b) the requested data is necessary for the purpose described in the data access application taking into account the provisions of data minimisation and purpose limitation in Article 44;	
	Article 46(-1), first subparagraph, poi	int (c)		
579c			(c) the processing complies with Article 6(1) of Regulation (EU)	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				2016/679 or Article 5(1) of Regulation (EU) 2018/1725, in case of access to pseudonymised electronic health data, as well as Chapter V in those Regulations respectively, where applicable;	
	Article	46(-1), first subparagraph, poi	nt (d)		
579d				(d) the information provided in the application demonstrates sufficient safeguards to protect the rights and interests of the health data holder and of the natural	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement	
				persons concerned as well as to prevent misuse;		
	Article	46(-1), first subparagraph, poi	nt (e)			
579e				(e) the information on the assessment of ethical aspects of the processing, where applicable, complies with national law;		
	Article 46(-1), first subparagraph, point (f)					
579f				(f) other requirements in		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				this Chapter.	
	Article	46(1), (1A)			
579g				1A. The health data access body shall also take into account the following risks:	
	Article	46(-1), second subparagraph,	point (a)		
579h				(a) risks for national defence, security, public security and public order;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement	
	Article	46(-1), second subparagraph,	point (b)			
579i				(b) risks of undermining protected IP-rights and trade secrets and privacy of natural persons;		
	Article 46(-1), second subparagraph, point (c)					
579j				(c) risk of undermining confidential data in governmental databases of regulatory authorities;		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	e 46(-1), second subparagraph,	point (d)		
579k				(d) risk of misuse, including the prohibited use in Article 35.	
	Article	2 46(2)			
580	2. Health data access bodies shall refuse all applications including one or more purposes listed in Article 35 or where requirements in this		 Health data access bodies shall refuse all applications <i>including one</i> <i>or more purposes listed in</i> <i>Article 35 or</i> where requirements in this Chapter 	2. If the health data access bodies shall refuse all applications including one or more purposes listed in Article 35 orbody in its assessment comes to the	

Chapter are not met. are not met. conclusion that the requirements in paragraph 1 are met and the risks referred to in paragraph 2 are sufficiently mitigated, the health data access body shall issue a data permit. Health data access bodies shall refuse all applications where the requirements in this Chapter are not met. Alternatively, a health data access body may decide to provide an answer in an anonymous statistical format under article 47, if this approach	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
paragraph 1 are met and the risks referred to in paragraph 2 are sufficiently mitigated, the health data access body shall issue a data permit. Health data access bodies shall refuse all applications where the requirements in this Chapter are not met. Alternatively, a health data access body may decide to provide an answer in an anonymous statistical format under	Chapter are not met.	are not met.	conclusion that the	
Image: statistical format under			requirements in	
Image: statistical format under			paragraph 1 are met and	
sufficiently mitigated, the health data access body shall issue a data permit. Health data access bodies shall refuse all applications where the requirements in this Chapter are not met. Alternatively, a health data access body may decide to provide an answer in an anonymous statistical format under			the risks referred to in	
health data access body shall issue a data permit. Health data access bodies shall refuse all applications where the requirements in this Chapter are not met. Alternatively, a health data access body may decide to provide an answer in an anonymous statistical format under			paragraph 2 are	
shall issue a data permit. Health data access bodies shall refuse all applications where the requirements in this Chapter are not met. Alternatively, a health data access body may decide to provide an answer in an anonymous statistical format under			sufficiently mitigated, the	
Health data access bodies shall refuse all applications where the requirements in this Chapter are not met. Alternatively, a health data access body may decide to provide an answer in an anonymous statistical format under			health data access body	
Image: statistical format under			shall issue a data permit.	
Image: statistical format underImage: statistical format under			Health data access bodies	
requirements in this Chapter are not met. Alternatively, a health data access body may decide to provide an answer in an anonymous statistical format under			shall refuse all	
are not met. Alternatively, a health data access body may decide to provide an answer in an anonymous statistical format under			applications where the	
a health data access body may decide to provide an answer in an anonymous statistical format under			requirements in this Chapter	
may decide to provide an answer in an anonymous statistical format under			are not met. Alternatively,	
answer in an anonymous statistical format under			a health data access body	
statistical format under			may decide to provide an	
			answer in an anonymous	
article 47. if this approach			statistical format under	
			article 47, if this approach	
mitigates the risks and if			mitigates the risks and if	
the purpose of the data			the purpose of the data	
access application can be			access application can be	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				fulfilled in this manner.	
	Article	e 46(3)			
	3. A health data access		3. A <u>After the health data</u>	3. By way of derogation	
	body shall issue or refuse a		applicant has demonstrated	from that Regulation (EU)	
	data permit within 2 months		the effective	2022/868, a health data	
	of receiving the data access		implementation of their	access body shall issue or	
	application. By way of		<u>security measures referred</u>	refuse a data permit within	
581	derogation from that		<u>to in Article 45(2), points</u>	23 months of receiving the	
501	Regulation [] [Data		<u>(e) and (f), the</u> health data	data access application. By	
	Governance Act		access body shall issue or	way of derogation from that	
	COM/2020/767 final], the		refuse a data permit within	Regulation [] [Data	
	health data access body		2 months of receiving <u>a</u>	Governance Act	
	may extend the period for		complete data access	COM/2020/767 final], The	
	responding to a data access		application. If the health	health data access body may	
	application by 2 additional		<u>data access body finds that</u>	extend the period for	
	months where necessary,		the data access application	responding to a data access	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
taking into account the	is incomplete, it shall notify	application by 23 additional	
complexity of the request.	the health data applicant,	months where necessary,	
In such cases, the health	who shall be given the	taking into account the	
data access body shall	possibility of completing	urgency and complexity of	
notify the applicant as soon	their application. If the	the request and the volume	
as possible that more time	health data applicant does	of requests submitted for	
is needed for examining the	not fulfill this request	decision. In such cases, the	
application, together with	<u>within four weeks, a permit</u>	health data access body	
the reasons for the delay.	<u>shall not be granted</u> . By	shall notify the applicant as	
Where a health data access	way of derogation from that	soon as possible that more	
body fails to provide a	Regulation [] [Data	time is needed for	
decision within the time	Governance Act	examining the application,	
limit, the data permit shall	COM/2020/767 final],(EU)	together with the reasons	
be issued.	2022/868 the health data	for the delay. Where a	
	access body may extend the	health data access body fails	
	period for responding to a	to provide a decision within	
	data access application by 2	the time limit, the data	
	additional months where	permit shall be issued.	
	necessary, taking into		
	account the complexity of		
	the request. In such cases,		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			the health data access body shall notify the applicant as soon as possible that more time is needed for examining the application, together with the reasons for the delay. <i>Where a</i> <i>health data access body</i> <i>fails to provide a decision</i> <i>within the time limit, the</i> <i>data permit shall be issued.</i>		
	Article	46(3A)			
581a				3A. When handling a data access application for cross-border access to electronic health data	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		referred to in Article	
		45(5A), health data access	
		bodies and relevant	
		authorised participants in	
		HealthData@EU referred	
		to in Article 52, shall	
		remain responsible for	
		taking decisions to grant	
		or refuse access to	
		electronic health data	
		within their remit in	
		accordance with the	
		requirements in this	
		Chapter. The concerned	
		health data access bodies	
		and authorised	
		participants shall inform	
		each other of their	
		decisions and may take	
		the information into	
		consideration when	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				deciding on granting or refusing access to electronic health data.	
				[MOVED FROM ARTICLE 54(1)]	
	Article	46(3AA)			
581b				3AA. Member States may provide for an accelerated application procedure for public sector bodies and Union institutions, bodies, offices and agencies if the processing of the data is to	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				be carried out for the purposes in Article 34(1), letters (a) to (c).	
	Article	46(4)			
582	4. Following the issuance of the data permit, the health data access body shall immediately request the electronic health data from the data holder. The health data access body shall make available the electronic health data to the data user within 2 months after receiving them from the data holders, unless the		4. Following the issuance of the data permit, the health data access body shall immediately request the electronic health data from the data holder <u>and</u> <u>inform them whether the</u> <u>data will be made</u> <u>accessible in anonymised</u> <u>or pseudonymised form</u> . The health data access body shall make available the	4. Following the issuance of the data permit, the health data access body shall immediately request the electronic health data from the health data holder. The health data access body shall make available the electronic health data to the health data user within 2 months after receiving them from the health data	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	health data access body specifies that it will provide the data within a longer specified timeframe.		electronic health data to the <u>health</u> data user within 2 months after receiving them from the data holders , unless the health data access body specifies that it will provide the data within a longer specified timeframe .	holders, unless the health data access body specifies that it will provide the data within a longer specified timeframe.	
	Article	46(4a)			
582a				4a. In situations referred to in paragraph 3A the concerned health data access bodies and authorised participants who issued a data permit,	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			may decide to provide access to the electronic health data in the secure processing environment provided by the Commission as referred to in Article 52(10).	
	Article 46(5)			
583	5. When the health data access body refuses to issue a data permit, it shall provide a justification for the refusal to the applicant.	5. When the health data access body refuses to issue a data permit, it shall provide a justification for the refusal to the <u>health</u> <u>data</u> applicant.	5. When the health data access body refuses to issue a data permit, it shall provide a justification for the refusal to the applicant.	

	Commission Prop	oosal		EP Mandate	Council Mandate	Draft Agreement
		Article	46(6)			
584	6. The data permit sh out the general condit applicable to the data in particular:	ions		6. The data permit shall set out the general conditions applicable to the <i>health</i> data user, in particular:	6. When the health data access body issues a The data permit, it shall set out the general conditions applicable to the health data user, in particular in the data permit. The data permit shall contain the following:	
		Article	46(6), point (a)			
585	(a) types and format electronic health data			(a) typescategories and format of electronic health	(a) typescategories, specification and format of	

	Commission Proposal	EP Mandate Council Mandate Draft Agreemer	nt
	accessed, covered by the data permit, including their sources;	data accessed, covered by the data permit, including their sources;electronic health data accessed, covered by the data permit, including their sources and if the electronic health data will 	
	Article 46(6), point (b)		
58	(b) purpose for which data are made available;	 (b) <u>a detailed description</u> (b) a detailed description of the purpose for which data are made available; (b) a detailed description of the purpose for which data are made available; 	

	Commission Proposa	al	EP Mandate	Council Mandate	Draft Agreement
	Art	ticle 46(6), point (ba)			
586a			(ba) the identity of the user as well as the concrete persons who are authorised to have access to the electronic health data in the secure processing environment;		
	Art	ticle 46(6), point (ba)			
586b				(ba) the identity of authorised persons who will have the right to access the electronic	

	Commission Propos	sal	EP Mandate	Council Mandate	Draft Agreement
				health data in the secure processing environment;	
	Ar	rticle 46(6), point (c)			
587	(c) duration of the data permit;		(c) duration of the data permit;	(c) duration of the data permit;	
	Ar	rticle 46(6), point (d)			
588	(d) information about th technical characteristics tools available to the data user within the secure	and	(d) information about the technical characteristics and tools available to the <i>health</i> data user within the secure	(d) information about the technical characteristics and tools available to the health data user within the secure	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	processing environment;		processing environment;	processing environment;	
	Artic	cle 46(6), point (e)			
589	(e) fees to be paid by the data user;		(e) fees to be paid by the <u>health</u> data user;	(e) fees to be paid by the health data user;	
	Artic	cle 46(6), point (f)			
590	(f) any additional specific conditions in the data permit granted.		(f) any additional specific conditions in the data permit granted.	(f) any additional specific conditions in the data permit granted.	

	Commission Prop	oosal		EP Mandate	Council Mandate	Draft Agreement
		Article	46(7)			
591	7. Data users shall har right to access and pro- the electronic health of accordance with the d permit delivered to the the basis of this Regu	ocess lata in lata em on		7. Data users shall have the right to access and process the electronic health data in <i>a secure processing environment in</i> accordance with the data permit delivered to them on the basis of this Regulation.	 7. Data users shall have the right to access and process the electronic health data in accordance with the data permit delivered to them on the basis of this Regulation. [MOVED TO ARTICLE 35C(1)] 	
		Article	46(8)			
592	8. The Commission i	S		8. The Commission is	8. The Commission is	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	empowered to adopt delegated acts to amend the list of aspects to be covered by a data permit in paragraph 7 of this Article, in accordance with the procedure set out in Article 67.		empowered to adopt delegated acts to amend the list of aspects to be covered by a data permit in paragraph 76 of this Article, in accordance with the procedure set out in Article 67.	empowered to adopt delegated acts to amend the list of aspects to be covered by a data permit in paragraph 7 of this Article, in accordance with the procedure set out in Article 67.	
	Article	e 46(9)			
593	9. A data permit shall be issued for the duration necessary to fulfil the requested purposes which shall not exceed 5 years. This duration may be extended once, at the		9. A data permit shall be issued for the duration necessary to fulfil the requested purposes which shall not exceed 5 years. This duration may be extended once, at the	9. A data permit shall be issued for the duration necessary to fulfil the requested purposes which shall not exceed 5-10 years. This duration may be extended once, at the	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
request of the data user,	request of the data user,	request of the health data	
based on arguments and	based on arguments and	user, based on arguments	
documents to justify this	documents to justify this	and documents to justify	
extension provided, 1	extension provided, 1	this extension provided, 1	
month before the expiry of	month before the expiry of	month before the expiry of	
the data permit, for a period	the data permit, for a period	the data permit, for a period	
which cannot exceed 5	which cannot exceed 5	which cannot exceed 5-10	
years. By way of derogation	years. By way of derogation	years. By way of derogation	
from Article 42, the health	from Article 42, the health	from Article 42, The	
data access body may	data access body may	health data access body may	
charge increasing fees to	charge increasing fees to	charge increasing fees to	
reflect the costs and risks of	reflect the costs and risks of	reflect the costs and risks of	
storing electronic health	storing electronic health	storing electronic health	
data for a longer period of	data for a longer period of	data for a longer period of	
time exceeding the initial 5	time exceeding the initial 5	time exceeding the initial $\frac{5}{2}$	
years. In order to reduce	years. In order to reduce	years period . In order to	
such costs and fees, the	such costs and fees, the	reduce such costs and fees,	
health data access body	health data access body may	the health data access body	
may also propose to the	also propose to the data user	may also propose to the	
data user to store the dataset	to store the dataset in	health data user to store the	
in storage system with	storage system with reduced	dataset in storage system	

Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
reduced capabilities. The		capabilities. The data within	with reduced capabilities.	
data within the secure		the secure processing	Such reduced capabilities	
processing environment		environment shall be	shall not affect the	
shall be deleted within 6		deleted within 6	security of the processed	
months following the		months without undue delay	dataset. The electronic	
expiry of the data permit.		following the expiry of the	health The d ata within the	
Upon request of the data		data permit. Upon request	secure processing	
user, the formula on the		of the data user, the formula	environment shall be	
creation of the requested		on the creation of the	deleted within 6 months	
dataset shall be stored by		requested dataset shall be	following the expiry of the	
the health data access body.		stored by the health data	data permit. Upon request	
		access body.	of the health data user, the	
			formula on the creation of	
			the requested dataset-shall	
			may be stored by the health	
			data access body.	
Article	46(10)			

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
594	10. If the data permit needs to be updated, the data user shall submit a request for an amendment of the data permit. Article 46(11)	10. If the data permit needs to be updated, the data user shall submit a request for an amendment of the data permit.	10. If the data permit needs to be updated, the health data user shall submit a request for an amendment of the data permit.	
595	11. Data users shall make public the results or output of the secondary use of electronic health data, including information relevant for the provision of healthcare, no later than 18 months after the completion	deleted	11. Data users shall make public the results or output of the secondary use of electronic health data, including information relevant for the provision of healthcare, no later than 18 months after the completion	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
of the electronic health data		of the electronic health data	
processing or after having		processing or after having	
received the answer to the		received the answer to the	
data request referred to in		data request referred to in	
Article 47. Those results or		Article 47. Those results or	
output shall only contain		output shall only contain	
anonymised data. The data		anonymised data. The data	
user shall inform the health		user shall inform the health	
data access bodies from		data access bodies from	
which a data permit was		which a data permit was	
obtained and support them		obtained and support them	
to make the information		to make the information	
public on health data access		public on health data access	
bodies' websites. Whenever		bodies' websites. Whenever	
the data users have used		the data users have used	
electronic health data in		electronic health data in	
accordance with this		accordance with this	
Chapter, they shall		Chapter, they shall	
acknowledge the electronic		acknowledge the electronic	
health data sources and the		health data sources and the	
fact that electronic health		fact that electronic health	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	data has been obtained in			data has been obtained in	
	the context of the EHDS.			the context of the EHDS.	
				[MOVED TO ARTICLE	
				35C(3)]	
	Article	46(12)			
	12. Data users shall inform			12. Data users shall inform	
	the health data access body			the health data access body	
596	of any clinically significant		deleted	of any clinically significant	
	findings that may influence			findings that may influence	
	the health status of the			the health status of the	
	natural persons whose data			natural persons whose data	
	are included in the dataset.			are included in the dataset.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				[MOVED TO ARTICLE 35C(4), SEE ALSO ARTICLE 35G]	
	Article	e 46(13)			
597	 13. The Commission may, by means of implementing act, develop a logo for acknowledging the contribution of the EHDS. That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 68(2). 		13. The Commission may, by means of implementing act, develop a logo for acknowledging the contribution of the EHDS. That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 68(2).	 13. The Commission may, by means of implementing act, develop a logo for acknowledging the contribution of the EHDS. That implementing act shall be adopted in accordance with the advisory examination procedure 	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement	
				referred to in Article 68(2).		
	Article	e 46(14)				
598	14. The liability of health data access bodies as joint controller is limited to the scope of the issued data permit until the completion of the processing activity.		14. The liability of health data access bodies as <i>joint</i> controller is limited to the scope of the issued data permit until the completion of the processing activity <i>and in accordance with Article 51</i> .	14. The liability of health data access bodies as joint controller is limited to the scope of the issued data permit until the completion of the processing activity.		
	Article 47					
599						

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 47		Article 47	Article 47	
	Data request		<u>Health</u> data request	Data request	
				[MOD.SU.6]	
	Article	. 47(1)			
600	1. Any natural or legal person may submit a data request for the purposes referred to in Article 34. A health data access body shall only provide an answer to a data request in an anonymised statistical format and the data user		1. Any natural or legal personThe health data applicant may submit a health data request for the purposes referred to in Article 34 with the aim of obtaining an answer only in anonymised or aggregated statistical	 AnyA natural or legal person may submit a-data request for the purposes referred to in Article 34. Aelectronic health data access body shall only provide an answer to a data request in an anonymisedin a statistical format and the 	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	shall have no access to the electronic health data used to provide this answer.		<i>format</i> . A health data access body shall <i>onlynot</i> provide an answer to a <i>health</i> data request in <i>an anonymised</i> <i>statisticalany other</i> format and the <i>health</i> data user shall have no access to the electronic health data used to provide this answer.	data user shall have noaccessfor the purposesreferred to in Article 34 tothe electronic health dataused to provide thisanswer.access body.[LAST SENTENCE MOVEDTO PARA 3 ANDAMENDED]	
	Article	47(2)			
601	2. A data request shall include the elements mentioned in paragraphs 2		 A <u>health</u> data request shall include the elements mentioned in paragraphs 2 	2. A data request shall include the elements mentioned in paragraphs 2	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	(a) and (b) of Article 45 and if needed may also include:		(a) and (b) of Article 45 and if needed may also include:	(a) and (b) of Article 45 and if needed may also includereferred to in paragraph 1 shall include the following information :	
	Artic	e 47(2), point (a)			
602	(a) a description of the result expected from the health data access body;		(a) a description of the result expected from the health data access body;	(a) a description of the result expected from the health data access bodyapplicant's identity, professional function and activities;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	e 47(2), point (b)			
603	(b) a description of the statistic's content.		(b) a description of the statistic's content.	(b) a description detailed explanation of the intended use of the electronic health data, including for which of the statistic's content.purposes referred to in Article 34(1) access is sought;	
	Article	e 47(2), point (c)		1	
603a				(c) a description of the requested electronic health data, their format	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				and data sources, where possible;	
	Article 47((2), point (d)			
603b				(d) a description of the statistic's content;	
	Article 47((2), point (e)			
603c				(e) a description of the safeguards planned to prevent any misuse of the electronic health data.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	e 47(2), point (f)			
603d				 (f) a description of how the processing would comply with Articles 6(1) of Regulation (EU) 2016/679 or Articles 5(1) and 10(2) of Regulation (EU) 2018/1725. 	
	Article	e 47(2a), first subparagraph			
603e				2a. The health data access body shall assess if the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				request is complete and take into account the following risks:	
	Article	47(2a), second subparagraph			
603f				(a) risks for national defense, security, public security and public order;	
	Article	47(2a), third subparagraph			
603g				(b) risks of undermining protected IP-rights and	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				trade secrets;	
	Article	47(2a), fourth subparagraph			
603h				(c) risks of undermining confidential data in governmental databases of market regulatory authorities;	
	Article	47(2a), fifth subparagraph			
603i				(d) risks of misuse, including the prohibited	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				use in Article 35.	
	Article	47(3)			
604	3. Where an applicant has requested a result in an anonymised form, including statistical format, based on a data request, the health data access body shall assess, within 2 months and, where possible, provide the result to the data user within 2 months.		3. Where an applicant has requested a result in an anonymised form, including statistical format, based on a data request, The health data access body shall assess the health data access body shall assessrequest, within 2 months and, where possible, provide the result to the health data user within 2 months.	3. Where an applicant has requested a result in an anonymised form, including statistical format, based on a data request, the health data access body shall assess the request, within-2 3 months and, where possible, provide the result to the health data user within-2 3 months. The health data access body shall only provide an answer in an anonymised statistical	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				format and the health data user shall have no access to the electronic health data used to provide the answer. [LAST SENTENCE MOVED FROM PARA 1]	
	Article	e 47A	-		
604a				Article 47A Templates to support access to electronic health data for secondary use	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	47a, first paragraph			
604b				1. The Commission may, by means of implementing acts, set out the templates for the data access application referred to in Article 45, the data permit referred to in Article 46 and the data request referred to in Article 47 [MOVED FROM ARTICLE 45(6)]	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Articl	e 47a, second paragraph			
604c				2. The Commission may, by means of implementing acts, adopt the necessary rules for facilitating the handling of data access applications for HealthData@EU referred to in Article 45(5A), including the single application template, a common data permit template, standard templates for common electronic health data access contractual arrangements, and common procedures for	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			handling cross-border requests, pursuant to Articles 45, 46 and 47. [MOVED FROM ARTICLE 54(3)]	
	Article 47a, third paragraph			
604d			3. The implementing acts referred to in paragraphs 1 and 2 shall be adopted in accordance with the examination procedure referred to in Article 68(2).	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	47B			
604e				Article 47B Data applications and data requests from third countries	
	Article	47b, first paragraph			
604f				1. Without prejudice to Articles 45, 46 and 47, for health data access bodies designated by the Member	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				States and the Union data access service, data applications and data requests submitted by a data user established in a third country shall be considered eligible if the third country concerned	
	Article	47b, first paragraph, point (a)			
604g				(a) is covered by an implementing act referred to in Article 52 (5); or	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement	
	Article	47b, first paragraph, point (b)				
604h				(b) allows EU applicants access to electronic health data in that third country under conditions that are not more restrictive than provided for in this regulation and therefore are covered by the implementing acts referred to in paragraph (2).		
	Article 47b, second paragraph					
604i						

Commission	Proposal	EP Mandate	Council Mandate	Draft Agreement
			2. The Commission shall adopt implementing acts establishing the list of third countries referred to in paragraph (1) point b). These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 68 (2). The Commission shall make the list of implementing acts adopted pursuant to this paragraph publicly available.	
	Article 47b, third paragraph			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
604j				3. Health data access bodies may also decide on the eligibility of data applications submitted by a data user established in a third country not covered by paragraph 1 on a case-by-case basis.	
	Article	48			
605	Article 48 Making data available for public sector bodies and Union institutions, bodies,		Article 48 Making data available, without a data permit, public sector bodies and	Article 48 Making data available for public sector bodies and Union institutions, bodies,	

	Commission Proposal	EP Mandate Council Mandate Draft Agreement
	offices and agencies without a data permit	Union institutions, bodies, offices and agencies withoutoffices and agencies without a data permita data permit with a legal mandate in the field of
	Article 48, first paragraph	
606	By derogation from Article 46 of this Regulation, a data permit shall not be required to access the electronic health data under this Article. When carrying out those tasks under Article 37 (1), points (b) and (c), the health data access body shall inform public sector	By derogation from ArticleBy derogation from Article46 of this Regulation, a46 of this Regulation, a datahealthpermit shall notbe required to access thepermit shall not be requiredelectronic health data underhealth data under thisthis Article. When carryingArticle. When carrying outout those tasks underthose tasks under Article 37Article 37 (1), points (b)(1), points (b) and (c), theand (c), the health datahealth data access bodyaccess body shall informshall inform public sector

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
bodies and the Union	public sector bodies and the	bodies and the Union	
institutions, offices,	Union institutions, offices,	institutions, offices,	
agencies and bodies, about	agencies and bodies with a	agencies and bodies, about	
the availability of data	legal mandate in the field	the availability of data	
within 2 months of the data	of public health, about the	within 2 months of the data	
access application, in	availability of data within 2	access application, in	
accordance with Article 9	months of the data access	accordance with Article 9 of	
of Regulation [] [Data	application, in accordance	Regulation [] [Data	
Governance Act	with Article 9 of Regulation	Governance Act	
COM/2020/767 final]. By	[] [Data Governance Act	COM/2020/767 final]. By	
way of derogation from that	COM/2020/767 final]. By	way of derogation from that	
Regulation [] [Data	way of derogation from that	Regulation [] [Data	
Governance Act	Regulation [] [Data	Governance Act	
COM/2020/767 final], the	Governance Act	COM/2020/767 final], the	
health data access body	COM/2020/767 final], the	health data access body may	
may extend the period by 2	health data access body may	extend the period by 2	
additional months where	extend the period by 2	additional months where	
necessary, taking into	additional months where	necessary, taking into	
account the complexity of	necessary, taking into	account the complexity of	
the request. The health data	account the complexity of	the request. The health data	
access body shall make	the request. The health data	access body shall make	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	available the electronic health data to the data user within 2 months after receiving them from the data holders, unless it specifies that it will provide the data within a longer specified timeframe.		access body shall make available the electronic health data to the <i>health</i> data user within 2 months after receiving them from the <i>health</i> data holders, unless it specifies that it will provide the data within a longer specified timeframe. <i>Articles 43 and</i> <i>43a shall be applicable to</i> <i>the situations covered</i> <i>under this Article.</i>	available the electronic health data to the data user within 2 months after receiving them from the data holders, unless it specifies that it will provide the data within a longer specified timeframe.	
	Article	49			
607	Article 49			Article 49	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Access to electronic health data from a single data holder		deleted	Access to electronic health data from a single health data holder in Member States	
	Article	49(1)			
608	1. Where an applicant requests access to electronic health data only from a single data holder in a single Member State, by way of derogation from Article 45(1), that applicant may file a data access application or a data request directly to the data holder. The data access application		deleted	 Member States may allow any or specific health data holder to fulfil the tasks referred to in Article 37(1)(a) in situations where an applicant requests access to electronic health data only from a single health data holder in a single Member State. In such cases, by 	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
shall comply with the		way of derogation from	
requirements set out in		Article 45(1) and Article	
Article 45 and the data		47(1) , that applicant may	
request shall comply with		file a data access	
requirements in Article 47.		application or a data request	
Multi-country requests and		directly to thethat health	
requests requiring a		data holder. The data access	
combination of datasets		application shall comply	
from several data holders		with the requirements set	
shall be adressed to health		out in Article 45 and the	
data access bodies.		data request shall comply	
		with requirements in Article	
		47. Multi-country requests	
		and requests requiring a	
		combination of datasets	
		from several data holders	
		shall be adressed to health	
		data access bodies.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement	
	Articl	e 49(1a)				
608a				1a. The Commission may allow that data applications or data requests are submitted directly to an Union institution, agency or body. In such case, this Article applies mutatis mutandis.		
	Article 49(2)					
609	2. In such case, the data holder may issue a data			2. In situations referred to in paragraph 1 in this		

Commission P	roposal	EP Mandate	Council Mandate	Draft Agreement			
permit in accordant Article 46 or provi- answer to a data re- accordance with A The data holder sh provide access to electronic health of secure processing environment in co- with Article 50 and charge fees in acc- with Article 42.	ide an equest in article 47. Hall then the lata in a mpliance d may	deleted	Article, the health -such ease, the data holder may issue a data permit in accordance with Article 46 or provide an answer to a data request in accordance with Article 47. When issuing a data permit, the healthThe data holder shall then- provide access to the electronic health data in a secure processing environment in compliance with Article 50 and may charge fees in accordance with Article 42.				
	Article 49(3)						

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
610	3. By way of derogation from Article 51, the single data provider and the data user shall be deemed joint controllers.	deleted	3. By way of derogation from Article 51, the single data provider and the data user shall be deemed joint controllers. [SEE ARTICLE 51]	
	Article 49(4)			
611	4. Within 3 months the data holder shall inform the relevant health data access body by electronic means of all data access applications	deleted	 4. Within 3 months the The single health data holder, referred to in paragraph 1 of this Article, shall within 3 months inform the 	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	filed and all the data permits issued and the data requests fulfilled under this Article in order to enable the health data access body to fulfil its obligations under Article 37(1) and Article 39.			relevant health data access body by electronic means of all data access applications filed and all the data permits issued and the data requests fulfilled under this Article in order to enable the health data access body to fulfil its obligations under Article 37(1) and Article-Articles 37 and 39.	
	Article	50			
612	Article 50 Secure processing environment		Article 50 Secure processing environment	Article 50 Secure processing environment	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	e 50(1)			
613	1. The health data access bodies shall provide access to electronic health data only through a secure processing environment, with technical and organisational measures and security and interoperability requirements. In particular, they shall take the following security measures:		1. The health data access bodies shall provide access to electronic health data <i>pursuant to a data permit</i> only through a secure processing environment, with technical and organisational measures and security and interoperability requirements. In particular, they shall take the following security measures:	1. The health data access bodies shall provide access to electronic health data pursuant to a data permit only through a secure processing environment, with technical and organisational measures and security and interoperability requirements. In particular, theythe secure processing environment shall take comply with the following security measures:	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	e 50(1), point (a)			
614	(a) restrict access to the secure processing environment to authorised persons listed in the respective data permit;		(a) restrict access to the secure processing environment to authorised persons listed in the respective data permit;	 (a) restrict access to the secure processing environment to authorised natural persons listed in the respective data permit; 	
	Article	2 50(1), point (b)			
615	(b) minimise the risk of the unauthorised reading, copying, modification or removal of electronic health		(b) minimise the risk of the unauthorised reading, copying, modification or removal of electronic health	(b) minimise the risk of the unauthorised reading, copying, modification or removal of electronic health	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	data hosted in the secure processing environment through state-of-the-art technological means;		data hosted in the secure processing environment through state-of-the-art <i>technological</i> <i>meanstechnical and</i> <i>organisational mesures</i> ;	data hosted in the secure processing environment through state-of-the-art technological means;	
	Article	50(1), point (c)			
616	(c) limit the input of electronic health data and the inspection, modification or deletion of electronic health data hosted in the secure processing environment to a limited number of authorised identifiable individuals;		(c) limit the input of electronic health data and the inspection, modification or deletion of electronic health data hosted in the secure processing environment to a limited number of authorised identifiable individuals;	(c) limit the input of electronic health data and the inspection, modification or deletion of electronic health data hosted in the secure processing environment to a limited number of authorised identifiable individuals;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement			
	Article	50(1), point (d)						
617	(d) ensure that data users have access only to the electronic health data covered by their data permit, by means of individual and unique user identities and confidential access modes only;		(d) ensure that <u>health</u> data users have access only to the electronic health data covered by their data permit, by means of individual and unique user identities and confidential access modes only;	(d) ensure that health data users have access only to the electronic health data covered by their data permit, by means of individual and unique user identities and confidential access modes only;				
	Article 50(1), point (e)							
618	(e) keep identifiable logs of		(e) keep identifiable logs of	(e) keep identifiable logs of				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	access to the secure processing environment for the period of time necessary to verify and audit all processing operations in that environment;		access to the secure processing environment for the period of time necessary to verify and audit all processing operations in that environment, <i>and in</i> <i>any event for not shorter</i> <i>than one year</i> ;	access to and activities in the secure processing environment for the period of time necessary to verify and audit all processing operations in that environment;	
	Article	50(1), point (f)			
619	(f) ensure compliance and monitor the security measures referred to in this Article to mitigate potential security threats.		(f) ensure compliance and monitor the security measures referred to in this Article to mitigate potential security threats.	(f) ensure compliance and monitor the security measures referred to in this Article to mitigate potential security threats.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement			
	Article 50(1), point (fa)						
619a		(fa) ensure that the secure processing environment is located within the Union.					
	Article 50(2)						
620	2. The health data access bodies shall ensure that electronic health data can be uploaded by data holders and can be accessed by the data user in a secure processing environment. The data users shall only be	2. The health data access bodies shall ensure that electronic health data <u>from</u> <u>health data holders in the</u> <u>format determined by the</u> <u>data permit</u> can be uploaded by <u>health</u> data holders and can be accessed	2. The health data access bodies shall ensure that electronic health data can be uploaded by health data holders and can be accessed by the health data user in a secure processing environment. The health				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	able to download non- personal electronic health data from the secure processing environment.		by the <u>health</u> data user in a secure processing environment. The <u>health</u> data users shall only be able to download <u>or copy</u> non- personal electronic health data from the secure processing environment, <u>in</u> <u>accordance with Article 37</u> .	data access bodies-data users shall only be ensure by reviewing that the health data users are only able to download-non- personal- electronic health data in an anonymised statistical format from the secure processing environment.	
	Article	50(3)			
621	3. The health data access bodies shall ensure regular audits of the secure processing environments.		3. The health data access bodies shall ensure regular audits, <i>including by third</i> <i>parties, of the secure</i> <i>processing environments</i>	3. The health data access bodies shall ensure regular third party audits of the secure processing environments.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			and take immediate corrective action for any shortcomings, risks or vulnerabilities identified in of the secure processing environments.		
	Article	50(3a)			
621a				3a. Where recognised data altruism organisations under Chapter IV of Regulation (EU) 2022/868 process personal electronic health data using a secure processing environment, such environments shall	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			also comply with the security measures set out in point (a) to (f) in paragraph 1 in this Article. [MOVED FROM ARTICLE 40(1)]	
	Article 50(4)			
622	4. The Commission shall, by means of implementing acts, provide for the technical, information security and interoperability	4. The Commission shall, by means of implementing acts, provide for the technical, <u>organisational</u> , information security,	4. The Commission shall, by means of implementing acts, provide for the technical, information security and interoperability	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement		
	requirements for the secure processing environments. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2).		<i>confidentiality, data</i> <i>protection</i> and interoperability requirements for the secure processing environments, <i>after having consulted with</i> <i>ENISA</i> . Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2).	requirements for the secure processing environments, including the technical characteristics and tools available to the health data user within the secure processing environment. Those implementing acts shall be adopted in accordance with the-advisory examination procedure referred to in Article 68(2).			
	Article 51						
623	Article 51		Article 51	Article 51			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Joint controllers		Joint controllers Controllership	Joint controllers Controllership	
	Article	51(1)			
624	1. The health data access bodies and the data users, including Union institutions, bodies, offices and agencies, shall be deemed joint controllers of electronic health data processed in accordance with data permit.		1. <u>The health data holder</u> <u>shall be deemed controller</u> <u>for e the requested</u> <u>personal electronic health</u> <u>data to</u> the health data access bodies and the data users, including Union institutions, bodies, offices and agencies, body pursuant to Article 41(1) and (1a) of this Regulation. <u>The health data access</u> body shall be deemed	1. The health data holder shall be deemed controller for the disclosure of the requested personal electronic health data to the health data access bodies and the data users, including Union institutions, bodies, offices and agencies,body pursuant to Article 35B(1) and (1a) of this Regulation. The health	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	controller for the	data access body shall be	
	processing of the personal	deemed controller for the	
	electronic health data	processing of the personal	
	when fulfilling its tasks	electronic health data	
	pursuant to Article 37(1),	when fulfilling its tasks	
	point (d), of this	pursuant to Article	
	Regulation. The health	37(1)(a)(i) of this	
	data user shall be deemed	Regulation. The health	
	joint controllers of	data user shall be deemed	
	<u>controller for the</u>	joint controllers of	
	processing of personal	controller for the	
	electronic health data	processing of personal	
	processed in accordance	electronic health data	
	with in pseudonymised form	processed in accordance	
	in the secure processing	with in pseudonymised	
	environment pursuant to	form in the secure	
	<u>its data permit. The health</u>	processing environment	
	data access body shall act	pursuant to its data permit	
	as a processor for the	and for the processing to	
	processing by the health	generate an answer in an	
	<u>data user pursuant to a</u>	anonymised statistical	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			data permit <u>in the secure</u> processing environment.	form following a data request pursuant to Article 46. The health data access body shall be deemed to act as a processor for the health data user's processing pursuant to a data permit in the secure processing environment when providing such environment and for the processing to generate an answer to a data request pursuant to Article 46.	
	Article	51(1a)			
624a					

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		1a. In situations referred	
		to in Article 49, the single	
		health data holder shall be	
		deemed controller for its	
		processing of personal	
		electronic health data	
		related to the providing of	
		electronic health data to	
		the health data user	
		pursuant to a data permit	
		or a data request. The	
		single health data holder	
		shall be deemed to act as a	
		processor for the health	
		data user's processing	
		pursuant to a data permit	
		when providing a secure	
		processing environment to	
		the health data user.	

	Commission Prop	oosal		EP Mandate	Council Mandate	Draft Agreement	
		Article	51(2)				
625	2. The Commission s by means of impleme acts, establish a templ for the joint controller arrangement. Those implementing acts sha adopted in accordance the advisory procedur out in Article 68(2).	nting late rs' all be e with		2. The Commission shall, by means of implementing acts, establish a template for the joint controllers' arrangement. Those implementing acts shall be adopted in accordance with the advisory procedure set out in Article 68(2).	2. The Commission shall, by means of implementing acts, establish a template for the joint controllers' arrangement. Those implementing acts shall be adopted in accordance with the advisory procedure set out in Article 68(2).		
	Section 4						
626	Section 4 Cross-Bord access to electronic he				Section 4 Cross-Border access toinfrastructure for		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	data for secondary use			secondary use of electronic health data-for secondary use	
	Article	52			
627	Article 52 Cross-border infrastructure for secondary use of electronic health data (HealthData@EU)		Article 52 Cross-border infrastructure for secondary use of electronic health data (HealthData@EU)	Article 52 Cross-border infrastructure for secondary use of electronic health data (HealthData@EUHealthDa ta@EU)	
	Article	52(1)			

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
628	1. Each Member State shall designate a national contact point for secondary use of electronic health data, responsible for making electronic health data available for secondary use in a cross-border context and shall communicate their names and contact details to the Commission. The national contact point may be the coordinator health data access body pursuant to Article 36. The Commission and the Member States shall make this information publicly available.	1. Each Member State shall designate a national contact point for secondary use of electronic health data, responsible for making electronic health data available for secondary use in a cross-border context and shall communicate their names and contact details to the Commission. The national contact point may be the coordinator health data access body pursuant to Article 36. The Commission and the Member States shall make this information publicly available.	1. Each Member State shall designate aone national contact point for secondary use of electronic health data. The national contact point shall be an organisational and technical gateway, enabling and ,-responsible for making electronic health data available for secondary use in a cross-border context. Each Member State -and-shall communicate their namesinform the Commission the name and contact details to the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				contact point by the date of application of this Regulation. The national contact point may be the coordinator health data access body pursuant to Article 36. The Commission and the Member States shall make this information publicly available.	
	Article	52(1a)			
628a				1a. The Union data access service shall act as the Union Institutions', bodies, offices and agencies' contact point for	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				secondary use of electronic health data and shall be responsible for making electronic health data available for secondary use.	
	Article 52(2)	:)			
629	2. The national contact points referred to in paragraph 1 shall be authorised participants in the cross-border infrastructure for secondary use of electronic health data (HealthData@EU). The national contact points shall	F F a t i u u	2. The national contact points referred to in paragraph 1 shall be authorised participants in the cross-border infrastructure for secondary use of electronic health data (HealthData@EU). The national contact points shall	 2. The national contact points referred to in paragraph 1 and the Union Institutions' contact point referred to in paragraph 1A shall be authorised participants in the crossborder infrastructure for secondary use of electronic 	

Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
facilitate the cross-border		facilitate the cross-border	health data	
access to electronic health		access to electronic health	(HealthData@EU). The	
data for secondary use for		data for secondary use for	national contact points and	
different authorised		different authorised	the Union Institutions'	
participants in the		participants in the	contact point shall	
infrastructure and shall		infrastructure and shall	facilitate the cross-border	
cooperate closely with each		cooperate closely with each	access to electronic health	
other and with the		other and with the	data for secondary use for	
Commission.		Commission.	different authorised	
			participants in the	
			infrastructure. The national	
			contact points and the	
			Union Institutions'	
			contact point -and shall	
			cooperate closely with each	
			other and with the	
			Commission.	
A	52(2)			
Article	52(3)			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
630	3. Union institutions, bodies, offices and agencies involved in research, health policy or analysis, shall be authorised participants of HealthData@EU.		3. Union institutions, bodies, offices and agencies involved in <i>health</i> research, health policy or analysis, shall be authorised participants of HealthData@EU.	3. Union institutions, bodies, offices and agencies involved in research, health policy or analysis, shall be authorised participants of HealthData@EU.	
	Article	52(4)			
631	4. Health-related research infrastructures or similar structures whose functioning is based on		4. Health-related research infrastructures or similar structures whose functioning is based on	43 . Health-related research infrastructures or similar structures whose functioning is based on	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Union law and which support the use of electronic health data for research, policy making, statistical, patient safety or regulatory		Union law and which support the use of electronic health data for research, policy making, statistical, patient safety or regulatory	Union law and which support the use of electronic health data for research, policy making, statistical, patient safety or regulatory	
	purposes shall be authorised participants of HealthData@EU.		purposes shall be authorised participants of HealthData@EU.	purposes-shall may be authorised participants of HealthData@EU.	
	Article	52(5)			
632	5. Third countries or international organisations may become authorised participants where they comply with the rules of Chapter IV of this Regulation and provide		5. Third countries or international organisations may become authorised participants where they comply with the rules of Chapter IV of this Regulation, <i>where the</i>	54 . Third countries or international organisations may become authorised participants where they comply with the rules of Chapter IV of this Regulation, the transfer	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
access to data users located	transfer stemming from	stemming from such	
in the Union, on equivalent	such connection complies	connection would comply	
terms and conditions, to the	with the rules in Chapter V	with the rules in Chapter	
electronic health data	of Regulation (EU)	V of Regulation (EU)	
available to their health data	2016/679 and Article 63a	2016/679 and they -and	
access bodies. The	of this Regulation and	provide access to health	
Commission may adopt	where -and-provide access	data users located in the	
implementing acts	to data users located in the	Union, on equivalent terms	
establishing that a national	Union, on equivalent terms	and conditions, to the	
contact point of a third	and conditions, to the	electronic health data	
country or a system	electronic health data	available to their health data	
established at an	available to their health dat	a access bodies. The	
international level is	access bodies. The	Commission mayshall	
compliant with	Commission may adopt	adopt implementing acts	
requirements of	implementing acts	establishing that a national	
HealthData@EU for the	establishing that a national	contact point of a third	
purposes of secondary use	contact point of a third	country or a system	
of health data, is compliant	country or a system	established at an	
with the Chapter IV of this	established at an	international level is	
Regulation and provides	international level is	compliant with	
access to data users located	compliant with	requirements of	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
in the Union to the	requirements of	HealthData@EU for the	
electronic health data it has	HealthData@EU for the	purposes of secondary use	
access to on equivalent	purposes of secondary use	of health data, is compliant	
terms and conditions. The	of health data, is compliant	with the Chapter IV of this	
compliance with these	with the Chapter IV of this	Regulation and Chapter V	
legal, organisational,	Regulation and Chapter V	of Regulation (EU)	
technical and security	of Regulation (EU)	2016/679 and provides	
requirements, including	2016/679 and provides	access to health data users	
with the standards for	access to data users located	located in the Union to the	
secure processing	in the Union to the	electronic health data it has	
environments pursuant to	electronic health data it has	access to on equivalent	
Article 50 shall be checked	access to on equivalent	terms and conditions. The	
under the control of the	terms and conditions. The	compliance with these legal,	
Commission. These	compliance with these legal,	organisational, technical	
implementing acts shall be	organisational, technical	and security requirements,	
adopted in accordance with	and security requirements,	including with the standards	
the advisory procedure	including with the standards	for secure processing	
referred to in Article 68 (2).	for secure processing	environments pursuant to	
The Commission shall	environments pursuant to	Article 50 shall be checked	
make the list of	Article 50 shall be checked	under the control of the	
implementing acts adopted	under the control of the	Commission. These	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	pursuant to this paragraph publicly available.		Commission. These implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68 (2). The Commission shall make the list of implementing acts adopted pursuant to this paragraph publicly available.	implementing acts shall be adopted in accordance with the-advisory examination procedure referred to in Article 68 (2). The Commission shall make the list of implementing acts adopted pursuant to this paragraph publicly available. When adopting the implementing act, the national security interests of Member States shall be taken into account.	
	Article	52(6)			
633	6. Each authorised		6. Each authorised	65. Each authorised	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	participant shall acquire the required technical capability to connect to and participate in HealthData@EU. Each participant shall comply with the requirements and technical specifications needed to operate the cross- border infrastructure and to allow the authorised participants to connect to each other within it.		participant shall acquire the required technical capability to connect to and participate in HealthData@EU. Each participant shall comply with the requirements and technical specifications needed to operate the cross- border infrastructure and to allow the authorised participants to connect to each other within it.	participant shall acquire the required technical capability to connect to and participate in HealthData@EU. Each participant shall comply with the requirements and technical specifications needed to operate the cross- border infrastructure and to allow the authorised participants to connect to each other within it.	
	Article	2 52(7)			
634	7. The Commission is empowered to adopt		7. The Commission is empowered to adopt	7. The Commission is empowered to adopt	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	delegated acts in accordance with Article 67 in order to amend this Article to add or remove categories of authorised participants in HealthData@EU, taking into account the opinion of the joint controllership group pursuant to Article 66 of this Regulation.		delegated acts in accordance with Article 67 in order to amend this Article to add or remove categories of authorised participants in HealthData@EU, taking into account the opinion of the joint controllership group pursuant to Article 66 of this Regulation.	delegated acts in accordance with Article 67 in order to amend this Article to add or remove categories of authorised participants in HealthData@EU, taking into account the opinion of the joint controllership group pursuant to Article 66 of this Regulation.	
	Article 5	52(8)			
635	8. The Member States and the Commission shall set up HealthData@EU to support and facilitate the cross-		8. The Member States and the Commission shall set up HealthData@EU to support and facilitate the cross-	86 . The Member States and the Commission shall set up HealthData@EU to support and facilitate the cross-	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	border access to electronic health data for secondary use, connecting the national contact points for secondary use of electronic health data of all Member States and authorised participants in that infrastructure.		border access to electronic health data for secondary use, connecting the national contact points for secondary use of electronic health data of all Member States and authorised participants in that infrastructure.	border access to electronic health data for secondary use, connecting the national contact points for secondary use of electronic health data of all Member States and authorised participants in that infrastructure and the central platform .	
	Article	52(9)			
636	9. The Commission shall develop, deploy and operate a core platform for HealthData@EU by providing information technology services needed		9. The Commission shall develop, deploy and operate a core platform for HealthData@EU by providing information technology services needed	97 . The Commission shall develop, deploy and operate a central and interoperability -core platform for HealthData@EU by	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	to facilitate the connection between health data access bodies as part of the cross- border infrastructure for the secondary use of electronic health data. The Commission shall only process electronic health data on behalf of the joint controllers as a processor.		to facilitate the connection between health data access bodies as part of the cross- border infrastructure for the secondary use of electronic health data. The Commission shall only process electronic health data on behalf of the joint controllers as a processor.	providing information technology services needed to support and facilitate the connection exchange of information between health data access bodies as part of the cross-border infrastructure for the secondary use of electronic health data. The Commission shall only process electronic health data on behalf of the-joint controllers as a processor.	
	Article	52(10)			
637	10. Where requested by		10. Where requested by	108. Where requested by	

Commiss	ion Proposal	EP Mandate	Council Mandate	Draft Agreement
two or more	health data	two or more health data	two or more health data	
access bodie	es, the	access bodies, the	access bodies or	
Commission	n may provide a	Commission may provide a	authorised participants in	
secure proce	essing	secure processing	this infrastructure, the	
environment	t for data from	environment for data from	Commission may shall	
more than or	ne Member	more than one Member	provide a secure processing	
State compli	ant with the	State compliant with the	environment for data from	
requirement	s of Article 50.	requirements of Article 50.	more than one Member	
Where two o	or more health	Where two or more health	State compliant with the	
data access l	podies put	data access bodies put	requirements of Article 50.	
electronic he	ealth data in the	electronic health data in the	Where two or more health	
secure proce	essing	secure processing	data access bodies put	
environment	t managed by	environment managed by	electronic health data in the	
the Commis	sion, they shall	the Commission, they shall	secure processing	
be joint cont	rollers and the	be joint controllers and the	environment managed by	
Commission	shall be	Commission shall be	the Commission, they shall	
processor.		processor.	be-joint controllers	
			controller and the	
			Commission shall be	
			processor.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	52(11)			
638	11. The authorised participants shall act as joint controllers of the processing operations in which they are involved carried out in HealthData@EU and the Commission shall act as a processor.		11. The authorised participants shall act as joint controllers of the processing operations in which they are involved carried out in HealthData@EU and the Commission shall act as a processor.	1419 . The authorised participants shall act as joint controllers of the processing operations in which they are involved carried out in HealthData@EU for which they determine the purpose and the means and the Commission shall act as a processor for the processing of electronic health data for the purposes of secondary use pursued by the health data user.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	2 52(12)			
639	12. Member States and the Commission shall seek to ensure interoperability of HealthData@EU with other relevant common European data spaces as referred to in Regulations [] [Data Governance Act COM/2020/767 final] and [] [Data Act COM/2022/68 final].		12. Member States and the Commission shall seek to ensure interoperability of HealthData@EU with other relevant common European data spaces as referred to in Regulations [] [Data Governance Act COM/2020/767 final] (EU) 2022/868 and [] [Data Act COM/2022/68 final].	 1210. Member States and the Commission shall seek to ensure interoperability of HealthData@EU with other relevant common European data spaces as referred to in Regulations [] [Data Governance Act COM/2020/767 final](EU) 2022/868 and [] [Data Act COM/2022/68 final]. 	
	Article	e 52(13), first subparagraph			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
640	13. The Commission may, by means of implementing acts, set out:		 13. The Commission mayshall, by means of implementingdelegated acts, set out: 	1311 . The Commission mayshall , by means of implementing acts, set out:	
	Article	52(13), first subparagraph, po	int (a)		
641	(a) requirements, technical specifications, the IT architecture of HealthData@EU, conditions and compliance checks for authorised participants to join and remain connected to HealthData@EU and		(a) requirements, technical specifications, the IT architecture of HealthData@EU, <i>conditions and compliance</i> <i>checks for authorised</i> <i>participants to join and</i> <i>remain connected to</i> <i>HealthData@EU and</i>	 (a) requirements, technical specifications, the IT architecture of HealthData@EU, conditions and compliance checks for authorised participants to join and remain connected to HealthData@EU and 	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	conditions for temporary or definitive exclusion from HealthData@EU;		conditions for temporary or definitive exclusion from HealthData@EUwhich shall ensure state-of-the- art data security, confidentiality, and protection of electronic health data in the cross border infrastructure;	conditions for temporary or definitive exclusion from HealthData@EU;	
	Article	52(13), first subparagraph, po	int (aa)		
641a			(aa) conditions and compliance checks for authorised participants to join and remain connected to HealthData@EU and conditions for temporary or		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement		
			definitive exclusion from HealthData@EU, including specific provisions for cases of serious misconduct or repeated violation;				
	Article	52(13), first subparagraph, po	int (b)				
642	(b) the minimum criteria that need to be met by the authorised participants in the infrastructure;		(b) the minimum criteria that need to be met by the authorised participants in the infrastructure;	(b) the minimum criteria that need to be met by the authorised participants in the infrastructure;			
	Article 52(13), first subparagraph, point (c)						

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
643	(c) the responsibilities of the joint controllers and processor(s) participating in the cross-border infrastructures;		(c) the responsibilities of the joint controllers and processor(s) participating in the cross-border infrastructures;	(c) the responsibilities of the joint- controllers and processor(s) participating in the cross-border infrastructures;	
	Article	52(13), first subparagraph, po	int (d)		
644	(d) the responsibilities of the joint controllers and processor(s) for the secure environment managed by the Commission;		(d) the responsibilities of the joint controllers and processor(s) for the secure environment managed by the Commission;	(d) the responsibilities of the joint controllers and processor(s) for the secure environment managed by the Commission;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Artic	le 52(13), first subparagraph, po	int (e)		
645	(e) common specifications for the interoperability and architecture concerning HealthData@EU with other common European data spaces.		(e) common specifications for the interoperability and architecture concerning HealthData@EU with other common European data spaces.	(e) common specifications for the interoperability and architecture concerning HealthData@EU with other common European data spaces.	
	Artic	le 52(13), second subparagraph			
646	accordance with the advisory procedure referred		<i>Those implementing</i> acts <u>The Commission</u> shall be adopted in accordance with the advisory procedure referred to in Article	Those implementing acts shall be adopted in accordance with the advisory examination procedure referred to in	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			68(2) <u>consult with the</u> ENISA in the drawing up of the delegated act.	Article 68(2).	
	Article	52(14)		<u> </u>	
647	14. The approval for individual authorised participant to join HealthData@EU or to disconnect a participant from the infrastructure shall be issued by the Joint Controllership group, based on the results of the compliance checks.		14. The approval for individual authorised participant to join HealthData@EU or to disconnect a participant from the infrastructure shall be issued by the Joint Controllership group, based on the results of the compliance checks.	14. Subject to the outcome of the compliance check performed by the Commission concerning the fulfilment of the requirements in this Article, the Commission shall, by means of implementing act, take decisions to connect The approval for individual authorised	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				participantparticipants to join HealthData@EUthe infrastructure or to disconnect a participant from the infrastructurethem. These implementing acts shall be issued by the Joint Controllership group, based on the results of the compliance checksadopted in accordance with the examination procedure referred to in Article 68(2).	
	Article	53		-	
648					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 53		Article 53	Article 53	
	Access to cross-border sources of electronic health data for secondary use		Access to cross-border sources of electronic health dataregistries and databases for secondary use	Access to cross-border registries or databases of electronic health data for secondary useAccess to cross-border sources of electronic health data for secondary use	
	Article 5	53(1)			
649	1. In the case of cross- border registries and databases, the health data access body in which the data holder is registered shall be competent to		1. In the case of cross- border registries and databases, the health data access body in which the data holder is registered shall be competent to decide	1. In the case of cross- border registries and databases, the health data access body in which the health data holder for the specific registry or	

Commission Prop	osal	EP Mandate	Council Mandate	Draft Agreement
decide on data access		on data access applications	database is registered shall	
applications to provide	2	to provide access to	be competent to decide on	
access to electronic he	alth	electronic health data.	data access applications to	
data. Where the registr	ry has	Where the registry has joint	provide access to electronic	
joint controllers, the h	ealth	controllers, the health data	health data pursuant to a	
data access body that s	shall	access body that shall	data permit. Where the	
provide access to elect	tronic	provide access to electronic	registry hassuch registries	
health data shall be the	2	health data shall be the body	or databases have joint	
body in the Member S	tate	in the Member State where	controllers, the health data	
where one of the joint		one of the joint controllers	access body that shall	
controllers is establish	ed.	is established.	decide on the data access	
			applications to provide	
			access to electronic health	
			data shall be the body in the	
			Member State where one of	
			the joint controllers is	
			established.	
	Article 53(2)			
	······································			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	health data for the network		health data for the network	health data for the network	
	of registries or databases.		of registries or databases.	of registries or databases.	
	Articl	le 53(3)			
	3. The Commission may,		3. The Commission may,	3. The Commission may,	
	by means of implementing		by means of implementing	by means of implementing	
	acts, adopt the necessary		acts, adopt the necessary	acts, adopt the necessary	
	rules for facilitating the		rules for facilitating the	rules for facilitating the	
	handling of data access		handling of data access	handling of data access	
651	applications for		applications for	applications for	
	HealthData@EU, including		HealthData@EU, including	HealthData@EU, including	
	a common application form,		a common application form,	a common application form,	
	a common data permit		a common data permit	a common data permit	
	template, standard forms for		template, standard forms for	template, standard forms for	
	common electronic health		common electronic health	common electronic health	
	data access contractual		data access contractual	data access contractual	
	arrangements, and common		arrangements, and common	arrangements, and common	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	procedures for handling cross-border requests, pursuant to Articles 45, 46, 47 and 48. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2).	procedures for handling cross-border requests, pursuant to Articles 45, 46, 47 and 48. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2).	procedures for handling eross border requests, pursuant to Articles 45, 46, 47 and 48. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2). [MOVED TO ARTICLE 37A]	
	Article			
652	Article 54	Article 54 <u>Cross-border access to and</u>	Article 54	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Mutual recognition		mutual recognition of data	Mutual recognition	
	Article	2 54(1)			
	1. When handling an		1. When handling an access	1. When handling an access	
	access application for cross-		application for cross-border	application for cross-border	
	border access to electronic		access to electronic health	access to electronic health	
	health data for secondary		data for secondary use,	data for secondary use,	
	use, health data access		health data access bodies	health data access bodies	
653	bodies and relevant		and relevant authorised	and relevant authorised	
	authorised participants shall		participants shall remain	participants shall remain	
	remain responsible for		responsible for taking	responsible for taking	
	taking decisions to grant or		decisions to grant or refuse	decisions to grant or refuse	
	refuse access to electronic		access to electronic health	access to electronic health	
	health data within their		data within their remit in	data within their remit in	
	remit in accordance with		accordance with the	accordance with the	
	the requirements for access		requirements for access laid	requirements for access laid	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	laid down in this Chapter.		down in this Chapter. <u>After</u> <u>a decision has been made</u> <u>regarding the granting or</u> <u>refusal of the health data</u> <u>permit, the health data</u> <u>access body shall inform</u> <u>the other health data</u> <u>bodies concerned by the</u> <u>same application about the</u> <u>decision.</u>	down in this Chapter. [MOVED TO ARTICLE 46(3A)]	
	Article	54(2)			
654	 A data permit issued by one concerned health data access body may benefit from mutual recognition by the other concerned health 		2. A data permit issued by one concerned health data access body may benefit from mutual recognition by the other concerned health	2. A data permit issued by one concerned health data access body may benefit from mutual recognition by the other concerned health	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement		
	data access bodies.		data access bodies.	data access bodies.			
				[SEE ARTICLE 46(3A)]			
	Sectio	on 5					
655	Section 5 Health data quality and utility for secondary use		Section 5 Health data quality and utility for secondary use	Section 5 Health data quality and utility for secondary use			
	Article 55						
656	Article 55		Article 55	Article 55			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Dataset description		Dataset description <u>and</u> <u>dataset catalogue</u>	Dataset description and datasets catalogue	
	Article	55(1)			
	1. The health data access bodies shall inform the data		1. The health data access	1. The health data access	
	users about the available		bodies shall inform the data users about the available	bodiesbody shall, through a publicly available and	
	datasets and their		datasets and their	standardised machine-	
	characteristics through a		characteristics through a	readable datasets	
657	metadata catalogue. Each		metadata catalogue. Each	catalogue, provide	
	dataset shall include		dataset shall include	information, in the form	
	information concerning the		information concerning the	of metadata, inform the	
	source, the scope, the main		source, the scope, the main	data users about the	
	characteristics, nature of		characteristics, nature of	available datasets and their	
	electronic health data and		electronic health data and	characteristics through a	
	conditions for making		conditions for making	metadata catalogue. . A	
	electronic health data		electronic health data	description of each dataset	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	available.		available.	shall include information concerning the source, the scope, the main characteristics, the nature of electronic health data and the conditions for making electronic health data available.	
	Article	55(1a)			
657a				1a. The dataset descriptions in the national datasets catalogue of the Member States shall be available, at least, in an official language of the Union.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				The dataset catalogue for Union institutions provided by the Union data access service shall be available in all official languages of the Union.	
	Article	55(1b)			
657b				1b. The datasets catalogue shall also be made available to single information points under Article 8 of Regulation (EU) 2022/868	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				37(1)(q) [MOD.SU.7.rev2]	
	Article	2 55(2)			
658	2. The Commission shall, by means of implementing acts, set out the minimum information elements data holders are to provide for datasets and their characteristics. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2).		2. The Commission shall, by means of implementing acts, set out the minimum information elements data holders are to provide for datasets and their characteristics. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2).	2. The Commission shall, by means of implementing acts, set out the minimum information- elements health data holders are to provide for datasets and their characteristics. Those implementing acts shall be adopted in accordance with the-advisory examination procedure referred to in Article 68(2).	

	Commission Propo	osal	EP Mandate	Council Mandate	Draft Agreement
	1	Article 56		·	
659	Article 56 Data quality and utility label		Article 56 Data quality and utility label	Article 56 Data quality and utility label	
	,	Article 56(1)			
660	1. Datasets made availathrough health data acc bodies may have a Unic data quality and utility provided by the data holders.	on	1. Datasets made available through health data access bodies may have a Union data quality and utility label provided by the data holders.	1. Datasets made available through health data access bodies may have a Union data quality and utility label provided applied by the health data holders.	

Commission Proposal		EP Mandate	Council Mandate	Draft Agreement			
		Article 56(2)					
661	2. Datasets with elect health data collected a processed with the sup of Union or national p funding shall have a d quality and utility labo accordance with the principles set out in paragraph 3.	and pport public lata		2. Datasets with electronic health data collected and processed with the support of Union or national public funding shall have a data quality and utility label, in accordance with the principles set out in paragraph 3.	2. Datasets with electronic health data collected and processed with the support of Union or national public funding shall have a data quality and utility label, in accordance with the principles elements set out in paragraph 3.		
	Article 56(2a)						
661a				<u>2a.</u> <u>The health data access</u> <u>body shall assess whether</u>			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			the data meets the requirements in paragraph 3 and shall revoke the label in the event the data does not meet the required guality.		
	Articl	e 56(3)			
662	3. The data quality and utility label shall comply with the following elements:		3. The data quality and utility label shall <i>comply</i> <i>withcover</i> the following elements:	3. The data quality and utility label shall comply with cover the following elements, where applicable:	
	Articl	e 56(3), point (a)			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
663	(a) for data documentation: meta-data, support documentation, data model, data dictionary, standards used, provenance;		 (a) for data documentation: meta-data, support documentation, data model, data dictionary, standards used, provenance; 	 (a) for data documentation: meta-data, support documentation, data model, data dictionary, dictionary, format and standards used, provenance, and when applicable, data model; 	
	Article	e 56(3), point (b)			
664	(b) technical quality, showing the completeness, uniqueness, accuracy, validity, timeliness and consistency of the data;		(b) technical quality, showing the completeness, uniqueness, accuracy, validity, timeliness and consistency of the data;	 (b) technical quality, showing the for assessment of technical quality: completeness, uniqueness, accuracy, validity, timeliness and consistency 	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement	
				of the data;		
	Article	56(3), point (c)				
665	(c) for data quality management processes: level of maturity of the data quality management processes, including review and audit processes, biases examination;		(c) for data quality management processes: level of maturity of the data quality management processes, including review and audit processes, biases examination;	(c) for data quality management processes: level of maturity of the data quality management processes, including review and audit processes, biases examination;		
	Article 56(3), point (d)					
666	(d) coverage:		(d) coverage:	(d) for assessment of		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	representation of multi- disciplinary electronic health data, representativity of population sampled, average timeframe in which a natural person appears in a dataset;		representation of multi- disciplinary electronic health data, representativity of population sampled, average timeframe in which a natural person appears in a dataset;	coverage: time period, population coverage and, when applicable representation of multi- disciplinary electronic health data, representativity of population sampled, and average timeframe in which a natural person appears in a dataset;	
	Article	56(3), point (e)			
667	 (e) information on access and provision: time between the collection of the electronic health data and their addition to the 		(e) information on access and provision: time between the collection of the electronic health data and their addition to the dataset,	(e) for information on access and provision: time between the collection of the electronic health data and their addition to the	

	Commission Propo	osal	EP Mandate	Council Mandate	Draft Agreement
	dataset, time to provide electronic health data following electronic hea data access application approval;	alth	time to provide electronic health data following electronic health data access application approval;	dataset, time to provide electronic health data following an electronic health data access application approval;	
	A	Article 56(3), point (f)			
668	(f) information on data enrichments: merging a adding data to an existin dataset, including links other datasets;	ng	(f) information on data enrichments: merging and adding data to an existing dataset, including links with other datasets;	(f) for information on data enrichmentsmodifications : merging and adding data to an existing dataset, including links with other datasets;.	
	A	Article 56(4)			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
669	4. The Commission is empowered to adopt delegated acts in accordance with Article 67 to amend the list of principles for data quality and utility label. Such delegated acts may also amend the list set out under paragraph 3 by adding, modifying or removing requirements for data quality and utility label.		4. The Commission is empowered to adopt delegated acts in accordance with Article 67 to amend the list of principles for data quality and utility label. Such delegated acts may also amend the list set out under paragraph 3 by adding, modifying or removing requirements for data quality and utility label.	4. The Commission is empowered to adopt delegated acts in accordance with Article 67 to amend the list of principles elements for data quality and utility label. Such delegated acts may also amend the list set out under paragraph 3 by adding, modifying or removing requirements for data quality and utility label.	
	Article	56(5)	r		
670					

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
5. The Commission shall,	5. The Commission shall,	5. The Commission shall,	
by means of implementing	by means of implementing	by means of implementing	
acts, set out the visual	acts, set out the visual	acts, set out the visual	
characteristics and technical	characteristics and technical	characteristics and technical	
specifications of the data	specifications of the data	specifications of the data	
quality and utility label,	quality and utility label,	quality and utility label,	
based on the elements	based on the elements	based on the elements	
referred to in paragraph 3.	referred to in paragraph 3.	referred to in paragraph 3.	
Those implementing acts	Those implementing acts	Those implementing acts	
shall be adopted in	shall be adopted in	shall be adopted in	
accordance with the	accordance with the	accordance with the	
advisory procedure referred	advisory procedure referred	advisory examination	
to in Article 68(2). Those	to in Article 68(2). Those	procedure referred to in	
implementing acts shall	implementing acts shall take	Article 68(2). Those	
take into account the	into account the	implementing acts shall take	
requirements in Article 10	requirements in Article 10	into account the	
of Regulation [] [AI Act	of Regulation [] [AI Act	requirements in Article 10	
COM/2021/206 final] and	COM/2021/206 final] and	of Regulation [] [AI Act	
any adopted common	any adopted common	COM/2021/206 final] and	
specifications or	specifications or	any adopted common	
harmonised standards	harmonised standards	specifications or	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	supporting those requirements.		supporting those requirements.	harmonised standards supporting those requirements, where applicable.	
	Artic	le 57			
671	Article 57 EU Datasets Catalogue		Article 57 EU Datasets Catalogue	Article 57 EU Datasets Catalogue	
	Artic	le 57(1)			
672	1. The Commission shall establish an EU Datasets		1. The Commission shall establish an EU Datasets	1. The Commission shall establish and publicly	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Catalogue connecting the national catalogues of datasets established by the health data access bodies and other authorised participants in HealthData@EU.		Catalogue connecting the national catalogues of datasets established by the health data access bodies and other authorised participants in HealthData@EU <u>taking</u> into consideration the health interoperability resources already developed across the Union.	provide an EU Datasets Catalogue connecting the national catalogues of datasets catalogues established by the health data access bodies and otherin each Member State as well as datasets catalogues of authorised participants in HealthData@EU.	
	Article	2 57(2)			
673	 The EU Datasets Catalogue and the national datasets catalogues shall be 		 The EU Datasets Catalogue and the national datasets catalogues shall be 	2. The EU Datasets Catalogue and the national datasets catalogues as well	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement		
	made publicly available.		made publicly available.	as datasets catalogues of authorised participants in HealthData@EU shall be made publicly available.			
	Article	58					
674	Article 58 Minimum dataset specifications		Article 58 Minimum dataset specifications	Article 58 Minimum dataset specifications			
	Article 58, first paragraph						
675	The Commission may, by		The Commission may, by	The Commission may, by			

Commission Proposal		EP Mandate	Council Mandate	Draft Agreement		
means of implementing acts, determine the minimum specifications for cross-border datasets for secondary use of electronic health data, taking into account existing Union infrastructures, standards, guidelines and recommendations. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2).		means of implementing acts, determine the minimum specifications for cross-border datasets for secondary use of electronic health data, taking into account existing Union infrastructures, standards, guidelines and recommendations. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2).	means of implementing acts, determine the minimum- specifications for datasets of high impact for the cross-border datasets for secondary use of electronic health data, taking into account existing Union infrastructures, standards, guidelines and recommendations. Those implementing acts shall be adopted in accordance with the advisory examination procedure referred to in Article 68(2).			
Chapter V						

Commission Proposal		EP Mandate	Council Mandate	Draft Agreement	
676	Chapter V Additional actions	IS	Chapter V Additional actions	Chapter V Additional actions	
		Article 59			
677	Article 59 Capacity building	g	Article 59 Capacity building	Article 59 Capacity building	
		Article 59, first paragraph			
678	The Commission shall support sharing of best		The Commission shall support sharing of best	The Commission shall support sharing of best	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
practices and expertise,	practices and expertise,	practices and expertise,	
aimed to build the capacity	aimed to build the capacity	aimed to build the capacity	
of Member States to	of Member States to	of Member States to	
strengthen digital health	strengthen digital health	strengthen digital health	
systems for primary and	systems for primary and	systems for primary and	
secondary use of electronic	secondary use of electronic	secondary use of electronic	
health data. To support	health data. To support	health data. To support	
capacity building, the	capacity building, the	capacity building, the	
Commission shall draw up	Commission shall draw up	Commission shall draw up	
benchmarking guidelines	benchmarking guidelines	benchmarking guidelines in	
for the primary and	for the primary and	close cooperation and	
secondary use of electronic	secondary use of electronic	consultation with Member	
health data.	health data. <u>The</u>	States establish indicators	
	Commission shall issue	for self assessment for the	
	guidance with regard to	primary and secondary use	
	<u>compliance of data holders</u>	of electronic health data.	
	with the provisions of		
	Chapter IV, taking into		
	account the specific		
	<u>conditions of data holders</u>		
	<u>that are civil society,</u>		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			<u>researchers, medical</u> <u>societies and SMEs</u>		
	Article	e 59a			
678a			<u>Article 59a</u> <u>Digital health literacy and</u> <u>digital health access</u>		
	Article	959a(1), first paragraph			
678b			<u>1.</u> <u>In order to ensure</u> successful implementation of the EHDS, Member		

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	States shall support digital		
	health literacy, promote		
	public awareness,		
	including through		
	educational programmes		
	<u>for natural persons, health</u>		
	professionals and		
	<u>stakeholders, to inform the</u>		
	public of the rights and		
	obligations in the EHDS		
	and inform natural persons		
	<u>of the advantages, risks</u>		
	<u>and potential gains to</u>		
	<u>science and society of the</u>		
	<u>primary and secondary use</u>		
	<u>of electronic health data,</u>		
	<u>and offer free of charge</u>		
	<u>accessible training to</u>		
	<u>health professionals in this</u>		
	<u>regard. Those programmes</u>		
	<u>shall be tailored to the</u>		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			needs of specific groups and shall be developed and reviewed, and where necessary updated, on a regular basis in consultation and cooperation with relevant experts and stakeholders.		
	Artic	le 59a(1), second paragraph			
678c			<u>The Commission shall</u> <u>support Member States in</u> <u>this regard.</u>		
	Artic	le 59a(2)			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
678d			2. Member States shall monitor and evaluate, on a regular basis, the digital health literacy of health professionals and natural persons, in particular about the primary and secondary use of health data, functionalities and conditions as well as rights of natural persons within the EHDS.		
	Article	59a(3)			
678e			<u>3.</u> <u>Member States shall</u>		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			promote the access to the infrastructure necessary for the effective management of natural persons' electronic health data, both within primary and secondary use.		
	Article	59a(4)			
678f			4. <u>Member States shall</u> regularly inform the public at large about the role and benefits of the secondary use of health data and the role of health data access bodies, as well as the risks and consequences linked		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			with individual and collective digital health data rights arising from this Regulation.		
	Articl	e 60			
679	Article 60 Additional requirements for public procurement and Union funding		Article 60 Additional requirements for public procurement and Union funding	Article 60 Additional requirements for public procurement and Union funding	
	Articl	e 60(1)			
680					

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
1. Public procurers,	1. Public procurers,	1. Public procurers,	
national competent	national competent	national	
authorities, including digital	authorities, including digital	competentContracting	
health authorities and health	health authorities and health	authorities, including digital	
data access bodies, and the	data access bodies, and the	health authorities and health	
Commission shall make	Commission shall make	data access bodies and	
reference to the applicable	reference to the applicable	Union institutions, bodies,	
technical specifications,	technical specifications,	offices or agencies,	
standards and profiles as	standards and profiles as	including , and the	
referred to in Articles 6, 23,	referred to in Articles 6, 23,	Commission, shall make	
50, 56, as relevant, as points	50, 56, as relevant, as points	reference to the applicable	
of orientation for public	of orientation for public	technical specifications,	
procurements and when	procurements and when	standards and profiles as	
formulating their tender	formulating their tender	referred to in Articles 6, 12,	
documents or calls for	documents or calls for	23, 50, 52, 56, as well as to	
proposals, as well as when	proposals, as well as when	the requirements laid	
defining the conditions for	defining the conditions for	down in Regulations (EU)	
Union funding regarding	Union funding regarding	2016/679 and (EU)	
this Regulation, including	this Regulation, including	2018/1725, as relevant, 23,	
enabling conditions for the	enabling conditions for the	50, 56, as relevant, as points	
structural and cohesion	structural and cohesion	of orientation for public	

	Commission Proposal	EP Mandate	Council Mandate Draft Agreemen	t
	funds.	funds.	procurements and when formulating their tender documents or calls for proposals, as well as when defining the conditions for Union funding regarding this Regulation, including enabling conditions for the structural and cohesion funds.	
	Article 60(2)			
681	2. The ex-ante conditionality for Union funding shall take into account the requirements developed in the framework	2. The ex-ante conditionality for Union funding shall take into account the requirements developed in the framework	2. The ex-ante conditionality for Unioncriteria for obtaining funding from the Union shall take into	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	of Chapters II, III and IV.		of Chapters II, III and IV.	account-the requirements developed in the framework of Chapters II, III and IV.:	
	Article	e 60(1a), second subparagraph			
681a				a) the requirements developed in Chapters II, III and IV;	
	Article	e 60(1a), third subparagraph			
681b				b) the requirements laid down in Regulations (EU) 2016/679 or (EU)	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				2018/1725, where applicable.	
	Article	e 60(2a)	L		
681c			2a. Public procurers, national competent authorities, including digital health authorities and health data access bodies, and the Commission shall require, as a condition to procure or fund services provided by controllers and processors established in the Union processing personal electronic health		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			<u>data, that such controllers</u> and processors:		
	Article	60(2a), point (a)			
681d			(a) store those data in the Union, in accordance with Article 60a of this Chapter: and		
	Article	60(2a), point (b)			
681e			(b) have duly demonstrated that they are not subject to third country		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			law conflicting with Union data protection rules.		
	Article	e 60a		<u> </u>	
681f			<u>Article 60a</u> <u>Storage of personal</u> <u>electronic health data</u>		
	Article	e 60a, first subparagraph			
681g			<u>For the purposes of</u> primary and secondary use of personal electronic		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			health data, the storage of personal electronic health data shall exclusively take place within the territory of the Union, without prejudice to the provisions of Article 63.		
	Article	60a			
681h				Article 60A Storage of personal electronic health data by health data access bodies and secure processing environments	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	60a(1)			
681i				1. Health data access bodies, single data holders and the Union data access service shall store and process, personal health electronic data in the European Union when performing pseudonymisation, anonymisation and any other personal data processing operations referred to in Articles 45 to 49, through secure processing environments	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			within the meaning of article 50 and article 52(8) or through HealthData@EU. This requirement shall apply to any entity performing these tasks on their behalf.	
	Article 60a(2)			
681j			2. By way of exception, the data referred to in paragraph 1 may be stored and processed in a third country, a territory or one or more specified sectors within that third country covered by an	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				adequacy decision, pursuant to Article 45 of Regulation (EU) 2016/679.	
	Article	61			
682	Article 61 Third country transfer of non-personal electronic data		Article 61 <i>Third country</i> <i>transfer.<u>Sensitive nature</u> of non-personal electronic data-<u>health data</u></i>	Article 61 Third country transfer of non-personal electronic data Transfer of anonymous electronic health data presenting a risk of re- identification to a third country or international organisation	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	61(1)			
683	Article1. Non-personal electronicdata made available byhealth data access bodies,that are based on a naturalperson's electronic datafalling within one of thecategories of Article 33[(a), (e), (f), (i), (j), (k),(m)] shall be deemed highlysensitive within themeaning of Article 5(13) ofRegulation [] [DataGovernance ActCOM/2020/767 final],provided that their transferto third countries presents arisk of re-identification	61(1)	1. Non-personal electronic health data made available by health data access bodies, that are based on a natural person's electronic data falling within one of the categories of Article 33 f(a), (c), (f), (i), (j), (k), (m)f shall be deemed highly sensitive within the meaning of Article 5(13) of Regulation [] [Data Governance Act COM/2020/767 final], provided that their transfer to third countries presents a risk of re-identification	1. Non- personalAnonymous electronic health data made available by health data access bodies to a health data user or its contractor in a third country according to a data permit pursuant to Article 46 or a data request pursuant to Article 47 or to an authorised participants or its contractor in a third country or an international organisation, that are based on a natural person's electronic health	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
through means going	through means going	data falling within one of	
beyond those likely	beyond those likely	the categories of Article 33	
reasonably to be used, in	reasonably to be used, in	[(a), (e), (f), (i), (j), (k), (m)]	
view of the limited number	view of the limited number	shall be deemed highly	
of natural persons involved	of natural persons involved	sensitive within the	
in that data, the fact that	in that data, the fact that	meaning of Article 5(13) of	
they are geographically	they are geographically	Regulation [] [Data	
scattered or the	scattered or the	Governance Act	
technological developments	technological developments	COM/2020/767 final] (EU)	
expected in the near future.	expected in the near future.	2022/868, provided that	
		their transfer to third	
		countries presents a risk of	
		becoming personal	
		electronic health data	
		allowing re-identification	
		through means going	
		beyond those likely	
		reasonably likely to be	
		used, in particular in view	
		of the limited number of	
		natural persons involved in	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				that data, the fact that they are geographically scattered or the technological developments expected in the near future.	
	Article	61(2)			
684	2. The protective measures for the categories of data mentioned in paragraph 1 shall depend on the nature of the data and anonymization techniques and shall be detailed in the Delegated Act under the empowerment set out in Article 5(13) of Regulation		2. The protective measures for the categories of data mentioned in paragraph 1 shall- <i>depend on the nature</i> <i>of the data and</i> <i>anonymization techniques</i> <i>and shall</i> be detailed in the Delegated Act under the empowerment set out in Article 5(13) of Regulation	2. The protective measures for the categories of data mentioned in paragraph 1 shall– depend on the nature of the data and anonymization techniques and shall be detailed in the Delegated Act under the empowerment set out in Article 5(13) of Regulation	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	[] [Data Governance Act COM/2020/767 final].		<i>[] [Data Governance Act</i> <i>COM/2020/767 final](EU)</i> 2022/868.	[] [Data Governance Act COM/2020/767 final](EU) 2022/868 .	
	Article	62			
685	Article 62 International access and transfer of non-personal electronic health data		Article 62 International access and transfer of non-personal electronic health data	Article 62 International access and Transfer of anonymous non-personal electronic health data to a third country or an international organisation	
	Article	e 62(1)			

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	1. The digital health	1. The digital health	1. The digital health	
	authorities, health data access bodies, the	authorities, health data access bodies, the	authorities, health data access bodies, the	
	authorised participants in the cross-border infrastructures provided for	authorised participants in the cross-border infrastructures provided for	authorised participants in the cross-border infrastructures provided for	
	in Articles 12 and 52 and data users shall take all	in Articles 12 and 52 and data users shall take all	in Articles 12 and 52 and health data users shall take	
686	reasonable technical, legal and organisational	reasonable technical, legal and organisational	all reasonable technical, legal and organisational	
	measures, including contractual arrangements,	measures, including contractual arrangements, in	measures, including contractual arrangements, in	
	in order to prevent international transfer or	order to prevent international transfer or	order to prevent transfer to a third country or an	
	governmental access to non-personal electronic health data held in the	governmental access to non- personal electronic health data held in the Union	international organisation, including -international transfer or governmental	
	Union where such transfer or access would create a	where such transfer or access would create a	access to non-personal in a third country of	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	conflict with Union law or the national law of the relevant Member State, without prejudice to paragraph 2 or 3 of this Article.		conflict with Union law or the national law of the relevant Member State, without prejudice to paragraph 2 or 3 of this Article.	anonymous electronic health data held in the Union where such transfer or access would create a conflict with Union law or the national law of the relevant Member State ₇ without prejudice to paragraph 2 or 3 of this Article.	
	Article	: 62(2)			
687	2. Any judgment of a third- country court or tribunal and any decision of a third- country administrative authority requiring a digital		2. Any judgment of a third- country court or tribunal and any decision of a third- country administrative authority requiring a digital	2. Any judgment of a third- country court or tribunal and any decision of a third- country administrative authority requiring a digital	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
health authority, health data	health authority, health data	health authority, health data	
access body or data users to	access body or data users to	access body or data users to	
transfer or give access to	transfer or give access to	transfer or give access to	
non-personal electronic	non-personal electronic	non-personal electronic	
health data within the scope	health data within the scope	health data within the scope	
of this Regulation held in	of this Regulation held in	of this Regulation held in	
the Union shall be	the Union shall be	the Union shall be	
recognised or enforceable	recognised or enforceable in	recognised or enforceable in	
in any manner only if based	any manner only if based on	any manner only if based on	
on an international	an international agreement,	an international agreement,	
agreement, such as a mutual	such as a mutual legal	such as a mutual legal	
legal assistance treaty, in	assistance treaty, in force	assistance treaty, in force	
force between the	between the requesting third	between the requesting third	
requesting third country and	country and the Union or	country and the Union or	
the Union or any such	any such agreement	any such agreement	
agreement between the	between the requesting third	between the requesting third	
requesting third country and	country and a Member	country and a Member	
a Member State.	State.	State.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Artic	cle 62(3)			
688	Artic 3. In the absence of an international agreement as referred to in paragraph 2 o this Article, where a digital health authority, a health data access body, data users is the addressee of a decision or judgment of a third-country court or tribunal or a decision of a third-country administrative authority to transfer or give access to non-personal data within the scope of this Regulation held in the	of 1 rs	3. In the absence of an international agreement as referred to in paragraph 2 of this Article, where a digital health authority, a health data access body, data users is the addressee of a decision or judgment of a third-country court or tribunal or a decision of a third-country administrative authority to transfer or give access to non-personal data within the scope of this Regulation held in the	3. In the absence of an international agreement as referred to in paragraph 2 of this Article, where a digital health authority, a health data access body, data users is the addressee of a decision or judgment of a third country court or tribunal or a decision of a third-country administrative authority to transfer or give access to non-personal data within the scope of this Regulation held in the	
	Union and compliance with such a decision would risk		Union and compliance with such a decision would risk	Union and compliance with such a decision would risk	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	putting the addressee in conflict with Union law or with the national law of the relevant Member State, transfer to or access to such data by that third-country authority shall take place only where:		putting the addressee in conflict with Union law or with the national law of the relevant Member State, transfer to or access to such data by that third-country authority shall take place only where:	putting the addressee in conflict with Union law or with the national law of the relevant Member State, transfer to or access to such data by that third-country authority shall take place only where:	
	Article	62(3), point (a)			
689	(a) the third-country system requires the reasons and proportionality of such a decision or judgment to be set out and requires such a decision or judgment to be specific in character, for		(a) the third-country system requires the reasons and proportionality of such a decision or judgment to be set out and requires such a decision or judgment to be specific in character, for	(a) the third-country system requires the reasons and proportionality of such a decision or judgment to be set out and requires such a decision or judgment to be specific in character, for	

	Commission Proposa	al	EP Mandate	Council Mandate	Draft Agreement
	instance by establishing a sufficient link to certain suspected persons or infringements;	1	instance by establishing a sufficient link to certain suspected persons or infringements;	instance by establishing a sufficient link to certain suspected persons or infringements;	
	Art	ticle 62(3), point (b)			
690	(b) the reasoned objection of the addressee is subject to a review by a competen third-country court or tribunal; and	et 🛛	(b) the reasoned objection of the addressee is subject to a review by a competent third-country court or tribunal; and	(b) the reasoned objection of the addressee is subject to a review by a competent third-country court or tribunal; and	
	Art	ticle 62(3), point (c)			
691					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	(c) the competent third- country court or tribunal issuing the decision or judgment or reviewing the decision of an administrative authority is empowered under the law of that third country to take duly into account the relevant legal interests of the provider of the data protected under Union law or the national law of the relevant Member State		(c) the competent third- country court or tribunal issuing the decision or judgment or reviewing the decision of an administrative authority is empowered under the law of that third country to take duly into account the relevant legal interests of the provider of the data protected under Union law or the national law of the relevant Member State	(c) the competent third- country court or tribunal issuing the decision or judgment or reviewing the decision of an administrative authority is empowered under the law of that third country to take duly into account the relevant legal interests of the provider of the data protected under Union law or the national law of the relevant Member State	
	Article	e 62(4)			
692	4. If the conditions laid		4. If the conditions laid	4. If the conditions laid	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	down in paragraph 2 or 3 are met, digital health authority, a health data access body or a data altruism body shall provide the minimum amount of data permissible in response to a request, based on a reasonable interpretation of the request.		down in paragraph 2 or 3 are met, digital health authority, a health data access body or a data altruism body shall provide the minimum amount of data permissible in response to a request, based on a reasonable interpretation of the request.	down in paragraph 2 or 3 are met, digital health authority, a health data access body or a data altruism body shall provide the minimum amount of data permissible in response to a request, based on a reasonable interpretation of the request.	
	Article	62(5)			
693	5. The digital health authorities, health data access bodies, data users shall inform the data holder about the existence of a		5. The digital health authorities, health data access bodies, data users shall inform the data holder about the existence of a	5. The digital health authorities, health data access bodies, data users shall inform the data holder about the existence of a	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	request of a third-country administrative authority to access its data before complying with that request, except where the request serves law enforcement purposes and for as long as this is necessary to preserve the effectiveness of the law enforcement activity.		request of a third-country administrative authority to access its data before complying with that request, except where the request serves law enforcement purposes and for as long as this is necessary to preserve the effectiveness of the law enforcement activity.	request of a third-country administrative authority to access its data before complying with that request, except where the request serves law enforcement purposes and for as long as this is necessary to preserve the effectiveness of the law enforcement activity.	
	Article	9 63			
694					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 63		Article 63	Article 63	
	International access and transfer of personal electronic health data		International access and transfer of personal electronic health data	International access and Additional conditions for transfer of personal electronic health data to a third country or an international organisation	
	Article	63, first paragraph			
695	In the context of international access and transfer of personal electronic health data, Member States may maintain or introduce further conditions,		<i>In the context of</i> International access and transfer of personal electronic health data , <i>shall</i> <i>be granted in accordance</i> <i>with Chapter V of</i> <i>Regulation (EU) 2016/679.</i>	In the context of international access and transfer of personal electronic health data to a third country or an international organisation, Member States may	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	including limitations, in accordance with and under the conditions of article 9(4) of the Regulation (EU) 2016/679.		Member States may maintain or introduce further conditions <u>on</u> international access to, and transfer of, personal electronic health data, including limitations, in accordance with and under the conditions of article 9(4) of the Regulation (EU) 2016/679.	maintain or introduce further conditions, including limitations, in accordance with and under the conditions of Article 9(4) of Regulation (EU) 2016/679, in addition to the requirements set out in Articles 13(3) and 52(5) of this Regulation and the requirements laid down in Chapter V ofthe Regulation (EU) 2016/679.	
	Article	63a			
695a			<u>Article 63a</u>		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			<u>Reciprocity of access to</u> <u>electronic health data for</u> <u>secondary use</u>		
	Article	e 63a(1)			
695b			1. Notwithstanding Articles 62 and 63, only entities and bodies that are established in third countries included in the list referred to in paragraph 2 shall be allowed access to electronic health data in the secure processing environment and have the possibility of downloading non-personal		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			<u>electronic health data held</u> <u>in the Union for the</u> purposes of secondary use.		
	Article	e 63a(2)	<u>.</u>		
695c			2. The Commission is empowered to adopt delegated acts in accordance with Article 67 supplementing this Regulation by setting up a list of third countries which are considered to provide for equivalent access to, and transfer of, electronic health data of its data holders for the purposes of		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			secondary use of electronic health data by entities and bodies within the Union.		
	Article	e 63a(3)			
695d			3. <u>The Commission shall</u> <u>monitor the list of third</u> <u>countries benefiting from</u> <u>such access, and shall</u> <u>provide for a periodic</u> <u>review of the functioning</u> <u>of this Article.</u>		
	Article	e 63a(4)			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
695e			4. Where the Commission considers that a third country no longer meets the requirement to be included on the list referred to in paragraph 2, it shall adopt a delegated act to remove such third country that benefits from access.		
	Chapte	er VI			
696	Chapter VI European governance and		Chapter VI European governance and	Chapter VI European governance and	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	coordination		coordination	coordination	
	Article	64			
697	Article 64 European Health Data Space Board (EHDS Board)		Article 64 European Health Data Space Board (EHDS Board)	Article 64 European Health Data Space Board (EHDS Board)	
	Article	e 64(1)			
698	1. A European Health Data Space Board (EHDS Board) is hereby established to facilitate cooperation and		 A European Health Data Space Board (EHDS Board) is hereby established to facilitate cooperation and 	 A European Health Data Space Board (EHDS Board) is hereby established to facilitate cooperation and 	

Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
the exchange of informatio	n	the exchange of information	the exchange of information	
among Member States. The		among Member States. The	among Member States and	
EHDS Board shall be		EHDS Board shall be	the Commission. The	
composed of the high level		composed of, one the high	EHDS Board shall be	
representatives of digital		level	composed of the high level	
health authorities and health	h	representatives<mark>representati</mark>	representatives of digital	
data access bodies of all th	2	<u>ve</u> of digital health	health authorities and health	
Member States. Other		authorities and one high	data access bodies of all the	
national authorities,		level representative of	Member States. Other	
including market		health data access bodies of	national authorities,	
surveillance authorities		all per Member State	including market	
referred to in Article 28,		appointed by the Member	surveillance authorities	
European Data Protection		States. State concerned.	referred to in Article 28,	
Board and European Data		Where a Member State has	European Data Protection	
Protection Supervisor may		designated several health	Board and European Data	
be invited to the meetings,		data access bodies, the	Protection Supervisor may	
where the issues discussed		representative of the	be invited to the meetings,	
are of relevance for them.		<u>coordinating health data</u>	where the issues discussed	
The Board may also invite		access body shall be a	are of relevance for them.	
experts and observers to		member of the EHDS	The Board may also invite	
attend its meetings, and		<u>Board;</u>	experts and observers to	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Commission Proposal may cooperate with other external experts as appropriate. Other Union institutions, bodies, offices and agencies, research infrastructures and other similar structures shall have an observer role.	Other national authorities, including market surveillance authorities referred to in Article 28, European Data Protection Board and European Data Protection Supervisor <i>may and Union agencies</i> <i>within the field of public</i> <i>health and cybersecurity</i> <i>shall also</i> be invited to the meetings, where the issues discussed are of relevance for them. The Board may	Council Mandate attend its meetings, and may cooperate with other external experts as appropriate. Other Union institutions, bodies, offices and agencies, research infrastructures and other similar structures nominated by each Member State. Each Member State shall have an observer roleone vote.	Draft Agreement
	also inviteinvite stakeholders, experts and observers to attend its meetings, and may cooperate with other	AMENDED AND MOVED TO PARA 1(B)-1(E)]	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			external experts as appropriate. Other Union institutions, bodies, offices and agencies, research infrastructures and other similar structures <i>shallmay</i> have an observer role. <i>The</i> <i>EHDS Board shall invite a</i> <i>representative of the</i> <i>European Parliament to</i> <i>attend its meetings as an</i> <i>observer</i> .		
	Article	64(1a)			
698a				1a. A representative of the Commission and a representative of the	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			Member States shall co- chair the meetings of the EHDS Board.	
			(MOVED FROM PARA 6)	
	Article 64(1b)			
698b			1b. Market surveillance authorities referred to in Article 28, European Data Protection Board and European Data Protection Supervisor, may be invited to the meetings, where the issues discussed	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				are of relevance for them. [MOVED FROM PARA 1 AND AMENDED]	
	Article	64(1c)			
698c				1c. The Board may also invite other national authorities, experts and observers as well as other Union institutions, bodies, offices and agencies, research infrastructures and other similar structures to attend its	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				meetings. When these participants are invited, they shall have an observer role.	
				[MOVED FROM PARA 1 AND AMENDED]	
	Article	e 64(1d)			
698d				1d. The Board may cooperate with other external experts as appropriate.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				[MOVED FROM PARA 1 AND AMENDED]	
	Articl	le 64(1e)	I		
698e				1e. Stakeholders and relevant third parties, including patients' representatives, may be invited to attend meetings of the EHDS Board and to participate in its work, depending on the topics discussed and their degree of sensitivity.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				[MOVED FROM PARA 4]	
	Article	e 64(2)			
	2. Depending on the		2. Depending on the	2. Depending on the	
	functions related to the use		functions related to the use	functions related to the use	
	of electronic health data,		of electronic health data, the	of electronic health data, the	
	the EHDS Board may work		EHDS Board may work in	EHDS Board may work in	
	in subgroups, where digital		subgroups, where digital	subgroups for certain	
699	health authorities or health		health authorities or health	topics, where digital health	
	data access bodies for a		data access bodies for a	authorities or health data	
	certain area shall be		certain area shall be	access bodies shall be	
	represented. The subgroups		represented. The subgroups	represented. The	
	may have joint meetings, as		may have joint meetings, as	subgroups for a certain	
	required.		required.	area shall be	
				represented support the	
				EHDS Board with specific	

	Commission Prop
Members of the EHDS Board shall not have in industries or economicexpertise: The subgroups may have joint meetings, as required.in industries or economicactivities which could affect their impartiality.Here their impartiality.They shall undertake to act in the public interest and in an independent manner, and shall make an annual declaration of their financial interests. All industries or economicHere their inancial interests. All industries or economicIndirect Interests which industries or economic activities shall be entered in a register held by the Commission which is accessible to the public, iten a suffices.Here their inancial interest.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		<u>The EHDS Board's code of</u> <u>conduct shall make</u> <u>reference to the application</u> of this Article, in particular in relation to the <u>acceptance of gifts.</u>		
	Article 64(3)			
700	3. The composition, organisation, functioning and cooperation of the sub- groups shall be set out in the rules of procedure put forward by the Commission.	3. The <i>composition</i> , <i>organisation, functioning</i> <i>and cooperation of the sub-</i> <i>groups shall be set out in</i> <i>the</i> <u>EHDS Board shall</u> <i>adopt rules of procedure</i> <i>and a code of conduct</i> ,	3. The EHDS Board shall adopt its rules of procedures on the basis of a proposal of the Commission. A two-thirds majority is required for the rules of procedures to	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Commission Proposal	EP Mandatefollowing a proposal fromthe Commission. Thoserules of procedure putforward by theCommissionshall providefor the composition,organisation, functioningand cooperation of theBoard and its cooperationwith the Advisory Board.	be adopted. The rules of procedures shall include rules pertaining to the composition, organisation, functioningstructure, operation and cooperation of the sub-groups and shall be set out in the regulate the role of invitees referred to in paragraphs	Draft Agreement
		1b to 1e, taking into account the topics under discussion and the level of confidentiality involved. Regarding voting rules, the EHDS Board shall deliberate by consensus as far as possible. If consensus cannot be reached the EHDS Board shall deliberate by a	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			majority of two thirds of the Member States representatives. Each member shall have one vote-of procedure put forward by the Commission.	
	Article 64(4)			
701	4. Stakeholders and relevant third parties, including patients' representatives, shall be invited to attend meetings of the EHDS Board and to participate in its work, depending on the topics	deleted	4. Stakeholders and relevant third parties, including patients' representatives, shall be invited to attend meetings of the EHDS Board and to participate in its work, depending on the topics	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	discussed and their degree			discussed and their degree	
	of sensitivity.			of sensitivity.	
				[MOVED TO PARA 1E]	
	Article 64(5	5)			
	5. The EHDS Board shall		5. The EHDS Board shall	5. The EHDS Board shall	
	cooperate with other		cooperate with other	cooperate with other	
	relevant bodies, entities and		relevant bodies, entities and	relevant bodies, entities and	
702	experts, such as the		experts, such as the	experts, such as the	
/ 01	European Data Innovation		European Data Innovation	European Data Innovation	
	Board referred to in Article		Board referred to in Article	Board referred to in Article	
	26 of Regulation [] [Data		26 of Regulation [] [Data	26 of Regulation [] [Data	
	Governance Act		Governance Act	Governance Act	
	COM/2020/767 final],		COM/2020/767 final],	COM/2020/767 final29 of	
	competent bodies set up		competent bodies set up	Regulation 2022/868],	

Co	ommission Proposal	EP Mandate	Council Mandate	Draft Agreement
unde	er Article 7 of	under Article 7 of	competent bodies set up	
Reg	ulation [] [Data Act	Regulation [] [Data Act	under Article 7 of	
CON	M/2022/68 final],	COM/2022/68 final],	Regulation [] [Data Act	
supe	ervisory bodies set up	supervisory bodies set up	COM/2022/68 final],	
unde	er Article 17 of	under Article 17 of	supervisory bodies set up	
Reg	ulation [] [eID	Regulation [] [eID	under Article 17 of	
Reg	ulation], European Data	Regulation], European Data	Regulation [] [eID	
Prot	tection Board referred to	Protection Board referred to	Regulation], European Data	
in A	Article 68 of Regulation	in Article 68 of Regulation	Protection Board referred to	
(EU)) 2016/679 and	(EU) 2016/679 and	in Article 68 of Regulation	
cybe	ersecurity bodies.	cybersecurity bodies, in	(EU) 2016/679 ,	
		particular the ENISA.	cybersecurity bodies, and	
			the European Open	
			Science Cloud, in the	
			effort of reaching	
			advanced solutions for the	
			FAIR data usage in	
			research and innovation	
			and cybersecurity bodies.	

	Commission Prop	oosal		EP Mandate	Council Mandate	Draft Agreement
		Article	64(6)			
703	6. The Commission s chair the meetings of EHDS Board.			6. The Commission shall chair the meetings of the EHDS Board.	6. The Commission shall chair the meetings of the EHDS Board. [MOVED TO PARA 1A]	
		Article	64(7)			
704	7. The EHDS Board be assisted by a secre provided by the Commission.			7. The EHDS Board shall be assisted by a secretariat provided by the Commission.	7. The EHDS Board shall be assisted by a secretariat provided by the Commission.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	e 64(7a)			
704a			7a. <u>The EHDS Board shall</u> publish meeting dates and minutes of the discussions and publish an annual report on its activities.		
	Article	e 64(8)			
705	8. The Commission shall, by means of implementing acts, adopt the necessary measures for the		8. The Commission shall, by means of implementing acts, adopt the necessary measures for the	8. The Commission shall, by means of implementing acts, adopt the necessary measures for the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	establishment, management and functioning of the EHDS Board. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2).		establishment , <i>management</i> and functioning and operations of the EHDS Board. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2).	establishment , management and functioning and management of the EHDS Board. Those implementing acts shall be adopted in accordance with the advisory examination procedure referred to in Article 68(2).	
	Article	e 64a			
705a			<u>Article 64a</u> <u>Advisory forum</u>		
	Article	e 64a(1)			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
705b			1. An advisory forum to advise the EHDS Board in the fulfilment of its tasks by providing stakeholder input in matters covered by this Regulation is hereby established.		
	Article	64a(2), first subparagraph			
705c			2. The advisory forum shall be composed of relevant stakeholders, including representatives of patients' organisations, health professionals,		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			industry, consumer organisations, scientific researchers and academia. The advisory forum shall have a balanced composition and represent the views of different relevant stakeholders.		
	Article	64a(2), second subparagraph			
705d			Where commercial interests are represented in the advisory forum, they shall be balanced between large companies, SMEs and start-ups. Focus on primary and secondary use		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			<u>of electronic health data</u> <u>shall also be balanced.</u>		
	Article	e 64a(3)	<u> </u>		
705e			3. <u>Members of the advisory</u> <u>forum shall be appointed</u> <u>by the Commission</u> <u>following a public call for</u> <u>interest and a transparent</u> <u>selection procedure, in</u> <u>consultation with the</u> <u>European Parliament.</u> <u>Members of the advisory</u> <u>forum shall make an</u> <u>annual declaration of their</u> <u>interests, which shall be</u> <u>updated whenever relevant</u>		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			<u>and shall be made publicly</u> available.		
	Article	e 64a(4)			
705f			4. <u>The term of office of the</u> <u>members of the advisory</u> <u>forum shall be two years</u> <u>and it shall be renewable</u> <u>only once consecutively.</u>		
	Article	e 64a(5)			
705g			<u>5.</u> <u>The advisory forum may</u> establish standing or		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			temporary subgroups as appropriate for the purpose of examining specific questions related to the objectives of this Regulation.		
	Article	64a(6)			
705h			6. <u>The advisory forum</u> shall draw up its rules of procedure and elect one co- chair from among its members whose term of office shall be two years, renewable once. <u>A</u> <u>Commission representative</u> shall be the other co-chair.		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement		
	Article	e 64a(7)					
705i			7. The advisory forum shall hold regular meetings. The advisory forum may invite relevant experts and other relevant stakeholders to its meetings. The Chair of the EHDS Board may attend, ex officio, the meetings of the advisory forum.				
	Article 64a(8)						

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
705j			8. In fulfilling its tasks as set out in paragraph 1, the advisory forum shall prepare opinions, recommendations or written contributions.		
	Article	64a(9)			
705k			9. The advisory forum shall prepare an annual report of its activities. That report shall be made publicly available.		

	Commission Propo	oosal	EP Mandate	Council Mandate	Draft Agreement
		Article 65		·	
706	Article 65 Tasks of the EHDS B	Board	Article 65 Tasks of the EHDS Board	Article 65 Tasks of the EHDS Board	
		Article 65(-1)			
706a			<u>-1.</u> <u>The EHDS Board shall</u> promote the consistent application of this <u>Regulation.</u>		
		Article 65(1)			<u>.</u>

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
707	1. The EHDS Board shall have the following tasks relating to the primary use of electronic health data in accordance with Chapters II and III:		1. The EHDS Board shall have the following tasks relating to the primary use of electronic health data in accordance with Chapters II and III:	1. The EHDS Board shall have the following tasks relating to the primary use of electronic health data in accordance with Chapters II and III:	
	Article	e 65(1), point (a)			
708	(a) to assist Member States in coordinating practices of digital health authorities;		(a) to assist Member States in coordinating practices of digital health authorities;	(a) to assist Member States in coordinating practices of digital health authorities;	
	Article	e 65(1), point (b)			<u> </u>

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
709	(b) to issue written contributions and to exchange best practices on matters related to the coordination of the implementation at Member State level of this Regulation and of the delegated and implementing acts adopted pursuant to it, in particular as regards:		(b) to issue written contributions and to exchange best practices on matters related to the coordination of the implementation at Member State level of this Regulation and of the delegated and implementing acts adopted pursuant to it, <i>taking into account the</i> <i>regional and local level,</i> in particular as regards:	(b) to issue written contributions and to exchange best practices on matters related to the coordination of the implementation at Member State level of this Regulation and of the delegated and implementing acts adopted pursuant to it, in particular as regards:	
	Article	65(1), point (ba)			
709a					

	Commission Propose	al	EP Mandate	Council Mandate	Draft Agreement
			deleted		
	Ar	ticle 65(1), point (b)(i)			
710	<i>(i)</i> the provisions set out Chapters II and III;	in	(i) the provisions set out in Chapters II and III;	(i) the provisions set out in Chapters II and III;	
	Ar	ticle 65(1), point (b)(ii)			
711	(ii) development of onlir services facilitating secur access, including secure electronic identification,	re	(ii) development of online services facilitating secure access, including secure electronic identification, to	(ii) development of online services facilitating secure access, including secure electronic identification, to	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	electronic health data for health professionals and natural persons;		electronic health data for health professionals and natural persons;	electronic health data for health professionals and natural persons;	
	Article	e 65(1), point (b)(iii)			
712	(iii) other aspects of the primary use of electronic health data.		(iii) other aspects of the primary use of electronic health data <u>without</u> prejudice to the powers of the supervisory authorities pursuant to Regulation (EU) 2016/679; the written contributions of the EHDS board shall not concern the interpretation or application of rights and obligations under	(iii) other aspects of the primary use of electronic health data.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			Regulation (EU) 2016/679 or Regulation 2018/175.		
	Article	65(1), point (ba)			
712a			(ba) to provide guidance and recommendations to digital health authorities;		
	Article	65(1), point (c)			
713	(c) to facilitate cooperation between digital health authorities through capacity-building,		(c) to facilitate cooperation between digital health authorities through capacity-building,	(c) to facilitate cooperation between digital health authorities through capacity-building,	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	establishing the structure for annual activity reporting, peer-review of annual activity reports and exchange of information;		establishing the structure for annual activity reporting, peer-review of annual activity reports and exchange of information;	establishing the structure for annual-biennial activity reporting, peer-review of annual activity and exchange of information in those reports and exchange of information;	
	Article	e 65(1), point (d)			
714	(d) to share information concerning risks posed by EHR systems and serious incidents as well as their handling;		(d) to share <u>among the</u> <u>Members of the Board</u> information concerning risks posed by EHR systems and serious incidents as well as their handling <u></u> . <u>without prejudice to the</u> <u>obligation to inform</u>	(d) to share information concerning risks posed by EHR systems and serious incidents as well as their handling;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			<u>competent supervisory</u> <u>authorities pursuant to</u> <u>Regulation (EU) 2016/679;</u>		
	Article 65(1)), point (e)			
715	(e) to facilitate the exchange of views on the primary use of electronic health data with the relevant stakeholders, including representatives of patients, health professionals, researchers, regulators and policy makers in the health sector.		 (e) to facilitate the exchange of views on the primary use of electronic health data with the <i>relevant</i> <i>stakeholders, including</i> <i>representatives of patients,</i> <i>health professionals,</i> <i>researchersAdvisory</i> <i>Forum referred to in</i> <i>Article 64(a)</i>, regulators and policy makers in the health sector <i>to support the design</i> 	(e) to facilitate the exchange of views on the primary use of electronic health data with the relevant stakeholders, including representatives of patients, health professionals, researchers, regulators and policy makers in the health sector.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			of aligned implementation strategies, guidance and standards and to assess the needs for further improvement. In addition, the co-chairs of the advisory forum shall be invited at least once annually to a meeting of the EHDS Board to present its activities.		
	Article	65(2)			
716	2. The EHDS Board shall have the following tasks related to the secondary use of electronic health data in		2. The EHDS Board shall have the following tasks related to the secondary use of electronic health data in	2. The EHDS Board shall have the following tasks related to the secondary use of electronic health data in	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	accordance with Chapter		accordance with Chapter IV:	accordance with Chapter IV:	
	Article	e 65(3)			
716a				3. The EHDS Board shall be consulted by the European Commission in the preparation of draft delegated acts before their adoption pursuant to the procedure laid down in Article 67, and in the preparation of draft implementing acts before presenting them to the committee referred to in Article 68.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	e 65(2), point (a)			
717	(a) to assist Member States in coordinating practices of health data access bodies in the implementation of provisions set out in Chapters IV, to ensure a consistent application of this Regulation;		(a) to assist Member States in coordinating practices of health data access bodies in the implementation of provisions set out in Chapters IV, to ensure a consistent application of this Regulation;	(a) to assist Member States in coordinating practices of health data access bodies in the implementation of provisions set out in Chapters IV, to ensure a consistent application of this Regulation;	
	Article	e 65(2), point (b)			
718	(b) to issue written		(b) to issue written	(b) to issue written	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	contributions and to exchange best practices on matters related to the coordination of the implementation at Member State level of this Regulation and of the delegated and implementing acts adopted pursuant to it, in particular as regards:		contributions and to exchange best practices on matters related to the coordination of the implementation at Member State level of this Regulation and of the delegated and implementing acts adopted pursuant to it, in particular as regards:	contributions and to exchange best practices on matters related to the coordination of the implementation at Member State level of this Regulation and of the delegated and implementing acts adopted pursuant to it, in particular as regards:	
	Article 65(2	2), point (b)(i)			
719	(i) implementation of rulesfor access to electronichealth data;		(i) implementation of rulesfor access to electronichealth data;	(i) implementation of rulesfor access to electronichealth data;	

	Commission Prop	oosal		EP Mandate	Council Mandate	Draft Agreement
		Article	65(2), point (b)(ii)			
720	(ii) technical specific or existing standards regarding the requirer set out in Chapter IV;	nents		 (ii) technical specifications or existing standards regarding the requirements set out in Chapter IV; 	(ii) technical specifications or existing standards regarding the requirements set out in Chapter IV;	
		Article	65(2), point (b)(iii)			
721	(iii) incentives policy promoting data quality interoperability improvement;			(iii) incentives policy for promoting data quality and interoperability improvement;	(iii) incentives policy for promoting data quality and interoperability improvement;	
	1	Article	65(2), point (b)(iv)		1	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
722	(iv) policies concerning fees to be charged by the health data access bodies and data holders;		(iv) policies concerning fees to be charged by the health data access bodies and data holders;	(iv) policies concerning fees to be charged by the health data access bodies and health data holders;	
	Article	e 65(2), point (b)(v)			
723	(v) the establishment and application of penalties;		deleted	(v) the establishment and application of penalties;	
	Article	e 65(2), point (b)(vi)		-	
724					

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	(vi) other aspects of the secondary use of electronic health data.	(vi) other aspects of the secondary use of electronic health data <u>without</u> <u>prejudice to the powers of</u> <u>the supervisory authorities</u> <u>pursuant to Regulation</u> (EU) 2016/679.	(vi) other aspects of the secondary use of electronic health data.	
	Article 65(2), point (c)			
725	(c) to facilitate cooperation between health data access bodies through capacity- building, establishing the structure for annual activity reporting, peer-review of annual activity reports and	 (c) to facilitate cooperation and exchange of best practices between health data access bodies through capacity-building, establishing the structure for annual activity reporting, peer-review of annual 	(c) to facilitate cooperation between health data access bodies through capacity- building, establishing the structure for annualbiennial activity reporting, peer- review of annual activity reports and and exchange	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	exchange of information;		activity reports and exchange of information <i>pursuant to the obligations</i> <i>laid down in Article 37(1)</i> , <i>point (q)</i> ;	of information in those reports ;	
	Article	65(2), point (d)			
726	(d) to share information concerning risks and data protection incidents related to secondary use of electronic health data, as well as their handling;		(d) to share information concerning risks and data protection incidents related to secondary use of electronic health data, as well as their handling; <i>without prejudice to the</i> <i>obligation to inform</i> <i>competent supervisory</i> <i>authorities pursuant to</i>	(d) to share information concerning risks and data protection- incidents related to secondary use of electronic health data, such as risks and incidents in the secure processing environment as referred to in Article 50, as well as their handling;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			<u>Regulation (EU) 2016/679;</u>		
	Article	e 65(2), point (e)			
727	(e) to contribute to the work of the European Data Innovation Board to be established in accordance with Article 29 of the Regulation [] [Data Governance Act COM/2020/767 final];		(e) to contribute to the work of the European Data Innovation Board to be established in accordance with Article 29 of the Regulation [] [Data Governance Act COM/2020/767 final];	(e) to contribute to the work of the European Data Innovation Board to be established in accordance with Article 29 of the Regulation [] [Data Governance Act COM/2020/767 final];	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	e 65(2), point (f)			
728	(f) to facilitate the exchange of views on the secondary use of electronic health data with the relevant stakeholders, including representatives of patients, health professionals, researchers, regulators and policy makers in the health sector.		(f) to <i>facilitate the</i> exchange <i>of</i> -views on the secondary use of electronic health data with the <i>relevant</i> <i>stakeholders, including</i> <i>representatives of patients,</i> <i>health professionals,</i> <i>researchers, Advisory</i> <i>Forum referred to in</i> <i>Article 64(a)</i> regulators and policy makers in the health sector., <i>to support the</i> <i>design of aligned</i> <i>implementation strategies,</i> <i>guidance and standards</i> <i>and to assess the needs for</i> <i>further improvement;</i>	(f) to facilitate the exchange of views on the secondary use of electronic health data with the relevant stakeholders, including health data holders, health data users, representatives of patients, health professionals, researchers, regulators and policy makers in the health sector.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement	
	Article	e 65(2), point (fa)				
728a			(fa) adopt recommendations to facilitate consistent provision of the secure processing environment compliant with the technical, information security and interoperability requirements.			
	Article 66					

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
729	Article 66 Joint controllership groups for Union infrastructures	Article 66 Joint controllership groups for Union infrastructures	Article 66 Joint controllership The Steering Groups for Unionthe infrastructures MyHealth@EU and HealthData@EU	
	Article 66(1)			
730	1. The Commission shall establish two groups dealing with joint controllership for the cross- border infrastructures provided for in Articles 12	1. The Commission shall establish two groups dealing with joint controllership for the cross- border infrastructures provided for in Articles 12	1. The Commission shall establish twoTwo Steering groups dealing with joint controllership are hereby established for the cross- border infrastructures	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	and 52. The groups shall be composed of the representatives of the national contact points and other authorised participants in those infrastructures.		and 52. The groups shall be composed of the representatives of the national contact points and other authorised participants in those infrastructures.	provided for in Articles 12 and 52. The groups; the MyHealth@EU Steering group and the HealthData@EU Steering group. Each group shall be composed of the representativesone representative per Member State of the respective national contact points and other authorised participants in those infrastructures.	
	Article	66(1a)			
730a				1a. The Steering groups	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Commission Proposal	EP Mandate	shall take operational decisions concerning the development and operation of the cross- border infrastructures referred to in Chapters II and IV, on changes of infrastructure, adding additional infrastructures or services, or ensuring interoperability with other infrastructures, digital systems or data spaces. The groups shall also state	Draft Agreement
		their view on accepting individual authorised participants to join the infrastructures or to disconnect them.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				[(MOVED FROM PARA 6 AND AMENDED)]	
	Article	e 66(1b)	L	L	
730Ь				1b. The Steering Groups shall take decisions by consensus. Where consensus cannot be reached, the adoption of a decision shall require the support of members representing two-thirds majority, where each Member State has one vote.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	e 66(2)			
731	2. The composition, organisation, functioning and cooperation of the sub- groups shall be set out in the rules of procedure adopted by those groups.		2. The composition, organisation, functioning and cooperation of the sub- groups shall be set out in the rules of procedure adopted by those groups.	2. The composition, organisation, functioning and cooperation of the sub- groups Steering groups shall be set out in the rules of procedure adopted by those groups.	
	Article	e 66(2a)			
731a			2a. <u>The EHDS board shall</u> provide recommendations		

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	to the Commission and the		
	Member States on the		
	implementation and		
	<u>enforcement of this</u>		
	Regulation, including		
	<u>cross-border</u>		
	<u>interoperability of health</u>		
	<u>data, and potential</u>		
	<u>mechanisms of funding</u>		
	support to ensure equal		
	<u>development of health data</u>		
	systems across Europe in		
	respect of the secondary		
	<u>use of electronic health</u>		
	<u>data, without prejudice to</u>		
	the competences of the		
	EDPB, where personal		
	<u>electronic health data are</u>		
	<u>concerned.</u>		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	e 66(2b)			
731b			2b. <u>The EHDS board may</u> commission studies and other initiatives in order to support the implementation and development of the EHDS.		
	Article	e 66(2c)			
731c			2c. <u>The EHDS Board shall</u> publish an annual report to include the implementation status of the EHDS and other relevant points of		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			development, including with respect to cross-border health data interoperability, and related implementation challenges.		
	Article	66(3)			
732	3. Stakeholders and relevant third parties, including patients' representatives, may be invited to attend meetings of the groups and to participate in their work.		3. Stakeholders and relevant third parties, including patients', <i>health</i> <i>professionals'</i> , <i>consumers'</i> <i>and industry</i> representatives, may be invited to attend meetings of the groups and to participate in their work.	3. Stakeholders and relevant third parties, including patients ² representatives, Other authorised participants may be invited to attend meetings of the groups and to participate in their workexchange information	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				and views on relevant matters related to the cross-border infrastructures respectively provided for in Articles 12, 13 and 52. When these participants are invited, they shall have an observer role. [MOVED FROM ARTICLE 66(1) AND AMENDED]	
	Article	66(3a)			
732a				3a. Stakeholders and	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				relevant third parties, including patients' representatives, may be invited to attend meetings of the groups and to participate in their work. [MOVED FROM ARTICLE 66(3)]	
	Article	2 66(4)			
733	4. The groups shall elect chairs for their meetings.		4. The groups shall elect chairs for their meetings.	4. The groups shall elect chairs for their meetings.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement	
		Article 66(5)				
734	5. The groups shall b assisted by a secretari provided by the Commission.			5. The groups shall be assisted by a secretariat provided by the Commission.	5. The groups shall be assisted by a secretariat provided by the Commission.	
735	6. The groups shall ta decisions concerning development and ope of the cross-border infrastructures pursua Chapters II and IV, or changes of infrastruct	the ration unt to n		6. The groups shall take decisions concerning the development and operation of the cross-border infrastructures pursuant to Chapters II and IV, on changes of infrastructure,	6. The groups shall take decisions concerning the development and operation of the cross-border infrastructures pursuant to Chapters II and IV, on changes of infrastructure,	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	adding additional infrastructures or services, or ensuring interoperability with other infrastructures, digital systems or data spaces. The group shall also take decisions to accept individual authorised participants to join the infrastructures or to disconnect them.		adding additional infrastructures or services, or ensuring interoperability with other infrastructures, digital systems or data spaces. The group shall also take decisions to accept individual authorised participants to join the infrastructures or to disconnect them.	adding additional infrastructures or services, or ensuring interoperability with other infrastructures, digital systems or data spaces. The group shall also take decisions to accept individual authorised participants to join the infrastructures or to disconnect them.	
	Article	e 66(6a)			
735a			<u>6a.</u> The groups shall		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			consult relevant experts when carrying out their tasks, as well as on technical implementing measures related to cybersecurity, confidentiality and data protection, in particular experts from ENISA, EDPB and EDPS.		
	Article	66a			
735b				Article 66A Roles and responsibilities of the Commission regarding the functioning	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				of the European Health Data Space	
	Article	66a(1), first subparagraph			
735c				1. In addition to its role in making available electronic health data held by Union institutions, bodies, or agencies, in accordance with 36, 36A, 52(1A) and its tasks under Chapter III, including Article 26A, the Commission shall provide the development, maintenance, hosting and operation of the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				infrastructures and central services required to support the functioning of the European Health Data Space, to all relevant connected entities:	
	Article	66a(1), second subparagraph			
735d				i. an interoperable, cross- border identification and authentication mechanism for natural persons and health professionals, in accordance with Article 9(3) and (4);	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	66a(1), third subparagraph			
735e				ii. the central services and infrastructures for digital health of MyHealth@EU, in accordance with Article 12(1);	
	Article	66a(1), fourth subparagraph			
735f				iii. compliance checks for connecting authorised participants to MyHealth@EU, in accordance with Article 12(9);	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	66a(1), fifth subparagraph			
735g				iv. the additional cross- border digital health services and infrastructures within the meaning of Article 13(1) of this Regulation	
	Article	66a(1), sixth subparagraph			
735h				v. as part of HealthData@EU, a service to submit	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				applications for making available electronic health data from health data holder in multiple Member States or from other authorised participants and to automatically forward them to the relevant contact points, in accordance with Article 45(5A);	
	Article	66a(1), seventh subparagraph			
735i				vi. the central services and infrastructures of HealthData@EU in	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			accordance with Article 52, paragraphs (6) and (7);	
	Article 66a(1), eighth subparagraph			
735j			vii. a secure processing environment in accordance with Article 52(8), in which health data access bodies may decide to make data available in accordance with Article 46(5A);	
	Article 66a(1), ninth subparagraph	· · · · · · · · · · · · · · · · · · ·	·	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
735k			viii. compliance checks for connecting authorised participants to HealthData@EU, in accordance with Article 52(12);	
	Article 66a(1), tenth subpara	graph		
7351			ix. a federated EU dataset catalogue connecting the national dataset catalogues, in accordance with Article 57;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	66a(1), eleventh subparagraph			
735 m				x. a secretariat for the EHDS Board, in accordance with Article 64(7);	
	Article	66a(1), twelfth subparagraph			
735n				xi. a secretariat for the steering groups, in accordance with Article 66(5).	
	Article	66a(2)			

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
7350			2. The services referred to in paragraph 1 shall meet sufficient quality standards in terms of availability, security, capacity, interoperability, maintenance, monitoring and evolution to ensure an effective functioning of the European Health Data Space. The Commission shall provide them in accordance with the operational decisions of the relevant Steering Groups. These standards, once defined, shall apply to subcontractors of the Commission.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	66a(3)			
735p				3. The Commission shall adopt, by means of implementing acts, the rules and measures for the operation of the infrastructures and all required central services of the European Health Data Space with the required quality of service, simultaneously with the adoption of the implementing acts	
				referred to in Articles 12, 13 and 52. Those	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				implementing acts shall be adopted in accordance with the examination procedure referred to in Article 68(2).	
	Article	e 66a(4)			
735q				4. The Commission shall issue a biennial public report on the infrastructures and services supporting the European Health Data Space that it provides in accordance with paragraph 1.	

	Commission Propo	osal	EP Mandate	Council Mandate	Draft Agreement	
	(CHAPTER VII				
736	CHAPTER VII Delegation and Comm		CHAPTER VII Delegation and Committee	CHAPTER VII Delegation and Committee		
	ŀ	Article 67				
737	Article 67 Exercise of the delegat	ation	Article 67 Exercise of the delegation	Article 67 Exercise of the delegation		
	Article 67(1)					

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
738	1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.	1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.	1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.	
	Article 67(2)			
739	 2. The power to adopt delegated acts referred to in Articles 5(2), 10(3), 25(3), 32(4), 33(7), 37(4), 39(3), 41(7), 45(7), 46(8), 52(7), 56(4) shall be conferred on the Commission for an indeterminate period of 	 2. The power to adopt delegated acts referred to in Articles 5(2), 7(3), 9(2) 10(3), 13(3) 10(3), 25(3), 32(4), 33(7), 37(4), 39(3), 41(7), 45(7), 46(8), 52(7), 52(13), 56(4) and 63a(2), 56(4) and 63a(2), 56(4) shall be 	2. The power to adopt delegated acts referred to in Articles 5(2), 10(3), 25(3), 32(4), 33(7), 37(4), 39(3), 41(7), 45(7), 46(8), 52(7),32(4), and 56(4) shall be conferred on the Commission for an	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	time from the date of entry into force of this Regulation.		conferred on the Commission for an indeterminate period of time from the date of entry into force of this Regulation.	indeterminate period of time from the date of entry into force of this Regulation.	
	Article	e 67(3)			
740	 3. The power to adopt delegated acts referred to in Articles 5(2), 10(3), 25(3), 32(4), 33(7), 37(4), 39(3), 41(7), 45(7), 46(8), 52(7), 56(4) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to 		 The power to adopt delegated acts referred to in Articles 5(2), 10(3), 25(3), 32(4), 33(7), 7(3) 37(4), 39(3), 41(7), 45(7), 46(8), 52(7), 52(13), 56(4) and 63a(2), 56(4) may be revoked at any time by the European Parliament or by the Council. A decision to 	3. The power to adopt delegated acts referred to in Articles 5(2), $\frac{10(3), 25(3),}{32(4), 33(7), 37(4), 39(3),}$ $\frac{41(7), 45(7), 46(8),}{52(7), 32(4)}$ and 56(4) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.		revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.	the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.	
	Article	e 67(4)			
741	4. Before adopting a delegated act, the Commission shall consult		4. Before adopting a delegated act, the Commission shall consult	4. Before adopting a delegated act, the Commission shall consult	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	experts designated by each Member State in accordance with the principles laid down in the Inter-institutional Agreement of 13 April		experts designated by each Member State in accordance with the principles laid down in the Inter- institutional Agreement of 13 April 2016 on Better	experts designated by each Member State in accordance with the principles laid down in the Inter- institutional Agreement of 13 April 2016 on Better	
	2016 on Better Law- Making.	e 67(5)	Law-Making.	Law-Making.	
742	5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.		5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.	5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	e 67(6)			
	6. A delegated act adopted		6. A delegated act adopted	6. A delegated act adopted	
	pursuant to Articles 5(2),		pursuant to Articles 5(2),	pursuant to Articles 5(2),	
	10(3), 25(3), 32(4), 33(7),		10(3) 7(3), 9(2), 13(3),	10(3), 25(3), 32(4), 33(7),	
	37(4), 39(3), 41(7), 45(7),		25(3), 32(4) , <u>33(7)</u>, 37(4),	37(4), 39(3), 41(7), 45(7),	
	46(8), 52(7), 56(4) shall		39(3), 41(7), 45(7), 46(8),	4 6(8), 52(7), 32(4), and	
	enter into force only if no		52(7), <u>52(13), 56(4) or</u>	56(4) shall enter into force	
743	objection has been		63a(2)56(4) shall enter into	only if no objection has	
	expressed either by the		force only if no objection	been expressed either by the	
	European Parliament or by		has been expressed either	European Parliament or by	
	the Council within a period		by the European Parliament	the Council within a period	
	of 3 months of notification		or by the Council within a	of 3 months of notification	
	of that act to the European		period of 3 months of	of that act to the European	
	Parliament and to the		notification of that act to the	Parliament and to the	
	Council or if, before the		European Parliament and to	Council or if, before the	
	expiry of that period, the		the Council or if, before the	expiry of that period, the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by 3 months at the initiative of the European Parliament or of the Council.		expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by 3 months at the initiative of the European Parliament or of the Council.	European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by 3 months at the initiative of the European Parliament or of the Council.	
	Article	68			
744	Article 68 Committee procedure		Article 68 Committee procedure	Article 68 Committee procedure	

	Commission Propo	osal	EP Mandate	Council Mandate	Draft Agreement
		Article 68(1)		·	
745	1. The Commission sh be assisted by a commi That committee shall b committee within the meaning of Regulation (EU) No 182/2011.	ittee. e a	1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.	1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.	
		Article 68(2)			
746	2. Where reference is 1 to this paragraph, Artic of Regulation (EU) No 182/2011 shall apply.	ele 4	2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.	2. Where reference is made to this paragraph, Article 45 of Regulation (EU) No 182/2011 shall apply.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	e 68(2a)			
746a			2a. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.		
	Chapte	er VIII			
747	Chapter VIII Miscellaneous		Chapter VIII Miscellaneous	Chapter VIII Miscellaneous	

	Commission Propo	osal	EP Mandate	Council Mandate	Draft Agreement
	1	Article 69		·	
748	Article 69 Penalties		Article 69 Penalties	Article 69 Penalties	
	,	Article 69, first paragraph			
749	Member States shall lay down the rules on pena applicable to infringem of this Regulation and s take all measures neces to ensure that they are implemented. The pena shall be effective, proportionate and	lities nents shall ssary	Member States shall lay down the rules on <i>other</i> penalties applicable to infringements of this Regulation <i>in particular for</i> <i>infringements which are</i> <i>not subject to</i> <i>administrative fines</i> <i>pursuant to Article 43a</i> ,	In addition to the measures laid down in Articles 30 and 43 of this Regulation and Chapter VIII of Regulation (EU) 2016/679, Member States shall lay down the rules on penalties applicable to infringements of this	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Commission Proposal dissuasive. Member States shall notify the Commission of those rules and measures by date of application of this Regulation and shall notify the Commission without delay of any subsequent amendment affecting them.	EP Mandate and shall take all measures necessary to ensure that they are implemented. The penalties shall be effective, proportionate and dissuasive. Member States shall notify the Commission of those rules and measures by date of application of this Regulation and shall notify the Commission without delay of any subsequent amendment affecting them.	Council Mandate Regulation and shall take all measures necessary to ensure that they are implemented. The penalties shall be effective, proportionate and dissuasive. Member States shall notify the Commission of those rules and measures by date of application of this Regulation and shall notify the Commission without delay of any subsequent amendment affecting them.	Draft Agreement
		[LAST SENTENCE MOVED TO PARA 3]	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	69, first paragraph a			
749a				Member States shall take into account the following non-exhaustive and indicative criteria for the imposition of penalties for infringements of this Regulation, where appropriate:	
	Article	69, first paragraph a, point (a)			
749b				(a) the nature, gravity, scale and duration of the infringement;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	69, first paragraph a, point (b)			
749c				(b) any action taken by the infringer to mitigate or remedy the damage caused by the infringement;	
	Article	69, first paragraph a, point (c)			
749d				(c) any previous infringements by the infringer;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	69, first paragraph a, point (d)			
749e				(d) the financial benefits gained or losses avoided by the infringer due to the infringement, insofar as such benefits or losses can be reliably established;	
	Article	69, first paragraph a, point (e)			
749f				(e) any other aggravating or mitigating factors applicable to the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				circumstances of the case;	
	Article	69, first paragraph a, point (f)			
749g				(f) infringer's annual turnover of the preceding financial year in the Union.	
	Article	69, third paragraph			
749h				3. Member States shall notify the Commission of those rules and measures by date of application of	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				this Regulation and shall notify the Commission without delay of any subsequent amendment affecting them.	
	Article	69a			
749i			<u>Article 69a</u> <u>Right to receive</u> <u>compensation</u>		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	e 69a, first paragraph			
749j			Any person who has suffered material or non- material damage as a result of an infringement of this Regulation shall have the right to receive compensation, in accordance with national and Union law.		
	Article	e 69b			
749k			<u>Article 69b</u> <u>Representation of a natural</u>		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			<u>person</u>		
	Article	69b, first paragraph			
7491			Where a natural person considers that their rights under this Regulation have been infringed, they shall have the right to mandate a not-for-profit body, organisation or association which is constituted in accordance with the law of a Member State, has statutory objectives which are in the public interest and is active in the field of the protection of personal		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement	
			<u>data, to lodge a complaint</u> on their behalf or to exercise the rights referred to in 11a.			
	Artic	le 69c				
749 m			<u>Article 69c</u> <u>Suspension of proceedings</u>			
	Article 69c(1)					
749n			<u>1.</u> Where a competent court of a Member State			

Commission Proposal		EP Mandate	Council Mandate	Draft Agreement	
		seised of proceedings against a decision by a digital health authority or health data access body has reason to believe that proceedings concerning the same access to electronic health data by the same health data by the same health data user, such as for the same purpose of processing for secondary use are brought before a competent court in another Member State, it shall contact that court in order to confirm the existence of such related proceedings.			
Article 69c(2)					

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
7490		2. Where proceedings concerning the same subject matter and the same digital health authority or health data access body are pending before a court in another Member State, any court other than the court first seised may stay its proceedings or may, at the request of one of the parties, decline jurisdiction in favour of the court first seised if that court has jurisdiction over the proceedings in question and its law permits the consolidation of such		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			<u>related proceedings.</u>		
	Article	2 70			
750	Article 70 Evaluation and review		Article 70 Evaluation and review	Article 70 <i>Evaluation, review and</i> <i>progress report</i> Evaluation and review	
	Article	2 70(1)			
751	 After 5 years from the entry into force of this Regulation, the 		 After By 5 years from the entry into force of this Regulation, the 	 After-5 7 years from the entry into force of this Regulation, the 	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Commission shall carry out	Commission shall carry out	Commission shall carry out	
a targeted evaluation of this	a targeted evaluation of this	a targeted evaluation of this	
Regulation especially with	Regulation especially with	Regulation especially with	
regards to Chapter III, and	regards to Chapter III, and	regards to Chapter III , and	
submit a report on its main	submit a report on its main	submit a report on its main	
findings to the European	findings to the European	findings to the European	
Parliament and to the	Parliament and to the	Parliament and to the	
Council, the European	Council, the European	Council, the European	
Economic and Social	Economic and Social	Economic and Social	
Committee and the	Committeethe possibilities	Committee and the	
Committee of the Regions,	to further extend	Committee of the Regions,	
accompanied, where	interoperability between	accompanied, where	
appropriate, by a proposal	EHR systems and	appropriate, by a proposal	
for its amendment. The	electronic health data	for its amendment. The	
evaluation shall include an	access services other than	evaluation shall include an	
assessment of the self-	those established by the	assessment of the self-	
certification of EHR	<u>Member States, the</u>	certification of EHR	
systems and reflect on the	possibility of expanding the	systems and reflect on the	
need to introduce a	access to MyHealth@EU	need to introduce a	
conformity assessment	infrastructure to third	conformity assessment	
procedure performed by	<u>countries and international</u>	procedure performed by	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
notified bodies.	organisations, the need to	notified bodies.the	
	update the data categories	following:	
	in Article 33 and the		
	Committee of the Regions,		
	accompanied, where		
	appropriate, by a proposal		
	for its amendment. The		
	evaluation shall include an		
	assessment purposes of use		
	in Article 34, the		
	implementation and use by		
	natural persons of the opt-		
	<u>out mechanism in</u>		
	secondary use as referred		
	to in Article 33(5a), and		
	<u>opt-in mechanism in</u>		
	secondary use as referred		
	to in Article 33(5b), the use		
	and implementation of the		
	self-certification of EHR		
	systems and reflect on the		

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	need to introduce a		
	conformity assessment		
	procedure performed by		
	notified bodies <mark>right</mark>		
	<u>referred to in Article 3(9),</u>		
	as well as the application		
	<u>of fees as referred to in</u>		
	Article 42 and submit a		
	<u>report on its main findings</u>		
	<u>to the European</u>		
	Parliament and to the		
	Council, the European		
	Economic and Social		
	Committee and the		
	Committee of the Regions,		
	accompanied, where		
	appropriate, by a proposal		
	<u>for its amendment</u> .		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	e 70(1), point (a)			
751a				(a) an assessment of the certification framework of EHR systems in Chapter III and the need to introduce further tools regarding conformity assessment ;	
	Article	e 70(1), point (aa)			
751b				(aa) an assessment of the functioning of the Internal Market for the EHR systems;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	70(1), point (b)			
751c				(b) an assessment of the costs and benefits of implementation of the provisions for secondary use laid out in Chapter IV.	
	Article	70(1a)			
751d			<u>1a.</u> <u>By [please insert the</u> <u>date two years from the</u> <u>entry into force of this</u> <u>Regulation], the</u>		

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Commission shall carry out		
	an evaluation of the Union		
	funding attributed to the		
	setting up and functioning		
	<u>of the EHDS, in particular</u>		
	<u>concerning the ability of</u>		
	<u>the bodies established</u>		
	under this Regulation to		
	<u>carry out their tasks and</u>		
	obligations under this		
	Regulation and of Member		
	<u>States in relation to</u>		
	applying the Regulation in		
	<u>a uniform and coherent</u>		
	manner. The Commission		
	<u>shall submit a report on its</u>		
	<u>main findings to the</u>		
	<u>European Parliament and</u>		
	to the Council, the		
	<u>European Economic and</u>		
	Social Committee and the		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			<u>Committee of the Regions,</u> <u>accompanied, where</u> <u>appropriate, by the</u> <u>necessary measures.</u>		
	Article	2 70(2)			
752	2. After 7 years from the entry into force of this Regulation, the Commission shall carry out an overall evaluation of this Regulation, and submit a report on its main findings to the European Parliament and to the Council, the European Economic and Social Committee and the		2. After 7 years from the entry into force of this Regulation, the Commission shall carry out an overall evaluation of this Regulation, and submit a report on its main findings to the European Parliament and to the Council, the European Economic and Social Committee and the	2. After-7 9 years from the entry into force of this Regulation, the Commission shall carry out an overall evaluation of this Regulation, and submit a report on its main findings to the European Parliament and to the Council, the European Economic and Social Committee and the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Committee of the Regions, accompanied, where appropriate, by a proposal for its amendment.		Committee of the Regions, accompanied, where appropriate, by a proposal for its amendment <u>or other</u> <u>appropriate measures</u> .	Committee of the Regions, accompanied, where appropriate, by a proposal for its amendment.	
	Article	70(3)			
753	3. Member States shall provide the Commission with the information necessary for the preparation of that report.		3. Member States shall provide the Commission with the information necessary for the preparation of that report.	3. Member States shall provide the Commission with the information necessary for the preparation of that report and the Commission shall take this information duly into account in that report.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	70(4)			
753a				4. Every year following the entry into force of this Regulation and until its full application, the Commission shall submit a progress report to the Council on the state of play of the preparations for the full implementation of this Regulation. The report shall contain information about the degree of progress and the readiness of the Member States	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				including an assessment of the feasibility of reaching the time frames laid down in Article 72 of this Regulation and may also contain recommendations to Member States to improve preparedness for the application of this Regulation.	
	Article	71			
754	Article 71 Amendment to Directive 2011/24/EU		Article 71 Amendment to Directive 2011/24/EU	Article 71 Amendment to Directive 2011/24/EU	

	Commission Proposal			EP Mandate	Council Mandate	Draft Agreement	
		Article	71, first paragraph				
755	Article 14 of Directive 2011/24/EU is deleted			Article 14 of Directive 2011/24/EU is deleted.	Article 14 of Directive 2011/24/EU is deleted.		
		Article	71a				
755a				<u>Article 71a</u> <u>Amendments to Directive</u> (EU) 2020/1828			
	Article 71a, first paragraph						

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
755b			In the Annex of Directive (EU) 2020/1828, the following point is added:		
	Articl	e 71a, second paragraph			
755c			(XX) Regulation (EU) XXX of the European Parliament and of the Council on the European Health Data Space.		
	Chap	ter IX			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement	
756	Chapter IX Deferred application and final provisions		Chapter IX Deferred application and final provisions	Chapter IX Deferred application, transitional and final provisions		
	Article	72				
757	Article 72 Entry into force and application		Article 72 Entry into force and application	Article 72 Entry into force and application		
	Article 72, first paragraph					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
758	This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.		This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.	1. This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.	
	Article	72, second paragraph			
759	It shall apply from 12 months after its entry into force.		It shall apply from <u>1224</u> months after its entry into force.	It-This Regulation shall apply-from 12 months 2 years after-its entry into force, unless provided otherwise in paragraph 2.	

	Commission Prop	oosal	EP Mandate	Council Mandate	Draft Agreement
		Article 72, third parage	raph		
760	However, Articles 3, 4 7, 12, 14, 23 and 31 sl apply as follows:		However, Articles 3, 4, 5, 6 7, 12, 14, 23 and 31 shall apply as follows:	 A. B. B.	
		Article 72, third parage	raph, point (a)		
761	(a) from 1 year after of of entry into application categories of personal	on to	(a) from 1 year after date of entry into application to categories of personal	f (a) from 1 year5 years after date of entry into application-force to	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	electronic health data referred to in Article 5(1), points (a), (b) and (c), and to EHR systems intended by the manufacturer to process such categories of data.;		electronic health data referred to in Article 5(1), points (a), (b) and (c), and to EHR systems intended by the manufacturer to process such categories of data.;	categories of personal electronic health data referred to in Article 5(1), points (a), (b) and (c), and to EHR systems intended by the manufacturer to process such categories of data-;	
	Article	272, third paragraph, point (b)			
762	(b) from 3 years after date of entry into application to categories of personal electronic health data referred to in Article 5(1), points (d), (e) and (f), and to EHR systems intended by the manufacturer to		(b) from 3 years after date of entry into application to categories of personal electronic health data referred to in Article 5(1), points (d), (e) <i>(f), and</i> <i>f(a) and (f),</i> and to EHR systems intended by the	(b) from 37 years after date of entry into application force to categories of personal electronic health data referred to in Article 5(1), points (d), (e) and (f), and to EHR systems intended by the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	process such categories of data;		manufacturer to process such categories of data;	manufacturer to process such categories of data;	
	Article	272, third paragraph, point (c)			
763	(c) from the date established in delegated acts pursuant to Article 5(2) for other categories of personal electronic health data.		deleted	(c) from 1 year after the date established in a delegated acts act pursuant to Article 5(2) for other amendments of the main characteristics of personal electronic health data in Annex 1, provided that this date of entry into application is subsequent to the date of entry into application referred to in point (a) and (b) for the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				categories of personal electronic health data concerned .	
	Article	72, first paragraph (after point	t 2)		
763a				The implementing acts referred to in Articles 2A(3), 6(1), 12(4) and 23(1) shall be adopted within 1 year after date of entry into force and apply as referred to in subparagraph 1 in this paragraph.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article	e 72, fourth paragraph			
764	Chapter III shall apply to EHR systems put into service in the Union pursuant to Article 15(2) from 3 years after date of entry into application.		Chapter III shall apply to EHR systems put into service in the Union pursuant to Article 15(2) from 3 years after date of entry into application.	Chapter III shall apply to EHR systems put into service in the Union pursuant toreferred to in Article 15(2) from 313B(2) from 7 years after date of entry into applicationforce.	
	Article	e 72, fourth paragraph a			
764a				Chapter IV shall apply from 5 years after date of entry into force, except Article 33(1), points (b)	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				(e), (ea) (j), (l) and (n) which shall apply from 7 years after date of entry into force.	
	Article	72, fourth paragraph (after po	pint 2)		
764b				The implementing acts referred to in Articles 35F(5), 50(4), 52(13), 53(3), 55 and 56(5) shall be adopted within 2 year after date of entry into force and apply from 4 years after this Regulation enter into force and article 52(4) which shall apply from 10 years after the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				data of entry into force.	
	Article	72, third paragraph (after poir	nt 2)	1	
764c	This Regulation shall be binding in its entirety and directly applicable in all Member States. Moved reference text		This Regulation shall be binding in its entirety and directly applicable in all Member States.	This Regulation shall be binding in its entirety and directly applicable in all Member States. Moved from row 765 [765 - 764c]	
	Article	72, fifth paragraph			
765					

	Commission Proposal	l	EP Mandate	Council Mandate	Draft Agreement
	This Regulation shall be binding in its entirety and directly applicable in all Member States.		This Regulation shall be binding in its entirety and directly applicable in all Member States.	Moved to row 764c [765 - 764c]	
	Arti	icle 72, last paragraph	-		
765a					
	For	mula			
766	Done at Strasbourg,		Done at Strasbourg,	Done at Strasbourg,	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
		Formula		·	
767	For the European Parliament		For the European Parliament	For the European Parliament	
		Formula	·		
768	The President		The President	The President	
		Formula			
769	For the Council		For the Council	For the Council	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement	
	F	Formu	la			
770	The President			The President	The President	
	,	Annex	I			
771	Annex I			Annex I AMs 534, 535 & 536	Annex I	
				merged.		

	Commission Proposa	1	EP Mandate	Council Mandate	Draft Agreement		
	Anr	nex I, first paragraph	·				
772	Main characteristics of electronic health data categories		Main characteristics of electronic health data categories	Main characteristics of priority categories of personal electronic health data categories for primary use			
	Anr	nex I, Table 1, Column 1, Row 1					
773	773 Electronic health data category		Electronic health data category	Electronic health data category			
	Annex I, Table 1, Column 1, Row 2						

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
774	1. Patient summary		1. Patient summary	1. Patient summary	
	Anne	x I, Table 1, Column 1, Row 3			
775	2. Electronic prescription		2. Electronic prescription	2. Electronic prescription	
	Anne	x I, Table 1, Column 1, Row 4			
776	776 3. Electronic dispensation		3. Electronic dispensation	3. Electronic dispensation	
	Anne	x I, Table 1, Column 1, Row 5	·	·	

	Commission Prop	oosal		EP Mandate	Council Mandate	Draft Agreement
777	4. Medical image and image report			4. Medical image and image report	4. Medical image and image report	
		Annex I, Table	1, Column 1, Row 6			
778	5. Laboratory result			5. Laboratory result	5. Laboratory result	
		Annex I, Table	1, Column 1, Row 7			
779	6. Discharge report			6. Discharge report	6. Discharge report	

	Commission Prope	osal		EP Mandate	Council Mandate	Draft Agreement
		Annex	I, Table 1, Column 2, Row 1			·
780	Main characteristics of electronic health data included under the category		Main characteristics of electronic health data included under the category	Main characteristics of electronic health data included under the category		
		Annex	I, Table 1, Column 2, Row 2			
781	Electronic health data that includes important clinical facts related to an identified person and that is essential for the provision of safe and efficient healthcare to that person. The following		Electronic health data that includes important clinical facts related to an identified person and that is essential for the provision of safe and efficient healthcare to that person. The <i>patient</i>	Electronic health data that includes important clinical facts related to an identified person and that is essential for the provision of safe and efficient healthcare to that person. The following		

Commission Pro	posal	EP Mandate	Council Mandate	Draft Agreement
information is part of	fa	summary shall be	information is part of a	
patient summary:		harmonized across	patient summary:	
1. Personal details		<u>Member States and include</u> <u>a minimum data set that</u>	1 Personal details	
2. Contact information	on	<u>can be expanded to include</u> disease-specific data. The	2 Contact information	
3. Information on ins	surance	following information is	3 Information on	
4. Allergies		part of a patient summary:	insurance	
5. Medical alerts		1. Personal details	4 Allergies	
6. Vaccination/proph	nylaxis	2. Contact information	5 Medical alerts	
information, possibly	y in the	3. Information on insurance	6.	
form of a vaccination	n card	4. Allergies	Vaccination/prophylaxis information, possibly in the	
7. Current, resolved, or inactive problems		5. Medical alerts	form of a vaccination card	
8. Textual information related to medical his		6. Vaccination/prophylaxis information, possibly in the	7 Current, resolved, closed or inactive problems	
9. Medical devices a		form of a vaccination card	8 Textual information related to medical history	
		7. Current, resolved, closed		

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
implants	or inactive problems <u>in an</u>	9 Medical devices and	
10. Procedures	international classification coding system	implants	
11. Functional status	8. Textual information	10. Procedures	
12. Current and relevant	related to medical history	11. Functional status	
past medicines	9Medical devices and	12. Current and relevant	
13. Social history	implants	past medicines	
observations related to	10. Medical procedures	13. Social history	
health 14. Pregnancy history	11. Functional status	observations related to health	
15. Patient provided data	<u>11a (new) Prescription,</u> <u>dispensation and</u>	14. Pregnancy history	
16. Observation results	administration of current	15. Patient provided data	
pertaining to the health	and past medications	16. Observation results	
condition	across the continuum of	pertaining to the health	
17. Plan of care	<u>care, including, hospital</u> and ambulatory/day	condition	
18. Information on a rare	<u>hospitals</u>	17. Plan of care	

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
disease such as details about the impact or characteristics of the disease	 12. Current and relevant past medicines 13. Social history observations related to health 14. Pregnancy history 15. Patient provided data 16. Observation results pertaining to the health condition 17. Plan of care 18. Information on a rare disease such as details about the impact or characteristics of the disease <i>18a (new) Blood type</i> 	18. Information on a rare disease such as details about the impact or characteristics of the disease	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Annex	I, Table 1, Column 2, Row 3			
782	Electronic health data constituting a prescription for a medicinal product as defined in Article 3(k) of Directive 2011/24/EU.		Electronic health data constituting a prescription for a medicinal product as defined in Article 3(k) of Directive 2011/24/EU.	Electronic health data constituting a prescription for a medicinal product as defined in Article 3(k) of Directive 2011/24/EU.	
	Annex	I, Table 1, Column 2, Row 4		<u>.</u>	
783	Information on the supply of a medicinal product to a natural person by a pharmacy based on an		Information on the supply of a medicinal product to a natural person by a pharmacy based on an	Information on the supply of a medicinal product to a natural person by a pharmacy based on an	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	electronic prescription.		electronic prescription.	electronic prescription.	
	Annex	I, Table 1, Column 2, Row 5			
784	Electronic health data related to the use of or produced by technologies that are used to view the human body in order to prevent, diagnose, monitor, or treat medical conditions.		Electronic health data related to the use of or produced by technologies that are used to view the human body in order to prevent, diagnose, monitor, or treat medical conditions.	Electronic health data related to the use of or produced by technologies that are used to view the human body in order to prevent, diagnose, monitor, or treat medical conditions.	
Annex I, Table 1, Column 2, Row 6					
785	Electronic health data		Electronic health data	Electronic health data	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	representing results of studies performed notably through in vitro diagnostics such as clinical biochemistry, haematology, transfusion medicine, microbiology, immunology, and others, and including, where relevant, reports supporting the interpretation of the results.		representing results of studies performed notably through in vitro diagnostics such as clinical biochemistry, haematology, transfusion medicine, microbiology, immunology, and others, and including, where relevant, reports supporting the interpretation of the results.	representing results of studies performed notably through in vitro diagnostics such as clinical biochemistry, haematology, transfusion medicine, microbiology, immunology, and others, and including, where relevant, reports supporting the interpretation of the results.	
	Annex	I, Table 1, Column 2, Row 7			
786	Electronic health data related to a healthcare encounter or episode of care and including essential		Electronic health data related to a healthcare encounter or episode of care and including essential	Electronic health data related to a healthcare encounter or episode of care and including essential	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	information about admission, treatment and discharge of a natural person.		information about admission, treatment and discharge of a natural person.	information about admission, treatment and discharge of a natural person.	
	Anne	x II			
787	Annex II		Annex II	Annex II	
	Anne	x II, first paragraph			
788	Essential requirements for EHR systems and products claiming interoperability		Essential requirements for EHR systems and products claiming interoperability	Essential requirements for the harmonised components of EHR systems and products	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	with EHR SYSTEMS		with EHR SYSTEMS	claiming interoperability with EHR SYSTEMS	
	Anne	ex II, second paragraph	•		
789	The essential requirements laid down in this Annex shall apply mutatis mutandis to products claiming interoperability with EHR systems.		The essential requirements laid down in this Annex shall apply mutatis mutandis to products claiming interoperability with EHR systems.	The essential requirements laid down in this Annex shall apply mutatis mutandis to productsmedical devices, in vitro diagnostic medical devices, AI systems, and wellness apps claiming interoperability with EHR systems.	

Commission Proposal				EP Mandate	Council Mandate	Draft Agreement
		Annex	ll, point 1.			
790	1. General requireme	nts		1. General requirements	1. General requirements	
Annex II, third paragraph			II, third paragraph			
	1.1. An electronic he	alth		1.1. An electronic health	1.1. The harmonised	
	record system (EHR			record system (EHR	components of an	
	system) shall achieve	the		system) shall achieve the	electronic health record	
791	performance intended	by its		performance intended by its	system (EHR system) shall	
/ / 1	manufacturer and sha			manufacturer and shall be	achieve the performance	
	designed and manufac	ctured		designed and manufactured	intended by its	
	•	in such a way that, during		in such a way that, during	manufacturer and shall be	
	normal conditions of	-		normal conditions of use, it	designed and manufactured	
	is suitable for its inter			is suitable for its intended	in such a way that, during	
	purpose and its use do	bes not		purpose and its use does not	normal conditions of use, it	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	put at risk patient safety.		put at risk patient safety.	isthey are suitable for itstheir intended purpose and itstheir use does not put at risk patient safety.	
	Annex	II, fourth paragraph			
792	1.2. An EHR system shall be designed and developed in such a way that it can be supplied and installed, taking into account the instructions and information provided by the manufacturer, without adversely affecting its characteristics and performance during its		1.2. An EHR system shall be designed and developed in such a way that it can be supplied and installed, taking into account the instructions and information provided by the manufacturer, without adversely affecting its characteristics and performance during its	1.2. An The harmonised components of the EHR system shall be designed and developed in such a way that it the system can be supplied and installed, taking into account the instructions and information provided by the manufacturer, without adversely affecting its	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	intended use.		intended use.	characteristics and performance during its intended use.	
	Annex	II, fifth paragraph			
793	1.3. An EHR system shall be designed and developed in such a way that its interoperability, safety and security features uphold the rights of natural persons, in line with the intended purpose of the EHR system, as set out in Chapter II of this Regulation.		1.3. An EHR system shall be designed and developed in such a way that its interoperability, safety and security features uphold the rights of natural persons, in line with the intended purpose of the EHR system, as set out in Chapter II of this Regulation.	1.3. An EHR system shall be designed and developed in such a way that its interoperability, safety and security features uphold the rights of natural persons, in line with the intended purpose of the EHR system, as set out in Chapter II of this Regulation.	

	Commission Prop	osal		EP Mandate	Council Mandate	Draft Agreement
		Annex	ll, point 2.			
795	2. Requirements for interoperability			2. Requirements for interoperability	2. Requirements for interoperability	
		Annex	II, seventh paragraph			
	2.1. An EHR system s	shall		2.1. An EHR system shall	2.1. An EHR system shall	
	allow personal electro			allow personal electronic	allow personal electronic	
	health data to be share	ed		health data to be shared	health data to be shared	
796	between health			between health	between health	
	professionals or other			professionals or other	professionals or other	
	entities from the health			entities from the health	entities from the health	
	system, and between h			system, and between health	system, and between health	
	professionals and patie			professionals and patient or	professionals and patient or	
	health professional po	rtals		health professional portals	health professional portals	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	in a commonly used electronic interoperable format, which includes, inter-alia, dataset content, data structures, formats, vocabularies, taxonomies, exchange formats, standards, specifications, profiles for exchange and code lists, thus enabling system to system communication.		in a commonly used electronic interoperable format, which includes, inter-alia, dataset content, data structures, formats, vocabularies, taxonomies, exchange formats, standards, specifications, profiles for exchange and code lists, thus enabling system to system communication.	in a commonly used electronic interoperable format, which includes, inter-alia, dataset content, data structures, formats, vocabularies, taxonomies, exchange formats, standards, specifications, profiles for exchange and code lists, thus enabling system to system communication.	
	Annex	II, point 2.1.a.			
796a				2.1.a. Where an EHR system is designed to store or intermediate personal	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				electronic health data, it shall provide an interface enabling access to the personal electronic health data processed by it in the European health record exchange format, by means of the European interoperability component for EHR systems.	
	Annex	II, point 2.1.b.			
796b				2.1.b. Where an EHR system is designed to store or intermediate personal electronic health data, it	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				shall be able to receive personal electronic health data in the European health record exchange format, by means of the European interoperability component for EHR systems.	
	Annex	II, point 2.1.c.		·	
796c				2.1.c. Where an EHR system is designed to provide access to personal electronic health data, it shall be able to receive personal electronic health data in the European	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				health record exchange format, by means of the European interoperability component for EHR systems.	
	Annex	II, eighth paragraph			
797	2.2. An EHR system shall be interoperable and compatible with the European infrastructures set out in this Regulation for the cross-border sharing of electronic health data.		2.2. An EHR system shall be interoperable and compatible with the European infrastructures set out in this Regulation for the cross-border sharing of electronic health data.	2.2. An EHR system shall be interoperable and compatible with the European infrastructures set out in this Regulation for the cross border sharing of electronic health data.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Annex	II, ninth paragraph			
798	2.3. An EHR system that includes a functionality for entering structured personal electronic health data shall enable the entry of data structured in a structured way that supports the data sharing in a structured, commonly used and machine-readable format, enabling system to system communication.	II, ninth paragraph	2.3. An EHR system that includes a functionality for entering structured personal electronic health data shall enable the entry of data structured in a structured way that supports the data sharing in a structured, commonly used, <i>open</i> and machine-readable format, enabling system to system communication .	2.3. An EHR system that includes a functionality for entering structured personal electronic health data shall enable the entry of data structured in a structured way that supports the data sharing in a structured, commonly used and machine-readable format, enabling system to system communication with granularity sufficient to enable the provision of the	
				entered personal electronic health data in the European health	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Δηρογ	II, tenth paragraph		record exchange format.	
	Annex				
799	2.4. An EHR system shall not include features that prohibit, restrict or place undue burden on authorised access, personal electronic health data sharing, or use of personal electronic health data for permitted purposes.		2.4. An EHR system shall not include features that prohibit, restrict or place undue burden on authorised access, personal electronic health data sharing, or use of personal electronic health data for permitted purposes.	2.4. The harmonised components of an EHR system shall not include features that prohibit, restrict or place undue burden on authorised access, personal electronic health data sharing, or use of personal electronic health data for permitted purposes.	
	Annex	II, eleventh paragraph			

	Commission Proposal	E	P Mandate	Council Mandate	Draft Agreement
800	Commission Proposal 2.5. An EHR system shall not include features that prohibit, restrict or place undue burden on authorised exporting of personal electronic health data for the reasons of replacing the EHR system by another product.	2.5. An inot incluiprohibit, undue buiexporting electronis the reason EHR system product.	P Mandate EHR system shall de features that restrict or place urden on authorised g of personal c health data for ns of replacing the tem by another Authorised g of personal ic health data shall f charge, without elay, or in in any thin one month request and in a ed, commonly used hine-readable in line with the rability and	Council Mandate 2.5. The harmonised components of an EHR system shall not include features that prohibit, restrict or place undue burden on authorised exporting of personal electronic health data for the reasons of replacing the EHR system by another product.	Draft Agreement

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement			
			security requirements to be developed according to Articles 23 and 50.					
	Anne	x II, eleventh paragraph a						
800a			<u>An EHR system shall be</u> <u>developed in interoperable</u> <u>format that enables data</u> <u>portability.</u>					
	Annex II, point 3.							
801	3. Requirements for		3. Requirements for	3. Requirements for				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	security		security	security and for logging	
	Annex	II, twelfth paragraph			
802	3.1. An EHR system shall be designed and developed in such a way that it ensures safe and secure processing of electronic health data, and that it prevents unauthorised access to such data.		3.1. An EHR system shall be designed and developed in such a way that it ensures <u>highly</u> safe and secure processing of electronic health data, and that it prevents unauthorised access to such data, <u>and</u> <u>that it duly takes into</u> <u>consideration the</u> <u>principles of data</u> <u>minimization and data</u> <u>protection by design</u> .	3.1. An EHR system shall be designed and developed in such a way that it ensures safe and secure processing of electronic health data, and that it prevents unauthorised access to such data.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			AMs 540&541 merged.		
	Annex	II, thirteenth paragraph			
803	3.2. An EHR system designed to be used by health professionals shall provide reliable mechanisms for the identification and authentication of health professionals, including checks on professional rights and qualifications.		3.2. An EHR system designed to be used by health professionals shall provide reliable mechanisms for the identification and authentication of health professionals, including checks on professional rights and qualifications.	3.2. An EHR system designed to be used by health professionals shall provide reliable mechanisms for the identification and authentication of health professionals, including checks on professional rights and qualifications.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Annex	II, fourteenth paragraph			
804	3.3. An EHR system designed to be used by health professionals shall support the use of information on professional rights and qualifications as part of the access control mechanisms, such as role- based access control.		3.3. An EHR system designed to be used by health professionals shall support the use of information on professional rights and qualifications as part of the access control mechanisms, such as role- based access control.	3.3. An EHR system designed to be used by health professionals shall support the use of information on professional rights and qualifications as part of the access control mechanisms, such as role- based access control.	
	Annex	II, fifteenth paragraph			
805	3.4. An EHR system designed to enable access		3.4. An EHR system designed to enable access	3.4. The harmonised logging component of an	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	by health professionals or other individuals to personal electronic health data shall provide sufficient logging mechanisms that record, at least the following information on every access event or group of events:		by health professionals or other individuals to personal electronic health data shall provide sufficient logging mechanisms that record, at least the following information on every access event or group of events:	EHR system designed to enable access by health professionalsproviders or other individuals to personal electronic health data shall provide sufficient logging mechanisms that record, at least the following information on every access event or group of events:	
	Annex	(II, fifteenth paragraph, point (a	a)		
806	(a) identification of the health professional or other individual having accessed electronic health data;		(a) identification of the health professional or other individual having accessed electronic health data;	(a) identification of the health professional provider or other individualindividuals	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement			
				having accessed personal electronic health data;				
	Annez	< II, fifteenth paragraph, point (b)					
807	(b) identification of the individual;		(b) identification of the individual;	(b) identification of the specific individual or individuals having accessed personal electronic health data;				
	Annex II, fifteenth paragraph, point (c)							
808	(c) categories of data		(c) categories of data	(c) categories of data				

	Commission Prop	osal		EP Mandate	Council Mandate	Draft Agreement
	accessed;			accessed;	accessed;	
		Annex	II, fifteenth paragraph, point (d)		
809	(d) time and date of a	iccess;		(d) time and date of access;	(d) time and date of access;	
		Annex	II, fifteenth paragraph, point (e)		
810	(e) origin(s) of data.			(e) origin(s) of data.	(e) origin(s) of data.	
		Annex	II, sixteenth paragraph			
811						

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	3.5. An EHR system shall include tools and mechanism to allow natural persons to restrict health professionals' access to their personal electronic health data. It shall also include mechanisms that allow access to personal electronic health data in emergency situations, and ensure that access is strictly logged.		3.5. An EHR system shall include tools and mechanism to allow natural persons to restrict health professionals' access to their personal electronic health data. It shall also include mechanisms that allow access to personal electronic health data in emergency situations, and ensure that access is strictly logged.	3.5. An EHR system shall include tools and mechanism to allow natural persons to restrict health professionals' access to their personal electronic health data. It shall also include mechanisms that allow access to personal electronic health data in emergency situations, and ensure that access is strictly logged.	
	Annex	II, seventeenth paragraph			
812	3.6. An EHR system shall include tools or		3.6. An EHR system shall include tools or	3.6. The harmonised components of an EHR	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	mechanisms to review and analyse the log data, or it shall support the connection and use of external software for the same purposes.		mechanisms to review and analyse the log data, or it shall support the connection and use of external software for the same purposes.	system shall include tools or mechanisms to review and analyse the log data, or it shall support the connection and use of external software	
		II, eighteenth paragraph		for the same purposes.	
	Annex	n, eighteentri paragraph			
813	3.7. An EHR system designed to be used by health professionals shall support digital signatures or similar non-repudiation mechanisms.		3.7. An EHR system designed to be used by health professionals shall support digital signatures or similar non-repudiation mechanisms.	3.7. An EHR system designed to be used by health professionals shall support digital signatures or similar non-repudiation mechanisms.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Annex	II, nineteenth paragraph			
814	3.8. An EHR system designed for the storage of electronic health data shall support different retention periods and access rights that take into account the origins and categories of electronic health data.		3.8. An EHR system designed for the storage of electronic health data shall support different retention periods and access rights that take into account the origins and categories of electronic health data <u>as</u> <u>well as the specific</u> <u>purposes of data</u> <u>processing</u> .	3.8. The harmonised components of an EHR system designed for the storage of that store personal electronic health data shall support different retention periods and access rights that take into account the origins and categories of electronic health data.	
	Annex	II, twentieth paragraph			
815					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	3.9. An EHR system		3.9. An EHR system	3.9. An EHR system	
	designed to be used by		designed to be used by	designed to be used by	
	natural persons shall enable		natural persons shall enable	natural persons shall enable	
	their identification using		their identification using	their identification using	
	any recognised electronic		any recognised electronic	any recognised electronic	
	identification means as		identification means as	identification means as	
	defined in Regulation (EU)		defined in Regulation (EU)	defined in Regulation (EU)	
	No 910/2014, regardless of		No 910/2014, regardless of	No 910/2014, regardless of	
	the Member State that has		the Member State that has	the Member State that has	
	issued it. If the service		issued it. If the service	issued it. If the service	
	supports other electronic		supports other electronic	supports other electronic	
	identification means, they		identification means, they	identification means, they	
	shall be of assurance levels		shall be of assurance levels	shall be of assurance levels	
	'substantial' or 'high'.		'substantial' or 'high'.	'substantial' or 'high'.	
	Annex	111			
816					

	Commission Propos	sal	EP Mandate	Council Mandate	Draft Agreement
	Annex III		Annex III	Annex III	
	A	Annex III, first paragraph	-	-	
817	Technical documentation	n	Technical documentation	Technical documentation	
	A	Annex III, second paragraph			
818	The technical documentation referred t in Article 24 shall contai at least the following information, as applicable to the relevant EHR syst	lin	The technical documentation referred to in Article 24 shall contain at least the following information, as applicable to the relevant EHR system:	The technical documentation referred to in Article 24 shall contain at least the following information, as applicable to the harmonised	

	Commission Prop	osal		EP Mandate	Council Mandate	Draft Agreement
					components of EHR systems in the relevant EHR system:	
		Annex	III, third paragraph			
819	1. A detailed descripti the EHR system includ			1. A detailed description of the EHR system including:	1. A detailed description of the EHR system including:	
		Annex	III, third paragraph, point (a)			
820	(a) its intended purpos the date and the version the EHR system;			(a) its intended purpose, the date and the version of the EHR system;	(a) its intended purpose, the date and the version of the EHR system;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Annex	(III, third paragraph, point (b)			
821	(b) the categories of electronic health data that the EHR system has been designed to process;		(b) the categories of electronic health data that the EHR system has been designed to process;	(b) the categories of personal electronic health data that the EHR system has been designed to process;	
	Annex	(III, third paragraph, point (c)			
822	(c) how the EHR system interacts or can be used to interact with hardware or software that is not part of		(c) how the EHR system interacts or can be used to interact with hardware or software that is not part of	(c) how the EHR system interacts or can be used to interact with hardware or software that is not part of	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	the EHR system itself;		the EHR system itself;	the EHR system itself;	
	Annex	III, third paragraph, point (d)			
823	(d) the versions of relevant software or firmware and any requirement related to version update;		(d) the versions of relevant software or firmware and any requirement related to version update;	(d) the versions of relevant software or firmware and any requirement related to version update;	
	Annex	III, third paragraph, point (e)			
824	(e) the description of all forms in which the EHR system is placed on the		(e) the description of all forms in which the EHR system is placed on the	(e) the description of all forms in which the EHR system is placed on the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	market or put into service;		market or put into service;	market or put into service;	
	Annex	K III, third paragraph, point (f)			
825	(f) the description of hardware on which the EHR system is intended to run;		(f) the description of hardware on which the EHR system is intended to run;	(f) the description of hardware on which the EHR system is intended to run;	
	Annex	k III, third paragraph, point (g)			
826	(g) a description of the system architecture explaining how software components build on or		(g) a description of the system architecture explaining how software components build on or	(g) a description of the system architecture explaining how software components build on or	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	feed into each other and integrate into the overall processing, including where appropriate, labelled pictorial representations (e.g. diagrams and drawings), clearly indicating key parts/components and including sufficient explanation to understand the drawings and diagrams;		feed into each other and integrate into the overall processing, including where appropriate, labelled pictorial representations (e.g. diagrams and drawings), clearly indicating key parts/components and including sufficient explanation to understand the drawings and diagrams;	feed into each other and integrate into the overall processing, including where appropriate, labelled pictorial representations (e.g. diagrams and drawings), clearly indicating key parts/components and including sufficient explanation to understand the drawings and diagrams;	
	Annex	III, third paragraph, point (h)			
827	(h) the technical specifications, such as features, dimensions and		(h) the technical specifications, such as features, dimensions and	(h) the technical specifications, such as features, dimensions and	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	performance attributes, of the EHR system and any variants/configurations and accessories that would typically appear in the product specification made available to the user, for example in brochures, catalogues and similar publications, including a detailed description of the		performance attributes, of the EHR system and any variants/configurations and accessories that would typically appear in the product specification made available to the user, for example in brochures, catalogues and similar publications, including a detailed description of the	performance attributes, of the EHR system and any variants/configurations and accessories that would typically appear in the product specification made available to the user, for example in brochures, catalogues and similar publications, including a detailed description of the	
	data structures, storage and input/output of data; Annex	III, third paragraph, point (i)	data structures, storage and input/output of data;	data structures, storage and input/output of data;	
828	(i) a description of any change made to the system		(i) a description of any change made to the system	(i) a description of any change made to the system	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	throughout its lifecycle;		throughout its lifecycle;	throughout its lifecycle;	
	Anne	<pre>c III, third paragraph, point (j)</pre>			
829	(j) the instructions of use for the user and, where applicable, installation instructions.		(j) the instructions of use for the user and, where applicable, installation instructions.	(j) the instructions of use for the user and, where applicable, installation instructions.	
	Annex	III, fourth paragraph			
830	2. A detailed description of the system in place to evaluate the EHR system performance, where		2. A detailed description of the system in place to evaluate the EHR system performance, where	2. A detailed description of the system in place to evaluate the EHR system performance, where	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	applicable.		applicable.	applicable.	
	Anne	x III, fifth paragraph			
831	3. The references to any common specification used in accordance with Article 23 and in relation to which conformity is declared.		 The references to any common specification used in accordance with Article and in relation to which conformity is declared. 	3. The references to any common specification used in accordance with Article 23 and in relation to which conformity is declared.	
	Anne	x III, sixth paragraph			
832	4. The results and critical analyses of all verifications and validation tests		4. The results and critical analyses of all verifications and validation tests	4. The results and critical analyses of all verifications and validation tests	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	undertaken to demonstrate conformity of the EHR system with the requirements laid down in Chapter III of this Regulation, in particular the applicable essential requirements;		undertaken to demonstrate conformity of the EHR system with the requirements laid down in Chapter III of this Regulation, in particular the applicable essential requirements;	undertaken to demonstrate conformity of the EHR system with the requirements laid down in Chapter III of this Regulation, in particular the applicable essential requirements ; .	
	Annex	III, seventh paragraph			
833	5. A copy of the information sheet referred to in Article 25.		5. A copy of the information sheet referred to in Article 25.	5.A copy of the information sheet referred to in Article25.	

	Commission Prop	posal	EP Mandate	Council Mandate	Draft Agreement
		Annex III, eighth paragraph			
834	6. A copy of the EU declaration of conform		6. A copy of the EU declaration of conformity.	6. A copy of the EU declaration of conformity.	
		Annex IV			
835	Annex IV		Annex IV	Annex IV	
		Annex IV, first paragraph			
836	EU declaration of conformity		EU declaration of conformity	EU declaration of conformity	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Annex	IV, second paragraph			
837	The EU declaration of conformity shall contain all of the following information:		The EU declaration of conformity shall contain all of the following information:	The EU declaration of conformity for the harmonised components of EHR systems shall contain all of the following information:	
	Annex	IV, third paragraph			
838	1. The name of the EHR system, version and any additional unambiguous		1. The name of the EHR system, version and any additional unambiguous	1. The name of the EHR system, version and any additional unambiguous	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	reference allowing identification of the EHR system.		reference allowing identification of the EHR system.	reference allowing identification of the EHR system.	
	Anne	ex IV, fourth paragraph			
839	2. Name and address of the manufacturer or, where applicable, their authorised representative.		2. Name and address of the manufacturer or, where applicable, their authorised representative.	2. Name and address of the manufacturer or, where applicable, their authorised representative.	
	Anne	ex IV, fifth paragraph			
840	3. A statement that the EU declaration of conformity is		3. A statement that the EU declaration of conformity is	3. A statement that the EU declaration of conformity is	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	issued under the sole		issued under the sole	issued under the sole	
	responsibility of the		responsibility of the	responsibility of the	
	manufacturer.		manufacturer.	manufacturer.	
	Annex	IV, sixth paragraph			
	4. A statement that the		4. A statement that the	4. A statement that the	
	EHR system in question is		EHR system in question is	EHR system in question is	
	in conformity with the		in conformity with the	in conformity with the	
	provisions laid down in		provisions laid down in	provisions laid down in	
841	Chapter III of this		Chapter III of this	Chapter III of this	
0+1	Regulation and, if		Regulation and, if	Regulation and, if	
	applicable, with any other		applicable, with any other	applicable, with any other	
	relevant EU legislation that		relevant EU legislation that	relevant EU legislation that	
	provides for the issuing of		provides for the issuing of	provides for the issuing of	
	an EU declaration of		an EU declaration of	an EU declaration of	
	conformity.		conformity.	conformity, complemented	
				by the result from the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement		
				testing environment mentioned in article 26A obtained for the EHR system.			
	Annex	IV, seventh paragraph					
842	5. References to any relevant harmonized standards used and in relation to which conformity is declared.		5. References to any relevant harmonized standards used and in relation to which conformity is declared.	5. References to any relevant harmonizedharmonised standards used and in relation to which conformity is declared.			
	Annex IV, eighth paragraph						

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
843	6. References to any common specifications used and in relation to which conformity is declared.		6. References to any common specifications used and in relation to which conformity is declared.	6. References to any common specifications used and in relation to which conformity is declared.	
	Annex	IV, ninth paragraph			
844	7. Place and date of issue of the declaration, signature plus name and function of the person who signed, and, if applicable, an indication of the person on whose behalf it was signed.		7. Place and date of issue of the declaration, signature plus name and function of the person who signed, and, if applicable, an indication of the person on whose behalf it was signed.	7. Place and date of issue of the declaration, signature plus name and function of the person who signed, and, if applicable, an indication of the person on whose behalf it was signed.	

	Commission Propo	osal		EP Mandate	Council Mandate	Draft Agreement
		Annex I\	V, tenth paragraph		·	
845	8. Where applicable, additional information.			8. Where applicable, additional information.	8. Where applicable, additional information.	
		Annex I\	Va			
845a				ANNEX IVa		
		Annex I\	Va, (1)			
845b				1. <u>EU type-examination is</u> the part of a conformity		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			assessment procedure in which a notified body examines the technical design of an EHR system and verifies and attests that the technical design of the EHR system meets the applicable requirements of this Regulation.		
	Annex	IVa, (2)			
845c			<u>EU type-examination shall</u> <u>be carried out by</u> assessment of the adequacy of the technical design of the EHR system through examination of the		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			technical documentation, plus examination of a specimen of the EHR system that is representative of the production envisaged (production type).		
	Annex	IVa(3), first subparagraph			
845d			3. Application for EU type- examination		
	Annex	IVa(3), second subparagraph			
845e					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			The manufacturer shall lodge an application for EU type-examination with a single notified body of his or her choice. The application shall include:		
	Annex	IVa(3), second subparagraph,	point a		
845f			(a) the name and address of the manufacturer and, if the application is lodged by an authorised representative, the name and address of that authorised representative;		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement	
	Ann	ex IVa(3), second subparagraph,	point b	·		
845g			(b) <u>a written declaration</u> that the same application has not been lodged with any other notified body;			
	Ann	ex IVa(3), second subparagraph,	point c			
845h			<u>(c)</u> <u>the technical</u> <u>documentation described in</u> <u>Annex III;</u>			
	Annex IVa(3), second subparagraph, point d					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
845i			(d) the specimen(s) of the EHR system representative of the production envisaged. The notified body may request further specimens if needed for carrying out the test programme.		
	Annex	(IVa(4), first subparagraph			
845j			4. EU type-examination		
	Annex	(IVa(4), second subparagraph			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement	
845k			The notified body shall:			
	Annex	IVa(4), second subparagraph,	point a			
8451			(a) examine the technical documentation to assess the adequacy of the technical design of the EHR system;			
	Annex IVa(4), second subparagraph, point b					
845 m			(b) verify that the EHR			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			system has been manufactured in conformity with the technical documentation, and identify the elements that have been designed in accordance with the applicable provisions of the relevant harmonised standards or technical specifications adopted by the Commission;		
	Annex	IVa(4), second subparagraph,	point c		
845n			(c) carry out appropriate examinations and tests, or have them carried out, to		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			check whether, where the manufacturer has chosen to apply the solutions in the relevant harmonised standards, those have been applied correctly;		
	Annex	IVa(4), second subparagraph,	point d		
8450			(d) carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant harmonised standards or technical specifications adopted by the Commission, the solutions		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement			
			adopted by the manufacturer, including those in other technical specifications applied, meet the corresponding essential requirements and have been applied correctly.					
	Annex	IVa(5), first subparagraph						
845p			5. Evaluation report					
	Annex IVa(5), second subparagraph							
845q			The notified body shall					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			draw up an evaluation report that records the activities undertaken in accordance with point 4 and their outcomes. Without prejudice to its obligations vis-à-vis the notifying authorities, as mentioned in Article 27, point (j), the notified body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.		
	Anne	ex IVa(6)			
845r					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			<u>6.</u> <u>EU type-examination</u> <u>certificate</u>		
	Annex	IVa(6), point 1			
845s			6.1 Where the type meets the applicable essential requirements, the notified body shall issue an EU type-examination certificate to the manufacturer. The period of validity of a newly issued certificate and, where appropriate, of a renewed certificate shall not exceed five years.		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Annex	IVa(6), point 2			
845t			<u>6.2</u> <u>The EU type-</u> <u>examination certificate</u> <u>shall contain at least the</u> <u>following information:</u>		
	Annex	IVa(6), point 2, point a			
845u			(a) the name and identification number of the notified body;		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Annex	IVa(6), point 2, point b			
845v			(b) the name and address of the manufacturer and, if the application is lodged by an authorised representative, the name and address of that authorised representative;		
	Annex	IVa(6), point 2, point c			
845 w			(c) an identification of the EHR system covered by the certificate (type number);		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Annex	IVa(6), point 2, point d			
845x			(d) a statement that the EHR system complies with the applicable essential requirements;		
	Annex	IVa(6), point 2, point e			
845y			(e) where harmonised standards or technical specifications adopted by the Commission have been fully or partially applied,		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			<u>the references of those</u> <u>standards or parts thereof;</u>		
	Annex	IVa(6), point 2, point f			
845z			(f) where other technical specifications have been applied, the references of those technical specifications;		
	Annex	IVa(6), point 2, point g			
845a a			(g) where applicable, the performance level(s) or		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement	
			protection class of the machinery product;			
	Annex	IVa(6), point 2, point h				
845a b			(h) the date of issue, the date of expiry and, where appropriate, the date(s) of renewal; (i) any conditions attached to the issuing of the certificate.			
	Annex IVa(6), point 3					
845a c			<u>6.3</u> Where the type does			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			not satisfy the applicable essential requirements, the notified body shall refuse to issue an EU type- examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.		
	Annex	IVa(7)			
845a d			7. <u>Review of the EU type-</u> examination certificate		
	Annex	IVa(7), point 1			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement			
845a e			7.1 The notified body shall keep itself apprised of any changes in the generally acknowledged state of the art, which indicate that the approved type may no longer comply with the applicable essential requirements, and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly.					
	Annex IVa(7), point 2							

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
845a f		7.2 The manufacturer shall inform the notified body that holds the technical documentation relating to the EU type- examination certificate of all modifications to the approved type and of all modifications to the technical documentation that may affect the conformity of the EHR system with the applicable essential health and safety requirements or the conditions for validity of that certificate. Such modifications shall require additional approval in the		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			<u>form of an addition to the</u> original EU type- examination certificate.		
	Annex	IVa(7), point 3			
845a g			7.3 <u>The manufacturer</u> shall ensure that the EHR system continues to fulfil the applicable essential requirements in light of the state of the art.		
	Annex	IVa(7), point 4	·	·	
845a					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
h			7.4 <u>The manufacturer</u> shall ask the notified body to review the EU type- examination certificate either:		
	Annex	IVa(7), point 4, point a			
845a i			(a) in the case of a modification to the approved type referred to in point 7.2;		
	Annex	IVa(7), point 4, point b		1	
845a					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
j			(b) in the case of a change in the state of the art referred to in point 7.3;		
	Annex	IVa(7), point 4, point c			
845a k			(c) at the latest, before the date of expiry of the certificate. In order to allow the notified body to fulfil its tasks, the manufacturer shall submit his or her application at the earliest 12 months and at the latest 6 months prior to the expiry date of the EU type-examination		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			<u>certificate.</u>		
	Annex	IVa(7), point 5	-		
			7.5 The notified body shall examine the EHR system type and, where necessary in the light of the changes made, carry out the		
845a 1			relevant tests to ensure that the approved type continues to fulfil the applicable essential requirements. If the notified body is satisfied that the approved type continues to fulfil the applicable essential		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			requirements, it shall renew the EU type- examination certificate. The notified body shall ensure that the review procedure is finalised before the expiry date of the EU type-examination certificate.		
	Annex	IVa(7), point 6			
845a m			7.6 Where the conditions referred to in points (a) and (b) of point 7.4 are not met, a simplified review procedure shall apply. The manufacturer shall supply		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			<u>the notified body with the</u> <u>following:</u>		
	Annex	IVa(7), point 6, point a	-	-	
845a n			(a) His or her name and address and data identifying the EU type- examination certificate concerned;		
	Annex	IVa(7), point 6, point b			
845a o			(b) confirmation that there has been no modification		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			to the approved type as referred to in point 7.2, nor to the relevant harmonised standards or technical specifications adopted by the Commission or other technical specifications applied;		
	Annex	IVa(7), point 6, point c	L		
845a p			(c) confirmation that there has been no change in the state of the art as referred to in point 7.3;		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Annex	IVa(7), point 7			
845a q			7.7 If, following the review, the notified body concludes that the EU type- examination certificate is no longer valid, the body shall withdraw it and the manufacturer shall cease the placing on the market of the EHR system concerned.		
	Annex IVa(8), first subparagraph				
845a r			8. Each notified body shall		

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	inform its notifying		
	authority concerning the		
	EU type-examination		
	certificates and/or any		
	additions thereto which it		
	<u>has issued or withdrawn,</u>		
	and shall, periodically or		
	<u>upon request, make</u>		
	<u>available to its notifying</u>		
	authority the list of such		
	<u>certificates and/or any</u>		
	additions thereto refused,		
	<u>suspended or otherwise</u>		
	restricted. Each notified		
	body shall inform the other		
	notified bodies concerning		
	the EU type-examination		
	<u>certificates and/or any</u>		
	additions thereto, which it		
	<u>has refused, withdrawn,</u>		
	<u>suspended or otherwise</u>		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			restricted, and, upon request, concerning the EU type-examination certificates and/or additions thereto which it has issued.		
	Annex	IVa(8), second subparagraph			
845a s			The Commission, the <u>Member States and the</u> other notified bodies may, on request, obtain a copy of the EU type-examination certificates and/or additions thereto. On request, the Commission and the Member States		

Commission Propo	osal	EP Mandate	Council Mandate	Draft Agreement		
		may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body. The notified body shall keep a copy of the EU type- examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer, for a period of five years after the expiry of the validity of that certificate.				
	Annex IVa(9)					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
845a t			9. The manufacturer shall keep a copy of the EU type- examination certificate together with the technical documentation at the disposal of the national authorities, for 10 years after the EHR system has been placed on the market.		
	Annex	IVa(10)			
845a u			<u>10.</u> <u>The manufacturer's</u> <u>authorised representative</u> <u>may lodge the application</u> <u>referred to in point 3 and</u>		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			<u>fulfil the obligations set out</u> <u>in points 7.2, 7.4 and 9,</u> <u>provided that they are</u> <u>specified in the mandate.</u>		
	Annex	IVa, re annex 1			
845a v			<u>Medical directives</u> AM 536, line 6a (new), first column		
	Annex	IVa, re annex I			
845a					

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
W		Electronic health data related to the legal documentation that states a person's wishes about receiving medical care if that person is no longer able to make medical decisions because of a serious illness or injury and that may also give a person (such as a spouse, relative, or friend) the authority to make medical decisions in such situations. Electronic health data related to the patient's will and consent in specific medical acts.		

Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	AM 536, line 6a (new), second column		
	This one refers to Annex I and introduces a new row in the table "6a.		
	Medical directives"		