

Thursday 11 November 2021

P9\_TA(2021)0449

## Serious cross-border threats to health \*\*\*I

Amendments adopted by the European Parliament on 14 September and 11 November 2021 on the proposal for a regulation of the European Parliament and of the Council on serious cross-border threats to health repealing Decision No 1082/2013/EU (COM(2020)0727 — C9-0367/2020 — 2020/0322(COD)) <sup>(1)</sup>

(Ordinary legislative procedure: first reading)

(2022/C 205/12)

### Amendment 1

#### Proposal for a regulation

#### Recital 1 a (new)

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*Text proposed by the Commission*

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*Amendment*

- (1a) *The health provisions of the Treaties are still largely under-used in terms of the purposes they were designed to achieve. This Regulation should therefore be aimed at making the best possible use of such health provisions, in order to demonstrate the strength of the Union's health policy, while preserving the normal functioning of the single market in the event serious cross-border threats to health arise.*

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<sup>(1)</sup> The matter was referred back for interinstitutional negotiations to the committee responsible, pursuant to Rule 59(4), fourth subparagraph (A9-0247/2021).

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## Amendments 2 and 244

## Proposal for a regulation

## Recital 2

Text proposed by the Commission

- (2) In light of the lessons learnt during the ongoing COVID-19 pandemic and in order to facilitate adequate Union-wide preparedness and response to all cross-border threats to health, the legal framework for epidemiological surveillance, monitoring, early warning of, and combating serious cross-border threats to health, as set out in Decision No 1082/2013/EU, needs to be broadened with regard to additional reporting requirements and analysis on health systems indicators, and cooperation **by** Member States **with** the European Centre for Disease Prevention and Control (ECDC). Moreover, in order to ensure effective Union response to novel cross-border threats to health, the legal framework to combat serious cross-border threats to health should enable to immediately adopt case definitions for the surveillance of novel threats and should provide for the establishment of a network of EU reference laboratories and a network to support monitoring of disease outbreaks that are relevant to substances of human origin. The capacity for contact tracing should be strengthened via the creation of an automated system, using modern technologies.

Amendment

- (2) In light of the lessons learnt during the ongoing COVID-19 pandemic and in order to facilitate adequate Union-wide **prevention of**, preparedness and response to all cross-border threats to health, **including zoonotic-related threats**, the legal framework for epidemiological surveillance, monitoring, early warning of, and combating serious cross-border threats to health, as set out in Decision No 1082/2013/EU, needs to be broadened with regard to additional reporting requirements and analysis on health systems indicators, and cooperation **between** Member States **and Union agencies, particularly** the European Centre for Disease Prevention and Control (ECDC), **the Health Emergency Preparedness and Response Authority (HERA), the European Medicines Agency (EMA), and international organisations, in particular the World Health Organization (WHO)**. Moreover, in order to ensure effective Union response to novel cross-border threats to health, the legal framework to combat serious cross-border threats to health should enable to immediately adopt case definitions for the surveillance of novel threats and should provide for the establishment of a network of EU reference laboratories and a network to support monitoring of disease outbreaks that are relevant to substances of human origin. The capacity for contact tracing should be strengthened via the creation of an automated system, using modern technologies, **while respecting Regulation (EU) 2016/679 of the European Parliament and of the Council ('GDPR')** <sup>(1a)</sup>.

<sup>(1a)</sup> 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 repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1).

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**Amendment 245**  
**Proposal for a regulation**  
**Recital 2 a (new)**

Text proposed by the Commission

Amendment

- (2a) *The HERA was set up to strengthen the Union's ability to prevent, detect and rapidly respond to cross-border health threats, by ensuring the supply of crisis-relevant medical countermeasures, including through their monitoring, procurement and purchase, by activating emergency research and innovation plans, providing emergency funding and financing, and by taking measures concerning the production, availability and supply of such key medical countermeasures.*

**Amendment 246**  
**Proposal for a regulation**  
**Recital 2 b (new)**

Text proposed by the Commission

Amendment

- (2b) *All such public investments in research, development, manufacturing, production, procurement, stockpiling, supply and distribution of medical countermeasures should be transparent.*

**Amendment 3**  
**Proposal for a regulation**  
**Recital 3**

Text proposed by the Commission

Amendment

- (3) An important role in the coordination of preparedness and response planning for serious cross-border threats to health is being played by the Health Security Committee (HSC), as formally established by Decision No 1082/2013/EU. This Committee should be given additional responsibilities with regard to the adoption of guidance and opinions to better support Member States in the prevention and control of serious cross-border threats to health.
- (3) An important role in the coordination of **prevention**, preparedness and response planning for serious cross-border threats to health is being played by the Health Security Committee (HSC), as formally established by Decision No 1082/2013/EU. This Committee should be given additional responsibilities with regard to the adoption of guidance and opinions to better support Member States in the prevention and control of serious cross-border threats to health, **and support better coordination between Member States to address those threats. Representatives designated by the European Parliament should be able to participate in the HSC as observers.**

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**Amendment 247**  
**Proposal for a regulation**  
**Recital 3 a (new)**

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*Text proposed by the Commission*

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*Amendment*

- (3a) *In order to avoid duplication of efforts and to have coherence in decision-making at Union level, the HSC should closely cooperate with the HERA Board, established under the Commission Decision of 16 September 2021, the Health Crisis Board, established under a Council Regulation on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level, and other relevant Union agencies and bodies, to ensure that effective preparedness and response mechanisms are in place for health emergencies.*

**Amendment 4**  
**Proposal for a regulation**  
**Recital 4 a (new)**

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*Text proposed by the Commission*

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*Amendment*

- (4a) *Prevention and promotion strategies concern all sectoral policies including fiscal, commercial, economic, agro-environmental, educational, housing, cultural and relating to social assistance. 'Health in all Policies' should be a principle of all public policies. An instrument already used at the national level to assess the health impact of the different sectoral policies is the so-called Health Test. A Health impact assessment should be undertaken for all programmes managed by the Union.*

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**Amendment 5**  
**Proposal for a regulation**  
**Recital 5**

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*Text proposed by the Commission*

- (5) This Regulation should apply without prejudice to other binding measures concerning specific activities or quality and safety standards for certain goods, which provide for special obligations and tools for monitoring, early warning and combatting specific threats of a cross-border nature. Those measures include, in particular, relevant Union legislation in the area of common safety concerns in public health matters, covering goods such as pharmaceutical products, medical devices and foodstuffs, substances of human origin (blood, tissues and cells, organs), and exposure to ionising radiation.

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*Amendment*

- (5) This Regulation should apply without prejudice to other binding measures concerning specific activities or quality and safety standards for certain goods, which provide for special obligations and tools for monitoring, early warning and combatting specific threats of a cross-border nature, **such as the International Health Regulations (IHR) of the World Health Organization (WHO)**. Those measures include, in particular, relevant Union legislation in the area of common safety concerns in public health **and environmental** matters, covering goods such as pharmaceutical products, medical devices, **in vitro diagnostic medical devices**, and foodstuffs, substances of human origin (blood, **plasma**, tissues and cells, organs), and exposure to ionising radiation.

**Amendment 242**  
**Proposal for a regulation**  
**Recital 5 a (new)**

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*Text proposed by the Commission*

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*Amendment*

- (5a) ***The over-exploitation of wildlife and other natural resources and the accelerated loss of biodiversity pose a risk to human health. As the health of humans, animals and the environment are inextricably linked, it is crucial to respect the principles of the 'One Health' approach to address current and emerging crises.***

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**Amendment 6**  
**Proposal for a regulation**  
**Recital 6**

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*Text proposed by the Commission*

- (6) The protection of human health is a matter which has a cross-cutting dimension and is relevant to numerous Union policies and activities. In order to achieve a high level of human health protection, and to avoid any overlap of activities, duplication or conflicting actions, the Commission, in liaison with the Member States, should ensure coordination and exchange of information between the mechanisms and structures established under this Regulation, and other mechanisms and structures established at Union level and under the Treaty establishing the European Atomic Energy Community (the Euratom Treaty), the activities of which are relevant to the preparedness and response planning, monitoring, early warning of, and combating serious cross-border threats to health. In particular, the Commission should ensure that relevant information from the various rapid alert and information systems at Union level and under the Euratom Treaty is gathered and communicated to the Member States through the Early Warning and Response System ('EWRS') set up by Decision No 2119/98/EC.

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*Amendment*

- (6) ***In line with the 'One Health' and 'Health in all policies' approaches***, the protection of human health is a matter which has a cross-cutting dimension and is relevant to numerous Union policies and activities. ***The Union should support Member States in reducing health inequalities, within and between Member States, in achieving universal health coverage and in addressing the challenges of vulnerable groups. The Union should also urge Member States to implement the health-specific country-specific recommendations and support Member States in strengthening the resilience, responsiveness and readiness of healthcare systems to address future challenges, including pandemics.*** In order to achieve a high level of human health protection, and to avoid any overlap of activities, duplication or conflicting actions, the Commission, in liaison with the Member States, ***and all relevant stakeholders, such as health professionals, patient associations, industry and supply chain actors***, should ensure coordination and exchange of information between the mechanisms and structures established under this Regulation, and other mechanisms and structures established at Union level and under the Treaty establishing the European Atomic Energy Community (the Euratom Treaty), the activities of which are relevant to the preparedness and response planning, monitoring, early warning of, and combating serious cross-border threats to health. ***Those mechanisms should look for synergies between Union and national measures, while seeking to avoid duplicating measures undertaken in the context of the WHO framework.*** In particular, the Commission should ensure that relevant information from the various rapid alert and information systems at Union level and under the Euratom Treaty is gathered and communicated to the Member States through the Early Warning and Response System ('EWRS') set up by Decision No 2119/98/EC.

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**Amendment 7**  
**Proposal for a regulation**  
**Recital 7**

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*Text proposed by the Commission*

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- (7) Preparedness and response planning are essential elements for effective monitoring, early warning of and combatting serious cross-border threats to health. As such, a Union health crisis and pandemic preparedness plan needs to be established by the Commission and approved by the HSC. This should be coupled with updates to Member States' preparedness and response plans so as to ensure they are compatible within the regional level structures. To support Member States in this endeavour, targeted training and **knowledge exchange activities** for healthcare staff and public health staff **should be provided** knowledge and necessary skills **should be provided by the Commission and Union Agencies**. To ensure the putting into operation and the running of these plans, the Commission should conduct stress tests, exercises and in-action and after-action reviews with Member States. These plans should be coordinated, be functional and updated, and have sufficient resources for their operationalisation. Following stress tests and reviews of the plans, corrective actions should be implemented and the Commission should be kept informed of all updates.

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*Amendment*

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- (7) **Prevention**, preparedness and response planning are essential elements for effective monitoring, early warning of and combatting serious cross-border threats to health. As such, a Union health crisis and pandemic preparedness plan needs to be established by the Commission and approved by the HSC. This should be coupled with updates to Member States' **prevention**, preparedness and response plans so as to ensure they are compatible within the regional level structures. **The plans should be implemented through interregional crisis anticipation planning with particular attention paid to cross-border regions to enhance their health cooperation. Where appropriate, regional authorities should participate in the drawing up of these plans.** To support Member States in this endeavour, **the Commission and Union agencies should provide** targeted training and **facilitate the sharing of best practices** for healthcare staff and public health staff **to improve their** knowledge and **ensure** necessary skills. To ensure the putting into operation and the running of these plans, the Commission should conduct stress tests, exercises and in-action and after-action reviews with Member States. These plans should **include recommendations for policy interventions related to mitigating the impact of communicable diseases on health services and care, including on major non-communicable diseases (NCDs). The plans should** be coordinated, be functional and updated, and have sufficient resources for their operationalisation. **Specific considerations should be given to border regions, where joint cross-border exercises should be promoted and health practitioners encouraged to gain familiarity with the public health systems in neighbouring countries.** Following stress tests and reviews of the plans, corrective actions should be implemented and the Commission should be kept informed of all updates.

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**Amendment 8**  
**Proposal for a regulation**  
**Recital 8**

*Text proposed by the Commission*

- (8) To this end, Member States should provide the Commission with an update on the latest situation with regard to their preparedness and response planning and implementation at national level. Information provided by the Member States should include the elements that Member States are obliged to report to the World Health Organization (WHO) in the context of the International Health Regulations (IHR) <sup>(15)</sup>. In turn, the Commission should report to the European Parliament and to the Council on the state of play and progress with preparedness, response planning and implementation at Union level, including on corrective actions, every **2 years** to ensure that national preparedness and response plans are adequate. In order to support the assessment of these plans, EU audits in Member States should be conducted, in coordination with the ECDC and Union agencies. Such planning should include in particular adequate preparedness of critical sectors of society, such as energy, transport, communication or civil protection, which rely, in a crisis situation, on well-prepared gender-sensitive public health systems that are also in turn dependent on the functioning of those sectors and on maintenance of essential services at an adequate level. In the event of a serious cross-border threat to health originating from a zoonotic infection, it is important to ensure the interoperability between health and veterinary sectors for preparedness and response planning.

<sup>(15)</sup> World Health Organization. International Health Regulation (IHR, 2005) <https://www.who.int/publications/i/item/9789241580496>

*Amendment*

- (8) To this end, Member States should provide the Commission with an update on the latest situation with regard to their **prevention**, preparedness and response planning and implementation at national level, **and regional level where applicable**. Information provided by the Member States should include the elements that Member States are obliged to report to the World Health Organization (WHO) in the context of the International Health Regulations (IHR) <sup>(15)</sup>. **Access to timely and complete data is a precondition for rapid risk assessments and crisis mitigation. To avoid duplication of efforts and diverging recommendations, standardised definitions, where possible, and fluid information exchanges should take place between Union agencies, the WHO and national agencies.** In turn, the Commission should report to the European Parliament and to the Council on the state of play and progress with **prevention**, preparedness, response planning and implementation at Union level, including on corrective actions, every **year** to ensure that national preparedness and response plans are adequate. In order to support the assessment of these plans, EU audits in Member States should be conducted, in coordination with the ECDC and Union agencies. Such planning should include in particular adequate preparedness of critical **long-term healthcare and critical** sectors of society, such as **agriculture**, energy, transport, communication or civil protection, which rely, in a crisis situation, on well-prepared gender-sensitive public health systems that are also in turn dependent on the functioning of those sectors and on maintenance of essential services at an adequate level. In the event of a serious cross-border threat to health originating from a zoonotic infection, it is important to ensure the interoperability between health and veterinary sectors for preparedness and response planning.

<sup>(15)</sup> World Health Organization. International Health Regulation (IHR, 2005) <https://www.who.int/publications/i/item/9789241580496>

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**Amendment 9**  
**Proposal for a regulation**  
**Recital 8 a (new)**

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*Text proposed by the Commission*

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*Amendment*

- (8a) *Experience from the ongoing COVID-19 crisis has demonstrated that there is a need for further firmer action at Union level to support cooperation and coordination among the Member States, in particular between neighbouring border regions. The national plans of Member States sharing a border with at least one other Member State should therefore include plans to improve the preparedness for, prevention of and response to health crises in border areas in neighbouring regions, including through mandatory cross-border training for healthcare staff and coordination exercises for the medical transfer of patients. The Commission should regularly report on the state of play of cross-border crisis preparation in neighbouring regions.*

**Amendment 10**  
**Proposal for a regulation**  
**Recital 8 b (new)**

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*Text proposed by the Commission*

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*Amendment*

- (8b) *The role of frontline health professionals has also become apparent during the pandemic as they have been key to ensuring access to medicine and continuity of care, providing moral support and being a source of trusted information against false information. For future emergencies, it is necessary to strengthen the knowledge of health professionals by laying down rules to provide training for workers in the fields of health care and public health. It is also necessary to integrate them through their professional organisations in the definition of public health policies as well as in the digital transformation in order to improve the quality and efficiency of health systems and ensure their sustainability for the health, social and territorial cohesion work they carry out.*

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**Amendment 11**  
**Proposal for a regulation**  
**Recital 8 c (new)**

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Text proposed by the Commission

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Amendment

- (8c) *Health literacy plays a fundamental role in preventing and mitigating the impact of cross-border threats and contributing to a better understanding on the part of the population of the countermeasures and risk assessment of different threats. Respiratory etiquette, correct hand washing, avoiding unnecessary close contact with anyone with flu-like symptoms, and avoiding unprotected contact with wild animals should be part of health education campaigns to improve the population's behaviour, based on the latest available evidence.*

**Amendments 12 and 248**  
**Proposal for a regulation**  
**Recital 8 d (new)**

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Text proposed by the Commission

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Amendment

- (8d) *Building on lessons learnt from the COVID-19 pandemic, this Regulation should create a more robust mandate for coordination at Union level. The declaration of a Union emergency situation would trigger increased coordination and allow for timely development, stockpiling and joint procurement of medical countermeasures, under the umbrella of the HERA.*

**Amendment 13**  
**Proposal for a regulation**  
**Recital 8 e (new)**

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Text proposed by the Commission

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Amendment

- (8e) *This Regulation also ensures coordinated action at Union level, in order to ensure that the internal market functions properly, and to ensure that basic supplies, including medicines, medical products and personal protective equipment (PPE) circulate freely.*

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**Amendment 14**  
**Proposal for a regulation**  
**Recital 8 f (new)**

*Text proposed by the Commission*

*Amendment*

**(8f) Health logistics mechanisms should meet the specific legal requirements of Directive 2001/83/EC of the European Parliament and of the Council <sup>(1a)</sup> and Regulation (EU) 2017/745 of the European Parliament and of the Council <sup>(1b)</sup>.**

<sup>(1a)</sup> Directive 2001/83/EC of the 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).

<sup>(1b)</sup> Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on 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, 5.5.2017, p. 1).

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## Amendments 15 and 249

## Proposal for a regulation

## Recital 9

Text proposed by the Commission

- (9) As serious cross-border threats to health are not limited to Union borders, joint procurement of medical countermeasures should be extended to include European Free Trade Association States and Union candidate countries, in accordance with the applicable Union legislation. The Joint Procurement Agreement, determining the practical arrangements governing the joint procurement procedure established under Article 5 of Decision No 1082/2013/EU, should also be adapted to include an exclusivity clause regarding negotiation and procurement for participating countries in a joint procurement procedure, to allow for better coordination within the EU. The Commission should ensure coordination and information exchange between the entities organizing any action under different mechanisms established under this Regulation and other relevant Union structures related to procurement and stockpiling of medical countermeasures, such as the strategic rescEU reserve under Decision No 1313/2013/EU of the European Parliament and of the Council <sup>(16)</sup>.

<sup>(16)</sup> Decision No 1313/2013/EU of the European Parliament and of the Council of 17 December 2013 on a Union Civil Protection Mechanism (OJ L 347, 20.12.2013, p. 924).

Amendment

- (9) As serious cross-border threats to health are not limited to Union borders, **the Union should adopt a coordinated approach, characterised by solidarity and responsibility, in combatting such threats.** The joint procurement of medical countermeasures should, **therefore**, be extended to include European Free Trade Association States and Union candidate countries, **the Principality of Andorra, the Principality of Monaco, the Republic of San Marino and the Vatican City State**, in accordance with the applicable Union legislation. **Joint procurement of medical countermeasures would strengthen the negotiating position of participating countries, improve the security of supply and ensure equitable access to medical countermeasures. Joint procurement procedures, including purchases coordinated by the HERA and related emergency funding programmes, such as rescEU, should abide by high standards of transparency, including in relation to the disclosure of the amounts ordered by and delivered to each participating country and details of their liabilities.** The Joint Procurement Agreement, determining the practical arrangements governing the joint procurement procedure established under Article 5 of Decision No 1082/2013/EU, should also be adapted to include an exclusivity clause regarding negotiation and procurement for participating countries in a joint procurement procedure, to allow for better coordination within the EU. **The exclusivity clause should entail that countries participating in the joint procurement procedure do not negotiate and sign parallel contracts with producers, and define clear consequences for those that do.** The Commission should ensure coordination and information exchange between the entities organizing **and participating in** any action under different mechanisms established under this Regulation and other relevant Union structures related to procurement and stockpiling of medical countermeasures, such as the **framework of measures adopted under a Council Regulation on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level, and the strategic rescEU reserve** under Decision No 1313/2013/EU of the European Parliament and of the Council <sup>(16)</sup>. **The Member States should ensure**

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Text proposed by the Commission

Amendment

***a sufficient reserve of critical medical products to counter the risk of shortages of critical products.***

<sup>(16)</sup> Decision No 1313/2013/EU of the European Parliament and of the Council of 17 December 2013 on a Union Civil Protection Mechanism (OJ L 347, 20.12.2013, p. 924).

#### Amendment 16

#### Proposal for a regulation

#### Recital 9 a (new)

Text proposed by the Commission

Amendment

***(9a) Joint procurement should be based on shared responsibilities and a fair approach with rights and obligations for all parties involved. Clear commitments should be provided and respected, with manufacturers delivering the agreed production levels and the authorities purchasing their agreed reserved volumes.***

#### Amendment 17

#### Proposal for a regulation

#### Recital 9 b (new)

Text proposed by the Commission

Amendment

***(9b) In times of crisis, temporary measures should be introduced by the Commission to mitigate shortages and facilitate the circulation of medicines between Member States, including the acceptance of different packaging formats, a reuse procedure to enable marketing authorisation holders to obtain approval in another Member State, extending the validity of good manufacturing practices certificates, longer expiry periods, and the use of veterinary medicinal products. The Commission should strictly monitor the use of such measures, to ensure that patient safety is not compromised and to keep medicines available in the event of difficulties or shortages.***

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**Amendment 18**  
**Proposal for a regulation**  
**Recital 9 c (new)**

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*Text proposed by the Commission*

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*Amendment*

- (9c) *Joint procurement should be carried out in a transparent, timely and effective way. In this respect, clear and transparent stages for the process, scope, tender, specifications, timelines and formalities should be defined. A preliminary consultation phase, subject to adequate safeguards against conflict of interest and asymmetry of information, involving relevant actors should be guaranteed, as well as two-way communication throughout the procedure.*

**Amendment 19**  
**Proposal for a regulation**  
**Recital 9 d (new)**

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*Text proposed by the Commission*

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*Amendment*

- (9d) *The Commission should pay special attention to ensuring that joint procurement of medical counter-measures within the meaning of Article 12 also includes procurement of orphan drugs.*

**Amendment 20**  
**Proposal for a regulation**  
**Recital 9 e (new)**

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*Text proposed by the Commission*

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*Amendment*

- (9e) *If joint procurement is deployed, the awarding process should take into account qualitative criteria, such as the ability of the manufacturer to ensure security of supply during a health crisis, as well as price.*

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**Amendment 21**  
**Proposal for a regulation**  
**Recital 9 f (new)**

*Text proposed by the Commission*

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*Amendment*

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- (9f) *In order to achieve transparency, the European Parliament should scrutinise contracts concluded under the Joint Procurement Procedure. The Commission should provide to the Parliament complete, timely and accurate information on the ongoing negotiations and give access to the tender documents as well as to the contracts concluded.*

**Amendment 22**  
**Proposal for a regulation**  
**Recital 9 g (new)**

*Text proposed by the Commission*

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*Amendment*

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- (9g) *Where a joint procurement procedure has not been used to purchase medical countermeasures, the Commission should encourage Member States to exchange information on pricing and delivery dates of medical countermeasures, to provide an increased level of transparency and thus allow Member States to access and negotiate medical countermeasures in more equitable conditions.*

**Amendment 23**  
**Proposal for a regulation**  
**Recital 9 h (new)**

*Text proposed by the Commission*

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*Amendment*

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- (9h) *In times of crisis, other mechanisms should be used to enable global response and crises mitigation. Such mechanisms could, for example, include a Union export control mechanism, enhanced cooperation agreements on the production of medical countermeasures, pre-allocating part of the Union joint procurement, and both voluntary and compulsory technology know-how pools and licensing agreements between companies, which should facilitate access to counter-measures for people, including those in Eastern Partnership and low- and middle-income countries.*

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**Amendment 24**  
**Proposal for a regulation**

**Recital 10**

*Text proposed by the Commission*

- (10) Unlike for communicable diseases, the surveillance of which at Union level is carried out on a permanent basis by the ECDC, other potentially serious cross-border threats to health do not currently necessitate monitoring by EU Agencies. A risk-based approach, whereby monitoring is carried out by Member States and available information is exchanged through EWRS, is therefore more appropriate for such threats.

*Amendment*

- (10) Unlike for communicable diseases, the surveillance of which at Union level is carried out on a permanent basis by the ECDC, other potentially serious cross-border threats to health do not currently necessitate monitoring by EU Agencies. A risk-based approach, whereby monitoring is carried out by Member States and available information is exchanged through EWRS, is therefore more appropriate for such threats. **Nevertheless, the ECDC should have the ability to monitor the impact of communicable diseases on major non-communicable diseases, including mental diseases, assessing the continuity of screening, diagnosis, monitoring, treatment and care in the healthcare system, in coordination with existing data sets, tools and registers.**

**Amendments 25 and 250**

**Proposal for a regulation**

**Recital 11**

*Text proposed by the Commission*

- (11) The Commission should strengthen cooperation and activities with the Member States, the ECDC, the European Medicines Agency ('EMA'), other Union Agencies, research infrastructures and the WHO to improve the prevention of communicable diseases, such as vaccine preventable diseases, as well as other health issues, such as antimicrobial resistance.

*Amendment*

- (11) The Commission, **in particular the HERA**, should strengthen cooperation and activities with the Member States, the ECDC, the European Medicines Agency('EMA'), other Union Agencies **or bodies**, research infrastructures and the WHO to improve, **through the One Health approach**, the prevention of communicable diseases, such as vaccine preventable diseases, as well as other health issues, such as antimicrobial resistance, **and other major non-communicable diseases. During health crises, particular attention should be paid to the continuity of screening, diagnosis, monitoring, treatment and care for other diseases and conditions, and to the mental health implications of the crisis and psychosocial needs of the population.**

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**Amendment 26**  
**Proposal for a regulation**  
**Recital 12**

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*Text proposed by the Commission*

- (12) In case of cross-border health threats due to a communicable disease, the blood and transplant services in the Member States can provide a means for rapid testing of the donor population and assessing exposure to and immunity from the disease in the general population. These services in return are dependent on rapid risk assessments by the ECDC to safeguard patients, in need of a therapy from a substance of human origin, from a transmission of such communicable disease. Such risk assessment serves then as basis to allow for the appropriate adaptation of measures setting standards for quality and safety of such substances of human origin. The ECDC should therefore set up and operate a network of national blood and transplant services and their authorities to serve this dual purpose.

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*Amendment*

- (12) In case of cross-border health threats due to a communicable disease, the blood and transplant services, **pharmacies and other licensed health care establishments** in the Member States can provide a means for rapid testing of the donor population and assessing exposure to and immunity from the disease in the general population. These services in return are dependent on rapid risk assessments by the ECDC to safeguard patients, in need of a therapy from a substance of human origin or **undergoing a process of medically assisted reproduction** from a transmission of such communicable disease. Such risk assessment serves then as basis to allow for the appropriate adaptation of measures setting standards for quality and safety of such substances of human origin. The ECDC should therefore set up and operate a network of national blood and transplant services and their authorities, **as well as pharmacy services and other licensed health services and establishments**, to serve this dual purpose.

**Amendments 27 and 251**  
**Proposal for a regulation**  
**Recital 12 a (new)**

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*Text proposed by the Commission*

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*Amendment*

- (12a) ***In order to improve early preparedness for, and response to, the emergence of cross-border health threats, it is crucial to enable continuous and rapid access to data on the availability of the necessary medical countermeasures. Therefore, a network of Member States' services providing up-to-date information on national strategic stockpiles and the availability of medical countermeasures, stockpiles of medical products, essential health products and diagnostic tests should be established, operated and coordinated at Union level by the HERA. Strengthening coordination and exchange of information with Member States on strategic stockpiles and medical countermeasures available is necessary to enhance the collection, modelling and use of prospective data that allow early alert notifications in the Union.***

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**Amendment 28**  
**Proposal for a regulation**  
**Recital 13**

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*Text proposed by the Commission*

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(13) A system enabling the notification at Union level of alerts related to serious cross-border threats to health has been put in place by Decision No 2119/98/EC in order to ensure that competent public health authorities in Member States and the Commission are duly informed in a timely manner. All serious cross-border threats to health covered by this Regulation are covered by the EWRS. The operation of the EWRS should remain within the remit of the ECDC. The notification of an alert should be required only where the scale and severity of the threat concerned are or could become so significant that they affect or could affect more than one Member State and require or could require a coordinated response at the Union level. To avoid duplication and ensure coordination across Union alert systems, the Commission and ECDC should ensure that alert notifications under the EWRS and other rapid alert systems at Union level are linked to each **other to** the extent possible so that the competent authorities of the Member States can avoid as much as possible notifying the same alert through different systems at Union level and can benefit from receiving all-hazard alerts from a single coordinated source.

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*Amendment*

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(13) A system enabling the notification at Union level of alerts related to serious cross-border threats to health has been put in place by Decision No 2119/98/EC in order to ensure that competent public health authorities in Member States and the Commission are duly informed in a timely manner. All serious cross-border threats to health covered by this Regulation are covered by the EWRS. The operation of the EWRS should remain within the remit of the ECDC. The notification of an alert should be required only where the scale and severity of the threat concerned are or could become so significant that they affect or could affect more than one Member State and require or could require a coordinated response at the Union level. To avoid duplication and ensure coordination across Union alert systems, the Commission and ECDC should ensure that alert notifications under the EWRS and other rapid alert systems at Union level are **fully interoperable and, subject to human oversight, automatically** linked to each **other to** the extent possible so that the competent authorities of the Member States can avoid as much as possible notifying the same alert through different systems at Union level and can benefit from receiving all-hazard alerts from a single coordinated source.

Thursday 11 November 2021

**Amendment 29**  
**Proposal for a regulation**  
**Recital 14**

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*Text proposed by the Commission*

- (14) In order to ensure that the assessment of risks to public health at the Union level from serious cross-border threats to health is consistent as well as comprehensive from a public health perspective, the available scientific expertise should be mobilised in a coordinated manner, through appropriate channels or structures depending on the type of threat concerned. That assessment of risks to public health should be developed by means of a fully transparent process and should be based on principles of excellence, independence, impartiality and transparency. The involvement of Union agencies in these risk assessments needs to be broadened according to their speciality in order to ensure an all hazard approach, via a permanent network of agencies and relevant Commission services to support the preparation of risk assessments.

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*Amendment*

- (14) In order to ensure that the assessment of risks to public health at the Union level from serious cross-border threats to health is consistent as well as comprehensive from a public health perspective, the available scientific expertise should be mobilised in a coordinated **and multidisciplinary** manner, through appropriate channels or structures depending on the type of threat concerned. That assessment of risks to public health should be developed by means of a fully transparent process and should be based on principles of excellence, independence, impartiality and transparency. The involvement of Union agencies **and bodies** in these risk assessments needs to be broadened according to their speciality in order to ensure an all hazard approach, via a permanent network of agencies and relevant Commission services to support the preparation of risk assessments. ***In order to achieve a sufficient degree of expertise and effectiveness, the financial and human resources of Union agencies and bodies should be increased.***

**Amendments 30 and 252**  
**Proposal for a regulation**  
**Recital 14 a (new)**

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*Text proposed by the Commission*

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*Amendment*

- (14a) ***Member States, the Commission, in particular the HERA, and Union agencies, while applying the One Health approach, should identify recognised public health organisations and experts, both in the area of communicable and major non-communicable diseases, and other relevant stakeholders across sectors, available to assist in Union responses to health threats. Such experts and stakeholders, including civil society organisations, should be structurally engaged throughout all crisis response activities and contribute to the decision-making processes. National authorities should also consult and involve representatives of patient organisations and national social partners in the healthcare and social services sector in the implementation of this regulation where appropriate. It is essential that there be full compliance with transparency and conflict of interest rules for stakeholder engagement.***

Thursday 11 November 2021

**Amendment 31**  
**Proposal for a regulation**  
**Recital 14 b (new)**

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*Text proposed by the Commission*

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*Amendment*

- (14b) *Green lanes should only be considered as an appropriate tool for pandemic situations of a declared public health emergency where they are aimed at ensuring that essential goods, medical countermeasures and cross border workers circulate freely and safely within the internal market. The creation of green lanes in such situations should not affect the relevant treaty provisions or legislation regulating border controls.*

**Amendment 32**  
**Proposal for a regulation**  
**Recital 15 a (new)**

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*Text proposed by the Commission*

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*Amendment*

- (15a) *The Commission should ensure that, at the time of the declaration of a state of emergency, the number of accommodation facilities in hospitals in the Member States, as well as the number of available accommodation units in intensive care units in the Member States, are known, for the purpose of cross-border movement of patients.*

**Amendment 33**  
**Proposal for a regulation**  
**Recital 16 a (new)**

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*Text proposed by the Commission*

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*Amendment*

- (16a) *Regular dialogue and exchange of information between authorities, industry, relevant entities of the pharmaceutical supply chain, healthcare professionals' and patients' organisations should also be ensured, in order to start early discussions about expected potential serious cross-border threats to health in the market, by way of sharing information about expected supply constraints or raising specific clinical needs, thereby allowing better coordination, synergies and appropriate reaction when needed.*

Thursday 11 November 2021

**Amendment 34**  
**Proposal for a regulation**  
**Recital 17**

*Text proposed by the Commission*

(17) Inconsistent communication with the public and stakeholders such as healthcare professionals can have a negative impact on the effectiveness of the response from a public health perspective as well as on economic operators. The coordination of the response within the HSC, assisted by relevant subgroups, should, therefore, encompass rapid information exchange concerning communication messages and strategies and addressing communication challenges with a view to coordinating risk and crisis communication, based on robust and independent evaluation of public health risks, to be adapted to national needs and circumstances. Such exchanges of information are intended to facilitate the monitoring of the clarity and coherence of messages to the public and to healthcare professionals. Given the cross-sectoral nature of this type of crises, coordination should also be ensured with other relevant constituencies, such as the Union Civil Protection Mechanism established by Decision (EU) 2019/420 of the European Parliament and of the Council<sup>(17)</sup>.

<sup>(17)</sup> Decision (EU) 2019/420 of the European Parliament and of the Council of 13 March 2019 amending Decision No 1313/2013/EU on a Union Civil Protection Mechanism (OJ L 77 I, 20.3.2019, p. 1).

*Amendment*

(17) Inconsistent communication with the public and stakeholders such as healthcare **and public health** professionals can have a negative impact on the effectiveness of the response from a public health perspective as well as on economic operators. The coordination of the response within the HSC, assisted by relevant subgroups, should, therefore, encompass rapid information exchange concerning communication messages and strategies and addressing communication challenges with a view to coordinating risk and crisis communication, based on **holistic**, robust and independent evaluation of public health risks, to be adapted to national **and regional** needs and circumstances. **In those Member States with regions having health competences, those regions should provide this information.** Such exchanges of information are intended to facilitate the monitoring of the clarity and coherence of messages to the public and to healthcare professionals. **Following its recommendations to Member States and healthcare professionals, the ECDC should broaden its communication activity to include the general public by establishing and managing an online portal to share verified information and fight against disinformation.** Given the cross-sectoral nature of this type of crises, coordination should also be ensured with other relevant constituencies, such as the Union Civil Protection Mechanism established by Decision (EU) 2019/420 of the European Parliament and of the Council<sup>(17)</sup>.

<sup>(17)</sup> Decision (EU) 2019/420 of the European Parliament and of the Council of 13 March 2019 amending Decision No 1313/2013/EU on a Union Civil Protection Mechanism (OJ L 77 I, 20.3.2019, p. 1).

Thursday 11 November 2021

## Amendments 35 and 253

## Proposal for a regulation

## Recital 18

*Text proposed by the Commission*

- (18) The recognition of public health emergency situations and the legal effects of this recognition provided by Decision No 1082/2013/EU should be broadened. To this end, this Regulation should allow for the Commission to formally recognise a public health emergency at Union level. In order to recognise such an emergency situation, the Commission should establish an independent advisory committee that will provide expertise on whether a threat constitutes a public health emergency at Union level, and advise on public health response measures and on the termination of this emergency recognition. The advisory committee should consist of independent experts, selected by the Commission from the fields of expertise and experience most relevant to the specific threat that is occurring, representatives of the ECDC, of the EMA, and of other Union bodies or agencies as observers. Recognition of a public health emergency at Union level will provide the basis for introducing operational public health measures for medical products and medical devices, flexible mechanisms to develop, procure, manage and deploy medical countermeasures as well as the activation of support from the ECDC to mobilise and deploy outbreak assistance teams, known as 'EU Health Task Force'.

*Amendment*

- (18) The recognition of public health emergency situations and the legal effects of this recognition provided by Decision No 1082/2013/EU should be broadened. To this end, this Regulation should allow for the Commission to formally recognise a public health emergency at Union level. In order to recognise such an emergency situation, the Commission should establish an independent advisory committee that will provide expertise on whether a threat constitutes a public health emergency at Union level, and advise on public health response measures and on the termination of this emergency recognition. The advisory committee should consist of independent experts, **representatives of health and care workers, including nurses and medical doctors, and representatives of civil society**, selected by the Commission from the fields of expertise and experience most relevant to the specific threat that is occurring, representatives of the ECDC, of the EMA, **of the HERA** and of other Union bodies or agencies as observers. **All members of the Advisory Committee should provide declarations of interest. The advisory committee should work in close cooperation with national advisory bodies.** Recognition of a public health emergency at Union level will provide the basis for introducing operational public health measures for medical products and medical devices, **Union export control mechanisms**, flexible mechanisms to develop, procure, manage and deploy medical countermeasures **through the HERA** as well as the activation of support from the ECDC to mobilise and deploy outbreak assistance teams, known as 'EU Health Task Force'. **The recognition of a public health emergency may trigger the activation of the framework set out in a Council Regulation on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level. That framework should remain operational for an initial period of 6 months, renewable as long as the public health emergency exists.**

Thursday 11 November 2021

**Amendment 36**  
**Proposal for a regulation**  
**Recital 20**

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*Text proposed by the Commission*

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(20) The occurrence of an event that corresponds to serious cross-border threats to health and is likely to have Union-wide consequences should require the Member States concerned to take particular control or contact-tracing measures in a coordinated manner in order to identify people already contaminated and those persons exposed to risk. Such cooperation could require the exchange of personal data through the system, including sensitive information related to health and information about confirmed or suspected human cases of the disease, between those Member States directly involved in the contact-tracing measures. The exchange of personal data concerning health by the Member States has to comply with Article 9(2)(i) of Regulation (EU) 2016/679 of the European Parliament and of the Council <sup>(18)</sup>.

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<sup>(18)</sup> 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 repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1).

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*Amendment*

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(20) The occurrence of an event that corresponds to serious cross-border threats to health and is likely to have Union-wide consequences should require the Member States **concerned or potentially** concerned to take particular control or contact-tracing measures in a coordinated manner in order to identify people already contaminated and those persons exposed to risk. Such cooperation could require the exchange of personal data through the system, including sensitive information related to health and information about confirmed or suspected human cases of the disease **or infection**, between those Member States directly involved in the contact-tracing measures. The exchange of personal data concerning health by the Member States has to comply with Article 9(2)(i) of Regulation (EU) 2016/679 of the European Parliament and of the Council <sup>(18)</sup>.

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<sup>(18)</sup> 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 repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1).

Thursday 11 November 2021

**Amendment 37**  
**Proposal for a regulation**  
**Recital 21**

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*Text proposed by the Commission*

- (21) Cooperation with third countries and international organisations in the field of public health should be fostered. It is particularly important to ensure the exchange of information with the WHO on the measures taken pursuant to this Regulation. This reinforced cooperation is also required to contribute to EU's commitment to strengthening support to health systems and reinforcing partners' preparedness and response capacity. The Union could benefit from concluding international cooperation agreements with third countries or international organisations, including the WHO, to foster the exchange of relevant information from monitoring and alerting systems on serious cross-border threats to health. Within the limits of the Union's competences, such agreements could include, where appropriate, the participation of such third countries or international organisations in the relevant epidemiological surveillance monitoring network and the EWRS, exchange of good practice in the areas of preparedness and response capacity and planning, public health risk-assessment and collaboration on response coordination, including the research response.

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*Amendment*

- (21) Cooperation with third countries and international organisations in the field of public health should be fostered. It is particularly important to ensure the exchange of information with the WHO on the measures taken pursuant to this Regulation. This reinforced cooperation is also required to contribute to EU's commitment to strengthening support to health systems and reinforcing partners' preparedness and response capacity. The Union could benefit from concluding international cooperation agreements with third countries or international organisations, including the WHO, to foster the exchange of relevant information from monitoring and alerting systems on serious cross-border threats to health. Within the limits of the Union's competences, such agreements could include, where appropriate, the participation of such third countries or international organisations in the relevant epidemiological surveillance monitoring network, **such as the European Surveillance System (TESSy)**, and the EWRS, exchange of good practice in the areas of preparedness and response capacity and planning, public health risk-assessment and collaboration on response coordination, including the research response. **The Commission and the Member States should actively work towards the establishment of a WHO framework convention on pandemic preparedness and response, which should lay down principles and priorities for pandemic preparedness and response. Such a framework convention should facilitate the implementation of the International Health Regulations (2005) <sup>(1a)</sup> and should support the strengthening of the international health framework and the improvement of cooperation with regard to early detection, prevention, response and resilience in respect of future pandemics.**

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<sup>(1a)</sup> World Health Organisation International Health Regulations (2005) Third Edition available at <https://www.who.int/publications/i/item/9789241580496>

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**Amendment 38**  
**Proposal for a regulation**  
**Recital 22**

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*Text proposed by the Commission*

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(22) The processing of personal data for the purpose of implementing this Regulation should comply with Regulation (EU) 2016/679 and Regulation (EU) 2018/1725 of the European Parliament and of the Council<sup>(19)</sup>. In particular, the operation of the EWRS should provide for specific safeguards for the safe and lawful exchange of personal data for the purpose of contact tracing measures implemented by Member States at national level. In this regard, the EWRS includes a messaging function in which personal data, including contact and health data, can be communicated to relevant authorities involved in contact tracing measures.

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<sup>(19)</sup> 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).

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*Amendment*

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(22) ***Due to the sensitive nature of health data, Member States, the Commission and Union agencies should safeguard and guarantee that their processing operations respect the data protection principles in accordance with Article 5 of the GDPR.*** The processing of personal data for the purpose of implementing this Regulation should comply with the GDPR and Regulation (EU) 2018/1725 of the European Parliament and of the Council<sup>(19)</sup>. In particular, the operation of the EWRS should provide for specific safeguards for the safe and lawful exchange of personal data for the purpose of contact tracing measures implemented by Member States at national level. In this regard, the EWRS includes a messaging function in which personal data, including contact and health data, can be communicated to relevant authorities involved in contact tracing. ***Regulation (EU) 2018/1725 of the European Parliament and of the Council should be strictly respected and appropriate technical and organisational security measures, in accordance with that Regulation, should be put in place.***

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<sup>(19)</sup> 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).

Thursday 11 November 2021

**Amendment 39**  
**Proposal for a regulation**  
**Recital 25**

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*Text proposed by the Commission*

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(25) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission to adopt implementing acts in relation to: templates to be used when providing the information on preparedness and response planning; organisation of the training activities for health care and public health staff; the establishment and update of a list of communicable diseases and related special health issues subject to the network of epidemiological surveillance **and the procedures for the operation of such a network; the adoption of case definitions for those communicable diseases and special health issues covered by the epidemiological surveillance network and, where necessary, for other serious cross-border threats to health subject to ad hoc monitoring; the procedures for the operation of the EWRS; the functioning of the surveillance platform;** the designation of EU reference laboratories to provide support to national reference laboratories; the procedures for the information exchange on and the coordination of the responses of the Member States; the recognition of situations of public health emergency at Union level and the termination of such a recognition and procedures necessary to ensure that the operation of the EWRS and the processing of data are in accordance with the data protection legislation.

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*Amendment*

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(25) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission to adopt implementing acts in relation to: templates to be used when providing the information on preparedness and response planning; organisation of the training activities for health care and public health staff; the establishment and update of a list of communicable diseases and related special health issues subject to the **procedures for the operation of the** network of epidemiological surveillance; the designation of EU reference laboratories to provide support to national **and regional** reference laboratories; the procedures for the information exchange on and the coordination of the responses of the Member States; the recognition of situations of public health emergency at Union level and the termination of such a recognition and procedures necessary to ensure that the operation of the EWRS and the processing of data are in accordance with the data protection legislation.

Thursday 11 November 2021

**Amendment 40**  
**Proposal for a regulation**  
**Recital 28**

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*Text proposed by the Commission*

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(28) In order to ascertain the state of implementation of the national preparedness plans and their coherence with the Union plan, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission **in respect of** procedures, standards and criteria for the audits aimed at the assessment of preparedness and response planning at national level. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016<sup>(21)</sup>. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

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<sup>(21)</sup> OJ L 123, 12.5.2016, p. 1.

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*Amendment*

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(28) ***In order to supplement certain aspects of this Regulation and*** to ascertain the state of implementation of the national ***and regional*** preparedness plans and their coherence with the Union plan, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission ***in respect of: the establishment and updating of a list of communicable diseases and related special health issues subject to the network of epidemiological surveillance; the adoption of case definitions for those communicable diseases and special health issues covered by the epidemiological surveillance network and, where necessary, for other serious cross-border threats to health that are the subject of ad hoc monitoring; the requirements necessary to ensure the compliance of the operation of the EWRS and the processing of data with the relevant Regulations; the establishment and updating of a list of relevant health data to be automatically collected by a digital platform, subject to human oversight; the functioning of the surveillance platform; and the*** procedures, standards and criteria for the audits aimed at the assessment of preparedness and response planning at national ***and regional*** level. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016<sup>(21)</sup>. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

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<sup>(21)</sup> OJ L 123, 12.5.2016, p. 1

Thursday 11 November 2021

**Amendment 41**  
**Proposal for a regulation**  
**Recital 28 a (new)**

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*Text proposed by the Commission*

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*Amendment*

(28a) *In respect of the establishment and updating of a list of communicable diseases and related special health issues subject to the network of epidemiological surveillance and the procedures for the operation of such a network, the adoption of case definitions for those communicable diseases and special health issues covered by the epidemiological surveillance network and the case definitions to be used for ad hoc monitoring, the Commission should adopt delegated acts under the urgency procedure where duly justified imperative grounds of urgency related to the severity or novelty of a serious cross-border threat to health or to the rapidity of its spread between the Member States so require.*

**Amendment 42**  
**Proposal for a regulation**  
**Article 1 — paragraph 1 — point c**

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*Text proposed by the Commission*

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*Amendment*

(c) joint procurement of medical countermeasures;

(c) joint procurement, **management and deployment** of medical countermeasures;

**Amendment 254**  
**Proposal for a regulation**  
**Article 1 — paragraph 1 — point c a (new)**

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*Text proposed by the Commission*

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*Amendment*

(ca) **emergency research and innovation plans, including clinical trial networks and innovation platforms;**

**Amendment 43**  
**Proposal for a regulation**  
**Article 1 — paragraph 2 — point b a (new)**

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*Text proposed by the Commission*

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*Amendment*

(ba) **a network of national strategic stockpiles and available medical countermeasures;**

Thursday 11 November 2021

#### Amendment 44

##### Proposal for a regulation

##### Article 1 — paragraph 3

*Text proposed by the Commission*

3. The implementation of this Regulation shall be supported by funding from relevant Union programmes and instruments.

*Amendment*

3. ***In keeping with the ‘One Health’ and ‘Health in all policies’ approaches***, the implementation of this Regulation shall be supported by funding from relevant Union programmes and instruments. ***The strengthened Union health framework addressing serious cross-border health threats shall work in synergy with and in a manner that is complementary to other Union policies and funds, such as actions implemented under the EU4Health programme, the European Structural and Investment Funds (ESIF), Horizon Europe, the Digital Europe Programme, rescEU reserve, the European Social Fund Plus (ESF+), the Emergency Support Instrument (ESI) and the Single Market Programme (SMP).***

#### Amendment 45

##### Proposal for a regulation

##### Article 1 — paragraph 3 a (new)

*Text proposed by the Commission*

*Amendment*

***3a. This Regulation shall ensure that in future health emergencies, the detection of, health interventions concerning and treatment of other serious diseases are not halted.***

#### Amendment 46

##### Proposal for a regulation

##### Article 1 — paragraph 3 b (new)

*Text proposed by the Commission*

*Amendment*

***3b. This Regulation shall be implemented with full respect for the dignity and fundamental rights and freedoms of persons.***

#### Amendment 243

##### Proposal for a regulation

##### Article 2 — paragraph 1 — point a — point i

*Text proposed by the Commission*

*Amendment*

(i) communicable diseases;

(i) communicable diseases, ***including those of zoonotic origin;***

Thursday 11 November 2021

**Amendment 47****Proposal for a regulation****Article 2 — paragraph 2**

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*Text proposed by the Commission*

2. This Regulation shall also apply to the epidemiological surveillance of communicable diseases **and of** related special health issues.

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*Amendment*

2. This Regulation shall also apply to the epidemiological surveillance of communicable diseases, **the monitoring of the impact of such diseases on major non-communicable diseases and on** related special health issues, **such as mental health, and the impact on deferred screening, diagnosis, monitoring, treatment and care for other diseases and conditions.**

**Amendment 48****Proposal for a regulation****Article 2 — paragraph 3 a (new)**

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*Text proposed by the Commission*

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*Amendment*

**3a. This Regulation shall promote the implementation of the International Health Regulations, reduce administrative burden and duplication of resources, and strengthen the gaps exposed during the COVID-19 pandemic in the prevention of, preparedness for and response to public health threats.**

**Amendment 49****Proposal for a regulation****Article 2 — paragraph 4**

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*Text proposed by the Commission*

4. In exceptional emergency situations, a Member State or the Commission may request the coordination of response within the HSC as referred to in Article 21, for serious cross-border threats to health other than those referred to in Article 2(1), if it is considered that public health measures taken previously have proven insufficient to ensure a high level of protection of human health.

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*Amendment*

4. In exceptional emergency situations, a Member State or the Commission may request the coordination of response within the HSC as referred to in Article 21, for serious cross-border threats to health other than those referred to in Article 2(1), **especially in relation to major non-communicable diseases**, if it is considered that public health measures taken previously have proven insufficient to ensure a high level of protection of human health.

Thursday 11 November 2021

**Amendment 50****Proposal for a regulation****Article 2 — paragraph 5***Text proposed by the Commission*

5. The Commission shall, in liaison with the Member States, ensure coordination and information exchange between the mechanisms and structures established under this Regulation and similar mechanisms and structures established at Union level or under the Euratom Treaty whose activities are relevant for preparedness and response planning, monitoring, early warning of, and combating serious cross-border threats to health.

*Amendment*

5. The Commission shall, in liaison with the Member States, ensure coordination and information exchange between the mechanisms and structures established under this Regulation and similar mechanisms and structures established at **international level**, Union level or under the Euratom Treaty whose activities are relevant for preparedness and response planning, monitoring, early warning of, and combating serious cross-border threats to health.

**Amendment 51****Proposal for a regulation****Article 2 — paragraph 6***Text proposed by the Commission*

6. Member States shall retain the right to maintain or introduce additional arrangements, procedures and measures for their national systems in the fields covered by this Regulation, including arrangements provided for in existing or future bilateral or multilateral agreements or conventions, on condition that such additional arrangements, procedures and measures do not impair the application of this Regulation.

*Amendment*

6. Member States shall retain the right to maintain or introduce additional arrangements, procedures and measures for their national systems in the fields covered by this Regulation, including arrangements provided for in existing or future bilateral or multilateral agreements or conventions, on condition that such additional arrangements, procedures and measures do not impair the application of this Regulation. **The Union shall call for the establishment of a WHO framework convention on pandemic preparedness and response. That convention shall be such as to facilitate the implementation of the International Health Regulation (2005) <sup>(1a)</sup> and resolve the weaknesses of that Regulation, identified during the COVID-19 crisis.**

<sup>(1a)</sup> World Health Organization. International Health Regulation (IHR, 2005) <https://www.who.int/ihr/publications/9789241596664/en/>

**Amendment 52****Proposal for a regulation****Article 2 — paragraph 6 a (new)***Text proposed by the Commission**Amendment*

**6a. This Regulation shall also apply, where appropriate, to regional competent authorities, systems and programmes in the fields covered by this Regulation.**

Thursday 11 November 2021

**Amendment 255****Proposal for a regulation****Article 3 — paragraph 1 — point - 1 (new)**

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*Text proposed by the Commission*

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*Amendment*

- (-1) **'public health emergency'** means a public health emergency at Union level recognised by the Commission based on an opinion of the Advisory Committee in accordance with Article 23 of this Regulation;

**Amendment 53****Proposal for a regulation****Article 3 — paragraph 1 — point 3**

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*Text proposed by the Commission*

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*Amendment*

- (3) 'contact tracing' means measures **implemented in order to trace** persons who have been exposed to a source of a serious cross-border threat to health, and who are in danger of **developing** or have developed a disease, through manual or other technological means;

- (3) 'contact tracing' means measures **to identify, assess and manage** persons who have been exposed to a source of a serious cross-border threat to health, and who are in danger of **being infected or being infectious** or who have developed a **communicable** disease, through manual or other technological means, **with the sole objective of rapidly identifying potentially newly infected persons who may have come into contact with existing cases, in order to reduce further onward transmission;**

**Amendment 54****Proposal for a regulation****Article 3 — paragraph 1 — point 4**

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*Text proposed by the Commission*

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*Amendment*

- (4) 'epidemiological surveillance' means the systematic collection, recording, analysis, interpretation and dissemination of data and analysis on communicable diseases and related special health issues;

- (4) 'epidemiological surveillance' means the systematic collection, recording, analysis, interpretation and dissemination of data and analysis on communicable diseases, **the monitoring of the impact of such diseases on major non-communicable diseases, such as those relating to mental health,** and on related special health issues;

Thursday 11 November 2021

**Amendment 55**

**Proposal for a regulation**

**Article 3 — paragraph 1 — point 5 a (new)**

*Text proposed by the Commission*

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*Amendment*

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**(5a) ‘One Health approach’ means a multisectoral approach which recognises that human health is connected to animal health and to the environment, and that actions to tackle threats to health must take into account those three dimensions;**

**Amendment 56**

**Proposal for a regulation**

**Article 3 — paragraph 1 — point 5 b (new)**

*Text proposed by the Commission*

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*Amendment*

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**(5b) ‘Health in All Policies’ means an approach to the development, implementation and review of public policies, regardless of the sector, whereby the health implications of decisions are taken into account, and which seeks to achieve synergies and to avoid harmful health impacts being caused by such policies, in order to improve the health of the population and health equity;**

**Amendment 57**

**Proposal for a regulation**

**Article 3 — paragraph 1 — point 7 a (new)**

*Text proposed by the Commission*

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*Amendment*

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**(7a) ‘major non-communicable disease’ means a disease as defined in point (4a) of Article 2 of Regulation (EU) [ECDC regulation, correct reference to be inserted];**

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**Amendment 58****Proposal for a regulation****Article 3 — paragraph 1 — point 8***Text proposed by the Commission*

(8) ‘medical countermeasure’ means medicinal products for human use and medical devices as defined in Directive 2001/83/EC of the European Parliament and of the Council<sup>(23)</sup> and in Regulation (EU) 2017/745 of the European Parliament and of the Council<sup>(24)</sup> or other goods or services for the **for the** purpose of preparedness and response to a serious cross-border threat to health.

<sup>(23)</sup> Directive 2001/83/EC of the 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).

<sup>(24)</sup> Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on 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, 5.5.2017, p. 1).

*Amendment*

(8) ‘medical countermeasure’ means medicinal products for human use and medical devices as defined in Directive 2001/83/EC of the European Parliament and of the Council<sup>(23)</sup> and in Regulation (EU) 2017/745 of the European Parliament and of the Council<sup>(24)</sup> or other goods or services for the purpose **of facilitating diagnosis and treatment in the framework** of preparedness and response to a serious cross-border threat to health.

<sup>(23)</sup> Directive 2001/83/EC of the 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).

<sup>(24)</sup> Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on 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, 5.5.2017, p. 1).

**Amendment 59****Proposal for a regulation****Article 3 — paragraph 1 — point 8 a (new)***Text proposed by the Commission**Amendment*

**(8a) ‘International Health Regulations’ mean the International Health Regulations adopted by the World Health Organization in 2005;**

**Amendment 60****Proposal for a regulation****Article 3 — paragraph 1 — point 8 b (new)***Text proposed by the Commission**Amendment*

**(8b) ‘medical device’ means both a medical device as defined in point (1) of Article 2 of Regulation (EU) 2017/745, read in conjunction with point (2) of Article 1 and point (a) of Article 1(6) of that Regulation, and an in vitro diagnostic medical device as defined in point (2) of Article 2 of Regulation (EU) 2017/746;**

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### Amendment 61

#### Proposal for a regulation

#### Article 3 — paragraph 1 — point 8 c (new)

Text proposed by the Commission

Amendment

(8c) **'green lanes'** means passable and safe transit corridors that preserve supply chains in the event of a declared public health emergency at Union level in a pandemic situation by ensuring that essential goods, medical countermeasures and cross border workers can circulate freely and safely within the internal market, while fully respecting Article 77 (2)(e) TFEU.

### Amendment 62

#### Proposal for a regulation

#### Article 4 — paragraph 1 a (new)

Text proposed by the Commission

Amendment

1a. **Representatives of relevant Union agencies shall participate in HSC meetings as observers.**

### Amendment 63

#### Proposal for a regulation

#### Article 4 — paragraph 2 — point b

Text proposed by the Commission

Amendment

(b) coordination in liaison with the Commission of the preparedness and response planning of the Member States in accordance with Article 10;

(b) coordination in liaison with the Commission **and relevant Union agencies** of the **prevention**, preparedness and response planning of the Member States in accordance with Article 10;

### Amendment 64

#### Proposal for a regulation

#### Article 4 — paragraph 2 — point c

Text proposed by the Commission

Amendment

(c) coordination in liaison with the Commission of the risk and crisis communication and responses of the Member States to serious cross-border threats to health, in accordance with Article 21;

(c) coordination in liaison with the Commission **and relevant Union agencies** of the risk and crisis communication and responses of the Member States to serious cross-border threats to health, in accordance with Article 21;

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**Amendment 65****Proposal for a regulation****Article 4 — paragraph 2 — point d a (new)**

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*Text proposed by the Commission*

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*Amendment*

**(da) adoption, on an annual basis, of an action programme to clearly set its priorities and objectives at the high level working group and the technical working group levels.**

**Amendment 66****Proposal for a regulation****Article 4 — paragraph 4**

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*Text proposed by the Commission*

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*Amendment*

4. The HSC shall be chaired by a representative of the Commission. The HSC shall meet at regular intervals and whenever the situation requires, on a request from the Commission or a Member State.

4. The HSC shall be chaired by a representative of the Commission **without the right to vote**. The HSC shall meet at regular intervals and whenever the situation requires, on a request from the Commission or a Member State.

**Amendment 67****Proposal for a regulation****Article 4 — paragraph 5 a (new)**

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*Text proposed by the Commission*

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*Amendment*

**5a. Members of the HSC and the Commission shall ensure thorough consultation with relevant Union agencies, public health experts, international organisations and stakeholders, including healthcare professionals.**

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**Amendment 68**

**Proposal for a regulation**

**Article 4 — paragraph 7 a (new)**

*Text proposed by the Commission*

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*Amendment*

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**7a.** *The European Parliament shall designate representatives to participate in the Health Security Committee ('HSC') as observers.*

**Amendment 69**

**Proposal for a regulation**

**Article 4 — paragraph 7 b (new)**

*Text proposed by the Commission*

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*Amendment*

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**7b.** *The list of members of the HSC at both the political and technical levels shall be made public on the Commission and Council websites. Members of the Committee shall have no financial or other interests that could affect their impartiality. They shall act in the public interest and in an independent manner and make an annual declaration of their financial interests. All direct interests which could relate to the medical or another relevant sector shall be entered in a register held by the Commission and be accessible to the public, upon request.*

**Amendment 70**

**Proposal for a regulation**

**Article 4 — paragraph 7 c (new)**

*Text proposed by the Commission*

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*Amendment*

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**7c.** *The rules of procedure, guidance, agendas and minutes of the meetings of the HSC shall be published on the Commission's web-portal.*

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## Amendment 256

## Proposal for a regulation

## Article 4 — paragraph 7 d (new)

*Text proposed by the Commission**Amendment*

7d. The HSC shall act in cooperation with the board of HERA established under the Commission decision of 16 September 2021 establishing the Health Emergency Preparedness and Response Authority, and the Health Crisis Board (HCB) to be established under a Council regulation on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level. The coordination between those bodies shall ensure the participation of all relevant stakeholders, including healthcare professionals' organisations, patients' associations, and industry and supply chain actors with recognised experience in disciplines related to the HSC, HCB and to the work of the HERA. The provisions related to conflict of interests and transparency, as provided for in paragraphs 7b and 7c, shall apply in relation to this paragraph also. The Commission shall invite a representative of the European Parliament to serve as an active member of the HCB.

## Amendment 71

## Proposal for a regulation

## Chapter II — title

*Text proposed by the Commission**Amendment*

II PREPAREDNESS AND RESPONSE PLANNING

II **PREVENTION**, PREPAREDNESS AND RESPONSE PLANNING

## Amendment 72

## Proposal for a regulation

## Article 5 — title

*Text proposed by the Commission**Amendment*

Union preparedness and response plan

Union **prevention**, preparedness and response plan

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### Amendment 73

#### Proposal for a regulation

#### Article 5 — paragraph 1

*Text proposed by the Commission*

1. The Commission, in cooperation with Member States and the relevant Union agencies, shall establish a Union health crisis and pandemic plan ('the Union preparedness and response plan') to promote effective and coordinated response to cross-border health threats at Union level.

*Amendment*

1. The Commission, in cooperation with Member States and the relevant Union agencies **and taking into account the WHO framework**, shall establish a Union health crisis and pandemic plan ('the Union **prevention**, preparedness and response plan') to promote effective and coordinated response to cross-border health threats at Union level.

### Amendment 74

#### Proposal for a regulation

#### Article 5 — paragraph 2

*Text proposed by the Commission*

2. The Union preparedness and response plan shall complement the national preparedness and response plans established in accordance with Article 6.

*Amendment*

2. The Union **prevention**, preparedness and response plan shall complement the national preparedness and response plans established in accordance with Article 6.

### Amendment 75

#### Proposal for a regulation

#### Article 5 — paragraph 3 — introductory part

*Text proposed by the Commission*

3. The Union preparedness and response plan shall, in particular, include arrangements for governance, capacities and resources for:

*Amendment*

3. The Union **prevention**, preparedness and response plan shall, in particular, include arrangements for governance, capacities and resources for:

### Amendment 257

#### Proposal for a regulation

#### Article 5 — paragraph 3 — point a

*Text proposed by the Commission*

(a) the timely cooperation between the Commission, the Member States and the Union agencies;

*Amendment*

(a) the timely cooperation between the Commission, the Member States and the Union agencies **and bodies**;

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**Amendment 258****Proposal for a regulation****Article 5 — paragraph 3 — point b***Text proposed by the Commission*

(b) the secure exchange of information between the Commission, Union agencies and the Member States;

*Amendment*

(b) the secure exchange of information between the Commission, Union agencies and **bodies and** the Member States;

**Amendment 76****Proposal for a regulation****Article 5 — paragraph 3 — point c***Text proposed by the Commission*

(c) the epidemiological surveillance and monitoring;

*Amendment*

(c) the epidemiological surveillance and monitoring, **as well as the impact of communicable diseases on major non-communicable diseases;**

**Amendment 77****Proposal for a regulation****Article 5 — paragraph 3 — point e***Text proposed by the Commission*

(e) the risk and crisis communication;

*Amendment*

(e) the risk and crisis communication, **aimed at health professionals and at citizens;**

**Amendment 78****Proposal for a regulation****Article 5 — paragraph 3 — point f a (new)***Text proposed by the Commission*

(e) the risk and crisis communication;

*Amendment*

**(fa) the mapping of the production capacities of medical products in the Union as a whole;**

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**Amendment 79**

**Proposal for a regulation**

**Article 5 — paragraph 3 — point f b (new)**

*Text proposed by the Commission*

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*Amendment*

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*(fb) the establishment of a Union stock of critical medicinal products, medical countermeasures and personal protective equipment as part of the rescEU emergency reserve;*

**Amendment 259**

**Proposal for a regulation**

**Article 5 — paragraph 3 — point f c (new)**

*Text proposed by the Commission*

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*Amendment*

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*(fc) the implementation of the provisions of the plan relating to emergency research and innovation aspects;*

**Amendment 80**

**Proposal for a regulation**

**Article 5 — paragraph 3 — point g a (new)**

*Text proposed by the Commission*

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*Amendment*

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*(ga) the criteria for activating and deactivating the actions;*

**Amendment 81**

**Proposal for a regulation**

**Article 5 — paragraph 3 — point g b (new)**

*Text proposed by the Commission*

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*Amendment*

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*(gb) ensuring that healthcare services, including the screening, diagnosis, monitoring, treatment and care for other diseases and conditions, are provided without disruption during health emergencies;*

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**Amendment 82****Proposal for a regulation****Article 5 — paragraph 3 — point g c (new)***Text proposed by the Commission**Amendment*

**(gc) ensuring that national health systems are inclusive and provide equal access to health and related services, and that quality treatments are available without delays;**

**Amendment 83****Proposal for a regulation****Article 5 — paragraph 3 — point g d (new)***Text proposed by the Commission**Amendment*

**(gd) an adequate and needs-oriented staffing level;**

**Amendment 84****Proposal for a regulation****Article 5 — paragraph 3 — point g e (new)***Text proposed by the Commission**Amendment*

**(ge) monitoring whether adequate risk assessments, preparedness plans and training courses are foreseen for health and social care professionals.**

**Amendment 85****Proposal for a regulation****Article 5 — paragraph 4***Text proposed by the Commission**Amendment*

4. The Union preparedness and response plan shall include interregional preparedness **elements** to establish coherent, multi-sectoral, cross-border public health measures, in particular considering capacities for testing, contact tracing, laboratories, and specialised treatment or intensive care across neighbouring regions. The plans shall include preparedness and response means to address the situation of those citizens with higher risks.

4. The Union **prevention**, preparedness and response plan shall include **cross-border and** interregional preparedness **plans** to establish coherent, multi-sectoral, cross-border public health measures, in particular considering capacities for testing, contact tracing, laboratories, **training of healthcare staff** and specialised treatment or intensive care across neighbouring regions. The plans shall include preparedness and response means to address the situation of those citizens with higher risks.

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### Amendment 86

#### Proposal for a regulation

#### Article 5 — paragraph 4 a (new)

*Text proposed by the Commission*

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*Amendment*

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**4a.** *The Union preparedness and response plan shall also provide for measures to ensure that the single market functions normally in the event serious cross-border threats to health arise.*

### Amendment 87

#### Proposal for a regulation

#### Article 5 — paragraph 5

*Text proposed by the Commission*

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*Amendment*

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5. In order to ensure the operation of the Union preparedness and response plan, the Commission shall conduct stress tests, exercises and in-action and after-action reviews with Member States, and update the plan as necessary.

5. In order to ensure the operation of the Union **prevention**, preparedness and response plan, the Commission shall conduct stress tests, exercises and in-action and after-action reviews with Member States, and update the plan as necessary. **The prevention, preparedness and response plan shall take into account health systems data and relevant data to be collected at national or regional level.**

### Amendment 88

#### Proposal for a regulation

#### Article 5 — paragraph 5 a (new)

*Text proposed by the Commission*

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*Amendment*

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**5a.** *In order to respond to public health emergencies, the European Commission may issue recommendations, based on Union health systems data, on the minimum resources needed, in relation, among other things, to each Member State's population, for the provision of baseline universal health coverage of adequate quality, including on the option of pooling resources at Union level.*

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**Amendment 89****Proposal for a regulation****Article 5 — paragraph 5 b (new)***Text proposed by the Commission**Amendment*

**5b.** *The reviews and any subsequent adjustments to the plan shall be published to increase the transparency of the process of prevention, preparedness and response planning.*

**Amendment 90****Proposal for a regulation****Article 6 — title***Text proposed by the Commission**Amendment*

National preparedness and response plans

National **prevention**, preparedness and response plans**Amendments 91 and 260****Proposal for a regulation****Article 6 — paragraph 1***Text proposed by the Commission**Amendment*

1. When preparing national preparedness and response plans each Member State shall coordinate with the Commission in order to reach consistency with the Union preparedness and response plan, **also** inform without delay the Commission and the HSC of any substantial revision of the national plan.

1. When preparing national **prevention**, preparedness and response plans each Member State shall **consult patients' organisations, healthcare professionals' organisations, industry and supply chain stakeholders, and national social partners**, coordinate with the Commission, **in particular with the HERA**, in order to reach consistency with the Union **prevention**, preparedness and response plan, **which shall be in accordance with arrangements for governance, capacities and resources referred to in Article 5(3), including with regard to national stockpiling requirements and the management of Union strategic reserves**, and inform without delay the Commission, **the HCB** and the HSC of any substantial revision of the national plan.

**Amendment 92****Proposal for a regulation****Article 6 — paragraph 1 a (new)***Text proposed by the Commission**Amendment*

**1a.** *National prevention, preparedness and response plans shall include arrangements for governance and information on capacities and resources referred to in Article 5(3).*

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**Amendment 93**  
**Proposal for a regulation**  
**Article 7 — title**

*Text proposed by the Commission*

Reporting on preparedness and response planning

*Amendment*

Reporting on **prevention**, preparedness and response planning

**Amendments 94 and 261**  
**Proposal for a regulation**  
**Article 7 — paragraph 1 — subparagraph 1**

*Text proposed by the Commission*

1. Member States shall **by the end of November 2021** and every 2 years thereafter provide the Commission with a report on their preparedness and response planning and implementation at national level.

*Amendment*

1. Member States shall **within 6 months of the entry into force of this regulation** and every 2 years thereafter provide the Commission **and relevant Union agencies and bodies** with an **updated** report on their **prevention**, preparedness and response planning and implementation at national level **and, where appropriate, regional and cross-border levels**.

**Amendment 95**  
**Proposal for a regulation**  
**Article 7 — paragraph 1 — subparagraph 2 — introductory part**

*Text proposed by the Commission*

That report shall cover the following:

*Amendment*

That report **shall be succinct, based on common indicators, give an overview of the actions implemented in the Member States, and** shall cover the following:

**Amendment 96**  
**Proposal for a regulation**  
**Article 7 — paragraph 1 — subparagraph 2 — point a**

*Text proposed by the Commission*

(a) identification of, and update on the status of the implementation of the capacity standards for preparedness and response planning as determined at national level for the health sector, as provided to the WHO in accordance with the IHR;

*Amendment*

(a) identification of, and update on the status of the implementation of the capacity standards for **prevention**, preparedness and response planning as determined at national **and, where appropriate, regional** level for the health sector, as provided to the WHO in accordance with the IHR;

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**Amendment 97****Proposal for a regulation****Article 7 — paragraph 1 — subparagraph 2 — point a a (new)***Text proposed by the Commission**Amendment*

**(aa) a description of the measures or arrangements aimed at ensuring interoperability between the health sector and other sectors that are critical in the case of an emergency;**

**Amendment 98****Proposal for a regulation****Article 7 — paragraph 1 — subparagraph 2 — point a b (new)***Text proposed by the Commission**Amendment*

**(ab) a description of the business continuity plans, measures or arrangements aimed at ensuring the continuous delivery of critical services and products;**

**Amendment 99****Proposal for a regulation****Article 7 — paragraph 1 — subparagraph 2 — point b***Text proposed by the Commission**Amendment*

(b) elements of emergency preparedness, in particular:

**(b) an update, if needed, on the elements of emergency prevention, preparedness and response, in particular:**

**Amendment 100****Proposal for a regulation****Article 7 — paragraph 1 — subparagraph 2 — point b — point i***Text proposed by the Commission**Amendment*

(i) governance: including national policies and legislation that integrate emergency preparedness; plans for emergency preparedness, response and recovery coordination mechanisms;

**(i) governance: including national and, if appropriate, regional policies and legislation that integrate emergency prevention and preparedness; plans for emergency prevention, preparedness, response and recovery coordination mechanisms at national and, where relevant, regional and cross-border levels; continuity of critical long-term healthcare;**

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## Amendment 101

## Proposal for a regulation

## Article 7 — paragraph 1 — subparagraph 2 — point b — point ii

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*Text proposed by the Commission*

(ii) capacities: including assessments of risks and capacities to determine priorities for emergency preparedness; surveillance and early warning, information management; access to diagnostic services during emergencies; basic and safe gender-sensitive health and emergency services; risk communications; research development and evaluations to inform and accelerate emergency preparedness;

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*Amendment*

(ii) capacities: including assessments of risks and capacities to determine priorities for emergency preparedness; surveillance and early warning, information management; **the capacities to produce medicinal products; stocks of medical countermeasures, including personal protective equipment of the highest quality; equitable** access to diagnostic services **and tools, and medical products** during emergencies; **information relevant for the internal market and Union strategic reserves of medical products; equitable, high-quality,** basic and safe gender-sensitive health and emergency services **that take account of the needs of populations at higher risk; continuity of screening, diagnosis, monitoring and treatment for care in relation to other diseases and conditions, in particular critical long-term healthcare;** risk communications; research development and evaluations to inform and accelerate emergency preparedness;

## Amendment 102

## Proposal for a regulation

## Article 7 — paragraph 1 — subparagraph 2 — point b — point iii

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*Text proposed by the Commission*

(iii) resources: including financial resources for emergency preparedness and contingency funding for response; logistics mechanisms and essential supplies for health; **and** dedicated, trained and equipped human resources for emergencies; **and**

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*Amendment*

(iii) resources: including financial resources for emergency preparedness and contingency funding for response; logistics mechanisms and essential supplies for health; **measures to ensure continuity of critical long-term healthcare; and health and social services with an adequate number of** dedicated, trained and equipped human resources for emergencies;

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**Amendment 103****Proposal for a regulation****Article 7 — paragraph 1 — subparagraph 2 — point b — point iii a (new)**

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*Text proposed by the Commission*

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*Amendment*

**(iiia) strategic stockpile: each Member State shall provide information on the number and availability of medical countermeasures and other essential medicinal products and critical medical devices for the control of the threats set out in Article 2(1), as well as the capacity for their safekeeping and storage. In order to have a greater response capacity, storage shall be carried out in the premises closest to and most accessible for the population centres, without compromising the accessibility of those products for people in remote, rural and outermost regions, which meet the necessary requirements to provide the service in accordance with the regulations applicable to medicinal products, medical devices <sup>(1b)</sup> and other medical countermeasures; and**

<sup>(1b)</sup> Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on 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, 5.5.2017, p. 1).

**Amendment 104****Proposal for a regulation****Article 7 — paragraph 1 — subparagraph 2 — point c a (new)**

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*Text proposed by the Commission*

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*Amendment*

**(ca) the consultation with relevant partners that has taken place to ensure risk assessments, prevention, preparedness and response plans and implementation are broadly shared and supported and in line with applicable labour legislation and collective agreements;**

**Amendment 105****Proposal for a regulation****Article 7 — paragraph 1 — subparagraph 2 — point c b (new)**

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*Text proposed by the Commission*

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*Amendment*

**(cb) gaps found in the implementation and any necessary actions that will be taken by the Member States to improve their preparedness and response capacity.**

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## Amendment 106

## Proposal for a regulation

## Article 7 — paragraph 1 — subparagraph 3

Text proposed by the Commission

The report shall include, *whenever relevant*, interregional preparedness and response elements *in line with the Union and national plans, covering in particular the existing capacities, resources* and coordination mechanisms *across neighbouring regions*.

Amendment

*For Member States sharing a land border with at least one other Member State*, the report shall include *cross-border, interregional and intersectoral prevention*, preparedness and response *plans with neighbouring regions including coordination mechanisms for all elements listed in points (a), (b) and (c), cross-border training and sharing of best practices for healthcare staff and public health staff* and coordination mechanisms *for the medical transfer of patients. Union or national entities that are engaged in stockpiling of medical products shall engage with the Commission and Member States in reporting of stocks that are available and taken into account in both Union and national preparedness and response planning.*

## Amendment 107

## Proposal for a regulation

## Article 7 — paragraph 1 — subparagraph 3 a (new)

Text proposed by the Commission

Amendment

*The report shall also include, as far as feasible, information on the impact of communicable diseases on major non-communicable diseases.*

## Amendment 108

## Proposal for a regulation

## Article 7 — paragraph 1 — subparagraph 3 b (new)

Text proposed by the Commission

Amendment

*The latest available version of the prevention, preparedness and response plans shall be attached to the report.*

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**Amendment 262****Proposal for a regulation****Article 7 — paragraph 2 — subparagraph 1***Text proposed by the Commission*

2. The Commission shall make the information received in accordance with paragraph 1 available to the HSC in a report prepared in cooperation with the ECDC and other relevant Union agencies and bodies every 2 years.

*Amendment*

2. The Commission shall make the information received in accordance with paragraph 1 available to the HSC in a report prepared in cooperation with the ECDC and other relevant Union agencies and bodies every 2 years. **For the purpose of drawing up the report, the HERA shall assess the availability of crisis-relevant medical countermeasures, the production capacity for and the existing stockpiles of such countermeasures and the risk of disruption in supply chains in the framework of the national preparedness and response planning, taking into account information obtained pursuant to Regulation (EU) .../... [O]: Please insert the number of the Regulation on EMA [ISC/2020/12532]] and in particular Articles XX [Article numbers to be confirmed after adoption] thereof, concerning the monitoring and mitigation of shortages of critical medicinal products, medical devices and in vitro diagnostic medical devices.**

**Amendment 109****Proposal for a regulation****Article 7 — paragraph 2 — subparagraph 4***Text proposed by the Commission*

The recommendations of the report shall be published on **at the website** of the Commission.

*Amendment*

The recommendations of the report shall be published on **the websites** of the Commission **and the ECDC**.

**Amendment 110****Proposal for a regulation****Article 8 — title***Text proposed by the Commission*

Auditing on preparedness and response planning

*Amendment*

Auditing on **prevention**, preparedness and response planning

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### Amendment 111

#### Proposal for a regulation

#### Article 8 — paragraph 1

*Text proposed by the Commission*

1. Every **3** years, the ECDC shall conduct audits in the Member States aimed at ascertaining the state of implementation of the national plans and their coherence with the Union plan. Such audits shall be implemented with the relevant Union agencies, aiming at the assessment of preparedness and response planning at national level with regard to the information referred to in Article 7(1).

*Amendment*

1. Every **2** years, the ECDC shall conduct audits in the Member States aimed at ascertaining the state of implementation of the national plans and their coherence with the Union plan. Such audits shall be **based on a set of indicators and implemented in cooperation** with the relevant Union agencies, aiming at the assessment of **prevention**, preparedness and response planning at national level with regard to the information referred to in Article 7(1)..

### Amendment 112

#### Proposal for a regulation

#### Article 8 — paragraph 2 — subparagraph 1

*Text proposed by the Commission*

2. Member **States** shall present an action plan addressing the proposed recommendations of the audit and the corresponding corrective actions and milestones.

*Amendment*

2. **In the event the audit identifies deficiencies, the Member State shall, within six months of receipt of its conclusions,** present an action plan addressing the proposed recommendations of the audit and **setting out** the corresponding corrective actions and milestones.

### Amendment 113

#### Proposal for a regulation

#### Article 8 — paragraph 2 — subparagraph 1 a (new)

*Text proposed by the Commission*

*Amendment*

**If a Member State decides not to follow a recommendation, it shall state its reasons for doing so.**

### Amendment 114

#### Proposal for a regulation

#### Article 9 — title

*Text proposed by the Commission*

Commission report on preparedness planning

*Amendment*

Commission report on **prevention**, preparedness planning

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**Amendment 115****Proposal for a regulation****Article 9 — paragraph 1***Text proposed by the Commission*

1. On the basis of the information provided by the Member States in accordance with Article 7, and of the results of the audits referred to in Article 8, the Commission shall by July 2022 and every 2 years afterwards, transmit to the European Parliament and to the Council a report on the state of play and progress on preparedness and response planning at Union level.

*Amendment*

1. On the basis of the information provided by the Member States in accordance with Article 7, and of the results of the audits referred to in Article 8, the Commission shall by July 2022 and every 2 years afterwards, transmit to the European Parliament and to the Council a report on the state of play and progress on **prevention**, preparedness and response planning at Union level.

**Amendment 116****Proposal for a regulation****Article 9 — paragraph 1 a (new)***Text proposed by the Commission**Amendment*

**1a. The Commission report shall include the state of cross-border preparedness and response planning in neighbouring regions.**

**Amendment 117****Proposal for a regulation****Article 9 — paragraph 2***Text proposed by the Commission*

2. The Commission may adopt recommendations on preparedness and response planning addressed to Member States based on the report referred to in paragraph 1.

*Amendment*

2. The Commission may adopt recommendations on **prevention**, preparedness and response planning addressed to Member States based on the report referred to in paragraph 1. **Those recommendations may cover, inter alia, the minimum resources needed to respond to public health emergencies in relation to, among other things, population size, and they shall be developed on the basis of good practice and policy assessments.**

**Amendment 118****Proposal for a regulation****Article 10 — title***Text proposed by the Commission*

Coordination of preparedness and response planning in the HSC

*Amendment*

Coordination of **prevention**, preparedness and response planning in the HSC

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### Amendments 119 and 263

#### Proposal for a regulation

#### Article 10 — paragraph 1 — subparagraph 1

*Text proposed by the Commission*

1. The Commission and the Member States shall work together within the HSC to coordinate their efforts to develop, strengthen and maintain their capacities for the monitoring, early warning and assessment of, and response to serious cross-border threats to health.

*Amendment*

1. The Commission, **relevant Union agencies and bodies, including the HERA**, and the Member States shall work together within the HSC to coordinate their efforts to develop, strengthen and maintain their capacities for the monitoring, **prevention**, early warning and assessment of, and response to serious cross-border threats to health.

### Amendment 120

#### Proposal for a regulation

#### Article 10 — paragraph 1 — subparagraph 2 — point a

*Text proposed by the Commission*

(a) sharing best practice and experience in preparedness and response planning;

*Amendment*

(a) sharing best practice and experience in **prevention**, preparedness and response planning;

### Amendment 121

#### Proposal for a regulation

#### Article 10 — paragraph 1 — subparagraph 2 — point b

*Text proposed by the Commission*

(b) promoting the interoperability of national preparedness planning and the intersectoral dimension of preparedness and response planning at Union level;

*Amendment*

(b) promoting the interoperability of national **prevention**, preparedness planning and the intersectoral dimension of **prevention**, preparedness and response planning at Union level;

### Amendment 122

#### Proposal for a regulation

#### Article 10 — paragraph 1 — subparagraph 2 — point e

*Text proposed by the Commission*

(e) monitoring progress, identifying gaps and actions to strengthen preparedness and response planning, including in the field of research, at national and at Union levels.

*Amendment*

(e) monitoring progress, identifying gaps and actions to strengthen **prevention**, preparedness and response planning, including in the field of research, at **regional**, national and at Union levels;

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**Amendment 123****Proposal for a regulation****Article 10 — paragraph 1 a (new)**

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*Text proposed by the Commission*

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*Amendment*

**1a.** *The Commission and the Member States shall, where appropriate, conduct a dialogue with stakeholders, including health and care workers' organisations, industry and supply chain stakeholders, and patient and consumer organisations. That dialogue shall include regular exchanges of information between authorities, industry and relevant actors in the pharmaceutical supply chain to identify expected supply constraints so as to allow better coordination, development of synergies and appropriate responses.*

**Amendment 124****Proposal for a regulation****Article 11 — paragraph 1 — subparagraph 1**

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*Text proposed by the Commission*

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*Amendment*

1. The Commission may organise training activities for healthcare staff and public health staff in the Member States, including preparedness capacities under the International Health Regulations.

1. The Commission may organise training activities, **supported by the relevant Union agencies, in close cooperation with medical associations and patient organisations**, for healthcare **staff, social service** staff and public health staff in the Member States **in particular interdisciplinary One Health training**, including preparedness capacities under the International Health Regulations.

**Amendment 125****Proposal for a regulation****Article 11 — paragraph 1 — subparagraph 2**

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*Text proposed by the Commission*

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*Amendment*

The Commission shall organise those activities in cooperation with the Member States concerned.

The Commission shall organise those activities in cooperation with the Member States concerned **or potentially concerned, and in coordination, where possible, with the WHO to avoid duplication of activities, including preparedness capacities under the International Health Regulations.**

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## Amendment 126

## Proposal for a regulation

## Article 11 — paragraph 1 — subparagraph 2 a (new)

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*Text proposed by the Commission*

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*Amendment*

***In cross-border regions, joint cross-border training and sharing of best practices for healthcare staff and public health staff shall be promoted and familiarity with public health systems shall be mandatory.***

## Amendment 127

## Proposal for a regulation

## Article 11 — paragraph 1 — subparagraph 2 b (new)

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*Text proposed by the Commission*

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*Amendment*

***The Commission shall use the fullest potential of distance learning to broaden the number of trainees.***

## Amendment 128

## Proposal for a regulation

## Article 11 — paragraph 2

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*Text proposed by the Commission*

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*Amendment*

2. The training activities referred to in paragraph 1 shall aim to provide staff referred to in that paragraph with knowledge and skills necessary in particular to develop and implement the national preparedness plans referred to in Article 6, implement activities to strengthen crisis preparedness and surveillance capacities including the use of digital tools.

2. The training activities referred to in paragraph 1 shall aim to provide staff referred to in that paragraph with knowledge and skills necessary in particular to develop and implement the national preparedness plans referred to in Article 6, implement activities to strengthen crisis preparedness and surveillance capacities including the use of digital tools, ***ensure the continuity of critical long-term healthcare services and be consistent with the One Health approach.***

## Amendment 129

## Proposal for a regulation

## Article 11 — paragraph 3

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*Text proposed by the Commission*

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*Amendment*

3. The training activities referred to in paragraph 1 may be open to staff of the competent authorities of third countries and may be organised outside the Union.

3. The training activities referred to in paragraph 1 may be open to staff of the competent authorities of third countries and may be organised outside the Union ***in coordination, where possible, with ECDC activities in this area.***

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**Amendment 130****Proposal for a regulation****Article 11 — paragraph 5***Text proposed by the Commission*

5. The Commission may support organising programmes, in cooperation with the Member States, for the exchange of healthcare staff and public health staff between two or more Member States and for the temporary secondment of staff from one Member State to the other.

*Amendment*

5. The Commission may support organising programmes, in cooperation with the Member States, for the exchange of healthcare staff and public health staff between two or more Member States and for the temporary secondment of staff from one Member State to the other. ***In organising those programmes, account shall be taken of the contribution made by professional health organisations in each of the Member States.***

**Amendments 131 and 264****Proposal for a regulation****Article 12 — paragraph 1***Text proposed by the Commission*

1. The Commission and any Member States ***which so desire*** may engage in a joint procurement procedure conducted pursuant to Article 165(2) of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council <sup>(29)</sup> with a view to the advance purchase of medical countermeasures for serious cross-border threats to health.

<sup>(29)</sup> Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012 (OJ L 193, 30.7.2018, p. 1).

*Amendment*

1. The Commission, ***in particular with the HERA***, and any Member States may engage in a joint procurement procedure ***as contracting parties*** conducted pursuant to Article 165(2) of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council <sup>(29)</sup> with a view to the advance purchase of medical countermeasures for serious cross-border threats to health ***within a reasonable time frame.***

<sup>(29)</sup> Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012 (OJ L 193, 30.7.2018, p. 1).

**Amendment 132****Proposal for a regulation****Article 12 — paragraph 2 — point a***Text proposed by the Commission*

(a) participation in the joint procurement procedure shall be open to all Members States, European Free Trade Association (EFTA) States ***and*** Union candidate countries in accordance with Article 165(2) of Regulation (EU, Euratom) 2018/1046;

*Amendment*

(a) participation in the joint procurement procedure shall be open to all Members States, European Free Trade Association (EFTA) States, Union candidate countries in accordance with Article 165(2) of Regulation (EU, Euratom) 2018/1046, ***and to the Principality of Andorra, the Principality of Monaco, the Republic of San Marino and the Vatican City State;***

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## Amendment 133

## Proposal for a regulation

## Article 12 — paragraph 2 — point c

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*Text proposed by the Commission*

(c) **Member States, EFTA States and Union candidate** countries participating in a joint procurement shall procure the medical countermeasure in question through that procedure and not through other channels, and shall not run parallel negotiation processes for that product;

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*Amendment*

(c) countries participating in a joint procurement shall procure the medical countermeasure in question through that procedure and not through other channels, and shall not run parallel negotiation processes for that product **from that moment onwards. Countries that engage in parallel negotiation processes from that moment onwards shall be excluded from the group of participating countries, irrespective of whether those processes have reached the signature stage;**

## Amendment 134

## Proposal for a regulation

## Article 12 — paragraph 2 — point c a (new)

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*Text proposed by the Commission*

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*Amendment*

(ca) **the joint procurement shall define clear procedural steps for the process, scope, tender specifications and timelines, and it shall require all parties to deliver and respect clear commitments, including manufacturers delivering agreed production quantities and authorities purchasing agreed reserved volumes. The precise amounts ordered by and provided to each participating country and details of their liabilities shall be disclosed;**

## Amendment 135

## Proposal for a regulation

## Article 12 — paragraph 2 — point c b (new)

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*Text proposed by the Commission*

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*Amendment*

(cb) **A high degree of transparency shall be applied to all joint procurement activities and related purchase agreements. The European Court of Auditors shall have full access to all relevant documents to provide accurate annual scrutiny of signed contracts and the public investment involved;**

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**Amendment 136****Proposal for a regulation****Article 12 — paragraph 2 — point c c (new)**

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*Text proposed by the Commission*

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*Amendment*

- (cc) *if joint procurement is deployed, qualitative criteria shall be considered in the award process, in addition to cost. Such criteria shall also take into consideration, for example, the ability of the manufacturer to ensure security of supply during a health crisis;*

**Amendment 137****Proposal for a regulation****Article 12 — paragraph 2 — point c d (new)**

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*Text proposed by the Commission*

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*Amendment*

- (cd) *the joint procurement shall be conducted in such a way so as to strengthen the purchasing power of participating countries, improve the security of supply and ensure equitable access to medical countermeasures against serious cross-border threats to health;*

**Amendment 265****Proposal for a regulation****Article 12 — paragraph 2 — point e a (new)**

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*Text proposed by the Commission*

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*Amendment*

- (ea) *when joint procurement is performed under Article 7 of a Council Regulation on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level (ISC/2020/12524), the Commission shall have the right to require the licensing, under fair and reasonable conditions, of intellectual property and know-how pertaining to such countermeasures, if an economic operator abandons their development effort or is unable to ensure the sufficient and timely delivery of such countermeasures under the terms of the agreement concluded. Further conditions and procedures relating to the exercise of that right may be set out in the specific agreements with economic operators;*

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## Amendment 266

## Proposal for a regulation

## Article 12 — paragraph 2 — point e b (new)

Text proposed by the Commission

Amendment

*(eb) to ensure transparency as regards the expenditure of public funds, when joint procurement is performed under Article 7 of a Council Regulation on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level [ISC/2020/12524], the Commission shall in a timely manner make publicly available the contracts and agreements established with economic operators at least stipulating the following:*

*(i) the delivery schedule of the good or service;*

*(ii) terms of liabilities and indemnifications;*

*(iii) where relevant, the quantity and number of manufacturing locations.*

## Amendment 138

## Proposal for a regulation

## Article 12 — paragraph 3 — introductory part

Text proposed by the Commission

Amendment

3. The Commission shall, in liaison with the Member States, ensure coordination and information exchange between the entities organizing any action, including, but not limited to joint procurement procedures, stockpiling and donation of medical countermeasures under different mechanisms established at Union level, in particular under:

3. The Commission shall, in liaison with the Member States, ensure coordination and information exchange between the entities organizing **and participating in** any action, including, but not limited to joint procurement procedures, **development, stockpiling in facilities that meet the specific legal requirements for the storage of medical countermeasures and having the greatest proximity to and accessibility for the greatest number of population centres, without compromising the accessibility of those products for people in remote, rural and outermost regions, distribution** and donation of medical countermeasures, **which shall be of benefit to low- and middle-income countries**, under different mechanisms established at Union level, in particular under:

## Amendment 139

## Proposal for a regulation

## Article 12 — paragraph 3 — point a

Text proposed by the Commission

Amendment

(a) stockpiling under the rescEU referred to in Article 12 of Decision No 1313/2013/EU;

(a) stockpiling under the rescEU referred to in Article 23 of Decision No 1313/2013/EU;

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## Amendments 140 and 267

## Proposal for a regulation

## Article 12 — paragraph 3 — point f

*Text proposed by the Commission*

(f) other instruments supporting biomedical research and development at Union level for enhanced capacity and readiness to respond to cross-border threats and emergencies.

*Amendment*

(f) other **programmes and** instruments supporting biomedical research and development at Union level for enhanced capacity and readiness to respond to cross-border threats and emergencies **such as a Council Regulation on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level [ISC/2020/12524].**

## Amendment 141

## Proposal for a regulation

## Article 12 — paragraph 3 a (new)

*Text proposed by the Commission**Amendment*

**3a. Participating countries shall ensure that there is adequate stockpiling and distribution of procured medical countermeasures. The main details and characteristics of that stockpiling and distribution shall be set out in national plans.**

## Amendment 142

## Proposal for a regulation

## Article 12 — paragraph 3 b (new)

*Text proposed by the Commission**Amendment*

**3b. In accordance with the principle of transparency, the Commission shall regularly inform the European Parliament about negotiations concerning the joint procurement of medical countermeasures.**

## Amendment 143

## Proposal for a regulation

## Article 12 — paragraph 3 c (new)

*Text proposed by the Commission**Amendment*

**3c. The European Parliament reserves at all times the right to scrutinize, under existing confidentiality rules, the uncensored content of all contracts concluded in proceedings under this Article.**

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**Amendment 144**

**Proposal for a regulation**

**Article 12 — paragraph 3 d (new)**

*Text proposed by the Commission*

*Amendment*

**3d. The Commission and Member States shall provide up-to-date, accessible and clear information to consumers on their rights and duties regarding jointly procured medical countermeasures, including details on liability for damages, and access to legal protection and to consumer representation.**

**Amendment 145**

**Proposal for a regulation**

**Article 12 — paragraph 3 e (new)**

*Text proposed by the Commission*

*Amendment*

**3e. Where the joint procurement procedure for medical countermeasures to cross-border threats to health is not applied, the Commission shall encourage Member States to exchange information on pricing and delivery dates for medical countermeasures.**

**Amendments 146 and 268**

**Proposal for a regulation**

**Article 13 — paragraph 1**

*Text proposed by the Commission*

*Amendment*

1. The network for the epidemiological surveillance of the communicable diseases and of the related special health issues referred to in points (i) and (ii) of point (a) of Article 2(1) shall ensure a permanent communication between the Commission, the ECDC, and the competent authorities responsible at national level for epidemiological surveillance.

1. The network for the epidemiological surveillance of the communicable diseases, **including communicable diseases of zoonotic origin**, and of the related special health issues referred to in points (i) and (ii) of point (a) of Article 2(1) shall ensure a permanent communication between the Commission, **in particular the HERA**, the ECDC, and the competent authorities responsible at national level for epidemiological surveillance.

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**Amendment 147****Proposal for a regulation****Article 13 — paragraph 2 — point b a (new)**

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*Text proposed by the Commission*

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*Amendment*

*(ba) monitor the impact of communicable diseases on the continuity of screening, diagnosis, monitoring, treatment and care for other diseases and conditions;*

**Amendment 148****Proposal for a regulation****Article 13 — paragraph 2 — point b b (new)**

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*Text proposed by the Commission*

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*Amendment*

*(bb) monitor the impact of communicable diseases on mental health;*

**Amendment 149****Proposal for a regulation****Article 13 — paragraph 2 — point d**

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*Text proposed by the Commission*

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*Amendment*

(d) identify risk factors for disease transmission, population groups at risk and in need of targeted prevention measures;

(d) identify **and monitor** risk factors for disease transmission, population groups at risk and in need of targeted prevention measures;

**Amendment 150****Proposal for a regulation****Article 13 — paragraph 2 — point e**

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*Text proposed by the Commission*

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*Amendment*

(e) contribute to the assessment of the burden of communicable diseases on the population using such data as disease prevalence, complications, hospitalisation **and** mortality;

(e) contribute to the assessment of the burden of communicable diseases **on health systems and care delivery and** on the population using such data as disease prevalence, complications, hospitalisation, mortality, **the mental health impact, deferred screening, diagnosis, monitoring, treatment and care for other diseases and conditions and their social and economic impact;**

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**Amendment 151**

**Proposal for a regulation**

**Article 13 — paragraph 2 — point h a (new)**

*Text proposed by the Commission*

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*Amendment*

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*(ha) identify any weaknesses in the global supply chain involved in the production and manufacturing of medical countermeasures needed for the prevention, diagnosis, treatment and follow up of communicable diseases, and make plans to mitigate such weaknesses. Other mechanisms, such as a Union export control mechanism, regulatory flexibility, cooperation agreements, compulsory or voluntary licensing agreements between companies, may enable the Union to facilitate access to counter-measures for its citizens and residents as well as for people from the Eastern Partnership countries and low and middle-income countries;*

**Amendment 152**

**Proposal for a regulation**

**Article 13 — paragraph 3 — point f a (new)**

*Text proposed by the Commission*

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*Amendment*

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*(fa) information on the availability of medical countermeasures needed for the prevention, diagnosis, treatment and follow up of the disease.*

**Amendment 153**

**Proposal for a regulation**

**Article 13 — paragraph 3 a (new)**

*Text proposed by the Commission*

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*Amendment*

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*3a. The information communicated by Member States referred to in point (a) of paragraph 3 shall be reported at least at NUTS II level to the European Surveillance System (TESSy) or another platform, on a timely basis determined in accordance with Article 7.*

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## Amendment 154

## Proposal for a regulation

## Article 13 — paragraph 6 — subparagraph 2 a (new)

Text proposed by the Commission

Amendment

*The ECDC shall support the Member States to ensure the collection and sharing of data in times of health crisis and the integrated operation of the network for the epidemiological surveillance of communicable diseases and of the related special health issues referred to in points (i) and (ii) of point (a) of Article 2(1). The ECDC shall, where appropriate, also make available its expertise in that domain to third countries.*

## Amendment 155

## Proposal for a regulation

## Article 13 — paragraph 9 — subparagraph 1 — introductory part

Text proposed by the Commission

Amendment

9. The Commission shall, **by means of implementing** acts, establish and update:

9. The Commission shall **adopt delegated** acts **in accordance with Article 28 concerning the establishment and** update of:

## Amendment 156

## Proposal for a regulation

## Article 13 — paragraph 9 — subparagraph 1 — point c

Text proposed by the Commission

Amendment

(c) *procedures for the operation of the epidemiological surveillance network as developed pursuant to Article 5 of Regulation (EU) .../... [OJ: Please insert the number of Regulation ECDC [ISC/2020/ 12527]].*

*deleted*

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## Amendment 157

## Proposal for a regulation

## Article 13 — paragraph 9 a (new)

Text proposed by the Commission

Amendment

**9a.** *Where duly justified imperative grounds of urgency related to the severity or novelty of a serious cross-border threat to health or to the rapidity of its spread between Member States so require, the procedure provided for in Article 28a shall apply to delegated acts adopted pursuant to this Article.*

## Amendment 158

## Proposal for a regulation

## Article 13 — paragraph 9 b (new)

Text proposed by the Commission

Amendment

**9b.** *The Commission shall, by means of implementing acts, establish and update procedures for the operation of the epidemiological surveillance network developed pursuant to Article 5 of Regulation (EU) .../... [O]: Please insert the number of Regulation ECDC [ISC/2020/12527]].*

## Amendment 159

## Proposal for a regulation

## Article 13 — paragraph 10

Text proposed by the Commission

Amendment

10. On duly justified imperative grounds of urgency related to the severity or novelty of a serious cross-border threat to health or to the rapidity of its spread among the Member States, the Commission may adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 27(3) for the adoption **of case definitions, procedures and indicators** for surveillance in Member States in the case of a threat referred to in points (i) and (ii) of point (a) of Article 2 (1). **The indicators mentioned above shall also support the assessment of capacity for diagnosis, prevention and treatment.**

10. On duly justified imperative grounds of urgency related to the severity or novelty of a serious cross-border threat to health or to the rapidity of its spread among the Member States, the Commission may adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 27(3) for the adoption procedures for surveillance in Member States in the case of a threat referred to in points (i) and (ii) of point (a) of Article 2(1).

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**Amendment 160**  
**Proposal for a regulation**  
**Article 14 — paragraph 1**

*Text proposed by the Commission*

1. The ECDC shall ensure the **further** development of the digital platform through which data are managed and automatically exchanged, to establish integrated and interoperable surveillance systems enabling real-time surveillance where appropriate, for the purpose of supporting communicable disease prevention and control.

*Amendment*

1. The ECDC shall ensure the **continued** development of the digital platform **after having conducted a data protection impact assessment and having mitigated any risks to the rights and freedoms of the data subjects**, through which data are managed and automatically exchanged, to establish integrated and interoperable surveillance systems enabling real-time surveillance where appropriate, , for the purpose of supporting communicable disease prevention and control. **It shall ensure there is human oversight of the digital platform and include specific measures for minimising risks that may emerge from the transfer of biases or incomplete data from multiple sources, as well as establish procedures for data quality review. Digital platforms and applications supporting epidemiological surveillance at Union and Member State level shall be implemented in compliance with the principle of data protection by design pursuant to Article 27(1) of Regulation (EU) 2018/1725.**

**Amendment 161**  
**Proposal for a regulation**  
**Article 14 — paragraph 2 — point a**

*Text proposed by the Commission*

(a) enable the automated collection of surveillance and laboratory data, make use of **information from** electronic health records, media monitoring, and apply artificial intelligence for data validation, analysis and automated reporting;

*Amendment*

(a) enable the automated collection of surveillance and laboratory data, make use of **relevant health data from a previously defined and authorised list from** electronic health records **and health databases**, media monitoring, and apply artificial intelligence for data validation, analysis and **statistical reporting in accordance with Article 22 GDPR**;

**Amendment 162**  
**Proposal for a regulation**  
**Article 14 — paragraph 2 — point b**

*Text proposed by the Commission*

(b) allow for the computerised handling and exchange of information, data and documents.

*Amendment*

(b) allow for the computerised processing and exchange of information, data and documents, **taking into account Union law concerning the protection of personal data**;

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### Amendment 163

#### Proposal for a regulation

#### Article 14 — paragraph 2 — point b a (new)

Text proposed by the Commission

Amendment

*(ba) allow for automated notification on EWRS when communicable diseases rise above warning thresholds, as referred to in point (a) of Article 13(2). The notification shall be validated by the competent health authority.*

### Amendment 164

#### Proposal for a regulation

#### Article 14 — paragraph 3

Text proposed by the Commission

Amendment

3. Member States are responsible for ensuring that the integrated surveillance system is fed on a regular basis with timely **and** complete information, data and documents transmitted and exchanged through the digital platform.

3. Member States are responsible for ensuring that the integrated surveillance system is fed on a regular basis with timely, complete **and accurate** information, data and documents transmitted and exchanged through the digital platform. **The Member States shall promote the automation of this process between the national and the Union surveillance system.**

### Amendment 165

#### Proposal for a regulation

#### Article 14 — paragraph 5

Text proposed by the Commission

Amendment

5. For epidemiological purposes, ECDC shall also have access to relevant health data accessed or made available through digital infrastructures enabling the use of health data for research, policy making and regulatory purposes.

5. For epidemiological **surveillance** purposes, ECDC shall also have access to relevant health data accessed or made available through digital infrastructures enabling the use of health data for research, policy making and regulatory purposes. **The access to the health data shall be proportionate to specific and concrete purposes that shall have been defined previously by ECDC.**

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**Amendment 166****Proposal for a regulation****Article 14 — paragraph 6 — introductory part***Text proposed by the Commission*

6. The Commission shall adopt **implementing** acts **for** the functioning of the surveillance platform **which lay** down:

*Amendment*

6. **The Commission, following the carrying out of a consultation procedure as set out in Article 42(2) of Regulation (EU) 2018/1725, shall adopt *delegated* acts in accordance with Article 28 concerning** the functioning of the surveillance platform **laying** down:

**Amendment 167****Proposal for a regulation****Article 14 — paragraph 6 — point a***Text proposed by the Commission*

(a) the technical specifications of the platform, including the electronic data exchange mechanism for exchanges with existing national systems, identification of applicable standards, definition of message structures, data dictionaries, exchange of protocols and procedures;

*Amendment*

(a) the technical specifications of the platform, including the electronic data exchange mechanism for exchanges with existing **international and** national systems, identification of applicable standards, definition of message structures, data dictionaries, exchange of protocols and procedures;

**Amendment 168****Proposal for a regulation****Article 14 — paragraph 6 — point c***Text proposed by the Commission*

(c) contingency arrangements to be applied in the event of unavailability of any of the functionalities of the platform;

*Amendment*

(c) contingency arrangements **and secure data backups** to be applied in the event of unavailability of any of the functionalities of the platform;

**Amendment 169****Proposal for a regulation****Article 14 — paragraph 6 — point d***Text proposed by the Commission*

(d) the cases where, and the conditions under which the **third countries and** international organisations concerned may be granted partial access to the functionalities of the platform and the practical arrangements of such access;

*Amendment*

(d) the cases where, and the conditions under which the international organisations concerned may be granted partial access to the functionalities of the platform and the practical arrangements of such access, **in full compliance with Regulations (EU) 2018/1725 and (EU) 2016/679 and Directive (EU) 2016/680;**

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**Amendment 170****Proposal for a regulation****Article 14 — paragraph 6 — point f a (new)***Text proposed by the Commission**Amendment*

**(fa) ensure standardisation of the infrastructure for storage, processing and analysis of data.**

**Amendment 171****Proposal for a regulation****Article 14 — paragraph 6 a (new)***Text proposed by the Commission**Amendment*

**6a. Digital platforms and applications supporting epidemiological surveillance at Union and Member State level shall be implemented in compliance with the principle of data protection by design pursuant to Article 27(1) of Regulation (EU) 2018/1725.**

**Amendment 172****Proposal for a regulation****Article 15 — paragraph 1***Text proposed by the Commission**Amendment*

1. In the area of public health or for specific areas of public health relevant for the implementation of this Regulation or of the national plans referred to in Article 6, the Commission may, by means of implementing acts, designate EU reference laboratories to provide support to national reference laboratories to promote good practice and alignment by Member States on **a voluntary basis on** diagnostics, testing methods, use of certain tests for the uniform surveillance, notification and reporting of diseases by Member States.

1. In the area of public health or for specific areas of public health relevant for the implementation of this Regulation or of the national plans referred to in Article 6, the Commission may, by means of implementing acts, designate EU reference laboratories to provide support to national reference laboratories to promote good practice and alignment by Member States on diagnostics, testing methods, use of certain tests for the uniform surveillance, notification and reporting of diseases by Member States.

**Amendment 173****Proposal for a regulation****Article 15 — paragraph 2 — point f***Text proposed by the Commission**Amendment*

(f) monitoring, alert and support in outbreak response and

(f) monitoring, alert and support in outbreak response, **in particular for emerging pathogens;** and

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**Amendment 174****Proposal for a regulation****Article 15 — paragraph 3**

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*Text proposed by the Commission*

3. The network of EU reference laboratories shall be operated and coordinated by the ECDC.

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*Amendment*

3. The network of EU reference laboratories shall be operated and coordinated by the ECDC, **in cooperation with WHO network laboratories to avoid duplication of activities. The governance structure of the network shall cover cooperation and coordination with existing national and regional reference laboratories and networks.**

**Amendment 175****Proposal for a regulation****Article 15 — paragraph 3 a (new)**

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*Text proposed by the Commission*

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*Amendment*

**3a. The laboratories referred to in paragraph 1 shall contribute to sharing good practices and to improving the epidemiological surveillance referred to in Article 13.**

**Amendment 176****Proposal for a regulation****Article 15 — paragraph 4**

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*Text proposed by the Commission*

4. The designations provided for in paragraph 1 shall follow a public selection process, be limited in time, with a minimum period of 5 years, and be reviewed regularly. Designations shall establish the responsibilities and tasks of the designated laboratories.

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*Amendment*

4. The designations provided for in paragraph 1 shall follow a public selection process, be limited in time, with a minimum period of 5 years, and be reviewed regularly. **The Commission shall consult the Member States and the ECDC to elaborate the terms of reference and the criteria of the designation process.** Designations shall establish the responsibilities and tasks of the designated laboratories. **Laboratory consortia shall be eligible for designation.**

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**Amendment 177****Proposal for a regulation****Article 15 — paragraph 5 — point a***Text proposed by the Commission*

(a) be impartial, free from any conflict of interest, and in particular not be in a situation which may, directly or indirectly, affect the impartiality of their professional conduct as regards the exercise of their tasks as EU reference laboratories;

*Amendment*

(a) be impartial, free from any conflict of interest, and in particular not be in a situation which may, directly or indirectly, affect the impartiality of their professional conduct as regards the exercise of their tasks as EU reference laboratories. ***Particular attention shall be paid to proprietary tests and methods that may be the property of laboratories;***

**Amendment 178****Proposal for a regulation****Article 17 — paragraph 1 a (new)***Text proposed by the Commission**Amendment*

***1a. The European Surveillance System (TESSy) shall be used for ad hoc monitoring of a serious cross-border threat to health referred to in point (iii) of point (a) of Article 2(1) and in points (b), (c) and (d) of Article 2(1).***

**Amendment 179****Proposal for a regulation****Article 17 — paragraph 3 — subparagraph 1***Text proposed by the Commission*

The Commission shall, ***by means of implementing acts***, adopt, where necessary, the case definitions to be used for ad hoc monitoring, in order to ensure the comparability and compatibility at Union level of the collected data.

*Amendment*

The Commission shall adopt, where necessary, ***delegated acts in accordance with Article 28*** concerning the case definitions to be used for ad hoc monitoring, in order to ensure the comparability and compatibility at Union level of the collected data.

**Amendment 180****Proposal for a regulation****Article 17 — paragraph 3 — subparagraph 2***Text proposed by the Commission*

***Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(2).***

*Amendment****deleted***

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**Amendment 181****Proposal for a regulation****Article 17 — paragraph 3 — subparagraph 3***Text proposed by the Commission*

**On** duly justified imperative grounds of urgency related to the severity of a serious cross-border threat to health or to the rapidity of its spread between the Member States, the **Commission may adopt or update the case definitions referred to in the first subparagraph through immediately applicable implementing acts in accordance with the procedure referred to in Article 27(3).**

*Amendment*

**Where** duly justified imperative grounds of urgency related to the severity **or novelty** of a serious cross-border threat to health or to the rapidity of its spread between the Member States **so require**, the **procedure provided for in Article 28a shall apply to delegated acts adopted pursuant to this Article.**

**Amendment 182****Proposal for a regulation****Article 18 — paragraph 1***Text proposed by the Commission*

1. The EWRS shall enable the Commission and the competent authorities responsible at national level to be in permanent communication for the purposes of preparedness, early warning and response, alerting, assessing public health risks and determining the measures that may be required to protect public health.

*Amendment*

1. The EWRS shall enable the Commission, **the ECDC**, and the competent authorities responsible at national level to be in permanent communication for the purposes of preparedness, early warning and response, alerting, assessing public health risks and determining the measures that may be required to protect public health.

**Amendment 183****Proposal for a regulation****Article 18 — paragraph 2 — subparagraph 1 — introductory part***Text proposed by the Commission*

The management and use of the EWRS involve the exchange of personal data in specific cases where the relevant legal instruments so provide. This includes:

*Amendment*

The management and **operational** use of the EWRS involve the exchange of personal data in specific cases where the relevant legal instruments so provide. This includes:

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#### Amendment 184

##### Proposal for a regulation

##### Article 18 — paragraph 2 — subparagraph 2

*Text proposed by the Commission*

The ECDC shall continuously update the EWRS allowing for the use of modern technologies, such as digital mobile applications, artificial intelligence models, space enabled applications, or other technologies for automated contact tracing, building upon the contact tracing technologies developed by the Member States.

*Amendment*

The ECDC shall continuously update the EWRS allowing for the use of modern technologies, such as digital mobile applications, artificial intelligence models, space enabled applications, or other technologies for automated contact tracing, building upon the contact tracing technologies developed by the Member States **or by the Union, used for the sole purpose of fighting the pandemic and proven to be adequate, necessary and proportionate, and in full compliance with Regulation (EU) 2016/679 and Directive 2002/58/EC.**

#### Amendment 185

##### Proposal for a regulation

##### Article 18 — paragraph 2 — subparagraph 2 a (new)

*Text proposed by the Commission*

*Amendment*

**To ensure data quality and consistency, the EWRS shall implement robust, accurate and interoperable data processes with Member States. The ECDC shall coordinate with Member States throughout such data exchange processes, from assessing the data requirements, transmission and collection, to up to date actualisation and interpretation, ensuring strong collaboration between the Commission, the ECDC and national and regional competent bodies.**

#### Amendment 186

##### Proposal for a regulation

##### Article 18 — paragraph 2 a (new)

*Text proposed by the Commission*

*Amendment*

**2a. The ECDC shall develop and improve the EWRS, to augment the automation of information collection and analysis, upgrade the categorisation of notifications, reduce open text communication, reduce the administrative burden and improve the standardisation of the notifications.**

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**Amendment 187****Proposal for a regulation****Article 18 — paragraph 2 b (new)**

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*Text proposed by the Commission*

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*Amendment*

**2b. The EWRS shall be improved to reduce the burden of bureaucracy and duplications of notification. The EWRS shall allow the national competent authorities to notify the WHO of events that may constitute public health emergencies of international concern in accordance with Article 6 of the IHR, and shall integrate this information in the EWRS system, in order to automatically notify an alert in the EWRS.**

**Amendment 188****Proposal for a regulation****Article 18 — paragraph 4**

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*Text proposed by the Commission*

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*Amendment*

4. The Commission shall, by means of implementing acts, adopt procedures concerning the information exchange with other rapid alert systems at Union level, including exchange of personal data, in order to ensure the proper functioning of the EWRS and to avoid overlap of activities or conflicting actions with existing structures and mechanisms for preparedness, monitoring, early warning and combating serious cross-border threats to health.

4. The Commission shall, by means of implementing acts, adopt procedures concerning the information exchange with other rapid alert systems at Union **and international** level, including exchange of personal data, in order to ensure the proper functioning of the EWRS and to avoid overlap of activities or conflicting actions with existing structures and mechanisms for preparedness, monitoring, early warning and combating serious cross-border threats to health.

**Amendment 189****Proposal for a regulation****Article 18 — paragraph 4 a (new)**

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*Text proposed by the Commission*

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*Amendment*

**4a. The EWRS shall be able to automatically collect information from other important databases, such as those comprising environmental data, climate data, water irrigation data and other data relevant to serious cross-border threats to health, that could facilitate understanding and mitigate the risk of potential health threats.**

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### Amendment 190

#### Proposal for a regulation

#### Article 19 — paragraph 2

*Text proposed by the Commission*

2. Where the national competent authorities notify the WHO of events that may constitute public health emergencies of international concern in accordance with Article 6 of the IHR, **they shall at the latest** simultaneously **notify an alert** in the EWRS, provided that the threat concerned falls within those referred to in Article 2(1) of this Regulation.

*Amendment*

2. Where the national competent authorities notify the WHO of events that may constitute public health emergencies of international concern in accordance with Article 6 of the IHR, **as referred to in Article 18(2b), an alert shall be** simultaneously **notified** in the EWRS, provided that the threat concerned falls within those referred to in Article 2(1) of this Regulation.

### Amendment 191

#### Proposal for a regulation

#### Article 19 — paragraph 3 — point f

*Text proposed by the Commission*

(f) public health risks;

*Amendment*

(f) public health risks, **especially for vulnerable groups, including, as far as possible, their impact on major non-communicable diseases;**

### Amendment 192

#### Proposal for a regulation

#### Article 19 — paragraph 3 — point h

*Text proposed by the Commission*

(h) measures other than public health measures;

*Amendment*

(h) **multisectoral** measures other than public health measures;

### Amendment 193

#### Proposal for a regulation

#### Article 19 — paragraph 3 — point i a (new)

*Text proposed by the Commission*

*Amendment*

(ia) **the existing and potential production sites, with the sole aim of allowing the Union to map the strategic production capacities for the Union as a whole;**

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**Amendment 194****Proposal for a regulation****Article 19 — paragraph 3 — point j***Text proposed by the Commission*

(j) requests and offers for cross-border emergency assistance;

*Amendment*

(j) requests and offers for cross-border emergency assistance, **such as the medical transfer of patients or provision of healthcare staff by one Member State to another, in particular in cross-border areas in neighbouring regions;**

**Amendment 195****Proposal for a regulation****Article 19 — paragraph 4 a (new)***Text proposed by the Commission**Amendment*

**4a. The Member State shall update the information referred to in paragraph 3 as new data become available.**

**Amendment 196****Proposal for a regulation****Article 20 — paragraph 1 — introductory part***Text proposed by the Commission*

1. Where an alert is notified pursuant to Article 19, the Commission shall, where necessary for the coordination of the response at Union level or upon request of the HSC referred to in Article 21 or on its own initiative, make promptly available to the national competent authorities and to the HSC, through the EWRS, a risk assessment of the potential severity of the threat to public health, including possible public health measures. That risk assessment shall be carried out by:

*Amendment*

1. Where an alert is notified pursuant to Article 19, the Commission shall, where necessary for the coordination of the response at Union level or upon request of the HSC referred to in Article 21 or on its own initiative, make promptly available to the national competent authorities and to the HSC, through the EWRS, a risk assessment of the potential severity of the threat to public health, including possible public health measures, **including a risk assessment of the mental health of the affected population.** That risk assessment shall be carried out by:

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## Amendment 269

## Proposal for a regulation

## Article 20 — paragraph 1 — point -a (new)

Text proposed by the Commission

Amendment

- (-a) *the HERA in accordance with Article 2(2) (a) of the Commission Decision of 16 September 2021. The assessment by the HERA shall be carried out in such a way as to allow a decision to be taken on the activation of the emergency framework as set out in Article 3 of a Council Regulation on a framework for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level, and on which measures as set out in Articles 5 to 11 and Article 13 of that Regulation it is appropriate to activate;*

## Amendment 197

## Proposal for a regulation

## Article 20 — paragraph 1 — point a

Text proposed by the Commission

Amendment

- (a) the ECDC in accordance with Article 8a of Regulation (EU) .../... [O]: Please insert the number of Regulation ECDC [ISC/2020/12527]] in the case of a threat referred to in **points (i) and (ii) of** point (a) of Article 2(1) including substances of human origin: blood, organs, tissues and cells potentially impacted by communicable diseases; or point (d) of Article 2(1); and/or

- (a) the ECDC in accordance with Article 8a of Regulation (EU) .../... [O]: Please insert the number of Regulation ECDC [ISC/2020/12527]] in the case of a threat referred to in point (a) of Article 2(1) including substances of human origin: **such as** blood, organs, tissues and cells potentially impacted by communicable diseases; or point (d) of Article 2(1); and/or

## Amendment 198

## Proposal for a regulation

## Article 20 — paragraph 1 — point a a (new)

Text proposed by the Commission

Amendment

- (aa) *the European Medicines Agency (EMA), in accordance with Article 1 of Regulation (EU) 2021/... [insert the number of revised EMA regulation 2020/0321(COD)], in the case of a threat linked to a defective medical product or in the event a threat is becoming more severe as a result of a shortage of medical products for human use or medical devices; and/or*

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**Amendment 199****Proposal for a regulation****Article 20 — paragraph 1 — point f a (new)***Text proposed by the Commission**Amendment*

**(fa) Union or national entities engaged in stockpiling of medical products.**

**Amendment 200****Proposal for a regulation****Article 20 — paragraph 2***Text proposed by the Commission**Amendment*

2. At the request of the agency or body carrying out the risk assessment within its mandate, the agencies and bodies referred to in paragraph 1 shall, without undue delay, provide any relevant information data at their disposal.

2. At the request of the agency or body carrying out the risk assessment within its mandate, the agencies and bodies referred to in paragraph 1 shall, without undue delay, provide any relevant information data **and expertise** at their disposal. **When delivering its risk assessment, the agency or body shall be designated as the 'lead' agency in accordance with paragraph 3 . The agency or body shall ensure that it takes note of any information or expertise obtained from other agencies or bodies referred to in paragraph 1.**

**Amendment 201****Proposal for a regulation****Article 20 — paragraph 3 — subparagraph 1***Text proposed by the Commission**Amendment*

Where the risk assessment needed is totally or partially outside the mandates of the agencies referred to in paragraph 1, and it is considered necessary for the coordination of the response at Union level, the Commission shall, upon request of the HSC or its own initiative, provide an ad hoc risk assessment.

Where the risk assessment needed is totally or partially outside the mandates of the agencies referred to in paragraph 1, and it is considered necessary for the coordination of the response at Union level, the Commission shall, upon request of the HSC or its own initiative, provide an ad hoc risk assessment. **Where the risk assessment needed falls under the mandate of several of the agencies referred to in paragraph 1, the Commission shall designate a lead agency to be in charge of carrying out the risk assessment, in collaboration with the other agencies concerned, and set a deadline for the submission of the assessment by that agency.**

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### Amendment 202

#### Proposal for a regulation

##### Article 20 — paragraph 3 — subparagraph 2

*Text proposed by the Commission*

The Commission shall make the risk assessment available to the national competent authorities promptly through the EWRS, and, if appropriate, through linked alerts systems. Where the risk assessment is to be made public, the national competent authorities shall receive it prior to its publication.

*Amendment*

The Commission shall make the risk assessment available to the national competent authorities promptly through the EWRS, and, if appropriate, through linked alerts systems. Where the risk assessment is to be made public, the national competent authorities shall receive it prior to its publication **through the EWRS and the HSC**.

### Amendment 203

#### Proposal for a regulation

##### Article 20 — paragraph 3 — subparagraph 3

*Text proposed by the Commission*

The risk assessment shall take into account, if available, relevant information provided by other entities, in particular by the WHO in the case of a public health emergency of international concern.

*Amendment*

The risk assessment shall take into account, if available, relevant information provided by **public health experts and** other entities, in particular by the WHO in the case of a public health emergency of international concern.

### Amendment 270

#### Proposal for a regulation

##### Article 21 — paragraph 1 — introductory part

*Text proposed by the Commission*

1. Following an alert notification pursuant to Article 19, on a request from the Commission or a Member State and on the basis of the available information, including the information referred to in Article 19 and the risk assessments referred to in Article 20, Member States shall coordinate within the HSC and in liaison with the Commission:

*Amendment*

1. Following an alert notification pursuant to Article 19, on a request from the Commission or a Member State and on the basis of the available information, including the information referred to in Article 19 and the risk assessments referred to in Article 20, Member States shall coordinate within the HSC and in liaison with the Commission **in particular with the HERA**:

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**Amendment 204****Proposal for a regulation****Article 21 — paragraph 1 — point b**

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*Text proposed by the Commission*

(b) risk and crisis communication, to be adapted to Member State needs and circumstances, aimed at providing consistent and coordinated information in the Union to the public **and** to healthcare professionals;

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*Amendment*

(b) risk and crisis communication, to be adapted to Member State needs and circumstances, aimed at providing consistent and coordinated information in the Union to the public, to healthcare professionals **and public health professionals**;

**Amendment 205****Proposal for a regulation****Article 21 — paragraph 1 — point c**

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*Text proposed by the Commission*

(c) adoption of opinions and guidance, including on specific response measures for the Member States for the prevention and control of a serious cross-border threat to health.

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*Amendment*

(c) adoption of opinions and guidance, including on specific response measures for the Member States for the prevention and control of a serious cross-border threat to health, **including coordination of response measures**.

**Amendment 206****Proposal for a regulation****Article 21 — paragraph 1 — point c a (new)**

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*Text proposed by the Commission*

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*Amendment*

(ca) **national travel restrictions and other cross-border restrictions on movement and the gathering of people, as well as quarantine requirements and supervision of quarantines following cross-border travel.**

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### Amendments 207 and 271

#### Proposal for a regulation

#### Article 21 — paragraph 2

*Text proposed by the Commission*

2. Where a Member State intends to adopt public health measures to combat a serious cross-border threat to health, it shall, before adopting those measures, inform **and** consult the other Member States **and** the Commission on the nature, purpose and scope of the measures, unless the need to protect public health is so urgent that the immediate adoption of the measures is necessary.

*Amendment*

2. Where a Member State intends to adopt public health measures to combat a serious cross-border threat to health, it shall, before adopting **or ceasing** those measures, inform, consult **and coordinate with** the other Member States, **in particular neighbouring Member States**, the Commission, **in particular the HERA, the HCB and the Health Security Committee** on the nature, purpose and scope of the measures, unless the need to protect public health is so urgent that the immediate adoption of the measures is necessary.

### Amendments 208 and 272

#### Proposal for a regulation

#### Article 21 — paragraph 3

*Text proposed by the Commission*

3. Where a Member State has to adopt, as a matter of urgency, public health measures in response to the appearance or resurgence of a serious cross-border threat to health, it shall, immediately upon adoption, inform the other Member States **and** the Commission on the nature, purpose and scope of those measures.

*Amendment*

3. Where a Member State has to adopt, as a matter of urgency, public health measures in response to the appearance or resurgence of a serious cross-border threat to health, it shall, immediately upon adoption, inform the other Member States, **relevant regional authorities**, the Commission, **in particular the HERA, the HCB and the Health Security Committee** on the nature, purpose and scope of those measures **especially in cross-border regions**.

### Amendment 209

#### Proposal for a regulation

#### Article 21 — paragraph 3 a (new)

*Text proposed by the Commission*

*Amendment*

**3a. In the event of a serious cross-border threat to health overwhelming national response capacities in a Member State, that Member State may also request assistance from other Member States through the ERCC provided for in Decision No 1313/2013/EU of the European Parliament and of the Council <sup>(1a)</sup>.**

<sup>(1a)</sup> Decision No 1313/2013/EU of the European Parliament and of the Council of 17 December 2013 on a Union Civil Protection Mechanism.

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**Amendment 273****Proposal for a regulation****Article 22 — paragraph 2 — point a***Text proposed by the Commission*


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(a) be based on in particular recommendations of the ECDC in particular, other relevant agencies or bodies, or the Advisory Committee referred to in Article 24;

*Amendment*


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(a) be based on in particular recommendations of the ECDC **and the HERA** in particular, other relevant agencies or bodies, or the Advisory Committee referred to in Article 24;

**Amendment 210****Proposal for a regulation****Article 22 — paragraph 2 — point c***Text proposed by the Commission*


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(c) be proportionate to the public health risks related to the threat in question, avoiding in particular any unnecessary restriction to the free movement of persons, of goods and of services.

*Amendment*


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(c) be **necessary, suitable and** proportionate to the public health risks related to the threat in question, avoiding in particular any unnecessary restriction to the free movement of persons, of goods and of services, **and to the rights, freedoms and principles enshrined in the Charter of Fundamental Rights of the European Union, and promote coordination of measures between Member States;**

**Amendment 211****Proposal for a regulation****Article 22 — paragraph 2 — point c a (new)***Text proposed by the Commission*


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*Amendment*


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(ca) **be time limited, and cease as soon as one of the applicable conditions set out in points (a), (b) and (c) is no longer met;**

**Amendment 212****Proposal for a regulation****Article 22 — paragraph 2 — point c b (new)***Text proposed by the Commission*


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*Amendment*


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(cb) **take into account the need for an internal market that functions normally, in particular the existence of green lanes for free circulation of food and medical counter-measures.**

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### Amendment 213

#### Proposal for a regulation

#### Article 23 — paragraph 3

*Text proposed by the Commission*

3. Before recognising a situation of public health emergency at Union level, the Commission **should** liaise with the WHO in order to share the Commission's analysis of the situation of the outbreak and to inform the WHO of its intention to adopt such a decision.

*Amendment*

3. Before recognising a situation of public health emergency at Union level, the Commission **shall** liaise with the WHO in order to share the Commission's analysis of the situation of the outbreak and to inform the WHO of its intention to adopt such a decision.

### Amendment 214

#### Proposal for a regulation

#### Article 23 — paragraph 4 — subparagraph 2

*Text proposed by the Commission*

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(2).

*Amendment*

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(3).

### Amendment 274

#### Proposal for a regulation

#### Article 23 — paragraph 4 a (new)

*Text proposed by the Commission*

*Amendment*

**4a. Following the recognition of public health emergency, the Council, upon the proposal of the Commission, may adopt a regulation activating the emergency framework where that is appropriate to the economic situation, pursuant to Article 3 of a Council Regulation on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level. Where the emergency framework is activated, the HCB shall be set up to coordinate action by the Council, the Commission, the relevant Union agencies and bodies, and Member States to ensure the supply and access of medical countermeasures. In such situations, pursuant to the Joint Declaration on budgetary scrutiny of new proposals based on Article 122 TFEU, a Joint Committee consisting of representatives of the European Parliament and of the Council shall be established.**

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**Amendment 215****Proposal for a regulation****Article 24 — paragraph 1 — introductory part***Text proposed by the Commission*

1. For the purpose of the formal recognition of a public health emergency at Union level, the Commission shall establish an Advisory Committee on public health emergencies ('Advisory Committee') which, at the request of the Commission, shall advise the Commission by providing its views on:

*Amendment*

1. For the purpose of the formal recognition of a public health emergency at Union level, the Commission, **with the consultation of the Health Security Committee** shall establish an Advisory Committee on public health emergencies ('Advisory Committee') which, at the request of the Commission **or the Health Security Committee**, shall advise the Commission **and the Health Security Committee** by providing its views on:

**Amendment 216****Proposal for a regulation****Article 24 — paragraph 1 — point c — point ii***Text proposed by the Commission*

(ii) identification and mitigation of significant gaps, inconsistencies or inadequacies in measures taken or to be taken to contain and manage the specific threat and overcome its impact, including in clinical management and treatment, **non-pharmaceutical countermeasures** and public health research needs;

*Amendment*

(ii) identification and mitigation of significant gaps, inconsistencies or inadequacies in measures taken or to be taken to contain and manage the specific threat and overcome its impact, including in clinical management and treatment, and public health research needs;

**Amendment 217****Proposal for a regulation****Article 24 — paragraph 1 — point c — point ii a (new)***Text proposed by the Commission**Amendment*

(iia) **in consultation with EMA pursuant to Regulation (EU) .../... [O]: Please insert the number of EMA Regulation], the stability of supply chains and production capacity of medical supply chains involved in the production and manufacturing of medical countermeasures needed for the diagnosis, treatment and follow-up of the disease concerned;**

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## Amendment 218

## Proposal for a regulation

## Article 24 — paragraph 2

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*Text proposed by the Commission*

2. The Advisory Committee shall be composed of independent experts, selected by the Commission according to the fields of expertise and experience most relevant to the specific threat that is occurring. The Committee should have multidisciplinary membership so it can advise on biomedical, behavioural, social, economic, cultural and international aspects. The representatives of the ECDC and of the EMA **participate as observers** in the Advisory Committee. The representatives of other Union bodies or agencies relevant to the specific threat shall participate as observers in this Committee as necessary. The Commission may invite experts with specific expertise with respect to a subject matter on the agenda to take part in the work of the Advisory Committee on an ad-hoc basis.

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*Amendment*

2. The Advisory Committee shall be composed of independent experts, **representatives of health and care workers and civil society representatives**, selected by the Commission according to the fields of expertise and experience most relevant to the specific threat that is occurring. The Committee should have multidisciplinary membership so it can advise on **sanitary, biomedical, behavioural, social, economic, research, development, manufacturing, cultural, transport** and international aspects. The representatives of the ECDC and of the EMA **shall take an active part** in the Advisory Committee. The representatives of other Union bodies or agencies relevant to the specific threat shall participate as observers in this Committee as necessary. The Commission **or the Health Security Committee** may invite experts **and stakeholders** with specific expertise with respect to a subject matter on the agenda to take part in the work of the Advisory Committee on an ad-hoc basis. **The Commission shall publish the names of the experts selected to form part of the Advisory Committee and details of the professional and/or scientific backgrounds that justify their appointment.**

## Amendment 219

## Proposal for a regulation

## Article 24 — paragraph 2 a (new)

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*Text proposed by the Commission*

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*Amendment*

**2a. The Commission shall publish on its website the list of members of the Advisory Committee and the qualifications supporting their appointment. A geographical balance of the membership shall be ensured whenever possible. The members shall act in the public interest and in an independent manner. They shall make declarations of interest and of commitments. Such declarations shall include any activity, position, circumstances or other facts potentially involving a direct or indirect interest, in order to make it possible to identify interests which might be considered prejudicial to those experts' independence.**

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**Amendment 275****Proposal for a regulation****Article 24 — paragraph 2 b (new)***Text proposed by the Commission**Amendment*

**2b. The Advisory Committee shall act in cooperation with the HCB and the HERA Advisory Forum established under the Commission Decision of 16 September 2021. Representatives of the HERA Advisory Forum shall participate as observers on the Advisory Committee. The coordination between those bodies shall ensure that there is participation by all relevant stakeholders, including healthcare professionals' organisations, patients' associations, and industry and supply chain actors with recognised experience in disciplines related to providing advice on response to health emergencies and to the work of the HERA.**

**Amendment 220****Proposal for a regulation****Article 24 — paragraph 3***Text proposed by the Commission**Amendment*

3. The Advisory Committee shall meet whenever the situation requires, on a request from the Commission or a Member State.

3. The Advisory Committee shall meet whenever the situation requires, on a request from the Commission, **the Health Security Committee** or a Member State.

**Amendment 221****Proposal for a regulation****Article 24 — paragraph 6***Text proposed by the Commission**Amendment*

6. The Advisory Committee shall establish its rules of procedure including on the rules for the declaration and termination of an emergency situation, and adoption of recommendations and voting. The rules of procedures shall enter into force after receiving a favourable opinion from the Commission.

6. The Advisory Committee shall establish its rules of procedure including on the rules for the declaration and termination of an emergency situation, and adoption of recommendations and voting. The rules of procedures shall enter into force after receiving a favourable opinion from the Commission **and the Health Security Committee.**

**Amendment 222****Proposal for a regulation****Article 24 — paragraph 6 a (new)***Text proposed by the Commission**Amendment*

**6a. The minutes of the Advisory Committee shall be public.**

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**Amendment 223****Proposal for a regulation****Article 24 — paragraph 6 b (new)***Text proposed by the Commission**Amendment*

**6b. The advisory committee shall work in close cooperation with national advisory bodies.**

**Amendments 224 and 276****Proposal for a regulation****Article 25 — paragraph 1 — point b***Text proposed by the Commission**Amendment*

(b) *mechanisms* to monitor shortages of, **develop, procure, manage and deploy** medical countermeasures;

(b) **measures, pursuant to a Council Regulation on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level**, to monitor shortages of, **the development, the manufacture, the procurement, actions taken to ensure security of supply, the management, the storage, the distribution and the deployment of** medical countermeasures;

**Amendment 225****Proposal for a regulation****Article 25 — paragraph 1 — point c***Text proposed by the Commission**Amendment*

(c) activation of support from the ECDC as referred to in Regulation (EU) .../... [O]: Please insert the number of Regulation ECDC [ISC/2020/12527]] to mobilise and deploy the EU Health Task Force.

(c) activation of support from the ECDC as referred to in Regulation (EU) .../... [O]: Please insert the number of Regulation ECDC [ISC/2020/12527]] to mobilise and deploy the EU Health Task Force **and in particular the establishment of a list of accommodation facilities in intensive care units in the Member States for the purpose of potential cross-border relocation of patients;**

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**Amendment 226****Proposal for a regulation****Article 25 — paragraph 1 — point c a (new)***Text proposed by the Commission**Amendment*

*(ca) a Union export control mechanism with the aim of enabling the Union to guarantee timely and effective access to counter-measures;*

**Amendment 227****Proposal for a regulation****Article 25 — paragraph 1 — point c b (new)***Text proposed by the Commission**Amendment*

*(cb) green lanes referred to in Article 25a of this Regulation, in exceptional cases.*

**Amendment 228****Proposal for a regulation****Article 25 a (new)***Text proposed by the Commission**Amendment***Article 25a****Green lanes**

1. *After recognising a public health emergency for a pandemic situation under Article 23(1), the Commission shall, in the case of border restrictions, establish green lanes to ensure that essential goods, medical countermeasures and cross border workers can move freely within the internal market.*
2. *The Commission is empowered to adopt delegated acts to supplement this Regulation with provisions on the establishment of the green lanes referred to in paragraph 1.*
3. *A Member State may only prohibit or restrict exports of medical countermeasures in cases defined in Article 36 TFEU during a public health emergency at Union level, on condition that it obtains prior authorisation from the Commission.*
4. *The Commission shall decide on the request for prior authorisation within five days of the request. If the Commission takes no decision within this period, the authorisation shall be deemed granted.*

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### Amendment 229

#### Proposal for a regulation

#### Article 26 — paragraph 1

*Text proposed by the Commission*

1. The EWRS shall include a selective messaging functionality allowing personal data, including contact and health data, to be communicated only to national competent authorities involved in the contact tracing measures concerned. That selective messaging functionality shall be designed **and** operated so as to ensure safe and lawful processing of personal data and to link with contact tracing systems at Union level.

*Amendment*

1. The EWRS shall include a selective messaging functionality allowing personal data, including contact and health data, to be communicated only to national competent authorities involved in the contact tracing measures concerned. That selective messaging functionality shall be designed **with respect for the principle of data minimisation and data protection by design and by default, and shall be** operated so as to ensure safe and lawful processing of personal data and to link with contact tracing systems at Union level.

### Amendment 230

#### Proposal for a regulation

#### Article 26 — paragraph 5

*Text proposed by the Commission*

5. Personal data may also be exchanged in the context of automated contact tracing, using contact tracing applications.

*Amendment*

5. Personal data may also be exchanged in the context of automated contact tracing, using contact tracing applications, **in full compliance with Regulation (EU) 2016/679 of the European Parliament and of the Council ('GDPR')<sup>(1a)</sup>**

<sup>(1a)</sup> 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 repealing Directive 95/46/EC (General Data Protection Regulation), (OJ L 119, 4.5.2016).

### Amendment 231

#### Proposal for a regulation

#### Article 26 — paragraph 6 — subparagraph 1 — introductory part

*Text proposed by the Commission*

6. **The** Commission shall, **by means of implementing acts**, adopt:

*Amendment*

6. **Following a prior consultation procedure as set out in Article 42(2) of Regulation (EU) 2018/1725, the** Commission shall adopt **delegated acts in accordance with Article 28 concerning:**

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**Amendment 232****Proposal for a regulation****Article 26 — paragraph 6 — subparagraph 1 — point b***Text proposed by the Commission*


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(b) procedures for the interlinking of the EWRS with contact tracing systems at Union level;

*Amendment*


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(b) procedures for the interlinking of the EWRS with contact tracing systems at Union level **and international level;**

**Amendment 233****Proposal for a regulation****Article 26 — paragraph 6 — subparagraph 1 — point d***Text proposed by the Commission*


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(d) the modalities for processing automated contract tracing applications and interoperability of these applications, as well as the cases where, and the conditions under which, the third countries may be granted access to contract tracing interoperability and the practical arrangements for such access.

*Amendment*


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(d) the modalities for processing automated contract tracing applications and interoperability of these applications, as well as the cases where, and the conditions under which, the third countries may be granted access to contract tracing interoperability and the practical arrangements for such access, **in full compliance with the EUDPR and applicable case law of the Court of Justice;**

**Amendment 234****Proposal for a regulation****Article 26 — paragraph 6 — subparagraph 1 — point d a (new)***Text proposed by the Commission*


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*Amendment*


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**(da) a detailed description of the roles of the actors involved in the processing of personal data through the proposed IT tools and systems.**

**Amendment 235****Proposal for a regulation****Article 26 — paragraph 6 — subparagraph 2***Text proposed by the Commission*


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**Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(2).**

*Amendment*


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**deleted**

Thursday 11 November 2021

**Amendment 236****Proposal for a regulation****Article 28 — paragraph 2***Text proposed by the Commission*

2. The power to adopt delegated acts referred to in **Article 8 (3)** shall be conferred on the Commission for an indeterminate period of time from ... [date of entry into force of the basic legislative act or any other date set by the co-legislators].

*Amendment*

2. The power to adopt delegated acts referred to in **Articles 8 (3), 13(9), 14(6), 17(3), 25a(2), and 26(6)** shall be conferred on the Commission for a **for a period of five years from ... [date of entry into force of the basic legislative act or any other date set by the co-legislators]**. **The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.**

**Amendment 237****Proposal for a regulation****Article 28 — paragraph 3***Text proposed by the Commission*

3. The delegation of power referred to in **Article 8(3)** may be revoked at any time by the European Parliament or by the Council. A decision to 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.

*Amendment*

3. The delegation of power referred to in **Articles 8(3), 13(9), 14(6), 17(3), 25a(2) and 26(6)** may be revoked at any time by the European Parliament or by the Council. A decision to 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.

**Amendment 238****Proposal for a regulation****Article 28 — paragraph 6***Text proposed by the Commission*

6. A delegated act adopted pursuant to **Article 8(3)** shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and to the Council or if, before the 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 two months at the initiative of the European Parliament or of the Council.

*Amendment*

6. A delegated act adopted pursuant to **Articles 8(3), 13(9), 14(6), 17(3), 25a(2) and 26(6)** shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and to the Council or if, before the 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 two months at the initiative of the European Parliament or of the Council.

Thursday 11 November 2021

**Amendment 239**  
**Proposal for a regulation**  
**Article 28 a (new)**

Text proposed by the Commission

Amendment

**Article 28a**

**Urgency procedure**

1. *Delegated acts adopted under this Article shall enter into force without delay and shall apply as long as no objection is expressed in accordance with paragraph 2. The notification of a delegated act to the European Parliament and to the Council shall state the reasons for the use of the urgency procedure.*
2. *Either the European Parliament or the Council may object to a delegated act in accordance with the procedure referred to in Article 28(6). In such a case, the Commission shall repeal the act immediately following the notification of the decision to object by the European Parliament or by the Council.*

**Amendments 240 and 277**  
**Proposal for a regulation**  
**Article 29 — paragraph 1**

Text proposed by the Commission

Amendment

By 2025 and every 5 years thereafter the Commission shall carry out an evaluation of this Regulation and present a report on the main findings to the European Parliament and the Council. The evaluation shall be conducted in accordance with the Commission's better regulation guidelines. The evaluation shall include, in particular, an assessment of the operation of the EWRS and the epidemiological surveillance network, as well as the coordination of the response with the HSC.

By 2025 and every 5 years thereafter the Commission shall carry out an evaluation of this Regulation and present a report on the main findings to the European Parliament and the Council. The evaluation shall be conducted in accordance with the Commission's better regulation guidelines. The evaluation shall include, in particular, an assessment of the operation of the EWRS and the epidemiological surveillance network, as well as the coordination of the response with the HSC, **the HERA and the impact of the Regulation on the proper functioning of the single market when serious cross-border threats to health arise. By 2023 and every 2 years thereafter, the Commission shall carry out an in-depth review of the implementation of the operations of HERA, including its structure, governance, funding and human resources. Those reviews shall address, in particular, any need to modify HERA's structure, including but not limited to the possibility of upgrading HERA to a standalone agency, the mandate of HERA and the financial implications of any such modification. The Commission shall report to the European Parliament and to the Council on the findings of the reviews. Those findings shall be made public. The reviews shall be accompanied, where appropriate, by a legislative proposal to address the issues referred to in this paragraph, in full respect of the role of the European Parliament as co-legislator.**

Thursday 11 November 2021

**Amendment 241**

**Proposal for a regulation**

**Article 29 — paragraph 1 a (new)**

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*Text proposed by the Commission*

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*Amendment*

***Based on the evaluation referred to in the previous paragraph, the Commission shall, where appropriate, submit a legislative proposal to amend this Regulation.***

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