EUROPEAN COMMISSION

Brussels, 10.12.2021
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REGULATORY SCRUTINY BOARD OPINION

Proposal for a Regulation of the European Parliament and of the Council on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC

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EUROPEAN COMMISSION
Regulatory Scrutiny Board

Brussels,
RSB

Opinion

Title: Impact assessment / Revision of the Union legislation on blood, tissues and cells

Overall opinion: POSITIVE WITH RESERVATIONS

(A) Policy context

The initiative forms part of the EU's ambition to build a stronger European Health Union. The legislation concerned is the Blood Directive 2002/98/EC and the Tissues and Cells Directive 2004/23/EC (the BTC legislation). These have helped to ensure the safety of patients undergoing blood transfusion, tissues transplantation and medically assisted reproduction. The legislation sets out quality and safety requirements for all steps from donation to human application, unless the donations are used to manufacture medicinal products or medical devices. In these cases the legislation only applies to donation, collection and testing.

Shortcomings were identified in an evaluation in 2019 and through the COVID-19 experience. This initiative aims to ensure a high level of health protection for patients and donors, strengthen oversight arrangements, support innovation and improve the resilience of the sector.

(B) Summary of findings

The Board notes the information provided in advance of the meeting and commitments to make changes to the report.

However, the report still contains significant shortcomings. The Board gives a positive opinion with reservations because it expects the DG to rectify the following aspects:

(1) The report is not sufficiently clear on the scope of the initiative and how it interacts coherently with the other ongoing initiatives in the health area.

(2) The report does not discuss the change of legal instrument and how this leaves sufficient room for Member States' choices.

(3) The design of the three regulatory options is not sufficiently clear. It does not integrate well enough the various measures and does not link well to the objectives.

This opinion concerns a draft impact assessment which may differ from the final version.

(C) What to improve

(1) The report should be clearer about the scope of this initiative, its relations with the other on-going revisions of related legislation, and whether, and where, all assumptions and definitions are streamlined across the health legislation.

(2) The report should explain more convincingly why there is a need for harmonised measures at EU level (beyond the current EU standards). It should include the cross-border dimension in the legal basis for the preferred options. The report should better explain why a different legal instrument ('regulation') has been chosen and it should demonstrate clearly that this choice still respects the subsidiarity principle.

(3) The report should better explain how the three regulatory options would function in practice. It should better connect them with the respective measures and the objectives. All measures (e.g. voluntary and unpaid donations, and digital tools) should be well reflected throughout the report (in the problem section and objectives). The discarded options should be better justified.

(4) The report should better present the methodology of the multi-criteria analysis (using the SOCRATES tool) and its results. It should be clearer about the underlying assumptions and drivers and how it integrated stakeholder views in the analysis. More generally, it should also reflect stakeholders' diverse opinions throughout the report.

(5) The report should be more transparent about the status of the planned data system and what choices are still left for this initiative.

The Board notes the estimated costs and benefits of the preferred option(s) in this initiative, as summarised in the attached quantification tables.

Some more technical comments have been sent directly to the author DG.

(D) Conclusion

The DG must revise the report in accordance with the Board's findings before launching the interservice consultation.

If there are any changes in the choice or design of the preferred option in the final version of the report, the DG may need to further adjust the attached quantification tables to reflect this.

Full title	Revision of the Union legislation on blood, tissues and cells
Reference number	Plan/2020/8495
Submitted to RSB on	11 November 2021
Date of RSB meeting	8 December 2021

ANNEX: Quantification tables extracted from the draft impact assessment report

The following tables contain information on the costs and benefits of the initiative on which the Board has given its opinion, as presented above.

If the draft report has been revised in line with the Board's recommendations, the content of these tables may be different from those in the final version of the impact assessment report, as published by the Commission.

I. Overview of Benefits (total for all provisions) – Preferred Option		
Description	***Amount***	***Comments***
Direct benefits		
Graded oversight approach allows to oversee some establishments with lighter approach and less resources than today (related to measure M1B)	EUR 4 m	750 establishments eligible, mainly saving on inspection costs for authorities and for themselves
Common IT-platform to share assessments of novel BTC technologies reduces duplications (related to measure M4B)	>EUR 2 m	Conservative estimate; Requests to authorize same new technologies are introduced and assessed in parallel across EU; Sensitive to unit cost of assessments and authorisations
Risk-based schedule allows to inspect same activities/establishments more efficiently (targeting high-risk activities) (related to measure M3A))	Not quantified	Model has rather assumed this to be a cost-neutral measure as the same number of resources (inspectors) allow for more oversight on most complex activities
Greater harmonisation of technical standards, through legal references to common rules set by expert bodies and joint Member State inspections will allow recognition of authorisations in other Member States, reducing the need for ad-hoc import authorisations in different Member States (M1A and 2B)	EUR 0.5 m / year	Applicable for almost 1,000 imports of bone marrow/stem cells though central registry (WMDA registry, could be subject to one joint authorisation)

Deleting obsolete tests and screening measures (related to measure M1A)	EUR 2 m (example – West Nile Virus NAT tests)	Very high potential, given that every saving is multiplied by number of donations Example: West Nile Virus can be tested for by individual NAT test or by pooled NAT test, which is EUR 7 cheaper per test. Applicable on good 300,000 blood donations per year in countries affected by WNV
Employment /skills		The investment in the digitalisation and future-proofing of the sector will increase the sector specific expertise (e.g. inspectors) and digital skills in an innovative, knowledge-intensive sector
Digitalization allows for more efficient administrative processes in authorities and establishments	To be further quantified	Common IT tools will facilitate local administration including registration and reporting by professionals as well as authorizations and oversight by authorities. E.g., annual reporting costs are estimated to go down from current 5,000-15,000EUR to 200-2000EUR with an automated reporting tool.
Indirect benefits		
EU patients	Not quantified	Access – streamlined and harmonized legal framework improves (cross-border) access to matching BTC and early access to safe new therapies
EU citizens donating BTC	Not quantified	Trust and willingness to donate – more donations by citizens that can trust their own health is well protected
Public health budget holders	Not quantified	Improved affordability - more and new therapies with high value, but typically offered at cost-price by public actors. Access to standardized data to help assess real value of therapies.
Medical device companies	Not quantified	Market increase - increase of BTC activities required equipment and continuous supply of devices and diagnostics.
Manufacturers of medicinal products	Not quantified	Market increase - streamlined and harmonised BTC framework facilitating access to starting materials for BTC-based medicinal products (plasma derivatives, advanced therapies)

Table 3.1 Overview of Benefits (total for all provisions) – Preferred Option

(1) Estimates are relative to the baseline for the preferred option as a whole (i.e. the impact of individual actions/obligations of the preferred option are aggregated together);

II. Overview of costs – Preferred option							
Over 10 years, 1000 EUR		EU		Businesses including BE/TEs and healthcare		National Administrations	
		One-off	Recurrent	One-off	Recurrent	One-off	Recurrent
Obj 1 – Patient protection	Direct costs	1 474.6	1 343.3	25 109.1	9 441.3	1 760.7	1 402
	Indirect costs						
Obj 2 – donors & offspring protection	Direct costs	1 224.6	1 057.6	28 475	12 241.3	-	722
	Indirect costs						
Obj 3 - Oversight	Direct costs	4 918.3	3 051.7	-	-	5 000	49.6
	Indirect costs						
Obj 4 - Innovation	Direct costs	2 846.1	1 944.3	992.3	4 137.8	2 810.7	667.5
	Indirect costs						
Obj 5 – supply monitoring	Direct costs	1 699.2	1 258.1	28 402.7	2 563.7	213.2	327.1
	Indirect costs						

Table 3.2 Overview of costs – Preferred option

(1) Estimates provided with respect to the baseline;

II. Overview of costs – Preferred option									
Over 10 years, 1000 EUR				Businesses including BE/TEs and healthcare		National Administrations		EU	
Objective	Measure			One-off	Recurrent	One-off	Recurrent	One-off	Recurrent
Patient protection	**M1A** - Up-to-date technical rules	M1.3: EU law requires MS to publish more stringent rules in an accessible format.	Direct costs				17.4	122.2	111.6
			Indirect costs						
		M1.7: EU law requires establishments to take into account ECDC/EDQM rules on quality & safety requirements.	Direct costs		3 525.8		485.5	787.8	928.7
			Indirect costs						
	M1B - Fill regulatory gaps (e.g. FMT, breast milk)	M1.2: EU law incorporates definitions ensuring that safety and quality provisions apply to all SOHO/BTC for which the Treaty give competence to the EU.	Direct costs	2 553.6	1 212.9	632.9	421.9	73.8	71.6
			Indirect costs						
		M1.9: "Same surgical procedure" exclusion for point of care preparations is refined/removed - hospitals, healthcare providers are required to register their activities and report.	Direct costs	22 555.5	4 702.5	1 127.8	477.1	375.6	231.6
			Indirect costs						
Donor & offspring protection	**M2A** - Set donor and offspring protection principles in law	M2.1: EU law on donor safety amended to regulate donor eligibility, protect donor health, protect donor personal data and ensure donor adverse outcomes are reported and	Direct costs	18 903.4	8 542.8		548.1	497.8	343.1
			Indirect						

		investigated.	costs						
	M2B - Up-to-date technical standards for donor and offspring protection	M2.7: EU law requires establishments to take into account ECDC/EDQM rules on quality & safety requirement for donors and offspring from MAR.	Direct costs	9 571.5	3 698.5		173.9	575.6	7145
			Indirect costs						
Oversight	**M3A** - Set principles for oversight in legislation (e.g. independence of authority, risk-based inspections)	M3.1: EU law incorporates oversight principles for the organisation and for staff	Direct costs			5 000		90.7	171.7
			Indirect costs						
		M3.2: EU law obligates NCAs to base their inspection regimes on a risk-based approach.	Direct costs				-118.7	90.7	171.7
			Indirect costs						
		M3.5: EU law provides legal framework for Joint Member State inspections of blood and tissue establishments	Direct costs				154.7	987.9	669.9
			Indirect costs						
		M3.4: Commission audits of national control systems, accompanied by MS experts	Direct costs				13.6	987.9	669.9
			Indirect costs						
		M3.6: EU Support for training & IT	Direct costs					2 307.4	1 368.3
			Indirect costs						
Innovation	**M4A** - Risk-based authorisation BTC processed	M4.4-5-6-7: Strengthened Preparation Process Authorisation: EU law modified so that, for major changes in the	Direct costs	992.3	4 137.8	2 810.7	667.5	2 029.6	1 257.4
			Indirect costs						

	or used in new ways, including clinical data when justified, with guidance	steps of collection, processing and use of BTC, competent authorities will have to grant prior authorisation based on data demonstrating safety and benefit for patients that justifies any risks associated with treatment with BTC prepared in innovative ways. And EU law obligates BE/TEs to conduct risk assessments on novel processes in compliance with technical guidance from expert bodies as referred to in EU legislation							
	M4B - Create BTC mechanism to advise on applicability of BTC legislation and liaise with equivalent MD and (AT)MP mechanisms	M4.1 & M4.3: Establishment of EU level advisory mechanism to recommend/advise MS on when/what BTC requirements should be applied in part or in full. And: Classification advice: advice related to other legal frameworks. EU level advisory mechanism will advise where other frameworks (in particular medical devices and medicinal products) might be applied for particular novel BTC. Implementation might involve exchange/mutual consultation with advisory bodies for MP (EMA innovation task force,	Direct costs					362.9	686.9
			Indirect costs						

		EMA CAT) and MD frameworks (Borderlines and Classification Working Party).							
Supply monitoring	**M5A** – introduce supply monitoring and notification rules	M5.3: EU law is amended to require mandatory emergency plans, for critical BTC, at the level of the blood and tissue establishments, and national competent authorities.	Direct costs	11 752.7	-523.8	0.1	306.1	276.2	429.1
			Indirect costs						
	M5B – Require emergency preparedness plans with guidance	M5.5-6-7-8: EU law is amended with references to guidance from expert bodies for rules on sufficiency data reporting (incl monitoring and notifications) and on emergency preparedness/contingency.	Direct costs	16 650	3 087.5	213.1	20.9	1 120.6	829.1
			Indirect costs						