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EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT REPORT

Accompanying the document

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

{COM(2022) 338 final} - {SEC(2022) 304 final} - {SWD(2022) 189 final} -
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Executive Summary Sheet

Impact assessment on the revision of the EU legislation on blood, tissues and cells (BTC)

A. Need for action

What is the problem and why is it a problem at EU level?

The evaluation of the Blood and Tissues and Cells Directives showed that patients, donors and children born from donated eggs, sperm or embryos are not fully protected from avoidable risks, as the legislation has not kept up to date with scientific and epidemiological developments; there are divergent approaches to oversight among Member States, leading to barriers for cross-border exchange of BTC; the full potential of innovative therapies is not reached for patients, who are also vulnerable to interruptions of BTC supply. There are also some undue burdens due to the absence of common IT systems.

What should be achieved?

The overall objective of this initiative is to ensure a high level of health protection, by providing safe access to BTC therapies for EU citizens. As new technologies or risks will continue to emerge, it is necessary for the framework to be future-proof, resilient and agile enough to accommodate new trends and continue providing appropriate safety and quality requirements.

What is the value added of action at EU level (subsidiarity)?

By providing a framework for cross-border cooperation, based on a common set of rules, EU-level measures are best placed to address the above issues effectively, with EU expertise. Establishing high standards of quality and safety for BTC at an EU level brings equal levels of access to safe therapies.

B. Solutions

What are the various options to achieve the objectives? Is there a preferred option or not? If not, why?

Three options to set and update technical standards were assessed:

- **Option 1 - Decentralised regulation**: blood and tissue establishments make reference to a variety of national and international guidance to set their internal technical standards for their own activities.
- **Option 2 - Joint regulation**: blood and tissue establishments have to follow the technical standards defined in guidance developed and maintained by nominated EU expert bodies.
- **Option 3 - Central Regulation:** blood and tissue establishments have to follow the technical standards defined in EU law.

The preferred option is Option 2, which brings the highest effectiveness and efficiency as it builds on established BTC expertise to get timely standards that are applied across the EU.

In addition, a series of **common measures** was assessed, to fill some legal gaps in the BTC framework, strengthen oversight, facilitate innovation, with advice on when the BTC legislation is applicable (the delineation with other frameworks will not change), a (risk-) proportionate authorisation for new processes, and (crisis) management of BTC supply. Regarding digital aspects, the preferred implementation is a new single IT system.

What are different stakeholders' views? Who supports which option?

There is broad support among stakeholders for option 2, and for the common measures. However, national competent authorities flagged concerns on the resources needed for the implementation of measures to strengthen oversight. Also, while supported, stakeholders pointed out that crisis preparedness measures will bring significant efforts without direct impact in reducing the risks of shortages of critical BTC.

C. Impacts of the preferred option

What are the benefits of the preferred option (if any, otherwise of main ones)?
The preferred option would ensure that **citizens** are better protected when donating, or being treated with a substance of human origin, with more harmonised safety and quality rules across EU. It would also bring a positive impact for **healthcare professionals**, in particular in blood and tissue establishments. Outdated, and sometimes costly, technical rules for safety and quality will be removed and replaced with standards based on the best scientific evidence and expertise available, and updated in a timely manner. The common measures will also strengthen oversight by **national competent authorities**. Digitalisation will allow for further efficiencies in administrative processes, and the possibility for sharing information will limit duplication of work across Member States.
What are the costs of the preferred option (if any; otherwise of main ones)?
The main costs relate to monitoring measures (donors, offspring, supply), to registration of bedside preparations of BTC and to the risk-proportionate pathway to authorise BTC processed or used in new ways. Those costs mostly fall on professionals in blood and tissues establishments, hospitals and clinics and, to a lesser degree, on national competent authorities. For EU institutions, the set-up of a common EU IT platform brings an important cost, but will allow to lighten (administrative) burden for national authorities and professionals. Further EU costs relate to coordination and co-funding of expert bodies. The overall costs for the measures under the preferred option are expected to be around EUR 38 million per year, above the baseline.
What are the impacts on small and medium-sized enterprises (SMEs)?
Only a small amount of for-profit 'small and medium-sized enterprises' (SMEs) will be directly impacted by the initiative; it concerns mostly establishments found in the sub-sector of medically assisted reproduction (private IVF clinics). The BTC sector is also dependent from developments in medical device technologies (e.g., test kits) and ICT (e.g., data-registries), two SME-rich sectors.
Will there be significant impacts on national budgets and administrations?
New measures such as authorisation of novel BTC preparations, oversight of bedside BTC preparations and of new SoHOs will require additional resources. The introduction of some risk-based measures will however enable a more efficient oversight with limited resources. Authorities will be further supported with measures like training, audits, common guidance and a dedicated EU IT platform.
Will there be other significant impacts?
There will be positive impacts on some fundamental rights of citizen (health protection, non-discrimination), although for most of the ethical aspects, in particular the rights of children born from medically assisted reproduction, the decisions are taken by Member States at national level. Digital impacts are expected: a single IT system can host flexible solutions, allowing Member States and blood and tissue establishments to maintain and connect with their own system or re-use existing components. It could become an important node in the European Health Data Space and more broadly the EU digital ecosystem.
Proportionality?
The overall initiative is limited to aspects that Member States cannot achieve satisfactorily on their own, and where there is an EU added value. The added value of the EU approach is to ensure the full use of the high level of scientific and technical expertise already available in expert bodies such as the ECDC and the EDQM.
D. Follow up
When will the policy be reviewed?
The Commission will review the monitoring indicators periodically and evaluate the impacts of the legislative act after 5 years.