Questions and answers on the new legislation on Substances of Human Origin

Brussels, 24 April 2024

The Regulation endorsed by the European Parliament is another building block of the European Health Union. Once implemented, it will promote pooling resources and creating economies of scale, with patients across the EU having access to the treatment they need, regardless of where they live. It will also facilitate both cross-border circulation of these critical substances and cooperation between public health authorities in different Member States. The Regulation will reinforce solidarity while ensuring the same high level and harmonised standards of safety and quality for all substances of human origin used for patient treatment (SoHO).

From 2027, this new future-proof and robust framework will better protect donors, recipients treated by transfusion, transplantation or medically assisted reproduction, and offspring born from donated sperm or eggs while fostering innovation in this crucial biotech sector.

The new legislation consists of a single Regulation that will be equally applicable in all Member States. This will improve harmonisation, simplify cross-border exchanges, and access to SoHO, and ensure a uniform level of protection across the EU.

Which products are we talking about?

SoHO-based treatments provide large numbers of:

- life-saving and life-enhancing therapies every year (such as 25 million units of blood transfused, e.g. for surgery or trauma care; 36,000 stem cell transplants for blood cancers and other conditions);
- life-creating therapies (over 200,000 babies born from medically assisted reproduction in Europe each year);
- and life-improving therapies (e.g. 10,000 cornea transplants for restoring sight, 2,000 skin transplants for burn wounds and other injuries).

What has been endorsed by the European Parliament?

Tabled in 2022 by the Commission, this Regulation is a comprehensive revision of the existing legislation to ensure safety and quality of blood, tissues, and cells (BTC).

It updates and reinforces the rules for safety and quality, and extends them to other substances of human origin (SoHO), such as human breast milk, which were previously left unregulated at EU level.

This text builds upon the existing legal framework, which came into force in 2002 for blood, and 2004 for tissues and cells, containing parallel provisions for donor selection, quality and safety management and oversight.

While this Regulation will bring a high level of safety and quality standards, it still leaves Member States the possibility to add more stringent requirements, in particular to ensure alignment to the set-up of national healthcare systems.

Why did the legislation on BTC need to be updated?

In place for more than 20 years, the legislation on blood and on tissues and cells was outdated and did not reflect the many relevant developments that have taken place since its adoption. New infectious disease risks have emerged during this time and the innovative biotechnologies available for preparing SoHO for clinical use have developed significantly, improving safety and effectiveness but also introducing new risks that need to be addressed with appropriate rules.

The Commission published an evaluation in 2019 which showed that the framework had increased safety and quality of SoHO across the EU, but the evaluation also identified five key areas where the legal framework no longer reflected the current situation.

Following a wide consultation with stakeholders, both on the objectives of the revision and its content, and incorporating lessons learnt from the COVID-19 pandemic, the new Regulation now includes measures tackling each of these problems.

It ensures that:

(1) technical rules for safety and quality are up-to-date and will continue to be responsive to changing risks and technologies

(2) donors and offspring are protected

(3) harmonisation of oversight requirements is strengthened

(4) innovation is supported

(5) measures supporting supply resilience, in general and during emergencies, are introduced.

What are the major changes compared to the legislation currently in place?

The new Regulation combines measures that apply to regulatory authorities, SoHO entities and establishments preparing SoHO, as well as to hospitals and clinics where SoHO are used to treat patients.

It includes a range of new measures which fill some gaps and were developed to support the functioning of the whole sector:

- It covers **all substances of human origin** (except for solid organs for transplantation, which remain regulated separately under a dedicated Directive). These include blood, tissues, and cells, as well as other substances such as human breast milk or microbiota, which present similar safety and quality concerns. Other substances of human origin that may, in the future, be applied to patients will automatically fall within the scope of this legislation;
- SoHO must be prepared, treated and stored according to **specific standards to ensure they are safe and effective for patients**. In addition to protecting patients, such standards will now be extended to protect offspring born from medically assisted reproduction as well as donors, including 15 million blood donors, over 34,000 stem cell donors and over 39,000 egg donors every year;
- To ensure that these rules continually reflect scientific progress, their development will be predominantly **carried outby scientific expert bodies active in the sector**. This means that new evidence can be taken on board more rapidly than before, and safety requirements can be kept up to date (e.g. testing for infectious or non-infectious diseases);
- Any entity conducting activities that affect the safety and quality of SoHO will have to **register with their competent authorities**. Those entities that carry out activities with greater impact on safety and quality will have to fulfil additional requirements to be authorised and inspected as a SoHO establishment;
- Entities working with SoHO will be required to **report their annual activity data** (for specific activities). These data will allow Member States to implement measures to improve donation rates or mitigate shortages in other ways, when needed. Entities working with critical SoHO will need to alert their authority in the case of a sudden fall in supply and will be required to have plans in place to address emergencies;
- Oversight requirements will be proportionate and risk-based. This way, protection of patients, donors, and offspring can be increased without creating undue burdens for competent authorities. In addition, the Commission will support joint oversight activities (for example in authorising new SoHO preparations) as well as provide training, IT support tools and opportunities for exchanging best practices.

How does the Regulation enhance the EU-wide dimension of innovation policies in this area?

The EU aims to facilitate innovation and research as well as cross-sector collaboration. To simplify the work of innovators in the SoHO sector, the framework includes a common procedure for the authorisation of SoHO preparations. This procedure extends the currently applicable rules for preparation process authorisations in the Tissue and Cell Directive to the blood field and introduces an up-front benefit/risk assessment followed by requirements for clinical outcome data collection, proportionate to the identified risks. The approach was developed and tested in a Joint Action carried out by a large number Member States.

The Regulation establishes a SoHO Coordination Board (SCB) as an advisory body that will support Member States in the implementation of the Regulation. The SCB will develop common good

practices for inspection and vigilance, provide advice on the applicability of the Regulation, and generally support the competent authorities in the oversight of the sector. The SCB will also increase cross-sector coherence and legal clarity by liaising with expert bodies and corresponding bodies in other legal frameworks regarding regulatory borderline issues that might arise.

Furthermore, the academic centres that develop innovative approaches to SoHO preparation and the use of SoHO in patients will share information on their work, which will facilitate access to the most innovative SoHO-preparations for therapies across the EU.

Does the new Regulation keep some provisions of the old legislative framework?

Yes, the new Regulation builds upon, and adds to, the standards of the previous legislative framework.

For instance, Member States retain the full competence on any organisational and ethical decisions concerning the provision of SoHO-based treatments in their healthcare systems.

In addition, the principle of voluntary and unpaid donation has been upheld and clarified, with an obligation for the conditions of any permitted compensation to be set at the national level and the details shared between Member States.

How will this legislation affect the lives of citizens?

This new legislation will improve access to safe and proven SoHO, which are critical to numerous aspects of healthcare systems in EU Member States.

The availability of these substances is dependent on the willingness of citizens to make donations and of the efforts made by principally public services, including blood and transplant services, as well as for medically assisted reproduction, to prepare and offer SoHO at affordable costs.

The Regulation also improves the protection of those citizens that donate to allow for these treatments to be carried out. For example, follow-up after donating certain types of SoHO will be required, in some cases for longer periods, so that any adverse reactions can be monitored and reported.

The increased harmonisation will facilitate the exchange of SoHO between Member States and hence optimise treatment options for all patients in the EU. New measures requiring activity data monitoring, supply alerts to authorities and the development of emergency plans will help Member States to take action when the supply of critical SoHO is threatened.

What will be the roles of the European Centre for Disease Prevention and Control (ECDC) and the European Directorate for the Quality and Medicines and HealthCare?

Leveraging the common European expertise is to the benefit of all Member States, further strengthening the European Health Union.

Technical rules need to reflect high-quality and state-of-the-art evidence in order to ensure the safety and quality of SoHO and the protection of donors, recipients, and offspring.

To meet this goal, the Regulation makes use of the expertise of the European Centre for Disease Prevention and Control (ECDC) and the European Directorate for the Quality of Medicines & HealthCare (EDQM[1]) of the Council of Europe to provide authoritative technical guidelines that will help the sector to meet the safety and quality standards required.

This guidance is already widely applied in the sector but will now become the primary means to meet the EU standards of quality and safety for SoHO. Both expert bodies will use their capacity and experience to adapt their guidance to scientific progress and frequently changing threats. Alternative technical approaches are also permitted if demonstrated to meet the standards of safety and quality defined in the Regulation.

How will digitalisation play a role in this new framework?

The new Regulation puts forward the creation of an **EU SoHO Platform**, a central digital tool for authorities and stakeholders to facilitate data exchange and administration in the sector. It will be developed and hosted by the Commission. and will provide a central hub for access to information on registrations, authorisations, technical guidelines for professionals in the field and best practices for Member State competent authorities.

The platform will publish aggregated data on donations, clinical use and adverse reactions, under clear governance and in line with European data protection rules. The platform will improve communication, transparency and efficiency in the sector, while pre-empting the need for Member States to establish multiple data platforms and information dissemination tools in a way that

safeguards the privacy of health data.

What are the next steps?

The new Regulation will now be adopted by the Council later this Spring and published in the Official Journal of the European Union.

There will be a three-year transition period before most provisions apply and a four-year period for a small number of specific provisions.

The Commission will adopt a series of Acts implementing certain provisions, such as import and traceability requirements, in more detail.

The Regulation will be applicable by mid-2027.

For More Information

New EU rules on substances of human origin

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[1] The European Directorate for the Quality of Medicines & HealthCare (EDQM) is a directorate of the Council of Europe (CoE), which has 46 Member States, including all EU Member States,

The origin of EDQM date back to 1964, when the Convention on the Elaboration of a European Pharmacopoeia was adopted by the Committee of Ministers of the CoE. To date, the Convention has been signed and ratified by 39 Member States of the Council of Europe, including the 27 EU Member States, and by the EU.

The EDQM is responsible for the development of technical rules for safety and quality of SoHO through dedicated expert groups, then adopted by its European Committees on Blood transfusion and Organ Transplantation (CD-P-TS and CD-P-TO). These committees are intergovernmental structures answerable to the Committee of Ministers of the CoE. Members eligible to these Committees are the Members that have signed the Convention on the Elaboration of a European Pharmacopoeia.

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