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Blood, tissues and cells: Council and Parliament strike deal

The Council has reached a provisional agreement with the European Parliament on new rules aimed at improving the **safety and quality of blood, tissues and cells** used in healthcare and facilitating **cross-border circulation** of these substances in the EU.

The regulation on **substances of human origin (SoHO)** will ensure better protection for donors and recipients, as well as for children born following medically assisted reproduction. The proposed new rules aim to strengthen the existing legal framework while also increasing flexibility in order to keep up with scientific and technical developments.

Under the provisional agreement, member states may choose to apply stricter measures to protect their citizens.

> One of the key lessons learned during the COVID pandemic was the vital importance of effective cross-border cooperation on matters of health care. Today's agreement not only guarantees the highest possible standards of safety and quality for SoHOs, it also makes it easier for patients to access potentially life-saving health products across member-state borders.
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> *Mónica García Gómez, Spanish Minister for Health*

Substances of human origin: more than just blood, tissues and cells

The text agreed upon today by the co-legislators broadens the scope of SoHO to include **human breast milk and intestinal microbiota**. It also aims to future-proof the EU's legislation by covering other SoHO that may be applied to humans in the future and by allowing more flexible future updates.

The proposed regulation covers a wide range of activities from registration and testing of donors, collection and processing to human application and clinical outcome monitoring of substances of human origin.

A common EU framework

In addition to improving quality and safety, the provisional agreement aims to increase harmonisation and **facilitate cross-border exchanges and access to** SoHO, including by:

- setting up an EU-level **SoHO coordination board** supporting member states in the implementation of the Regulation
- introducing **common EU-wide procedures** for the authorisation and assessment of SoHO preparations
- requiring member states to designate a **SoHO national authority** and other competent authorities to authorise SoHO preparations and ensure independent and transparent oversight of SoHO-related activities
- setting out **additional authorisation and inspection requirements** for establishments that both process and store, release, import or export substances of human origin
- establishing a new common IT platform, the **EU SoHO platform**, to register and exchange information on related activities

Voluntary and unpaid donation

Under the provisional agreement, donations of SoHO should be **voluntary and unpaid** as a matter of principle, and donors must not be provided with financial incentives to donate. Living donors may receive compensation or reimbursement as appropriate in line with national legislation.

Vigilance, supply continuity and national plans to response to emergency situations

The draft regulation also provides for a **rapid alerts system** to cope with serious incidents or reactions that are likely to pose a risk for recipients or donors. Member states should also make reasonable efforts to ensure the sufficient, adequate and resilient

supply of critical SoHO in their countries, including by drawing up **national emergency plans**, including measures to respond to critical shortages.

Next steps

The provisional agreement will now have to be endorsed by the Council and the Parliament. It will then be formally adopted by both institutions after legal-linguistic revision. The regulation will enter into force following publication in the EU's Official Journal.

Background

The existing directives on bloods, tissues and cells were adopted in response to the transmission of communicable diseases in the 1980s and 1990s. Their recent evaluation showed that patients, donors and children born from donated eggs, sperm or embryos were not fully protected from avoidable risks, as the current framework is not up to date with scientific development. Moreover, member states have been applying different oversight systems. This has hampered the cross-border exchange of blood, tissues and cells and has not promoted innovation in this sector.

On 19 July 2022, the European Commission presented a proposal for a regulation on standards of quality and safety for substances of human origin intended for human application. The proposal builds upon lessons learnt, including from the recent Covid-19 pandemic. It addresses the risk of disease transmission by blood, tissues and cells and the need for sufficiency of supply.

The Council agreed on its negotiating mandate on 25 October 2023. Negotiations with the European Parliament began on 6 November 2023 and conclude with today's provisional agreement.

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