AUG. 22

INFORMATIVE NOTE

HEALTHCARE, LIFE SCIENCES & PHARMACEUTICALS

Substances of human origin intended for human application

Proposal for a regulation of the European Parliament and of the Council on standards of quality and safety

Current regulatory framework and scope of application

The EU regulatory framework on substances of human origin ("SoHO") is reflected in Directives 2002/98/EC for blood and 2004/23/EC for tissues and cells. This Proposal will repeal these directives and address the shortcomings resulting from the lack of harmonisation between Member States and the scientific and technical inadequacy of the 2002 and 2004 Directives.

The European Parliament and the Council have found that patients, blood, tissue and cell donors ("BTC") and children born from donated eggs, sperm or embryos are not fully protected against avoidable risks, and that the divergence of national rules hampers cross-border exchanges of BTS. Consequently, the proposed new Regulation covers all substances of human origin applied to humans, regardless of whether they meet the definition of 'blood', 'tissue' or 'cells', with specific exceptions. Placing a substance in the body, when it has no biological or physiological interaction with that body, as in the case of wigs made of human hair, is therefore outside the scope.

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Guiding objectives of the Proposal

1. **Protection of the health of donors and recipients** – The work of the proposed SoHO Coordination Board will be geared towards monitoring the uniform application of the proposed Regulation's rules in order to safeguard the quality and safety of donors and patients in all EU countries. Better reporting of adverse reactions will also be implemented, including self-reporting by donors and SoHO recipients of these reactions.

2. **Optimising access** – supervision of Member States will be strengthened in order to facilitate the exchange of SoHO and allow for better access to therapies for patients. Thus, one of the **new features** proposed is the creation of a legal basis for Commission checks on national authorities, including **joint audits and inspections with inspectors from more than one Member State**. Audits will be carried out both on competent authorities and on systems of supervisory activities to verify the effective application of the Regulation.

   In addition, The Regulation is intended to improve the resilience of the sector. It will do so by mitigating the risk of shortages and disruptions in SoHO supply, which is one of the major difficulties at present, by proposing the establishment of supply monitoring obligations, supported by an EU SoHO Platform to report, aggregate, extract and publish data.

3. **Promoting innovation** – The intention is to implement a risk-based authorisation for use of new forms of SoHO and processed SoHO, with proportionate requirements for clinical data to demonstrate the efficacy of new SoHO preparations. The idea is that these authorisations will be registered on the EU SoHO Platform and can be invoked and accepted by other Member States to facilitate the use of the same process with minimal administrative burden. Furthermore, the adaptation of the sector to digital developments will be achieved by setting up an EU-wide data system in this sector.

European harmonisation

A key element of the proposal is to establish more harmonised measures for Member States and organisations involved in the collection, testing, processing, distribution and use of SoHO, from donors to patients. Nevertheless, **Member States remain free to make ethical and organisational decisions**, such as deciding who can have access to certain therapies with SoHO, for example, access to in vitro fertilisation therapies.

Furthermore, Member States are always free to maintain or introduce more stringent measures when they consider them necessary (see Article 4 of the current Proposal).

By proposing the establishment of supply monitoring obligations, supported by an EU SoHO Platform to report, aggregate, extract and publish data.

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Impact on fundamental rights

The Proposal strengthens the provisions on the protection and monitoring of donors and the reporting of genetic defects in children born from medically assisted reproduction with third-party donation in view of **the principle of voluntary and unpaid donation**, in line with Article 3 of the EU Charter of Fundamental Rights. The Proposal is also intended to harmonise the current regulatory framework and adapt it to the principle of "financial neutrality" recently recommended by the Bioethics Committee of the Council of Europe.

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Structure and entry into force

The proposal defines the scope of application and the competent authorities (Chapters I and II), the supervisory activities (Chapter III) and the general obligations of SoHO entities and establishments (Chapters IV and V). The protection of donors, recipients and the offspring of medically assisted reproduction is appropriately addressed in Chapters VI and VII, and the continuity of supply is also covered (Chapter VIII).

It is proposed that the Union will play an active role in the supervision and control of this sector. The powers of the SoHO Coordination Board, chaired by the Commission, and the activities of the Union are strictly defined (Chapters IX and X respectively).

When it comes to timing, the Proposal provides that the Regulation will only apply **two years** after the date of entry into force, except for some specific obligations on competent authorities, which will only enter into force **three years** after the entry into force of this Regulation. ■