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Proposed Overhaul of EU Regulation of Substances of Human Origin

Introduction

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In recent decades, technologies and medical treatments involving substances of human origin ('SoHOs') have proliferated and undergone significant advancements, improving their potential clinical applications. In addition, the COVID-19 pandemic, along with other emerging infectious agents that could be harboured in SoHOs, has highlighted that existing EU law instruments governing control of SoHOs do not adequately address the broader public health considerations. On 14 July 2022, the European Commission published a proposed regulation on quality and safety standards for SoHOs intended for human application (the 'Proposal').

Consistent with the other EU-wide reviews affecting the life-sciences sector, the Proposal seeks to protect public health, patient safety, and consumer interests, while fostering innovation to improve patient access to novel therapies based on SoHOs.

The Proposal would repeal and replace two existing directives: the Blood Directive (2002/98/EC1) and the Tissues and Cells Directive (2004/23/EC2) (together, the 'Directives'). For nearly twenty years, both Directives have laid out quality and safety requirements for patients undergoing medical procedures involving blood transfusion, transplantation, and medically assisted reproduction—therapies that are not necessarily regulated as medicinal products, medical devices, or their combinations. The Proposal aims to update the Directives, ensuring that the regulatory framework remains relevant in view of technological and medical advancements to produce novel SoHO-based therapies.

The requirements provided by the Proposal would apply directly to all EU Member States without the need for local law transposition. Following adoption by the ordinary legislative procedure, the Proposal would enter into force two years after publication in the Official Journal.

In alignment with the existing Directives, the Proposal seeks to protect human health and achieve consistency with all Union policies and activities under the single market principle. At the same time, the Proposal would allow Member States to maintain or introduce more stringent protective measures if desired, in accordance with the so-called subsidiarity principle (which the Directives also recognise). The subsidiarity principle safeguards Member States' ability to take action; it authorises intervention by the EU institutions only when necessary '*by reason of the scale and effects of the proposed action*'. In this context, Member States remain responsible for ethical and organisational decisions, such as whether to allow the donation of certain SoHO therapies (*e.g.*, in vitro fertilisation).

Implications

As indicated below, the Proposal would introduce significant changes to the regulation of SoHOs in the European Union and the European Economic Area.

The Proposal would affect entities involved in any action(s) with a direct impact on the safety, quality, or efficacy of SoHOs. Such actions would include the preparation, manufacture, or collection of such substances for use in developing and manufacturing finished products that could also be regulated by other sector-specific rules (*e.g.*, advanced therapies). Such entities would include certain pharmaceutical companies, hospitals, and fertility clinics. Notably, entities handling SoHOs like breast milk and microbiota, which fall outside the scope of the existing Directives, would also need to comply with this updated Proposal. All potentially regulated entities should closely follow this Proposal and any related developments.

The Proposal

The salient points of the Proposal, including the significant legislative changes, are as follows.

- The over-arching objectives of the Proposal are five-fold:

    1. To ensure safety and quality for patients treated with SoHO therapies, and to fully protect such patients from avoidable risks that may arise from use of SoHOs;

    2. To ensure safety and quality for SoHO donors and for children born from donated eggs, sperm, or embryos;

    3. To strengthen and promote harmonisation of oversight practices among EU Member States;

    4. To facilitate the development of safe and effective innovative SoHO therapies; and

    5. To improve resilience of the sector in order to manage the risk of supply shortages.

- The Proposal would apply to SoHO preparations, to products manufactured from SoHOs and intended for human application, and to SoHO donors and recipients.

- The Proposal would also govern certain stated activities, including SoHO donor recruitment; SoHO collection, processing, and quality control testing; SoHO storage, release, and distribution; SoHO import and export; human application of SoHOs; and SoHO clinical outcome monitoring.

- The scope of the regulated human materials under the Proposal would significantly widen. The Proposal applies to any SoHO intended for human application, 'regardless of whether it meets the definition of "blood", "tissue" or "cell"', with the exception of solid organs. Unlike the current Directives, which only apply to blood, tissues, and cells, the Proposal applies to substances such as 'human breast milk, intestinal microbiota, [and] blood preparations that are not used for transfusion'.

- Moreover, the Proposal redefines the term '*intended for human application*' to mean SoHOs 'inserted, implanted, injected, infused, transfused, transplanted, ingested, transferred (as in transfer to the uterus or fallopian tube of a woman), inseminated or otherwise added to the human body in order to create a biological, mechanical or physiological interaction with that body'. Therefore, the Proposal would not apply to SoHOs intended for other purposes, such as for recreation.

- Similar to the Directives, the Proposal would require that Member States have national SoHO supervisory authorities meeting all requirements enumerated in the Proposal. Member States would further be required to establish national SoHO emergency plans.

- The Proposal also places certain obligations on 'SoHO entities'—entities carrying out any activities within the scope of the Proposal. Such obligations include registration, data collection and reporting, and import and export responsibilities. Additional requirements would apply to 'SoHO establishments' (SoHO entities that carry out both processing and storage of SoHOs). The Proposal would also institute protections for SoHO donors, recipients, and offspring.

- The Proposal would establish an 'EU SoHO Platform', which would 'facilitate effective and efficient exchange of information concerning SoHO activities in the Union'.