Standards of quality and safety for substances of human origin intended for human application

2022/0216(COD) - 14/07/2022 - Legislative proposal

PURPOSE: to ensure a high level of health protection for EU citizens and ensure access to safe and effective substances of human origin (blood, tissue and cells) (SoHOs).

PROPOSED ACT: Regulation of the European Parliament and of the Council.

ROLE OF THE EUROPEAN PARLIAMENT: the European Parliament decides in accordance with the ordinary legislative procedure and on an equal footing with the Council.

BACKGROUND: every year, EU patients are treated with 25 million blood transfusions (during emergency surgery, cancer or other care), a million cycles of medically assisted reproduction, over 35 000 transplants of stem cells (mainly for blood cancers) and hundreds of thousands of replacement tissues (e. g., for orthopaedic, skin, cardiac or eye problems).

The EU framework for safety and quality of substances of human origin (SoHOs) has currently three main Directives, respectively for **Blood, Tissues and Cells, and Organs**, together with implementing legislation.

Although these Directives have harmonised to a certain degree the rules of Member States in the area of safety and quality of blood, tissues and cells, they include a significant number of options and possibilities for Member States to implement the rules they laid down. This results in **divergences between national rules**, which can create obstacles to cross-border sharing of these substances.

A fundamental revision of those Directives is needed for a robust, transparent, up-to-date and sustainable regulatory framework for these substances, which achieves safety and quality for all parties involved, enhances legal certainty and supports continuous supply, whilst facilitating innovation for the benefit of public health. In addition, the proposal aims to tackle concerns regarding the sufficiency of supply highlighted by the COVID-19 pandemic.

This initiative is part of the EU’s ambition to build a stronger European Health Union.

CONTENT: the proposed Regulation aims to establish measures setting high standards of quality and safety for all substances of human origin intended for human applications and for activities related to these substances, in order to ensure a high level of human health protection, in particular for donors of substances of human origin, recipients of substances of human origin and offspring of medically assisted reproduction.

All substances of human origin would be covered, with the exception of solid organs. Human breast milk is one of the new substances covered by the proposal.

More specifically, the proposal provides for measures to:

- ensure **safety and quality for patients** receiving SoHO therapies and fully protect them from avoidable risks related to substances of human origin;

- ensure **safety and quality for donors** of substances of human origin and for **children** born from donated eggs, sperm or embryos;

- empower the EU and its Member States to **better prevent and combat future pandemics** (surveillance, data analysis, risk assessment, early warning and rapid response);

- facilitate the development of **innovative, safe and effective SoHO therapies**;

- improve the **resilience of European health systems** (sufficient supply of human-derived substances) by mitigating the risk of shortages.

Specifically, the proposal:

- improves the **protection of patients** treated with SoHO (recipients) and offspring from medically assisted reproduction, with standards, and how to implement these standards concerning recipient and offspring protection;

- contains provisions on the competent authorities for substances of human origin, which are responsible for the supervisory activities;

- covers all activities that competent authorities undertake in relation to SoHO entities or registration procedures, with the obligation to maintain a register of SoHO entities and to establish a procedure for their **registration**;

- describes all general obligations on SoHO entities, namely their registration, the nomination of a Responsible Person if they release substances of human origin for clinical use, as well as obligations regarding the export of SoHOs;

- requires blood and tissue establishments to meet safety and quality standards by following **guidelines** developed and updated by **designated expert bodies** such as the European Centre for Disease Prevention and Control (ECDC) and the European Directorate for the Quality of Medicines and Health Care (Council of Europe);

- lays down provisions to ensure the **continuity of supply of SoHOs**. It covers the obligation for Member States to have national SoHO emergency plans (for SoHOs that are critically important for patients) and the responsibilities of competent authorities and entities regarding supply alerts for critical SoHOs.

A SoHO Coordination Board (SCB) would be established with and for the Member States to support a common implementation of the new Regulation.

The creation of the **EU SoHO Platform**, to gather all required information, streamline reporting and increase visibility to citizens will give a new impetus to digitalisation.

BUDGETARY IMPLICATIONS: the financial impact of the proposal is estimated at **EUR 55.411 million** in commitment appropriations for the period 2024-2027. The appropriations will be reallocated within the financial envelope of the EU Health Programme in the Multiannual Financial Framework (MFF) 2021-2027.