Better quality standards for substances of human origin intended for human application

During its September session, Parliament is expected to vote on the report adopted by its Committee on the Environment, Public Health and Food Safety on a proposal to revise the EU laws on blood, tissues and cells. The proposal is a new step towards building a strong European health union. The report as voted would form Parliament’s position for negotiations with the Council.

Background
EU legislation on blood, tissues and cells was subject to an evaluation in October 2019. This confirmed that the laws on substances of human origin (referred to as ‘SoHOs’) had improved the safety and quality of blood, tissues and cells used for transfusion, transplantation or medically assisted reproduction. However, the evaluation highlighted a number of gaps and shortcomings (such as new infectious disease risks) needing addressed to ensure the framework was up to date, fit for purpose and future-proof.

SoHO-based treatments are of high value. They provide large numbers of life-saving and life-enhancing therapies every year: 25 million units of blood for transfusion (e.g. for surgery or trauma care); 36 000 stem cell transplants for blood cancers, life-creating therapies (medically assisted reproduction treatments, e.g. 940 000 cycles of in vitro fertilisation), and life-improving therapies (e.g.14 500 cornea transplants for restoring sight, and 2 000 skin transplants for burn wounds and other injuries).

European Commission proposal
On 14 July 2022, the European Commission put forward a proposal to update and expand EU legislation on blood, tissues and cells. The aim is to establish high standards of quality and safety for SoHOs intended for human application, to improve the protection of donors, recipients, and offspring born from medically assisted reproduction, and to ensure that the legislation can respond to future challenges. The proposal updates and reinforces the rules for safety and quality and extends them to other SoHOs, such as human breast milk and intestinal microbiota, which were previously unregulated at EU level.

To improve harmonisation, ensuring a uniform level of protection across the EU and simplifying cross-border exchange and access to SoHO therapies, the Commission is proposing to repeal the existing directives (the ‘Blood Directive’ 2002/98/EC and the ‘Tissues and Cells Directive’ 2004/23/EC) and replace them with a single regulation that will be equally applicable in all Member States.

In September 2022, EPRS published an implementation appraisal on the existing EU legislation on blood, tissues and cells.

European Parliament position
On 18 July 2023, the European Parliament’s Committee on the Environment, Public Health and Food Safety (ENVI) adopted its report on the proposal, with 59 votes in favour, 4 against and 4 abstentions. Parliament is expected to vote on the text during its September plenary session (and may amend the report). The report as adopted will form Parliament’s position for future negotiations with the Council.