PRO Article
Health Care

Commission launches once-in-a-generation overhaul of blood, tissues and cells rules

The proposed regulation covers all substances of human origin — including poop transplants.

The Commission's proposal combines two directives — one for blood and the other for tissues and cells | Javier Soriano/AFP via Getty Images

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The European Commission has launched a plan to improve the safety and quality standards for people treated with substances of human origin (SoHO), donors, and children conceived through medically assisted reproduction.

It has laid it all out in a 118-page proposal, set to replace the current two decades-old blood, tissues and cells legislation.

"Every year, millions of EU citizens need either a blood transfusion during surgery or after an accident, bone marrow transplants to treat leukaemia or cycles of IVF to become parents. These are just a few examples of how important these treatments are," said Health Commissioner Stella Kyriakides in a statement.

"They form a critical part of healthcare systems across the EU and the stronger rules we are proposing today will ensure that our citizens can count on the highest standards of quality and safety of these vital products, whether it is for cancer care or emergency surgery," she said.

As previewed in a draft of the proposal obtained by POLITICO, the Commission's proposal combines two directives — one for blood and the other for tissues and cells — into a single regulation. The proposal will be debated in the Parliament and Council, and will come into force once a final text is agreed upon and adopted.

The proposal oversees important parts of many Europeans' care. Every year, 165,000 babies are born from medically assisted reproduction in the EU, 15 million people donate blood, and there are 14,500 cornea transplants, according to the Commission.

All substances of human origin

The proposed regulation also now extends to all substances of human origin such as donated human breast milk, since these also need to be screened for communicable diseases and have traceability systems in place, a senior Commission official told reporters during a briefing. Fecal microbiota transplants — poop transplants, in short — also now fall under the regulation, marking the first time stool microbiota is regulated at the EU level. The regulation proposed does not include solid organs for transplantation, as these are regulated separately.

One of the key updates in the Commission's proposal is how it hopes to enable greater flexibility when it comes to evolving scientific information. The current directives are outdated and could not be updated frequently enough, a senior Commission official said.

To that end, the Commission proposes that scientific and technical requirements for substances of human origin not be dictated in the regulation, instead entrusting them to expert bodies. The European Centre for Disease Prevention and Control (ECDC) and the European Directorate for the Quality of Medicines & HealthCare (EDQM) would be responsible for the technical guidelines on substances of human origin, allowing these to be more easily updated. Following the ECDC and EDQM guidelines — or ones shown to have the same quality, efficacy and safety standards — would be considered as compliant with the regulation.

A 2019 review found that existing legislation provided insufficient protection to donors — the Commission's revisions seek to address this. In the case of egg donors, for instance, this will include longer term follow-up as well as donor registries available across member states to ensure donations don't occur more often than is deemed safe, a senior Commission official said.

The proposal also aims to better monitor the bloc's supply of substances of human origin. The EU is short of plasma needed to make life-saving medicines, for instance, and depends on imports from the United States. The Commission proposes new measures to monitor supply, and asks national authorities to have emergency plans in place when supply is at risk. Some substances of human origin are the starting materials for advanced therapy medicinal products (ATMPs).

The Commission's proposal also strives to facilitate cross-border movement of these substances. Countries' differing interpretation and implementation of the current directives has created some barriers to these exchanges, a senior Commission official said. The proposal hopes to improve harmonization between countries, to make cross-border movement of these substances easier and improve patients' access to these therapies.

There's also work to be done in digitization. The Commission's proposal sets out its vision for an EU SoHO Platform, a one-stop shop for information when it comes to registrations, authorizations and technical guidelines for substances of human origin. It's also where data on donations will be collected, the Commission said, and where users can find other information such as possible adverse reactions.