

EN
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Answer given by Mr Várhelyi
on behalf of the European Commission
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Human plasma is important for public health and some derived medicinal products, such as immunoglobulins, are listed on the Union List of Critical Medicines¹.

The collection of plasma and manufacturing of medicinal products requires sufficient donations, collection and manufacturing capacity, and a rational utilisation. The Commission supports these objectives through EU4Health funding, and through possible strategic projects under the proposed Critical Medicines Act².

Plasma collection is covered by the new Regulation (EU) 2024/1938 on substances of human origin (SoHO)³, and EU4Health funding will be used to ensure its effective implementation. The new regulatory framework also reinforces the requirement for voluntary unpaid donation, requiring each Member State to define proportionate compensations for plasma donations.

Medicinal products manufactured from plasma are subject to the EU pharmaceutical framework, and to related actions on shortages, e.g. through the European Medicines Agency network of Single Points of Contact (SPOC) working group, and the Medicines Shortages Steering Group (MSSG).

Furthermore, the Commission ensures regular interactions between the SoHO and pharmaceutical sectors and is establishing the coordination between the SoHO Coordination Board that steers the implementation of Regulation (EU) 2024/1938 and its counterparts under the medicinal products framework.

¹ <https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/medicine-shortages-availability-issues/availability-medicines-during-crises/union-list-critical-medicines>.

² Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL laying a framework for strengthening the availability and security of supply of critical medicinal products as well as the availability of, and accessibility of, medicinal products of common interest, and amending Regulation (EU) 2024/795.

³ Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June 2024 on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC OJ L, 2024/1938, 17.7.2024.