

EN
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Answer given by Mr Várhelyi
on behalf of the European Commission
(7.1.2025)

The role of the EU in healthcare is defined by Article 168 of the Treaty on the Functioning of the European Union¹, which in the field of substances of human origin (SoHO) like blood, is limited to adopting measures setting high standards of quality and safety. In that legal context, the Commission has recently proposed to the co-legislator such measures, that were adopted with the 2002 Blood Directive (2002/98/EC)² and the 2024 SoHO Regulation (EU/2024/1938)³.

The Commission has, therefore, no direct role in the management of specific diseases like anaemia.

The importance of an appropriate use of SoHO is fully recognised in the new SoHO Regulation, which refers explicitly to the Patient Blood Management (PBM) approach⁴ and its endorsement by the World Health Organization.

Furthermore, the Commission has supported the development of a Guide for Health Authorities to build national programmes of PBM in the EU⁵ and a complementary guide for hospitals⁶ to help implement PBM.

¹ http://data.europa.eu/eli/treaty/tfeu_2008/art_168/oj

² <http://data.europa.eu/eli/dir/2002/98/oj>

³ <http://data.europa.eu/eli/reg/2024/1938/oj>

⁴ Recital 67 of 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.

⁵ https://health.ec.europa.eu/document/download/e0e9ebc8-ac93-4124-88a2-4352360371b0_en?filename=2017_eupbm_authorities_en.pdf

⁶ https://health.ec.europa.eu/document/download/d0926de8-aaed-4c07-a50e-e5daf5f01e10_en?filename=2017_eupbm_hospitals_en.pdf