

EuropaBio Statement on the proposal for a Regulation on substances of human origin (SoHO)

EuropaBio welcomes the adoption of the proposal for a Regulation on SoHO revising the EU's Blood, Tissues, and Cells (BTC) legislation. The EU needs a predictable, future-proof, and robust SoHO framework to ensure the uptake of transformative advanced therapies which hold great potential for both the health and wellbeing of patients and the sustainability of healthcare systems. The revision of the BTC legislation is important for the ATMP sector as requirements for donation, procurement and testing apply to SoHO used in the production of ATMPs.

EuropaBio considers the proposal to be an opportunity for convergence of these requirements across Member States and ensures regulatory standards protecting patient safety and public health keep pace with technical and scientific advances. EuropaBio believes that the governance of the new SoHO framework could be further strengthened to avoid divergence between Member States over time. The governance should also enable collaborative dialogue with industry stakeholders to facilitate the resolution of classification issues for borderline products.

The revision is also important to improve the sustainability of supplies of SoHO across the EU for both direct administration and for the manufacture of products derived from SoHO. It is important that the legislation supports Member States in ensuring reliable supply of plasma for fractionation to manufacture plasma-derived therapies in order to address Europe's reliance on the US for this essential starting material.

As the European Association of innovative biopharmaceutical and biotechnology companies representing developers of cell-based and plasma-derived medicines, EuropaBio is committed to supporting patient access to essential and innovative therapies and to becoming a global leader in ATMP innovation.

About EuropaBio

EuropaBio, the European Association for Bioindustries, promotes an innovative and dynamic European biotechnology industry. EuropaBio and its members are committed to the socially responsible use of biotechnology to improve quality of life, to prevent, diagnose, treat and cure diseases, to improve the quality and quantity of food and feedstuffs and to move towards a biobased and zero-waste economy. EuropaBio represents 79 corporate and associate members and bio-regions, and 19 national biotechnology associations in turn representing over 2300 biotech SMEs. Read more about our work at www.europabio.org.

