

EuropaBio response to the public consultation 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.

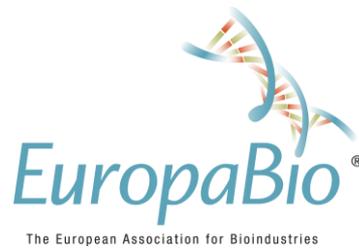
EuropaBio considers the proposal to be an opportunity for convergence of requirements across Member States and ensure that regulatory standards protecting patient safety and public health keep pace with technical and scientific advances. EuropaBio welcomes the proposal's definitions and interplay with the ATMP Regulation and considers that they should be maintained in the adopted Regulation.

EuropaBio is concerned about instances where the SoHO Regulation would interfere with the EU rules on medicinal products. Classification decisions from SoHO Coordination Board could contradict the decisions of the EMA's Committee for Advanced Therapies (CAT) which currently participates in providing scientific recommendations on the classification of ATMPs. Such situations would add unnecessary uncertainty and burden for developers of ATMPs. EuropaBio is likewise concerned as regards the reference to genetically modified organisms (GMOs) in the proposal's recital and considers that ATMPs that consist of or contain GMOs should continue to be regulated by the ATMP Regulation.

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 and the EMA's CAT to facilitate the resolution of classification issues for borderline products. This collaborative dialogue will be particularly important for technical expert bodies like EDQM and ECDC as they develop or update technical guidelines to help adapt the legislation to scientific progress.

Additional clarifications are also necessary to avoid legal uncertainty with respect to the equivalence assessment referred to in Article 23, the recognition of the SoHO establishment authorisation in another Member State in Article 25, and the content of the EU SoHO Platform in Article 41.





The revision is also important to improve the sustainability of supply of SoHO across the EU for both direct administration and the manufacture of products derived from SoHO. However, certain provisions of the proposal, specifically Articles 42-44, could interfere with the pharmaceutical legislation as regards the distribution of SoHOs used in medicinal products manufacturing. EuropaBio believes the proposal insufficiently guarantees access to SoHO for the pharmaceutical companies and manufacturers of SoHO-derived products and encourages the co-legislators to introduce the principles of equal treatment and non-discrimination to access to SoHO to the Regulation. It is important that the legislation supports Member States in ensuring reliable supply of essential SoHO, including plasma for fractionation to manufacture plasma-derived therapies to address Europe's reliance on the US for this essential starting material. As such, while we welcome the differentiation between plasma for fractionation and blood components for transfusion, we are concerned to see plasma donation defined as a "procedure of significant risk" without scientific justification as this may discourage plasma donations.

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 2,300 biotech SMEs. Read more about our work at www.europabio.org.

