

EuropaBio Response to the Public Consultation on Blood, tissues and cells for medical treatments & therapies

FEEDBACK

Brussels, 16 April 2021 EuropaBio sent the response to the European Commission's public consultation on the use of blood, tissues and cells for medical treatments and therapies (hereafter, BTC). Representing developers of cell-based and plasma-derived medicinal products, EuropaBio advocates the European Union's uptake of transformative advanced therapies which hold a great potential for the health and wellbeing of patients and the sustainability of healthcare systems.

EuropaBio believes, that while the Commission consultations cover the full scope of the BTC legislation, there is need for bespoke policies for different categories of products.

Cell-based medicinal products

A revision of the BTC legislation should address the existing inconsistencies within the regulatory framework and set clear boundaries between the legislation for human medicinal products and the BTC legislation. For example, some advanced therapy medicinal products (hereafter, ATMPs) are at the borderline between the two frameworks which creates administrative burden for many sector's developers. The BTC legislation should apply up to the point of procurement and testing of the drug substance. Once the drug product enters manufacturing, the available ATMP guidance applies. Moreover, the BTC legislation should clarify the minimum requirements for donation, procurement and testing in cases where human tissues and cells are used as a starting material for ATMPs.

The lack of harmonisation at national level should also be addressed. Existing practice shows that very often multiple responsible authorities are assigned for both facility licensing and inspections procedures. More harmonisation is needed also on international level. In addition, the new framework should be adaptive to new scientific and technical developments in the field of ATMPs and any new EU-level requirements should be justified.



Plasma-derived medicinal products

Therapy developers need to collect sufficient plasma to manufacture plasma-derived therapies to meet the needs of European patients and mitigate the possible supply disruptions which increases a dependency from the third countries. We, therefore, call on the EU to take a leadership role in supporting Member States to increase their plasma collection. We need a framework that differentiates between whole blood for transfusion and plasma for fractionation and develops bespoke rules and allows the coexistence of public sector and private sector plasma collection centres as well as compensation of donors for the expenses and inconvenience related to the donation.

A constant development of science and innovation requires consistent updates of testing requirements. EuropaBio suggests creating a clear mechanism to facilitate this process. The relevant expert bodies such as the [European Centre for Disease Prevention \(ECDC\)](#) or the [European Directorate for the Quality of Medicines \(EDQM\)](#) or any other EU body could help to ensure that pace with scientific innovation can be kept while avoiding the potential delays of updates via legislation.

ENDS

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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 corporate and associate members across sectors, plus national and regional biotechnology associations which, in turn, represent over 1800 biotech SMEs. Read more about our work at www.europabio.org.

