EUROPEAN BLOOD ALLIANCE

General Position on the European Commission's proposal for a reform of the EU pharmaceutical legislation

The European Blood Alliance, representing public/not-for-profit blood establishments, welcomes the European Commission's publication of its proposal for a reform of the EU pharmaceutical legislation.

The review aims to reach a number of important goals, such as improving access to innovative medicines, promoting innovation in the sector and addressing shortages. These important objectives should not be reached at the detriment of other key sectors in public health, such as the safe and sustainable supply of blood components and other substances of human origin (SoHO) to everyone in Europe.

Need for a better defined border between SoHO and medicinal products

It is therefore crucial that the proposal for a Directive on the Union code relating to medicinal products for human use is as clear and categorical as possible in defining SoHO-derived medicinal product. **The proposal needs to be improved in this respect.**

The definition of 'SoHO-derived medicinal product other than ATMPs' in Article 4 number 1 (31) of the proposed directive leaves too much room for interpretation and there is a serious risk of inadvertently including blood components that should and must be regulated by the current blood directive and, in the future, by the SoHO Regulation.

Examples of what could be interpreted as medicinal products include platelet concentrates, granulocytes concentrates, serum eye drops, and blood components which have undergone pathogen inactivation and/or other processes that keep blood products safe.

To consider these as medicinal products would be incorrect and would bring severe disruption to the work of blood establishments in ensuring the safe and sufficient supply of blood components.

While legislators must ensure that the definition is as clear as possible, we acknowledge that there will be doubts when new products are developed on the border between SoHO and medicines. **EBA welcomes the provisions in article 201 of the proposed directive** stating that in the event of doubt about the regulatory status of a human border product, the European Medicines Agency (EMA) must consult the SoHO Coordination Committee (SCB). This should lead to more consistent advice.

Protection of donors and patients

EBA also welcomes the important reminder, in Article 1 number 7 of the Directive, of the ethical framework within which the collection of substances of human origin used in the production of medicinal products must take place. Such collection must always happen respecting the principle of

voluntary unpaid donation, as defined by the future SoHO Regulation, as a way to ensure the safety and wellbeing of donors and patients.

ATMPs prepared under hospital exemption

Finally, EBA welcomes the proposal to safeguard and strengthen of the Hospital Exemption. The introduction of measures for data collection, reporting and regular reviewing will improve transparency while the increased responsibility of Member States regarding GMP compliance, traceability, pharmacovigilance and notification of revoked authorisations will ensure harmonisation of HE practices and safety for patients.

EBA will now work closely with all legislators in the process ahead to seek clarifications and complement this proposal.

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About EBA

The European Blood Alliance (EBA) is an association of not-for-profit Blood Establishments, with 25 members throughout the European Union, United Kingdom, and EFTA States. Our mission is threefold:

- To contribute to the availability, quality, safety and cost-effectiveness of the blood and tissue supply for the citizens of Europe by developing and maintaining an efficient and strong collaboration amongst European blood and tissue services.
- To increase public and professional awareness of voluntary and non-remunerated donation (VNRD) of blood and blood components, and of preparation of blood components as an indispensable therapeutic means to help patients.
- To assist European blood establishments to continuously improve their performance, based on scientific and ethical principles for the benefit of patients.

EBA strives towards this mission by assisting our members to improve performance through collaboration, to engage in regulatory affairs to promote best practice and to facilitate information collection and knowledge exchange.

Contact:
Peter O'Leary, Executive Director; info@europeanbloodalliance.eu
europeanbloodalliance.eu