EUROPEAN BLOOD ALLIANCE

General Position on the proposal of the European Commission for a Regulation on standards of quality and safety for substances of human origin intended for human application (SoHO Regulation)

The European Blood Alliance, representing public/not-for-profit blood establishments, welcomes the European Commission's publication of its proposal for a Regulation on standards of quality and safety for substances of human origin intended for human application (SoHO Regulation).

EBA is pleased with the general direction of the proposal and its level of ambition. Nevertheless EBA wishes to highlight that certain elements of the proposal can still be improved.

We welcome in particular the **strengthening of the health protection for donors and patients** and recipients and were pleased to read the references to the European Charter of Human Rights (ECHR) and specifically to "integrity of the person" (article 3 ECHR). The setting up of the SoHO platform and of cross-entity registry exchanges have great potential to enhance donor and patient health, both on a day-to-day basis as well as in terms of long-term research. EBA is also keen to understand how these instruments will interact with the future European Health Data Space. More detail is now required to ensure they become useful tools, while avoiding unnecessary burdens on the system.

Some elements still need work, for instance the notion of "frequent and repeated" donation (article 53.3) is not defined, even though this qualification entails additional requirements and follow-up for the SoHO entities concerned. Similarly, article 58.11 allows for interviews of "donors that donate repeatedly" to be scrapped, which raises concerns both about donor and recipient health, as well as what is meant by "repeatedly".

Still on donor health, EBA believes it is important that the regulation also reaffirms the principle of "absence of profit on the part of the establishments involved in blood transfusion services", currently included in Directive 2002/98 on safety and quality of human blood and blood components but not in the current proposal.

We urge the European Commission to continue working with blood establishments and donor associations in developing these tools and when detailing donor protection standards.

Another very positive element in the regulation, key to donor and patient health, is the **reaffirming of the principle of voluntary non-remunerated donation**. In addition to referencing the work of the Council of Europe in this area, EBA would nevertheless welcome a clearer definition of "compensation", which is currently too broad and vague, as well as a clearer European framework on how member states can ensure that financial neutrality is respected, in particular when fixed rate allowances are considered. In addition, the regulation should include references to the Nuffield Council on Bioethics' intervention ladder[1], which, based on clearer definitions and ethical principles,

[1] Nuffield Council on Bioethics. Human bodies: donation for medicine and research. 2011

is in this regard a useful tool for considering the ethical acceptability of different forms of encouragement to donors.

When it comes to the **scope of the regulation**, EBA would like to see a firmer delimitation of the legal framework. The fact that the regulation, in its recital 9, considers that "the criteria that define when SoHOs or SOHO preparations become products regulated under other Union legislation are not defined in this Regulation but are defined in those other acts" seems to us to introduce too much legal uncertainty and should be restricted.

EBA was pleased to see the recognition of the importance of **building and supporting a strong public and non-profit sector for ensuring resilience and continuity in supply of SoHOs**. We believe that the EU should be even more ambitious: the regulation should require Member States to develop national plans addressing the sufficiency of supply of blood components through voluntary non-remunerated donations. Specifically on plasma, the regulation should foresee the development of a European strategy, with concrete timeframes, to address the current European dependency on third countries for the plasma required for plasma-derived medicinal products (PDMPs).

Still with the aim of **strengthening supply**, the Regulation should be clear that building resilience and continuity hinges on Member States developing a broad donor-base composed of mostly infrequent donors. High-frequency, narrow donor bases are not only less resilient to crisis, as the recent pandemic has shown, but the approach is also less protective of donor health and lowers the quality of blood components, so it is therefore also not in the interest of patients.

Finally on this point, and to ensure a sound and fair SoHO supply system is ensured, it should be specified that all SoHO entities providing blood components must supply all blood components, including to recipients with special or rare needs.

EBA also welcomes the proposal to **incorporate the expertise of EDQM and ECDC**. This should allow for a regulatory framework that is future-proof, better equipped to deal with crisis and flexible enough to take account of new risks and trends, while continuing to impose appropriate safety and quality requirements. However, the regulation is silent on the requirements that must be in place for these bodies to ensure the appropriate level of expertise and transparency in their work.

EBA also welcomes the introduction of an **appropriate risk-based frequency for inspection of SOHO facilities**, with a maximum interval between two on-site inspections extended to four years instead of the current two years. We are assessing where other provisions can remove disproportionate burdens to blood establishments or where new proposals might add unnecessary complexity and will be raising those issues with legislators in the negotiation process ahead.

Finally, EBA wishes to point out that provisions related to SoHO safety during infectious disease outbreaks are missing, in particular regarding the roles that different levels and institutions should play during national or multi-country outbreaks, in terms of risk assessment and risk management. Similarly, regarding the establishment of national SoHO emergency plans, and in case of an isolated national outbreak that does not need the activation of the emergency plans but requires risk

assessment and implementation of local SoHO safety measures, the role of competent authorities and SoHO entities is missing.

Also missing are references to technical capacity in our SoHO systems. **Education** in current science concerning blood transfusion safety and the whole process of blood procurement should be made mandatory in medical training. Although not an EU competence, Member States must be encouraged to establish transfusion medicine as an independent medical subject with structured training, including programmes for continuous medical education for all medical staff.

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 28 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.

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