**Response of the European Hematology Association (EHA) to the European Commission regarding the Proposal for a *REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC*.**

September 6, 2022

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The European Hematology Association (EHA) warmly welcomes the legislative proposal for an EU SoHO Regulation which represents a big step forward for protecting patient and donor safety, improving access to SoHOs and innovative SoHO-derived therapies, ensuring sustainability of supply, facilitating innovation, and for increasing efficiency and coherence of regulation and oversight.

During the revision of the blood, tissues and cells legislation EHA has consistently flagged the need for (1) strengthening harmonization and supervision to ensure **patient and donor safety**; (2) a more flexible legislative network that could adapt to and facilitate **scientific and medical innovation**; (3) harmonized and efficient **evidence-based implementation** with a larger role for experts and expert bodies; and (4) concerted action to increase and sustain **plasma supplies**.

We therefore particularly welcome the Regulation's emphasis and provisions on the following aspects:

Ad (1) safety and quality:
- Common standards and guidelines, set mostly by expert bodies (ECDC, EDQM)
- Coverage of (almost) all SoHOs applied to humans
- Improved safety reporting
- Training and exchange of Competent Authorities' personnel
- Possibility to introduce binding rules via Delegated Acts if needed for safety/quality

Ad (2) facilitating innovation:
- Risk-based authorization and evidence-based benefit assessment of SoHOs processed or applied in new ways
- Creation of a registry of authorizations to reduce administrative burdens

Ad (3) implementation:
- Better linkage and complementarity with other EU legislation (pharmaceutical, clinical trials, devices/IVD)
- Creation of a SoHO Coordination Board for more efficient and harmonized implementation and oversight (including advice on applicability of the SoHO Regulation in borderline cases)
- Common platform for data sharing (EU SoHO Platform)
- Clear division of roles/responsibilities between EU (overall regulatory and data framework, coordination, resilience, controls/audits, funding of collaborative work), expert bodies (esp. ECDC, EDQM – technical standards and guidelines) and Member States/NCAs (supervision of SoHO entities, ethics framework).

Ad (4) access to and supply of plasma:

- Strengthened oversight
- Improved crisis preparedness, via central EU requirements for emergency response, supply monitoring, and mitigation of shortages

More emphasis and/or stronger wording is needed to ensure that:

(a) Involvement of experts/professionals and interaction with medical societies including EHA via the proposed expert group should be timely, structural and substantial

(b) The EU SoHO Platform is set up in a way that serves data sharing and use by professionals as well as the interests of patients and donors, in addition to serving the needs of regulators, companies and institutions

(c) With a view to secure and sustainable supply, especially of plasma:

- Both healthcare professionals and patients should be involved in discussions on compensation of donors and their views must be taken into account in decision making on forms of compensation
- In addition to mandating better monitoring and notification of shortages, Member States should be encouraged explicitly to take active measures to improve security of supply and agree on proactive, EU-level planning to reduce dependency on third countries
- Measures to improve the collection of and access to plasma should be guided by the work of and involve the members of the SUPPLY consortium, led by the European Blood Alliance (EBA) and including the European Hematology Association (EHA)

(d) The multiple references to “SoHOs prepared or used in new ways” are reworded to make clear that ‘new ways’ should imply ‘meaningful innovation’, especially in the section on Impact Assessments of the Explanatory Memorandum which states that “a clear and (risk-) proportionate pathway will facilitate access to SoHOs prepared or used in new ways”

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