Brussels, 22 May 2023

Dear Member of the ENVI Committee,

We are writing to you on behalf of the Common Representation of Substances of Human Origin (CoRe SoHO), a consortium of professional scientific associations formed to provide representative technical expertise to the European decision-making organizations in the field of SoHO, which includes:

- European Association of Tissue and Cell Banks (EATCB)
- European Blood Alliance (EBA)
- European Eye Bank Association (EEBA)
- European Society for Blood and Marrow Transplantation (EBMT)

We are concerned about some of the amendments that have been suggested in response to the European Commission's proposal for a Regulation on standards of quality and safety for substances of human origin intended for human application (SoHO Regulation).

A threat to high safety standards and protection of human health

We are concerned in particular about amendments 174 and 177 to 185, which propose to remove the sentence "Voluntary and unpaid SoHO donation is also a factor which can contribute to high safety standards for SoHOs and therefore to the protection of human health."

There is vast scientific evidence, consolidated over at least the last 20 years, which proves that remunerated whole blood donations have a statistically significant higher prevalence of infectious disease markers than non-remunerated donations.[1] Moreover, the commodification of SoHO "might jeopardise the altruistic donation of SoHO, essential for the treatment and survival of thousands of patients".[2]

Deleting that sentence from the original proposal undermines the progress made in Europe in the last 20 years on guaranteeing safer blood, tissues and cells made in Europe in the last 20 years as well as the sustainability of all SoHO ecosystems and we therefore urge you not to support these amendments.

The role of the public and non-profit sector

We also noted that amendments 248-251, 253-256 and 749-758 propose to remove the existing references to the role that a strong public and non-profit sector plays in the provision of SoHO services.

While the private sector has a role to play in SoHO, for-profit companies are primarily moved by commercial interests. This is wholly legitimate but it also means they are not in a position to ensure a sustainable and comprehensive coverage of Europe's needs:

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[1] Remunerated first-time and repeat blood and blood component donations have a statistically significant higher prevalence of transfusion-transmitted infectious disease markers than non-remunerated (2022) https://pubmed.ncbi.nlm.nih.gov/36378657/

[2] Risk of commodification of Substances of Human Origin. A position statement of the European Committee on Organ Transplantation of the Council of Europe (CD-P-TO) (2022) https://www.edqm.eu/documents/52006/0/OTC-CD-P-TO-Position-statement-Risk-of-commodification-of-SoHO-2022-11-18-Final.pdf/79e289b0-a02e-d3db-60c9-b9110ef704f2?t=1669631797556

- not geographically, as the private sector often deserts the less profitable regions, and
- not when it comes to the full range of SoHO, as companies collecting and providing SoHO often only dedicate their activities to the most profitable SoHO components, leaving the public and non-profit sector to cover the rest, which they often have to do at loss.

The public and non-profit sector are fundamental to ensure a resilient and sustainable provision of all SoHO services to all Europeans and their role must be recognised and encouraged in the Regulation, as per the original proposal from the European Commission.

Introducing unacceptable uncertainty to scope of regulation

The borderline between SoHO and medicinal products has always been difficult to define. This regulation should make it clear that all SoHO fall under its scope up until the point where they are utilized in the manufacture of medicinal products or ATMPs.

CoRe SoHO finds that

- amendment 135, which proposes to introduce only a partial application of the SoHO regulation when the SoHO are subsequently used in medicinal products, and
- amendments 198 and 275, which proposes to classify as a medicinal product or ATMP, by default, all SoHO that can be classified both as SoHO or SoHO preparation and medicinal product or ATMP,

introduce an unacceptable uncertainty to the scope of the regulation, including in some clinical practices, for the different SoHO sectors we represent.

Such borderline decisions must be made on the basis of available scientific evidence, a critical assessment of accessibility implications to SoHO, relevant ethical considerations, among other factors.

Overall, the SoHO regulation is too important to SoHO ecosystems for its scope to be defined negatively in relation to other legislative frameworks.

Introducing uncertainty to status of ECDC and EDQM guidelines

Finally, we are concerned that amendments 225, 226, 596, 668 and 672 all dilute the position of ECDC and EDQM guidelines in the hierarchy of applicable guidelines.

These proposed amendments go in the opposite direction to the common objective of harmonising standards across the EU, one of the main goals of this Regulation and one which CoRe SoHO organisations very much support.

We remain at your disposal should you wish to discuss the aforementioned points in more detail.

Sincerely,

The members of the Common Representation of Substance of Human Origin (CoRe SoHO),

European Association of Tissue and Cell Banks (EATCB)
European Blood Alliance (EBA)
European Eye Bank Association (EEBA)
European Society for Blood and Marrow Transplantation (EBMT)