



CoRe SoHO statement welcoming the proposed Regulation on standards of quality and safety for substances of human origin (SoHO) intended for human application

The Common Representation of Substances of Human Origin (CoRe SoHO), the consortium of professional scientific associations in the field of SoHO, welcomes the proposed Regulation that reaffirms its central principles:

- **VUD - non financial gain**

The principle of voluntary and unpaid donation has been upheld in the proposal, which also includes references to the provisions in the European Charter of Human Rights, such as integrity of the person and non-commercialisation of the human body.

- **Donor protection**

The proposal includes standards to strengthen the safety and wellbeing of SoHO donors, patients and children born from donated eggs, sperm or embryos as well as the requirement to collect data in these groups, such as Serious Adverse Occurrences. Nevertheless, there is a need for some clarifications, for instance what is meant by a “frequent and repeated donation” or what are specific requirements for post-mortem tissue donation, currently not considered in the proposal.

While we encourage reporting of SAOs in general, the regulation should be more specific on what should be reported to avoid unnecessary administrative burden. Specifically we would like to limit reporting obligations to occurrences that may be attributed to the SoHO activity or the SoHO quality and safety; we reference the current Directives that distinguish adverse reactions from adverse events. Finally, we also want to avoid reporting obligations for adverse occurrences in SoHO recipients when these are known to be a result of the treatment, such as Graft versus Host Disease.

- **Sufficiency and access**

The Commission’s choice to legislate through a Regulation, directly applicable in all Member States (MS), will improve harmonization across MS and facilitate exchange of SoHO between them, which is necessary for ensuring patient access and sufficiency of supply. CoRe SoHO was also 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 SoHO.

However CoRe SoHO would also like the regulation to foresee the development of policies or strategies at the EU-level to encourage sufficiency of SoHO in the EU, in support and beyond existing national strategies, to optimize SoHO collection, utilization rates and schemes as well as to ensure EU-added value in the fostering and safeguarding of sufficient levels of donation and transplantation/therapeutic application, and not only in times of crisis.

- **Promotion of clinical efficacy, quality and safety of treatments and the development of new treatments**

The more comprehensive approach to regulating SoHO should mean that it will be easier to develop innovative products and methodologies, as well as ensure patients' access to these. In addition, the

new framework to include the expertise of EDQM and ECDC will also contribute to a more flexible and future-proof regulatory environment. Moreover, the established collaboration between these bodies and expert societies from the specific SoHO fields ensures that guidance is based on the latest scientific evidence.

The regulation should also seek to develop common standards and guidelines, and thus EU added value, for the consent and use of donated blood, tissues and cells that have been evaluated as being unsuitable for use on patients instead to be used for research, training and educational purposes, so as to support the development of new therapies and increase understanding of the value and utility of SoHO.

Finally, we support risk based data collection requirements to improve monitoring of the efficacy and safety of treatments, particularly in the case of innovative treatments. However, resources should be made available to all entities involved to offset the increased administrative burden.

Overall, the CoRe SoHO consortium and its individual constituent professional scientific associations look forward to engaging with the European decision-making organisations in the finalisation of this legislation. We also look forward to collaborating with the European Commission, ECDC, EDQM and MS competent authorities in the implementation, assessment, progress monitoring/oversight of the resulting Regulation, through adequate representation in the SoHO Platform and in the coming process of developing the new proposed standards and quality for SoHO.

The CoRe SoHO consortium is composed of representatives from:

- 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)

Although not a full partner of CoRe SoHO, the European Society of Human Reproduction and Embryology (ESHRE) supports this statement.

You can read more about the CoRe SoHO consortium and its members below.

CoRe SoHO

The Common representation of Substances of Human Origin (CoRe SoHO) is a consortium of professional scientific associations formed to provide representative technical expertise to the European decision-making organizations in the field of SoHO; above all, it seeks to be represented in official consultation forums responsible for the drafting of new regulations and revising existing legislation.

CoRe SoHO's key identified activities and goals are to:

1. Promote ethical principles (non-financial gain, voluntary and altruistic donation) by demonstrating their impact for the quality and safety of BTC
2. Sponsor the high value of SoHO therapies
3. Promote the safety and quality and the development of new therapies involving SoHO
4. Provide technical inputs to the drafting of European legislation and regulations

CoRe SoHO is committed to ensuring that SoHO activities at EU level are governed by the same principles of:

- A. Not-for-profit/non-financial gain
- B. Voluntary and altruistic donation

- C. Donor safety and protection
- D. Sufficiency
- E. Cost efficiency/sustainable and equal access to health care

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The European Society of Human Reproduction and Embryology (ESHRE) joins the CoRe SoHO consortium as an observer.