

SUBSTANCES OF HUMAN ORIGIN

Proposal COM(2022) 338 of 14 July 2022 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.

cepPolicyBrief No 15/2022

SHORT VERSION [\[Go to Long Version\]](#)

Context | Objective | Interested Parties

Context: Substances of Human Origin (SoHOs) are any substances collected from the human body, such as blood, plasma, stem cells in bone marrow and reproductive cells. These substances are mainly used for SoHO-based therapies, such as blood transfusions, and for the creation of medicines. The Commission wants to repeal the existing legislation on blood, tissues, and cells (the BTC legislation) and provide a comprehensive Regulation covering all SoHOs.

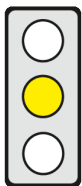
Objective: The proposal aims to adapt the current BTC legislation to accommodate new technologies and risks. Its main aim is to ensure access to safe and effective BTC and providing a high level of health protection for patients receiving treatment with SoHOs, donors of SoHOs and children born from medically assisted reproduction (MAR).

Interested Parties: Patients, donors, children born from MAR, the entire SoHO supply chain, pharmaceutical companies developing plasma derived medicines.

Brief Assessment

Pro

- ▶ Voluntary and unpaid donations are in line with the EU Charter of Fundamental Rights, which prohibits commercialization of the human body.
- ▶ Sharing authorisations of new SoHO preparations via an EU SoHO IT platform will reduce the administrative burden on competent authorities and applicants and save costs.

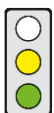


Contra

- ▶ The legal status of decisions by Member States on the applicable legal regime for SoHO-based therapies or products, e.g., pharmaceutical law or medical devices law, is unclear and requires clarification.
- ▶ Allowing for the application of standards other than EU guidelines on the safety and quality of SoHOs may lead to divergent levels of safety, quality, and efficacy. It would be advisable to apply EU guidelines only, as this would promote useful harmonisation in this regard.
- ▶ It is reasonable to base the requirements for clinical monitoring on the level of risk of a new SoHO product. However, these levels need to be defined in the proposed Regulation. Otherwise, this leads to uncertainty regarding the concrete provisions to be adhered to.
- ▶ It is unlikely that the envisaged measures can sufficiently address EU dependency on SoHOs from third countries.

Voluntary and Unpaid SoHO Donation [Long Version A.2.4, C.1.1 and C.2.4]

Commission proposal: Donation is to remain voluntary and unpaid. This will protect donors from donating too frequently. Equally, however, donors should not incur any financial disadvantage due to their donation. Member States can set rules regarding the compensation of donors, in line with the disadvantages/losses incurred, in the form of fixed rate allowances based on national context.



cep-Assessment: This is in line with the EU Charter of Fundamental Rights (Charter), which prohibits commercialization of the human body, but donors are and should be allowed to receive compensation so that they are not financially disadvantaged. This needs to be closely monitored to ensure compliance with the Charter. National rules on compensation may also result in making certain Member States more attractive for donations, which can negatively impact donor health and national supply.

EU SoHO Platform [Long Version A.2.6 and C.1.4]

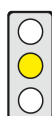
Commission proposal: The Commission will establish an IT Platform called the “EU SoHO Platform” for the exchange of data on SoHO activities in the EU, between SoHO entities, competent authorities, Member States and the Commission. This includes information on adverse reactions, authorisations of new SoHO preparations, and SoHO supply. The Commission believes that its introduction will reduce the administrative burden and save costs.



cep-Assessment: Sharing information on authorisations of new SoHO preparations via this type of IT platform will reduce the administrative burden on competent authorities and applicants. However, as seen with similar projects, such as the EUDAMED database for medical devices, the practical hurdles of implementation need to be considered at all times.

Applicable Legal Regime [Long Version A.3 and C.1.3]

Commission proposal: The issue of which legal regime is applicable to SoHO-based therapies or products, e.g. pharmaceutical law or medical devices law, is not coherently interpreted by Member States. National authorities must decide on a case-by-case basis. The Commission can also decide on the applicable legal regime, on its own initiative or at the request of a Member State, to ensure consistency across the EU via legally binding implementing acts.



cep-Assessment: The proposed consultation procedure may delay approval of and access to SoHO treatments. The legal status of decisions taken by a Member State in this regard is not clear and requires clarification. Among other things, this causes uncertainty in cases where it is not clear whether e.g. pharmaceutical law or medical devices law applies. This is hindering the functioning of the internal market. Only Commission decisions will provide legal certainty in this regard, but they are currently framed as exceptions to the rule.

Common Safety and Quality Standards [Long Version A.4.1 and C.1.6]

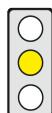
Commission proposal: A “hierarchy” of standards on the quality and safety of SoHOs is introduced, with the guidelines from the European Centre for Disease Prevention and Control (ECDC) and from the European Directorate for the Quality of Medicines & Healthcare (EDQM) at the top. However, other national and international guidelines, providing the same quality and safety, are also accepted. The idea is that constantly updated EU guidelines will be preferred. This would eventually “harmonise” the standards and in turn ensure an equal level of health protection across the EU.



cep-Assessment: There is already a high degree of harmonisation regarding such standards. Allowing for the application of standards other than ECDC and EDQM guidelines may lead to divergent levels of safety, quality and efficacy. It would be advisable to apply only EDQM and ECDC guidelines as this would promote useful harmonisation in this regard. Additionally, explicit instructions are required as to when and how the ECDC/EDQM guidelines are to be updated, especially regarding new technology and disease threats.

Clinical Monitoring [Long Version A.4.2 and C.1.7]

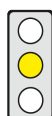
Commission proposal: Applicants for new SoHO preparations must conduct a proportionate risk assessment. This must include a plan for clinical outcome monitoring which must be aligned with the level of risk – low, moderate or high – applicable to the new SoHO preparation and aimed at demonstrating safety, quality and efficacy.



cep-Assessment: It is reasonable to base the requirements for clinical monitoring on the level of risk. However, these levels are not defined in the proposed Regulation, making it difficult for applicants to determine the level of risk involved. This can lead to divergent interpretations and delay the authorisation of new SoHO preparations and products.

Access to SoHOs and EU dependency [Long Version A.5.2 and C.1.8]

Commission proposal: The EU has no mandate to intervene directly in supply management. Yet, according to the Commission, reliable monitoring and notification of shortages will help Member States to act. To mitigate shortages, Member States must establish a SoHO emergency plan and make efforts to promote SoHO donation. The Commission believes this is particularly relevant for SoHOs such as plasma as the EU is dependent on third countries to meet demand. Such a dependency increases the risk of shortages due to possible supply chain interruptions.



cep-Assessment: The proposed measures are unlikely to sufficiently address EU dependency on SoHOs from third countries. Additional measures are needed, e.g., facilitating best practise on donor campaigns to address the low number of donations across the EU. Generally, reducing the dependency on third countries may reduce risks associated with the worldwide transportation of SoHOs.