MedTech Europe's position on the Regulation on Standards of quality and safety for substances of human origin intended for human application

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POSITION PAPER

MedTech Europe
from diagnosis to cure

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Introduction

MedTech Europe welcomes the Proposal for a Regulation on standards of quality and safety for substances of human origin intended for human application adopted by the European Commission in July 2022. The medical technology industry makes a clear contribution to raising the bar on the safety of substances of human origin (SoHO) all along the process, from donation to patient care and follow up.

MedTech Europe agrees that the sector needs an updated legislation on the matter and recognizes that the proposed Regulation aims to reinforce the rules for safety and quality of SoHO. The medical technology industry is looking forward to patients having improved access to care in the EU. In that regard, MedTech Europe believes that the Regulation will be more likely to achieve its objectives if the five recommendations outlined in this paper are implemented.

MedTech Europe supports the proposed timetable for the review of the legislation. At the same time, there is a link of SoHO to other relevant legislations such as the In Vitro Diagnostics Regulation (IVDR), Medical Devices Regulation (MDR) and the REACH Regulation. MedTech Europe stresses the importance of coordination and coherence between these pieces of legislation.

Five recommendations to further enhance the proposed Regulation

1. **Accurately characterise risk to donors and patients**
2. **Ensure that the supply chain is fit for Europe's strategic autonomy**
3. **Avoid additional validation where EU legislation guarantees quality and safety**
4. **Enhance stakeholder consultation**
5. **Support innovation**

1. Accurately characterise risk to donors and patients

Some sections of the proposed Regulation do not accurately characterise risk to donors and patients. For example, blood and plasma donation procedures carry minimal risk to donors and cannot be compared to the donation of stem cells or bone marrow (Recital 13).

2. Ensure that the supply chain is fit for Europe's strategic autonomy

MedTech Europe sees the new SoHO revision as an important opportunity to strengthen Europe's strategic autonomy in terms of the supply chain of medical technologies and ultimately the availability of SoHO. The approach proposed by the European Commission could enhance the availability for European patients through a harmonised approach on 'SoHO preparations' as defined in Article 3. As such, this proposal should remain in the law.

MedTech Europe welcomes the new provisions on National SoHO Emergency Plans (Articles 62-65) and suggest that they be strengthened, through regularly updated assessment of risks, for example on climate change impacts on health resulting in appearance of new pathogens and vectors (see Article 58.2).

To further strengthen the availability of substances of human origin, MedTech Europe recommends setting up dedicated blood donation and apheresis programs which are in line with the Regulation's goal to increase EU self-sufficiency.

3. Avoid additional validations where EU legislation guarantees quality and safety

MedTech Europe welcomes the various proposed measures to ensure greater European coordination on SoHO preparation standards (in Chapters III, IV and VIII), as these are currently fragmented across Member States. However, validation should not imply a complete reassessment of products that have undergone CE marking under the IVDR or MDR and which are being used according to the manufacturer's instructions.

4. Enhance stakeholder consultation

MedTech Europe welcomes that the proposal contains a mixture of legislation, delegated and implementing acts, standards, and expert guidance to improve quality and safety in SoHO. It is important that all SoHO stakeholders, including industry, be systematically consulted throughout the development of these implementing measures via involvement in the SoHO Coordination Board (Articles 67-68).

5. Support innovation

MedTech Europe supports healthcare digitalization. When negotiating the proposed Regulation, it is critical that the co-legislators make sure that its provisions benefit patients and do not overwhelm the system with administrative tasks. Scientific developments in digitalization, personalized healthcare and automation should be supported by this legislation. The legislation will likely be in place for at least two decades as per the previous Directive and considering the foreseen provisions to update for new scientific and technical developments.

About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.
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