MedTech Europe welcomes the adoption of the Substances of Human Origin Regulation

MedTech Europe welcomes the final adoption of the Substances of Human Origin (SoHO) Regulation by the Council of the EU. This achievement marks a significant milestone in advancing the safety and quality standards of blood, tissues and cells across Europe.

The Regulation, replacing the two-decades-old Directives, aligns safety and quality protocols, strengthens safeguards for donors and recipients, and implements measures to enable the movement of SoHOs across European borders. This Regulation aims to prioritise donor and recipient safety and mitigate risks associated with supply shortages.

The SoHO Regulation recognises that compensation is compatible with voluntary unpaid donation principles when complying with certain conditions, which MedTech Europe deems reinforces the adoption of safe and ethical healthcare practices.

MedTech Europe values the focus on supply chain safety and advocates for reducing administrative burdens while promoting the interoperability of the SoHO Platform with EUDAMED. Although some details of the regulation still need to be defined through implementing acts—such as the technical specifications for the EU SoHO Platform regarding its management, maintenance, and minimal functionalities—the adopted text represents progress aligned with the five pillars outlined in MedTech Europe's 2022 Position Paper.

MedTech Europe underscores the significance of harmonising interconnected requirements from Regulation (EU) 2017/746 on In Vitro Diagnostic Medical Devices, Regulation (EU) 2017/745 on Medical Devices, and Regulation (EC) No 1907/2006 (REACH) and the approved SoHO Regulation.

MedTech Europe is prepared to assist the Commission in navigating these Regulations and stress the importance of simplification and a smooth transition. Our industry is committed to compliance and anticipates collaborating with all stakeholders during implementation.

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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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