MedTech Europe
from diagnosis to cure

Press Release

The European Health Data Space Regulation: an opportunity to harness the power of health data

Brussels, 3 May 2022 – The proposed European Health Data Space legislation, published today, sets out to create an ecosystem for better exchange of and access to health data. MedTech Europe calls on EU legislators to ensure the new legislation overcomes existing legal and technical barriers to truly enable safe and secure sharing of health data in the EU.

Many opportunities that emanate from sharing and using health data are currently constrained by legal, technical, and other barriers which means that aggregating health data from different sources and across borders is often difficult in practice. For stakeholders such as the medical technology industry to be able to support the digital transformation of healthcare and to develop innovative solutions and treatments, the ability to access, aggregate and use health data is of critical importance.

"MedTech Europe welcomes the Commission's intention to create an enabling environment for health data sharing in the European Union. To be successful, the proposed EHDS legislation needs to address the barriers to data sharing, advance investment in infrastructure, and foster the adoption of international interoperability standards. But first and foremost, it needs to lay the foundation for the building of trust in health data sharing amongst EU citizens", said MedTech Europe CEO Serge Bernasconi.

MedTech Europe calls on EU legislators to involve industry in discussions on the secondary use of health data for research. The medical technology industry relies on access to high-quality data when developing new technologies and in the roll-out to healthcare systems.

Furthermore, provisions to improve data sharing require significant investment in regional, national, and European infrastructure as well as in the upskilling of the digital health workforce. They also need to build on international processes and harmonised standards on data interoperability, to allow for seamless data exchange. Where new requirements for medical technologies are unavoidable, they should be consistent and proportional.

Finally, EU legislators need to ensure that the EHDS regulation is in clear alignment with existing legislation, such as the Medical Devices Regulation, the *In Vitro* Diagnostic Medical Devices Regulation, the General Data Protection Regulation, and the recently proposed Data Act. A consistent legal framework paired with clear and transparent rules on citizens' access to their data will provide the right context for a trustworthy ecosystem that protects individuals' rights and unlocks the potential of health data.

MedTech Europe and its members will closely collaborate with legislators to ensure that the European Health Data Space legislation can become a true enabler of improved healthcare delivery and better health research and innovation.

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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