

Data Act: MedTech Europe calls for a data-sharing ecosystem that supports innovation in healthcare

Brussels, 28 February 2022 – Following the publication of the new Data Act by the European Commission, MedTech Europe calls on EU legislators to foster a data-sharing ecosystem that supports data-driven innovation whilst ensuring citizens' rights.

MedTech Europe shares the Commission's overarching objective to remove barriers for the safe and secure sharing of non-personal data in the EU and leveraging the potential of data for research and innovation.

In the context of the publication of the new Data Act, we caution EU legislators about adding another regulatory layer to the EU digital legislative landscape without due consideration to sectoral regulation. MedTech Europe encourages legislators to ensure that the Data Act is clearly aligned with current legislation relevant to the medical technologies industry, such as the Medical Devices Regulation, the In Vitro Diagnostic Medical Devices Regulation and the General Data Protection Regulation.

Given the Data Act's intent to empower citizens to exert more control over the data they generate through the use of devices and software, the medical technology sector would welcome clarifications to ensure that new requirements are consistent with existing sectoral legislation.

Proposed measures on access to user-generated data are encouraging, but MedTech Europe would welcome more clarity on how such requirements would interact with the design of medical technologies, knowing existing sectoral legislation already addresses design characteristics of such devices.

MedTech Europe appreciates the interoperability provisions included within the Data Act, which will provide one of the foundations for the future European Health Data Space. These provisions should build on internationally accepted standards on data interoperability, to avoid unnecessary fragmentation within the broader data ecosystem.

MedTech Europe and its members look forward to closely collaborating with EU legislators and stakeholders to ensure that the Data Act can foster data-driven innovation whilst protecting the rights of European citizens.

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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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