

Commission Feedback

Data Act & amended rules on the legal protection of databases - the view from MedTech Europe

13 May 2022

MedTech Europe welcomes the opportunity to provide feedback to the proposed Data Act and amended rules on the legal protection of databases, published on 23 February 2022.

As indicated in our initial statement¹, MedTech Europe shares the Commission's overarching objective to address barriers for the safe and secure sharing of data in the EU and leveraging the economic and societal potential of data. We call on EU legislators to support a data-driven economy that harnesses the power of data to advance and accelerate research and innovation in medical technologies and services for the benefit of European citizens, while preserving incentives for industry to invest in data innovation and protect citizens' rights and interests.

The medical technology industry is committed to doing its part by delivering medical devices that produce meaningful data available to healthcare professionals and patients to further improve patient outcomes whilst upholding the highest patient safety standards.

General comments and recommendations on the Data Act requirements

The Data Act impacts the medical technology industry in so far that it designs, manufactures, or operates connected products, or offers related services, which generate data.

The proposed Data Act seeks to remove barriers to data sharing through new measures on user-generated data. The regulation needs to provide precise and clear definitions, in clear alignment with definitions in existing legislation. It should be noted that where health data is generated as part of the authorised use of medical devices, healthcare professionals play a crucial role in interpreting the data and translating them for patients. Therefore, special consideration should be given to data generated in the medical context. Providing access to such data outside this regulated framework for interpretation by a third-party may present risks for patients' safety which must be carefully considered.

As such, terms such as "data", "product", and "user" require further clarification and need to be narrowed down to avoid unintended or inadvertent consequences. Additionally, other terms and concepts such as "competing products", "related services", or "connected product" are not sufficiently clear and merit clarification.

By proposing obligations to make data easily, securely, and directly accessible *by design*, the Data Act adds a new layer of product regulatory requirements in the EU. More legal clarity is needed on how the Data Act's new requirements would interact with the design of medical technologies, where existing sectoral legislation such as the Medical Devices Regulation and the *In Vitro* Diagnostic Medical Devices Regulation already lay down product design requirements for medical technology manufacturers. Such

¹ See MedTech Europe's [press release](#) on the Data act, published on 28 February 2022

duplicative requirements without clear alignment between Data Act and sectoral provisions will lead to unnecessary legal uncertainty. We therefore encourage policymakers to ensure the Data Act's clear alignment with such legislation.

In addition, MedTech Europe is seeking clarification on the interplay between the Data Act and the General Data Protection Regulation (GDPR), particularly on the terminology used in both regulations and the roles of the parties (controller and processor). It is important to have clear distinctions between "data holder", "user", and "data recipient", as the value chains are very complex where, for example, the device manufacturer may not be the data holder and in control of data, also considering clinicians and patients. Furthermore, we strongly encourage the alignment with future legislation, such as the European Health Data Space (EHDS) Regulation and the Artificial Intelligence Act.

The proposal envisions compulsory disclosures of data to public sector bodies (business-to-government data sharing) in cases of "exceptional need", such as public emergencies. MedTech Europe considers the definitions of "public emergency" and "exceptional need" too broad and open to interpretation. We suggest limiting these definitions to defined cases where the sectors affected or impacted are described, clear instructions are given on what type of data should be disclosed and for which purposes without giving room for misinterpretations. Though public sector bodies authorised to compel access are required to comply with procedures set out by the Data Act, MedTech Europe would like to highlight the need for further clarity on the terms of such business-to-government data sharing obligations, particularly reassurances that companies which share data in the public interest will not see their competitiveness unduly impacted by the sharing of such data, as well as adequate measures to protect commercially sensitive data (e.g., trade secrets, know-how).

The Data Act also sets out rules for data portability and data transfers to third parties, as specified by the user. With regards to those transfers, the Data Act aims to address instances where disclosures of data might reveal trade secrets belonging to data holders which, in our view, does not sufficiently address the related risks. MedTech Europe would welcome a clearer definition of data portability, consistent with GDPR, in order to better protect confidentiality when facilitating data portability to third-party data recipients, including an effective sanction regime. Further, whilst we recognise the Commission's effort to avoid a situation where the implementation of the Data Act results in loss of intellectual property (IP), we are concerned that ambiguity as to the type of data to be made available under the Act could have unintended and potentially detrimental consequences on a company's general ability to protect critical IP assets. Protection should also cover sensitive data sets that could lead to loss of trade secrets through possible "reverse-engineering".

MedTech Europe supports portability and interoperability requirements that allow users to switch between data processing service providers, especially to the extent that this may support the implementation of the future EHDS. We call for the further development of open interoperability specifications or European standards for interoperability for data processing services, which should build on international consensus interoperability standards that will prevent creating unnecessary hurdles to seamless international data flows.

We believe that a successful Data Act will depend on clear rules that are aligned with existing legislation, and that will support individual rights, confidentiality of business information, the upholding of IP rights and better access to technology innovation. MedTech Europe and our members look forward to closely collaborating with legislators and stakeholders to ensure that the Data Act protects the rights of European citizens and fosters data-driven 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.

Contact

Michael Strübin

Director Digital Health

m.strubin@medtecheurope.org