

Commission Feedback

Regulation for a European Health Data Space - the view from MedTech Europe

28 July 2022

MedTech Europe welcomes the opportunity to provide feedback on the [proposed European Health Data Space \(EHDS\) regulation](#), published on 3 May 2022.

As expressed through previous public statements (including our [statement on the European Strategy for Data in May 2020](#) and our [press release in May 2022](#)), MedTech Europe welcomes the Commission's goal of creating an environment which fosters access to health data and health data sharing across the European Union. As the voice of the medical technology industry, it is our view that the EHDS is a pioneering initiative and has the potential to empower patients, accelerate the European Single Market for digital health and data by tackling barriers to cross-border data sharing. While the proposal represents a tangible first step toward a European health data ecosystem, MedTech Europe sees areas of improvements as outlined below.

For MedTech Europe, a truly enabling EHDS should meet several key criteria:

- It should maintain a reasoned and logical scope to achieve its intended objectives.
- Its requirements and provisions need to be clear and consistent.
- It should not simply enable, but also encourage access to good quality data for secondary use while ensuring compliance with the General Data Protection Regulation (GDPR), for example, by providing additional clarifications.
- Finally, it needs to be consistent and coherent with the existing EU regulatory environment, and in particular with sectoral legislation.

General comments and recommendations on the proposed EHDS regulation

[Interplay with other legislation](#)

The EHDS regulation is meant to complement other EU laws, including existing sectoral legislation such as the Medical Devices Regulation (Regulation (EU) 2017/745, hereafter called "MDR") and the *In Vitro* Diagnostic Medical Devices Regulation (Regulation (EU) 2017/746, hereafter called "IVDR"), but also horizontal legislations such as the General Data Protection Regulation (Regulation (EU) 2016/679, hereafter called "GDPR"), the proposed Artificial Intelligence Act (AIA), the Data Act, the Data Governance Act, and the Cyber Resilience Act. MedTech Europe stresses the risk of disproportionate over-regulation of the medical technology industry in complying not only with existing legislation but with several additional regulatory requirements arising from new legislation.

MedTech Europe also asks for more legal clarity on the interaction between existing legislation with new EHDS requirements, as the proposal appears to assume a possible demarcation between electronic health records (EHR) systems, medical devices, and high-risk AI systems. Yet, the proposal does not consider the nature of medical technologies, which may have a modular design that may not allow an easy delineation of functions and modules. Therefore, MedTech Europe strongly urges that special consideration should be

given to the fact that medical technology manufacturers could be mandated to conduct conformity assessments under different regulations if a product or service were to qualify for different categories. Ultimately, this creates additional pressure for the medical technology industry, especially for European SMEs, and impacts for future innovation in and for the EU market.

Primary and secondary use of electronic health data

MedTech Europe seeks clarification on various definitions, particularly on terminologies including 'EHR systems', 'appliances' and '(non) personal electronic health data' or concepts such as 'general software' and 'health systems'. Specifically, for EHR systems, we recommend a definition that focuses on systems intended to share patient information with authorised providers, healthcare professionals or patients and to a data flow between healthcare facilities, may be more in line with the intended aim of the EHDS. We note that the EHDS regulation needs to delineate the scope from other regulated product definitions, avoid inadvertent overlaps, clarify which rules apply if a product falls under several regulated categories and ensure harmonised regulations to avoid uncertainty, duplication, and arbitrage risk.

The proposal aims to enable better exchange and access to different types of health data and foster primary use of electronic data in healthcare delivery. If undertaken correctly, this will empower individuals to access their personal health data better digitally across borders. In this regard, the medical technology sector sees an opportunity for multi-stakeholder initiatives aiming to facilitate integration of prioritised (meaning relevant and actionable) health data in EHR systems. If this opportunity is taken forward, it would come with a need to adopt and further develop standards that facilitate such integration.

Access to relevant data is a key enabler for research, ensuring high standards of quality and safety of medical devices and innovation, and a necessity for delivering innovative and personalised medical solutions to patients and users. MedTech Europe supports the goal of increasing the cross-border secondary use of electronic health data in the EU. For this to be successful, the EHDS urgently needs to provide a stand-alone legal basis to process health data for research purposes, in compliance with the GDPR. Similarly, we want to stress the need for a truly harmonised regime as the proposal includes many references to national laws, such as in the case of access (see Article 1.6, Article 45 par. 4, b). For the EHDS to become a true enabler for innovation, these issues need to be addressed to deliver a more harmonised framework and legal certainty to organisations engaging in research on health data. In this regard, it will also be key to demonstrate to citizens and patients the benefits of health data sharing to make the EHDS a true enabler.

Protection of intellectual property rights (IPRs) and trade secrets

The EHDS regulation compels data holders to make certain categories of data available for secondary use. This would be required even if the data contained intellectual property rights (IPRs) and trade secrets. The proposal assigns Access Bodies, which are designated by the Member States, to take the necessary measures to preserve their confidentiality, yet it is unclear what these measures could be. As such, MedTech Europe seeks additional clarifications. In addition, we want to stress the risk of increased litigation, which will

be solved by the respective national courts potentially creating divergent standards between the different Member States. All in all, this could lead to fragmentation, for both the protection of IPRs by the Access Bodies, as well as in terms of litigation, creating the opposite effect as initially foreseen by the proposal. Furthermore, it is unclear who will assess the adequacy of the measures (especially as requests for data may come from competitors) and whether data will be made available without adequate measures. IPR protection should be paramount to ensure that the EHDS is ready for industry participation and to promote the EU as an attractive market for launching new products, conducting research, and delivering innovation. As recognised in the Data Act, respect for trade secrets and IPRs in the handling of data are key to preserving incentives to invest in products with functionalities based on the use of data from sensors built into that product. In this context, MedTech Europe seeks additional clarification on the interplay between the Data Act and the EHDS. In particular, regarding the obligations related to patient data access to EHR and, for the sake of legal certainty, which Act would prevail if there was a conflict on IPRs between the Data Act and the EHDS.

Interoperability

The key common specifications for interoperability and security in respect of the essential requirements are listed in general terms in Annex II and will be further defined. However, it should be noted that the use of common specifications for interoperability and security may be problematic as they may not accurately reflect the state of the art. Furthermore, they may not align or may even contradict internationally recognised interoperability standards and formats for creating, storing, and exchanging electronic health records. MedTech Europe wants to outline that using common specifications instead of internationally accepted harmonised standards may lead to using outdated data formats that are no longer secure, state of the art, and therefore restrictive, hampering innovation and introducing additional barriers for European companies operating globally. MedTech Europe therefore urges EU policymakers to duly consider industry best practice in this regard, or promote development of same.

Achieving technical and semantic interoperability and seamless exchange of data and information is critical to the success of the EHDS and improvements in clinical operations, patient outcomes and cost of healthcare. The interoperability of EHR, in line with the existing European Electronic Health Record Exchange Format and internationally recognised standards (e.g., HL7 FHIR, IEEE 11073), as well as semantic and technical interoperability, should be strengthened. The governance framework should prioritise standardisation needs, improve data interoperability and should be an extension of existing structures, as for instance the E-health Network or the Multi-Stakeholder Platform for ICT standardisation. Furthermore, there should be a link to all relevant European and international standards development organisations (SDOs), including industry consortia. This collaborative effort requires input from the industry and other stakeholders, digital health authorities at national and regional levels, and relevant SDOs.

EHDS Governance

The proposal foresees that EU Member States establish one or more Access Bodies to oversee and enforce the provisions applying to electronic health data sharing and Digital Health Authorities. As a result of the involved actors, MedTech Europe urges policymakers to address the potential risk of fragmentation. If

fragmentation occurs, it may lead to deviating implementation and enforcement of the provisions of the EHDS Regulation. MedTech Europe sees value in industry representation in the Access Bodies to ensure that it can achieve the optimum result.

[Implementing and Delegated Acts in the proposal](#)

We note that the proposal defers the implementation and regulation of essential elements to the European Commission through several Implementing and Delegated Acts. Accordingly, various key aspects of the regulation remain unclear, such as essential requirements for interoperability or the fee structure for access. MedTech Europe is concerned that this leaves room for considerable legal uncertainty and calls for clarification. Clear guidance and intent must be developed to inform secondary legislation, thus avoiding confusion and fragmentation in Member State implementation and laying the foundation for provisions adopted by the Commission in Delegated Acts in the future. Furthermore, we wish to note that the timely delivery of the Implementing and Delegated Acts is a crucial aspect of the operationalisation of the EHDS.

We believe that a successful EHDS will depend on clear rules aligned with existing legislation, support of individual rights, effective access by the medical technology industry to health data, the confidentiality of business information, and better access to technology innovation.

MedTech Europe and our members look forward to closely collaborating with legislators and stakeholders to ensure that the EHDS will empower European citizens, accelerate an EU single market for health and remove barriers from health data sharing to foster data-driven 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.

www.medtecheurope.org.

For more information, please contact:

Verena Thaler, Manager Digital Health, Industry Strategic Initiatives, v.thaler@medtecheurope.org