

## Call to address key challenges in the final EHDS

### MedTech Europe's recommendations on the EHDS Trilogue negotiations

6 February 2024

As the proposed European Health Data Space (EHDS)<sup>1</sup> regulation is currently being discussed in the interinstitutional “Trilogue” negotiations, MedTech Europe would like to reiterate its [position](#) and highlight areas of specific importance to the medical technology industry. Our sector's mission is to make safe, secure, and performant medical devices, in vitro diagnostic medical devices, and digital health solutions available in the EU. We are committed to being an active partner and a keen collaborator in this new health data ecosystem envisaged by the EHDS. This pioneering initiative will help harness the benefits of health data sharing, and we strongly believe that to unlock the full potential of the system and make it workable, it will be crucial to address outstanding challenges.

#### 1. Create a workable framework for ‘EHR systems’.

We acknowledge that the EU institutions sought to address the complex interplay between the EHDS and existing sectoral legislation, such as the Medical Devices Regulation (MDR)<sup>2</sup> and the *In Vitro* Diagnostic Medical Devices Regulation (IVDR)<sup>3</sup>. The co-legislators' positions require further clarification of the key principles to regulate ‘Electronic Health Record (EHR) systems’, to ensure appropriate delineation from already regulated and CE-marked medical technologies to avoid double regulations.

**Standard ‘EHR systems’ and medical technologies have different primary purposes.** The primary goal of an ‘EHR system’ is to share data between different actors in health systems and exchange patient information cross-border. In contrast, medical technologies must, as their *primary intended purpose* as defined by law under MDR and IVDR, meet a specific medical need (e.g., diagnosis, therapy delivery), while some may also allow sharing of data. An extremely broad definition of ‘EHR systems’ in the EHDS creates legal uncertainty for medical technology manufacturers due to uncertainty regarding the corresponding conformity assessment procedures.

→ To reflect this aspect, the definition of “EHR systems” in Art. 2(2)(n) should focus on any product (hardware or software) which is *primarily* intended by the manufacturer to be used for the purpose of sharing data between different actors of health systems for personal electronic health data of *all* priority categories defined in Article 5(1). This allows for a delineation of standard hospital information systems from medical technologies.

**Avoid duplicative conformity assessments for technologies that are already regulated.** Even with a clearer definition of an EHR system, some medical technologies may qualify as EHR systems. In this instance, it is important to avoid duplicative conformity assessments. Both the European Parliament's and the Council's positions lack clarity on how affected systems can demonstrate conformity with the EHDS, the sectoral regulatory framework (MDR and IVDR) and horizontal legislation (AI Act) altogether. The EHDS needs to fully align with existing conformity assessment procedures, including the related

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1 [Proposal for a regulation - The European Health Data Space](#)

2 [Medical Devices Regulation \(Regulation \(EU\) 2017/745\)](#)

3 [In Vitro Diagnostic Medical Devices Regulation \(Regulation \(EU\) 2017/746\)](#)

designation of appropriate notified bodies. Additional requirements in individual Member States, as foreseen in the Council's position (Recital 20, Art.27A), would defeat the overall purpose of the EHDS to create a true, harmonised single market for EHR systems in the EU.

→ It is imperative to capture in the legislative text that wherever a medical device or *in vitro* diagnostic medical device qualifies also as an 'EHR system', the relevant conformity assessment shall be carried out as part of the procedures laid out under MDR and IVDR to be the sole responsible procedure.

## 2. Clearly specify the scope of electronic health data for secondary use.

Access to relevant electronic health data is a key enabler for research, ensuring high standards of quality and safety of medical devices, and for delivering innovative and personalised medical solutions to patients and users. To achieve this, electronic health data categories listed in Article 33(1) need to be clarified to only include data related to the primary use of health data as contemplated by Chapter II of the EHDS proposal. We are concerned that the original text of the proposal, as well as the co-legislators' positions, could lead to ambiguity due to broad definitions of the data types and could potentially also entail device-generated data in the scope of the EHDS (e.g., under Art. 33(1)(f)).

→ The list of minimum categories of electronic data for secondary use (Art. 33(1)) should be refined to not include raw/pre-processed, processed and annotated data sets. Co-legislators should also exclude the compulsory sharing of data of medical technologies in pre-clinical phases and the sharing of both input and output data to avoid reverse engineering of algorithms.

## 3. Avoid the erosion of the existing IP and trade secrets protection.

The co-legislators' positions on the EHDS explicitly oblige data holders to disclose their electronic health data for secondary use to data users established in the EU, even if requested data entails intellectual property rights (IPRs) and trade secrets. This risks severely impacting already established rights of data holders on IPRs and trade secrets without providing sufficient safeguards to protect them compared to the existing legislative framework, encouraging innovation-related activities. Both EU and national law, as well as international treaties like TRIPS,<sup>4</sup> protect IPRs and trade secrets as fundamental rights<sup>5</sup> and/or general principles of EU law. While we acknowledge some amendments from the co-legislators, they do not adequately address our concerns. We, therefore, encourage the co-legislators to introduce stronger safeguards to protect IPRs and trade secrets in the final text, consistent with existing law.

→ Include stronger references to the protection of undisclosed know-how and business information under existing law on the protection of IPRs and Trade Secrets<sup>6</sup> and in line with TRIPS.

→ In line with the Data Act<sup>7</sup>, data users and data holders should consensually agree on the arrangements for making the data available. This shall also include the data holder's right to refuse

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<sup>4</sup> WTO Agreement on [Trade-related aspects of Intellectual Property Rights](#)

<sup>5</sup> The right to property as provided for by (1) Article 17 of the EU Charter of the Fundamental Rights and (2) Article 1 of Protocol 1 to the European Convention of Human Rights.

<sup>6</sup> [Directive \(EU\) 2016/943](#) on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure

<sup>7</sup> [Regulation \(EU\) 2023/2854](#) on harmonised rules on fair access to and use of data and amending Regulation (EU) 2017/2394 and Directive (EU) 2020/1828 (Data Act)

a request under certain conditions, i.e., when the data holder's legitimate interests can be detrimentally affected in the absence of sufficient protective measures or safeguards for protected data.

- Article 33 should include the involvement of data holders in the identification of datasets which are protected, including the relevant metadata, and on sufficient and proportionate technical and organisational legal (ex-ante) measures necessary.
- Prohibited purposes for secondary use of electronic health data should entail all acts of unfair competition or unfair commercial use. Sufficient ex-ante protection is needed to ensure that disclosed data is not used for anti-competitive purposes.

#### **4. Reinforce the EU's commitment to international free flow of data.**

As recognised by the EU Commission, it is vital that EU companies can move their data across borders. International transfers of health data are crucial for the continued delivery of life-saving healthcare solutions and innovation to address unmet medical needs.

We have serious concerns about the addition of data localisation and sovereignty requirements in both the European Parliament's and the Council's position, as they would also go against the EU's international agreements, such as GATS<sup>8</sup>. We recognise the Council's position of limiting the new obligations related to the storage of electronic health data to the Health Data Access Bodies and Secure Processing Environments as a sensible approach. However, we call on legislators to not expand the new obligations to all health data but instead ensure alignment with existing legislative frameworks and agreements that already provide solid safeguards for the international transfer of data, including personal and non-personal health data. It was recognised by both the European Data Protection Board (EDPB) and the European Data Protection Supervisor (EDPS) that the provisions outlined in the GDPR are sufficient to achieve the objectives pursued by policymakers on data protection, i.e., to mitigate the risk of non-EU jurisdictions undermining EU laws, norms and values.

- We recommend avoiding data localisation requirements and ensuring the alignment with the existing EU data protection regime under Chapter V rules of the GDPR. Existing legislation already regulates effectively how to safeguard cross-border transfers of personal data through various data transfer mechanisms and supplementary measures, such as pseudonymisation and/or encryption.

#### **Conclusion**

We hope that these key challenges receive due attention and sufficient time for consideration by policymakers. The political objective to finalise the EHDS before the EU elections should not compromise the quality of the final legislative text. It is crucial for the co-legislators to consider the impact of the Trilogue negotiations, which will shape healthcare delivery and research for the decades to come. Our commitment to cooperation with the co-legislators remains unwavering, and MedTech Europe remains a dedicated partner in this ongoing process to create a truly enabling health data ecosystem through the EHDS.

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<sup>8</sup> [General Agreement on Trade in Services](#)

### **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](http://www.medtecheurope.org).

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