Medical technology industry's reaction to the EHDS agreement

The European Parliament's endorsement of the European Health Data Space (EHDS) [1] regulation marks a pivotal advancement in the legislative trajectory. With the endorsement of the Council and the publication in the Official Journal of the European Union approaching, MedTech Europe and COCIR would like to present a joint medical technology industry's initial response on the final agreement.

We welcome the significant efforts and the political will to establish the EHDS as a building block of a strong European Health Union, aiming to harness the advantages of health data sharing. However, for the EHDS to transition from concept to reality, it is imperative that lingering concerns outlined within the final text are adequately addressed in the implementation process. These issues necessitate attention through secondary legislation and further clarification through dialogue with key actors.

1. **Establish clear implementation timelines and involve key stakeholders.**

   The implementation of the EHDS Regulation would greatly benefit from a well-defined vision, particularly concerning funding allocation in the Member States and clear timelines for implementation steps in the Member States and drafting of secondary legislation guidelines. A structured, stage-by-stage roadmap with precise funding outlines is essential to enhance the effectiveness and feasibility of achieving the EHDS. Additionally, early involvement of key stakeholders from early in the implementation, especially through the stakeholder forum, is crucial. Clear governancein relation to the interactions between the EHDS board and the stakeholder forums will enhance collaboration and ensure that processes are both transparent and effective.

2. **Avoid fragmented implementation in the Member States.**

   The final provisions of EHDS allow significant discretion for the Member States to establish rules by national law, potentially leading to highly fragmented implementation and unequal access to healthcare services across the EU. To realize the EHDS objectives and full potential, it is crucial to avoid the creation of 27 different frameworks resulting from variations within the health data scope or differing governance mechanisms. Alignment, particularly in governance processes such as the data applications, will be crucial for ensuring coherence and effectiveness throughout the implementation process

3. **Provide further clarity on the broad scope and definitions.**

   Clear definitions and scope of the Regulation are critical for its success. The definitions provided for "electronic health data" and "EHR system," are excessively wide-ranging, complicating the Regulation's applicability and pose challenges during implementation. Additionally, it is crucial to

1 Proposal for a regulation - The European Health Data Space

refine data types for secondary use. The current categories, such as “other data from medical devices”, are still overly broad and would benefit from further clarification.

4. Create a workable framework for ‘EHR systems’.

The overly broad understanding of “EHR systems” in the final text risks legal uncertainty, particularly as it fails to consider the complex design of innovative technologies. This hampers the objective to facilitate (cross-border) sharing of electronic health records. The co-legislators have opted for a self-assessment of conformity and have introduced a more nuanced approach towards EHR systems by limiting the requirements to the European interoperability component and logging component (also referred to as the ‘harmonized components’). However, clarity on these harmonized components and their associated requirements is still lacking . It is crucial to establish an feasible approach to underpin a harmonised system through clear guidance and secondary legislation, especially in the interplay with existing sectoral legislation such as the MDR[2] and IVDR[3]. Additionally, the testing environments for EHR systems set up in the Member States must not become a bottleneck for testing the requirements, and timely availability of such systems across the EU must be ensured.

5. Avoid the erosion of the existing IP and trade secrets protection.

While the adopted text expands on the protection of trade secrets and intellectual property rights compared to the original proposal, persistent challenges continue ~~persist~~, as the final text lacks alignment with the protection of undisclosed know-how and business information under existing law[4]. Although the involvement of the data holder in identifying protected datasets is welcome, the EHDS does not specify the information about specific measures of protection before the datasets are shared with the health data access bodies (HDABs). Given that HDABs are required to preserve confidentiality in trade secrets and intellectual property rights, sufficient technical and human resources with the appropriate expertise is needed.

Successful implementation of the EHDS depends heavily on strong involvement from health stakeholders and ensuring a harmonised interpretation and implementation. We trust policymakers will address these crucial challenges in upcoming secondary legislation. MedTech Europe and COCIR are committed to close cooperation and collaboration with legislators during the implementation and operationalisation phases, remaining dedicated partners in establishing a health data ecosystem via the EHDS.

[2] Medical Devices Regulation (Regulation (EU) 2017/745)
[3] In Vitro Diagnostic Medical Devices Regulation (Regulation (EU) 2017/746)
[4] Directive (EU) 2016/943 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure

About us:

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.

COCIR is the European Trade Association representing the medical imaging, radiotherapy, health ICT and electromedical industries. Founded in 1959, COCIR is a non-profit association headquartered in Brussels (Belgium). COCIR is unique as it brings together the healthcare, IT and telecommunications industries.

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