MedTech Europe's position on the proposed European Health Data Space Regulation

22 February 2023

Executive Summary

MedTech Europe believes that the European Health Data Space (EHDS) represents a pioneering initiative that will not only empower citizens but that will contribute to improving healthcare in the EU. It will herald a new era of health data sharing and help to harness the benefits of health data sharing for better health outcomes. The EHDS brings with it the potential to accelerate a European single market for digital health and data by tackling the most prevalent barriers to the cross-border availability and sharing of health data.

The medical technology industry is committed to being an active partner and a keen collaborator in this new health data ecosystem. It is therefore pivotal to establish a truly enabling and implementable framework for which we provide the following recommendations:

- **Consistency and coherence with the existing EU regulatory environment for medical technologies must be ensured**, in particular with the existing horizontal and sectoral legislation, such as the Medical Devices Regulation (MDR), the *In Vitro* Diagnostic Medical Devices Regulation (IVDR), and the General Data Protection Regulation (GDPR). Duplication of regulatory oversight and administrative burden must be avoided.

- Additionally, the EHDS needs to be future-proof and align clearly with upcoming EU legislation, such as the AI Act, the Data Act, and the Cyber Resilience Act.

- The EHDS should have a **reasoned and logical scope with clear definitions** to achieve its intended objectives. We, therefore, suggest clarifying key terms throughout the legislation (e.g., 'electronic health data', '(non) personal electronic health data', **'electronic health record (EHR) system'**), and aligning definitions across existing legislation, as appropriate (e.g., 'data holder').

- **To avoid redundancy and inefficiencies, manufacturers should be required to follow a single conformity assessment, under an MDR/IVDR-designated notified body**, and only address differences between applicable regulations (MDR, AI Act and EHDS) separately.

- EHDS should **consider industry's best practice in terms of interoperability and cybersecurity**, employing, where appropriate and available, internationally recognised standards, or promote the development of such.

- To **encourage access to and sharing of good quality data for secondary use**, the EHDS needs to build on the existing **trade secrets and IP rights** framework. Any IP and trade secret data sharing provisions should build on voluntary disclosure models and data holder-user agreements. Adequate safeguards need to be put in place to allow protection of IP and trade secrets. Furthermore, **clear and harmonised mechanisms for health data access across the Member States need to be established.** In order to incentivise innovation, data holders

and data users should agree on an **adequate compensation** for disclosure of IP and /or trade secret protected data.

- **It is necessary to further define and clarify the competencies of the newly established Health Data Access Bodies (HDABs)** to avoid ambiguity and duplication of tasks with other authorities. The criteria for the assessment of data permits should also be clarified and harmonised.
- A truly enabling EHDS should **avoid additional barriers for international transfers of data beyond the existing legal framework.**
- Lastly, the system needs the trust, buy-in, and expertise of all stakeholders along the healthcare value chain, including patients, healthcare professionals, innovators as well as policymakers and regulators. The EHDS governance should **ensure strong stakeholder involvement and consultation throughout the design, planning, development, and implementation process and ensure their involvement in its governance structures**.

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 to health data sharing to foster data-driven research and innovation.

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Introduction

MedTech Europe welcomes the European Commission's goal of creating an environment which fosters access to health data and health data sharing across the EU. As the voice of the medical technology industry, MedTech Europe believes that the European Health Data Space (EHDS)[1] represents a pioneering initiative that will not only empower citizens to have greater access to their health data but will also contribute to improving healthcare in the EU. Its goal is to harness of the benefits of the digital age for better health outcomes through more effective health data use and re-use. It has the great potential to accelerate a European single market for digital health and data by tackling the most prevalent barriers to the cross-border availability and sharing of health data for research and innovation, and policymaking.

The medical technology industry is an integral part of the health data ecosystem. Connected medical technologies are widely used by patients and healthcare professionals (HCPs) and are increasingly integrated across a variety of electronic platforms and information systems. They enable diagnosis, and support clinical care practice and decision-making, by leveraging the benefits of digitalisation to provide better, faster, and more efficient healthcare. As such, medical technologies are a crucial component of a health data-sharing ecosystem enabled by the EHDS.

With this position paper, MedTech Europe would like to call to attention the potential challenges of the proposal for the medical technology industry and propose possible solutions for a thriving health data ecosystem in the EU.

1. Scope and definitions

The EHDS regulation is intended to complement other (existing and proposed) laws in the EU. MedTech Europe calls on legislators to ensure that the regulatory framework of the EHDS will act as a facilitator for European health innovation by providing regulatory certainty, and not eroding relevant, well-established legal rights and principles. Clear guidance and intent must be developed to clarify the interaction of the new provisions of the EHDS with existing secondary legislation and ensure much-needed alignment to make the EHDS workable in practice and create an attractive environment for investment.

It is essential that the interplay between current and future legislation is clear and prevents duplicative and conflicting or multi-level requirements as well as legislative inconsistencies. For instance, the Medical Devices Regulation (MDR)[2] and the *In Vitro* Diagnostic Medical Devices Regulation (IVDR)[3] set out strict rules and requirements for products and manufacturers of medical technologies. Mandated conformity assessment procedures under these regulations assess quality systems and the safety and

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[1] Proposal for a Regulation on the European Health Data Space
[2] Medical Devices Regulation (Regulation (EU) 2017/745)
[3] *In Vitro* Diagnostic Medical Devices Regulation (Regulation (EU) 2017/746)

performance of medical technologies being placed on the EU market. Some provisions in the EHDS could potentially duplicate such conformity assessments. In addition, the proposed AI Act (AIA)[4] foresees conformity assessment for AI-enabled medical technologies, adding an unnecessary additional layer of complexity and legal uncertainty. Similar issues of scope and regulatory alignment also concern other horizontal legislation which apply to medical technologies and digital health solutions. These include the General Data Protection Regulation (GDPR)[5], the Trade Secrets Directive[6], the Data Act[7], the Data Governance Act[8], and the Cyber Resilience Act[9].

These issues could lead to pressure and uncertainty for medical technology manufacturers, and health systems and might inadvertently impact innovation within and for the EU market. In this regard, MedTech Europe highlights the risk of disproportionate over-regulation of the medical technology industry in complying not only with existing legislation but with several additional requirements arising from new legislation. Additionally, we would welcome more clarity about the relation and interaction with national legislation, to avoid unnecessary confusion, possible duplications and further fragmentation.

For these reasons, MedTech Europe asks co-legislators for further clarification on the proposal's interplay with other laws and suggests strict alignment with sectoral legislation (especially with MDR and IVDR) and other existing and future horizontal legislative frameworks to avoid overlap, duplicative assessments, and unnecessary complexity for medical technology manufacturers.

Regarding the proposal's scope, MedTech Europe welcomes the distinction between the use of electronic health data for the provision of health services ('primary use'), and the use for various secondary purposes such as research and quality enhancement ('secondary use') in the proposed EHDS. However, a successful EHDS needs to be clear in outlining the scope and definitions.

Manufacturers of medical technologies need clarity in regulatory requirements to understand and anticipate the consequences of either their products or themselves being classified under those definitions. These requirements will ultimately affect the way in which medical technologies are manufactured and reach the EU market. While MedTech Europe recognises that certain new terms need to be created to account for recent and emerging technological developments, such terms should be aligned with the relevant existing definitions. It is essential to ensure consistency with the (above-mentioned) existing legislative landscape as well as the 'New Legislative Framework'[10], which already includes terminology and requirements covering various aspects of products that would fall into the scope of the EHDS.

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[4] Proposal for a Regulation on Artificial Intelligence (Artificial Intelligence Act)

[5] General Data Protection Regulation (Regulation (EU) 2016/679)

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

[7] Proposal for a Regulation on harmonized rules on fair access to and use of data (Data Act)

[8] Data Governance Act

[9] Proposal for a Regulation on cybersecurity requirements for products with digital elements (Cyber Resilience Act)

[10] New legislative framework

> **We, therefore, call on co-legislators to further clarify key terms and definitions and to ensure strict and clear alignment with existing terms and concepts which are already established in the EU. There must be no regulatory overlap and redundancies.**

To have further clarity about the scope of the proposal, MedTech Europe recommends to further clarify the definition of 'electronic health data' in the proposal, as it includes both personal and non-personal electronic health data. These concepts are indispensable not only for defining the scope of the EHDS, but also for its objective to make the re-use of health data more effective. 'Non-personal electronic health data' must be defined, otherwise it will be open to broad interpretation due to various applications of the GDPR and health data processing rules in the Member States. Contrary to the definition of 'personal electronic health data', the definition of 'non-personal electronic health data' does not contain a link to primary care, which can potentially make the definition and related obligations extremely broad.

> **MedTech Europe recommends that co-legislator clarify terms related to electronic health data within the scope. The aim should be to ensure that only meaningful data will be available for the primary and secondary use of electronic health data which, in turn, will be critical for the success of the EHDS.**

2. Primary use of electronic health data

The proposal aims to enable better exchange and access to different types of electronic health data and foster the primary use of electronic health data in healthcare delivery. This should empower individuals to better access and control their personal health data digitally, even across borders.

Access to and management of electronic health data can have great benefits for citizens, patients, and HCPs. To make this a reality, the definition of 'electronic health data' (Art. 2 (2, c)) should be clarified to encompass only patient data that is managed by healthcare providers in the context of primary care. Including raw data and technical parameters, might not be in the interest of users (citizens, patients or HCPs) as it will be irrelevant to the needs of patient care or (personal) health management and might overload them.

Although Article 5 seems to imply that citizens' access to and control over their health data, should go via their EHRs, MedTech Europe calls for a specification in Article 3 to state that citizens have the right to access actionable data that are easily readable, consolidated and accessible. Article 5 should clarify that any expansion of the list of categories of electronic health data, should take into consideration whether the additional category of data constitutes actionable data. Finally, to ensure clarity which categories of data are shared with patients, carers or third parties for the provision and delivery of healthcare, Article 3 would benefit from clarification that the rights of patients as described in Article 3(1) relate to their personal electronic health data of the priority categories in Article 5(1).

> **To ensure that appropriate, meaningful and relevant data, such as data that is processed and analysed in the provision of healthcare and intended to be understood by HCPs, is shared with the respective user, MedTech Europe suggests clarifying the relationship between Articles 2, 3, and 5.**

MedTech Europe sees an opportunity in integrating relevant and meaningful electronic health data in EHR systems along the continuum of care. To create more clarity for medical technology manufacturers, descriptions of the categories of electronic health data in the scope and their main characteristics (Annex I) should be clarified as they appear to include data derived directly from medical technologies. This clarification and a harmonised implementation will be crucial to avoid fundamentally different data spaces in the European Member States.

> **MedTech Europe asks for further clarification of categories of electronic health data in the scope and their main characteristics described in Annex I of the proposal. Additionally, any expansion should be part of stakeholder consultation to ensure broadly accepted interoperable data definitions, focusing on the inclusion of actionable data and ultimately high data quality.**

3. EHR Systems

While we understand the Commission's intention to fill a regulatory gap regarding EHR systems in the health sector, MedTech Europe contends that the proposed definition of an EHR system is overly broad, encompassing all connected medical technologies that store, intermediate, import, export, convert, edit, or view electronic health records.

> **MedTech Europe recommends a definition that focuses on any product (hardware or software) which is *primarily* intended by the manufacturer to be used for storing, intermediating, importing, exporting, converting, editing or viewing electronic health records. Such a definition should *not* include MDR/IVDR-regulated devices, with any interaction between MDR/IVDR and the EHDS being confined to those MDR/IVDR-regulated devices which claim interoperability with EHR systems.**

This, we believe, would be more in line with the intended aim of the proposal, all the while contributing to the required legal consistency. EHDS regulation should delineate the scope from product definitions of other regulations, avoids inadvertent overlaps, clarify which rules apply if a product falls under several regulated categories and ensure harmonised regulations to avoid uncertainty, duplication, and the risk of arbitrage.

> **To ensure consistency and clear understanding of key concepts, MedTech Europe recommends refining the definition of 'electronic health record' to reflect the above-mentioned suggestion and to define 'general software' under Article 2.**

Conformity assessments

As outlined in the section covering the scope of the proposal, MedTech Europe calls for legal clarity on the interaction between existing legislation and new EHDS requirements. The proposed Article 14 intends to clarify the interplay with medical devices under MDR and high-risk AI systems, and the EHDS proposal appears to assume a possible demarcation between 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 does not always allow an easy delineation of functions and modules**.**

For manufacturers of medical technologies, it is crucial that the interplay and prevalence of the diverse requirements are clear, avoiding increased compliance costs, administrative burden, and undue regulatory complexity for manufacturers, especially European SMEs, which could impact innovation in and for the EU market.

MedTech Europe recommends further clarification. There should be no future requirement for medical technology manufacturers to conduct individual conformity assessments under all three regulations (MDR, AI Act and EHDS). A single conformity assessment under the MDR/IVDR-designated framework is advised for any device that is considered a medical device classified under the MDR or IVDR.

Both the MDR and IVDR are under capacity limitations in their respective Notified Body systems, which impacts the availability of medical technologies to patients. Under the EHDS, the European Commission will evaluate the implementation of the regulation after 5 years, also considering the need for a third-party conformity assessment via notified bodies. While MedTech Europe recognises the need for future-proof regulation, it is essential to ensure that the current regulatory system for medical technologies is not compounded by additional conformity assessment requirements.

MedTech Europe urgently calls for any further regulatory burden, cost and complexity in our sector to be fully assessed and minimised to ensure continued availability of medical technologies to patients and our healthcare systems.

Interoperability of EHR systems

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 (EEHRxF, Art. 6) and internationally recognised standards, as well as semantic and technical interoperability (e.g., HL7 FHIR and IHE profiles), should be strengthened.

> **MedTech Europe stresses the importance to promote the use of fit-for-purpose standards, that are in close alignment with Standard Developing Organisations (SDOs) and the state of the art in industry.**

The use of common specifications for interoperability and security (Article 23 and Annex II,) is problematic as they do not accurately reflect state of the art, especially when considering cybersecurity developments. Furthermore, common specifications may not align, or could even contradict internationally recognised interoperability standards and formats for creating, storing and exchanging electronic health data. Applying common specifications instead of internationally accepted standards may lead to using outdated data formats that are e.g., no longer secure and therefore restrictive, hampering patient safety, innovation and introducing additional barriers for European companies operating globally. The development of appropriate and international standards requires input from the industry and other stakeholders, digital health authorities at national and regional levels, and relevant SDOs. MedTech Europe is committed to contributing to this collaborative effort.

> **MedTech Europe, urges EU policymakers to duly consider existing best practices in terms of interoperability or promote the development of the same, employing, where appropriate and available, internationally recognised standards. The enforcement of national standards for universal concepts should be avoided.**

4. Secondary use of electronic health data

Access to relevant electronic health data is a key enabler for research, ensuring high standards of quality and safety of medical devices and innovation, the development of trustworthy AI and a necessity for delivering innovative and personalised medical solutions to patients and users. MedTech Europe highlights the great potential of the EHDS to enable increased re-use of cross-border electronic health data in the EU if the access is well-defined.

General conditions for secondary use of data

Types of data

The EHDS should take into account the wide range of medical technologies use cases, which can generate data sets of various complexity and volume to derive tangible insights from datasets. Nevertheless, more clarity is needed for the medical technology industry to understand which types of electronic health data are in the scope of the categories listed in Article 33(1). MedTech Europe is concerned that the proposal could lead to ambiguity as it could potentially entail also device-generated data in the scope of the EHDS. However, MedTech Europe would like to emphasise that sharing *all* types of data could result in huge data sets (including from ongoing monitoring of patients) being inserted into the infrastructure healthdata@EU which could create difficulties to derive meaningful insights for EHDS participants.

MedTech Europe recommends further clarifying Article 33 on the data types included. In this regard, we recommend to only include validated and actionable output data of the products rather than device-generated data and raw data sets which often are too large and granular and therefore not fit for purpose.

Furthermore, the list of the minimum categories of electronic health data for secondary use should be harmonised across EU Member States and cover products or services contributing to health and care in general, not just public health and social security. In addition, it should include actionable data that is crucial in the diagnosis and treatment of diseases as well in providing insights into how to improve outcomes at the population level. Additional types of data could include inter alia clinical data, registries (e.g., from European Cancer Data), prescription data as well as post-market and surveillance data.

MedTech Europe recommends that any change to the data types and/or their main characteristics should be part of a stakeholder consultation, to ensure that actionable data is included in the EHDS to derive meaningful insights.

Anonymisation of datasets

Maintaining high-quality datasets, while respecting the principle of data minimisation is crucial to deriving actionable insights for the improvement of health systems. Pseudonymised data is often valuable to enable data linkage for longitudinal analysis, which is recognised in the Regulation. However, we recommend that criteria for approving pseudonymised data use and data linkage be more formally specified at a European level to encourage a more harmonised and consistent approach. As outlined in Recital 41, the training, testing, and evaluating of algorithms is part of the intent of the EHDS. Anonymised data sets that are stripped from core characteristics may not allow researchers to derive conclusions crucial for the development of better devices, therapies, and treatments. Also, considering that the effectiveness of anonymisation for some types of electronic health data (such as for instance medical images, etc.) is uncertain, some may never become available for download, blocking the training, testing and evaluating of algorithms, which is part of the intent of the EHDS.

The EHDS should be supported by updated guidelines from the European Data Protection Board (EDPB) on the concept of personal data and non-personal data, as well as those on the anonymisation techniques to ensure legal certainty for stakeholders.

Definition of 'data holder' and related concepts

In addition to the clarification of key definitions and the scope of electronic health data outlined in Chapter 1 of this position paper, MedTech Europe seeks further clarification of the concepts that are already established in other legislation, such as the GDPR or the proposed Data Act.

The proposal does not differentiate nor assign the roles of the 'data controller' and 'data processor' which are already established concepts under the GDPR, and the proposal also does not clarify the

delineation between these. This is important as the value chains in healthcare are very complex and for instance, a medical technology manufacturer may not be the data holder and in control of data.

Lastly, the proposal imposes additional obligations on data holders (Arts. 41, 43, and 49) which may trigger a significant additional administrative, legal and financial burden. MedTech Europe, therefore, asks for further clarification of the definition and tasks associated with this role.

MedTech Europe believes that these fundamental roles need to be clarified as to ensure a clear workable interplay in line with the GDPR, the proposed Data Act and other legislation. It is important to create a clear understanding of the rights and obligations of and delineation between all participants in the system: data holders, controllers and processors. Additionally, we recommend further refining the terms of and creating a clear distinction between 'data holder', 'user', and 'data recipient'.

Purposes and prohibited purposes for secondary use

Article 34 outlines the purposes for the re-use of electronic health data. We acknowledge that the provisions are directed to development and innovation activities and are not limited to public research.

In view of the high potential of medical technologies to advance innovation and improve patient outcomes, MedTech Europe recommends defining Art. 33 (f) more broadly to cover products or services contributing to health and care in general, not just public health and social security. In addition, we recommend clarifying the provisions by including research conducted by private entities for product development and improvement, including health economics and outcomes research studies to the list of purposes.

MedTech Europe also recommends revising the prohibited cases for secondary use of electronic health data to cover deriving insights about the economic situation, assets and production method of a competitor's product or service.

Approvals for secondary use of electronic health data

The EHDS proposal foresees establishing one or more Health Data Access Bodies (HDABs) in the Member States which are tasked with examining a data user's application for access to electronic health data and will grant a permit detailing duration, fees payable, and the permitted purposes.

MedTech Europe believes that rules for data access must be harmonised across Europe and that general health data access prioritisation e.g., of public institutions before private entities, as indicated in Recital 51, could heavily restrict data access for research and the further development of technologies that help prevent, predict, diagnose, and treat potentially life-threatening conditions.

MedTech Europe suggests removing the prioritisation of the research requests from public entities to ensure equal data access and opportunities to advance science and innovation.

Furthermore, Art. 46 lays out that the HDABs will assess if the applications fulfil one or more of the purposes, if the requested data is necessary for the purpose listed in the application and if the requirements in this Chapter are fulfilled by the applicant. If that is the case, the health data access body shall issue a data permit. This would mean that the HDABs would also be required to assess the request and verify of the necessity of the requested data for the permitted purpose. As of yet, there is little clarity as to how these new authorities will interpret requirements and perform their assessment.

MedTech Europe, therefore, calls on legislators to further define and clarify the competencies of the newly established HDABs to avoid ambiguity, and duplication of tasks with other authorities and to have clarity about the criteria for the assessment of data permits. With regards to the latter, we suggest that HDABs closely collaborate with relevant stakeholders and to consult data holders before making data available.

Continuation of voluntary data sharing agreements

In Art. 49 the proposal regulates applications from single data holders, outlining that an applicant may file a data access application or a data request directly to the data holder. MedTech Europe welcomes this approach and highlights that the EHDS should facilitate voluntary, contractual relationships between parties outside the EHDS confines. This could help avoid unnecessary delays and burden for data user applicants, maintain existing agreements and partnerships and incentivise data sharing on terms protecting interests of all involved parties.

Protection of Intellectual Property and trade secrets

The proposed EHDS regulation explicitly obliges data holders to disclose their electronic health data for secondary use (directly or through HDABs) to data users established in the EU. This would be required even if electronic health data entails intellectual property rights (IPRs) and trade secrets (Recital 40 and Art. 33(4)).

Through these provisions, the proposed EHDS Regulation sets aside and severely impacts already established rights of data holders on intellectual property and trade secrets. Both, EU and national law protect IP rights and Trade Secrets as fundamental rights and/or general principles of EU law. Any interference with such fundamental rights should therefore be subject to a proportionality assessment. However, the proposed EHDS does not provide for such a detailed assessment of its impact on such rights. The necessity requirement is not demonstrated by the general and broad scope of the proposal since it only refers to specific events such as a pandemic or severe public health crisis (PIP) as a justification for limiting IP rights such as copyrights. Similarly, under the TRIPS Agreement, IP rights such as copyright and database rights, and rights to undisclosed information also benefit from protection. The TRIPS Agreement edicts minimum standards of protection at an international level (directly or by reference).

MedTech Europe is concerned that the proposed EHDS draft may set aside the rights which holders of IP and Trade Secrets Rights might have on certain data sets. We would like to emphasise that the EHDS should build on and respect established principles and international agreements on trade secrets

and IPRs to avoid precedent leading to the erosion of these rights. Obliging data holders to share protected data with any third party, including competing entities, would deprive them of the essence of their rights. In addition, the proposal also does not foresee any compensation corresponding to the value of the IPRs or trade secrets.

The current provisions may discourage manufacturers of medical technologies from certain investments in technology development if there is a risk that such investments do not return value or provide an unfair advantage for potential competitors. This in consequence would also weaken innovation attractiveness of the EU in the global setting.

The medical technology industry is committed to positively contributing to the EHDS, while ensuring that IP and trade secret protected data is adequately addressed. This will serve as an incentive for collaboration and making this system work, for all stakeholders. MedTech Europe supports greater empowerment of private enterprises to decide which IP and trade secret data can be disclosed and under what conditions. We believe that a fair compensation for disclosure of IP and/or trade secret data should be determined in an agreement between data holder and data user(s).

In addition, we highlight the risk of IP litigation and potentially divergent standards between Member States due to differences in national court rulings. This could lead to fragmentation 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. Legal clarity, coherence, preservation of existing rights should be paramount for the EHDS to promote the EU as an attractive market for launching new products, conducting research, and delivering innovation. Respect for trade secrets and IPRs in the handling of data are key to preserving incentives to invest in Innovation.

In this context, MedTech Europe seeks additional clarification on the interplay between the Data Act and the EHDS with regards to the obligations related to patient data access to EHR and, which Act would prevail if there was a conflict on IPRs between the Data Act and the EHDS.

We welcome more clarity regarding dispute resolution to address disagreements between involved parties, for instance on questions related to, but not limited to IP.

5. EHDS Governance

For the vision of the EHDS to create a functioning cross-border health data ecosystem to be achieved, harmonised interpretation and implementation of the Regulation will be essential. The EHDS foresees establishing new national public authorities, such as the Digital Health Authorities and HDABs, whereas the latter could be more than one in each EU Member State. MedTech Europe highlights that the need

to sufficiently equip EU Member States with necessary resources and funding, as the possibility of establishing several HDABs goes hand-in-hand with a high risk of fragmentation, not only between the Member States but even within single EU countries. As a result of the involved actors, MedTech Europe urges policymakers to address the potential risk of fragmentation, which may lead to deviating implementation and enforcement of the provisions of the EHDS Regulation.

Furthermore, MedTech Europe encourages strong stakeholder inclusiveness and private sector participation in the new governance structures, such as the EHDS board. Both public and private sectors offer significant experience, expertise and best practices that can ensure a robust framework that enables data flows to guarantee the success of the EHDS and to establish Europe as a leader in the emerging data economy. **The medical technology industry is highly committed to supporting the design, planning, implementation, and technical operationalisation of the EHDS.**

MedTech Europe urges legislators to establish and maintain a comprehensive harmonisation among EU Member States and greater inclusivity of the medical technology industry in the governance of EHDS.

6. International Data Flows

MedTech Europe would like to underline that there should be a clear legal framework for international data flows. The EHDS proposal as it stands may further complicate an already complex legal framework for international transfers and access of both, personal and non-personal data. In light of this, we seek clarification on key questions, as for instance on the territorial scope of the EHDS obligations and voluntary sharing. A clear legislative framework is important as European and international companies are deeply intertwined with the research and SME communities in Europe. Through their cooperation, these communities have the needed resources (funding, expertise, partnerships with public research and people), needed capabilities and a global reach.

MedTech Europe, therefore, calls on legislators to avoid additional layers that go beyond the existing legal framework for "highly sensitive" non-personal data. We believe that it is important to protect cross-border transfer of healthcare data that allows the aggregation of data from different countries, enabling scientific advances for medical breakthroughs and providing more data and certainty in regulatory filings with health authorities around the world.

7. Implementation

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, their link with reimbursement, or the fee structure for access. MedTech Europe is concerned that this leaves room for considerable legal uncertainty and potential shortage of medical technologies causing

discontinuity of care delivery. The mismatch of interoperability requirements and their implementation timelines with the industry could pose a threat on the availability of medical devices and related services.

Clear and timely guidance and intent should be developed, 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.

Lastly, the successful implementation of the EHDS requires significant resources. It is vital that this initiative is adequately resourced, including appropriate investments in capacity building and training, particularly of smaller and non-profit organisations, and that there is a strong, well-funded commitment to public consultation and engagement.

MedTech Europe, therefore, highlights the need for significant new EU funding throughout the health, health ICT and research ecosystems at European and national levels.

8. Conclusion

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, preserving 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 to 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.

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