SPECTARIS Position Paper

On the proposal for a Regulation for a European Health Data Space (EHDS)

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Feedback – EHDS

I. Introduction

On May 3rd 2022, the European Commission published the draft proposal for a Regulation on the European Health Data Space (EHDS). Based on the European strategy for data, this presents the first proposal for a sector-specific EU data space. Due to the increased relevance of using and exchanging health data, the EHDS aims at strengthening EU citizens' control over their own data, while also improving data access for research and innovation. The EHDS lays the groundwork for establishing a harmonised and secure common space for health data within the EU that could ultimately improve patient care, research, and innovation altogether. Therefore, SPECTARIS welcomes this initiative and agrees with its objectives.

However, from a medical technology perspective, the current EHDS proposal contains several key issues that need to be properly addressed in the forthcoming legislative process. SPECTARIS especially recommends to:

- further streamline the proposal in order to avoid regulatory overlaps with the MDR/IVDR and other legal frameworks;
- improve definitions of essential EHDS terms, which are necessary to gain clear insight into requirements for medical device manufacturers;
- emphasise the importance of secondary use of data for the researching medical technology industry to increase innovation capabilities;
- clarify requirements and increase efforts for EU-wide harmonization of national EHDS governance frameworks to avoid fragmented legal interpretations; and
- use internationally recognised and state-of-the-art standards on interoperability and cyber security instead of common specifications.

Detailed feedback on these issues, as well as on other areas for potential improvement, are outlined in the following sections.

II. In Detail

- Medical devices fall under the recently applicable Medical Device Regulation (MDR) or In Vitro Diagnostic Medical Devices Regulation (IVDR), which has resulted in a stark increase of requirements for products and manufacturers. Additional legal frameworks, such as the established General Data Protection Regulation (GDPR) and the forthcoming AI Act (AIA), Data Act, NIS 2 Directive, and Cyber Resilience Act (CRA), also address important digital health issues. This will result in a highly complex and intertwined regulatory web of requirements and the looming risk of regulatory overlapping and redundancies. Since medical device manufacturers are currently faced with the challenge of transitioning to MDR/IVDR frameworks, **SPECTARIS emphasises that further regulatory burdens on medical technology companies, particularly small and medium-sized enterprises (SMEs), must be kept at an appropriate level.** Also, we ask for further clarification on the scope of the EHDS proposal and its link with MDR/IVDR and other digital health-related EU legislation.

- On a definitional level, the EHDS proposal lacks a clear distinction between electronic health record (EHR) systems, medical devices and high-risk AI systems. While the general referral to MDR definitions (see Art. 2 (1e)) is to be commended, the characterization of EHR systems as *"any appliance or software intended by the manufacturer to be used for storing, intermediating, importing, exporting, converting, editing or viewing electronic health records"* (Art. 2 (2)(n)) is too broad. Due to the complexity of medical devices, both in form and function, this current definition could result in a classification as an EHR system - leading to additional requirements, duplication, and potential conformity assessments. **SPECTARIS asks for clarification on the term "EHR system" and its regulatory implications, and recommends narrowing-down the definitional scope to avoid legal uncertainty.**

- Secondary use of health data for research and innovation purposes is also an important cornerstone of this proposal. SPECTARIS has been an outspoken advocate for future- and innovation-oriented data use and analysis.[1] The EHDS could lay important legal groundwork for transparent access to care and research data in the EU. In this context, **we stress the importance of access to pseudonymised health data for the researching medical device industry in order to foster product innovation, advance clinical studies, and improve patient care overall.** To achieve this, the EHDS needs to establish a strong GDPR-compliant legal basis to process health data.

- In relation to this, the EHDS proposal text is currently focused on public research when it comes to secondary use cases regarding medical devices (Art. 34 (1(g)). To realise the high potential of innovation in the medical technology sector – with a view to increase quality of treatment and patient safety - **we recommend an additional emphasis on private research for product developments and improvements.** Furthermore, the possibility of product development should not only be limited to medical software and AI medical devices (as mentioned in Art. 34(1)(g)), but also include existing 'analogue' medical devices and (digital) accessories of medical devices.

- Health data for secondary use that should be made available by data holders include trade secrets and companies' intellectual property (Art. 33 (4)). Although access bodies should take *"all measures necessary to preserve the confidentiality of IP rights and trade secrets"*, it remains unclear what these measures entail. SPECTARIS therefore asks for clarification on this matter and emphasises the importance of comprehensively limiting risks for medical device manufacturers when disclosing data that is necessary to remain competitive.

- According to Recital 51, health data bodies can apply data access prioritisation. This could in turn lead to *"for instance prioritising public institutions before private entities"*. In general, prioritising public stakeholders could heavily restrict data access and should therefore be avoided. On this basis, we suggest to omit the mentioned prioritisation efforts from the proposal.

[1] See also: SPECTARIS-Positionspapier zur Nutzung von Gesundheitsdaten zu Zwecken der Forschung und Entwicklung durch die Medizintechnikindustrie (March 2021):
https://www.spectaris.de/fileadmin/Content/Medizintechnik/Positionen/2021_03_12_Positionspapier_Datennutzung_final.pdf

- With wide-ranging requirements on a national level, harmonisation of EHDS implementation is of essential importance for a functioning cross-border data ecosystem. The possibility of establishing several national Access Bodies in each EU member state (s. Art. 36) goes hand-in-hand with a high risk of fragmentation (differences in interpretation and implementation of EHDS requirements) - between member states and even within a country. Both of these scenarios can be observed in the case of Germany's GDPR implementation. In Germany, authorities tend to interpret GDPR requirements more strictly than in other EU member states. Since 17 federal data protection authorities supervise implementation in Germany, a high degree of fragmentation has been established, resulting in equally high legal uncertainty and complexity.
  Thus, regarding EHDS Governance, SPECTARIS urges legislators to set out for and maintain comprehensive harmonisation among EU member states – without national and potentially restrictive solo efforts.

- Interoperability and cyber security provisions are a decisive factor for a thriving EHDS. In its proposal, the European Commission has suggested common specifications as the policy tool to achieve an interoperable and secure cross-border health data exchange. SPECTARIS notes, however, that common specifications in these areas could deviate from - or even contradict - internationally recognised digital health standards. **Instead of common specifications, we strongly suggest the use of harmonised state-of-the-art standards to avoid outdated and, at worst, rigid interoperability and cyber security requirements.**

SPECTARIS believes that, if these key issues are addressed properly, the EHDS has the chance to deliver a functioning cross-border digital health ecosystem that could empower citizens, improve patient care, and foster research and innovation efforts of medical device manufacturers in the European Union. To help unlocking the full potential of the European Health Data Space, we stand ready for an open and constructive dialogue with policy-makers.