COCIR Feedback

Proposal for a European Health Data Space

Introduction

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) with a China Desk based in Beijing since 2007. COCIR is unique as it brings together the healthcare, IT and telecommunications industries. Our industry provides safe and high-quality products and services, which contribute to reducing health inequalities and enhance cost efficiency in healthcare systems. COCIR aims to contribute to sustainability of healthcare systems through integrated care approach and to promote Research and Innovation as a key enabler for economic growth We provide a wide range of services on regulatory, technical, market intelligence, environmental, standardization, international and legal affairs. COCIR is also a founding member of DITTA, the Global Diagnostic Imaging, Healthcare IT and Radiation Therapy Trade Association.

Feedback

Access to data and data systems' interoperability are the cornerstone of the digital transformation of healthcare in EU member states. A robust regulatory sectorial framework is needed to provide certainty to all actors for the digital technologies use for electronic health records, as well as exchange of health data within and among Member States for primary and secondary use.

COCIR has always been very supportive of the Commission's goals and intentions for the European Health Data Space (EHDS) regulation. We advocate for a patient centric pursuit of clinical excellence and safety, clear governance mechanisms and secure processing environment allowing researchers and innovators to access relevant health data to develop products and services for better diagnosis, treatment, and well-being of individuals.

The released proposal for the EHDS regulation aims to address the barriers in a systemic manner and will play a critical role in delivering modern, innovative, and patient-centric healthcare. The EHDS regulation will make a significant contribution to the European innovation capacity in healthcare and support the Commission's pursue of "modern, responsive and sustainable health systems"[1] in the EU.

The proposed process of the single health data space creation on the EU level should lead to a fair, balanced, and efficient framework to support the ambitious goals of the goals of the EU Data Strategy in the healthcare, which is one of the top priorities areas to establish vertical data space regulations.

To achieve this goal, EHDS regulation should be fully aligned with relevant horizontal and sectoral legislation, namely General Data Protection Regulation (GDPR), the proposed Data Act, Medical Device Regulation, and In-vitro Device Regulation (MDR/IVDR), as well as the proposed Artificial Intelligence (AI) Act in order to establish clear, transparent, and fair obligations to all parties under the EHDS regulation.

Detailed comments

You find here some detailed recommendations to further improve the framework of electronic health records (EHR) under the EHDS regulation.

GENERAL PROVISIONS

1. Misalignment between the EHDS regulation and the GDPR, as well as the proposed Data Act will create significant legal uncertainty and may lead to reduced security and privacy of the patients' personal data. Therefore, the interplay between the GDPR and the EHDS will have to be clarified when it comes to controlling and processing of personal data. For this reason, clarity should be introduced regarding how data holder under the EHDS relates to the concepts of data controller and data processor under the GDPR for personal and non-personal electronic health data.

Recommendations:

- Align the definition of non-personal health data with the GDPR;
- Introduce the definition of critical infrastructure under the EHDS and align its interpretation with the European critical infrastructures (ECI) directive 2008/114/EC;
- Introduce the definitions of data controller and data processor and align the interpretation of stakeholders in relevant articles in harmonised way to improve legal clarity of GDPR application in the context of the EHDS;
- Align the definition of 'data holder' between the EHDS and the Data Act.
- Align the wording for serious incident definition with MDR/IVDR and New Legislative Framework (NLF);
- The document uses the term "healthcare provider" or "healthcare providers" 54 times and "health professional" or "health professionals" 58 times. While both definitions follow the referenced Directive 2011/24/EU on the application of patients' rights in cross-border healthcare, the context of their use is different and should be aligned with the context and purpose of the EHDS to avoid legal confusion, especially where legal responsibilities for data processing or storage arise for healthcare professionals and healthcare institutions as health providers.

PRIMARY USE OF ELECTRONIC HEALTH DATA

2. Scope of data to be provided should be aligned with the requirements under the MDR/IVDR and limited to the primary purpose of the device or service to minimise potential breach of personal data privacy under the GDPR, ensure data interoperability not only within the EU, but also internationally for fully comprehensive state of the art secondary use of health data to secure patients' interests, to access medical innovations in the shortest possible timelines and to ensure prevention of cybersecurity risks, which are likely to increase under current formulations.

Recommendations:

- Elaborate Articles 3 and 5 to enhance clarity on alignment with GDPR as well as to ensure compliance with international interoperability standards to ensure that patients' rights to use their health data for treatment purposes are not limited to the EU context only, especially for health emergencies where health record history may be vital. This is also important to foster and support clinical excellence in R&D under the secondary health data use scenario.
- Review Annex I Clauses 1 and 3, as well as Annex III to ensure that only information that is relevant to the intended purpose of the device or system is obliged to be collected, stored and upon request provided under Annex II, as well as included into technical specifications under Annex III.

EHR SYSTEMS AND WELLNESS APPLICATIONS

3. Legal clarity of the responsibilities under the EHDS between healthcare professionals and healthcare providers, as well as third parties if any are present should be established to avoid confusion between responsibilities attributable to each of them, especially for personal data safety and quality.

Recommendations:

- Article 16 should be elaborated to cover different scenarios of EHR system deployment and corresponding allocation of responsibilities between the manufacturer, the user and third-party deployer in case of its presence.
- Also, the difference between healthcare professionals and patients as users should be established. Patient safety in many cases requires that health data is explained to them by the health professional to avoid misconceptions that may lead to harmful effects to the patient. Therefore, it should be clearly established that the information sheet should be developed with the intended medical device user in mind, clearly establishing limits of data provision obligations to healthcare providers and patients.

4. The proposed requirements for conformity of EHR systems and products claiming interoperability with EHR systems should align with MDR/IVDR to avoid additional unnecessary costs for national healthcare systems and patients. Also, new obligations, imposed by the Data Act on the medical device manufacturers should be considered, to harmonise all the applicable legislations and avoid differences in requirements for conformity. The interoperability of electronic health records, in line with the existing European Electronic Health Record Exchange Format and internationally recognized standards (e.g. HL7 FHIR, DICOM, DICOM Web, and IHE profiles), as well as semantic and technical interoperability should be strengthened.

Recommendations:

- The definition of EHR system should be adapted, as the proposed, very broad, definition will potentially encompass all medical devices which store, intermediate, import, export, convert, edit or view electronic health records and thus make the delineation between EHR systems, medical devices and high-risk AI systems very challenging.
- Article 23 should have a reference to the international state of the art standards.
- Article 29 should be aligned to MDR/IVDR
- Article 31 should be adjusted to reflect the fact that wellness application may be downloaded by the user online. Therefore, it would be more appropriate to oblige the label to be shown in the application itself.
- Article 68 under Chapter VII should also be elaborated with a reference to international state of the art standards.

SECONDARY USE OF ELECTRONIC HEALTH DATA

5. The protection of IP rights and trade secrets and fair cost coverage should be secured to preserve incentives for companies to invest into quality data collection. Also, when the public interest requires to limit the fees for the data provision below the full costs for the data holder to provide it, a more simple and more standardized principle should be applied to minimize subjectivity and ensure better comparability and transparency.

Recommendations:

- Article 33 should be elaborated to align data sharing for the secondary use purposes with GDPR and avoid confusion of which stakeholders are data holders under the EHDS to sustain consistency of the interpretation of the definition.
- More clarity on provision of electronic health data entailing protected intellectual property and trade secrets under the Article 34 should be provided to sustain and foster investments into high value adding activities, protected by the IP rights and trade secrets.

6. Health-related private legal entities, including the developers of wellness applications should be ensured access to health data for secondary use when the request comply with the requirements under this Regulation.

Recommendation:

- Adjust Articles 34 and 52 accordingly.

7. Industry provides valuable expertise for the efficient development of a European health data space. Industry representatives should thus be included in stakeholder consultations to ensure full coverage of competencies and experience to comment on practical implications and feasible, as well as economically rational and sustainable solutions.

Recommendation:

- Adjust Articles 37, as well as Article 65 under the Chapter VI and Article 68 under Chapter VII accordingly.

8. Ensure proper cost coverage for data provision for secondary use and consider a different mechanism for deductions in fees for providing data under Article 42.

Recommendation:

- Adjust Articles 42 and 49 to reflect all the costs related to making data available for secondary use.

9. There may be cases when secondary use of health data cannot be processed in the secure environment provided by the data access bodies for R&D activities.

Recommendation:

- Article 50 should reflect on specific situations. If due to the research or product development specifics it is technically not possible to complete health data processing in the secure environment, provided by the health data access bodies, other secure processing safeguards should be introduced and used to ensure safeguard of personal information, as well as compliance with the GDPR.

10. Restrictions on non-personal data movement to third countries for secondary use purposes should be proportionate to the objective risks and shall rely on clear criteria, which are definable and objectively assessable.

Recommendation:

- Article 61 should be revised and more clarity on restriction criteria introduced.

11. National frameworks for implementing EHDS and safeguarding its performance compliance should be well aligned to ensure harmonised conditions for developers and deployers of EHR systems to conduct activities under the EHDS, and to ensure patients' rights across the European Union are respected. Therefore, to prevent differences in the deployment of the legislation across the Member States, it may be beneficial to consider centralised principle for sanctions following

the example set in the GDPR or the proposed AI Act for penalties upon the misconduct of stakeholders under the EHDS.

Recommendation:

- Article 69 should be reviewed and elaborated to provide explicit principles and guidelines for penalties.

Conclusions

We look forward to working with the EU institutions to ensure that the EHDS regulation achieves its goals, i. e.

- Citizens in the EU are provided with increased control over their electronic health data and
- trusted EU and Member State governance mechanisms foster cross-border health data accessibility and interoperability for primary and secondary use governed by a clear legal framework.

The EHDS regulation can play a very important role in promoting better diagnosis, treatment, and well-being of natural persons, and assist national and EU level legislators for better informed policies.

It is also of critical importance to achieve a genuine single market for digital health products and services, sustaining and enhancing the capacity to attract and retain high value creating investments into healthcare innovations.