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Dansk Industri
Confederation of Danish Industry

DI input to European Health Data Space

Specific comments on the proposal for a regulation on the European Health Data Space (EHDS)

DI strongly supports the European Union's efforts to increase patients' control of, and access to, their health data, while at the same time giving researchers and innovators the opportunity to realize the potential of health data in a trusted and secure way. Removing the barriers to health data for scientific research will mean that patients can benefit from the discovery of innovative treatments, medical devices, diagnostics enabled by access to health data and more effective healthcare in Europe. DI shares the vision of the proposal and the enormous potential of a European Health Data Space. We find the primary and secondary use of data equally important in this endeavour.

On the economic level, linking the health data regimes of the 27 Member States will scale up the amount of aggregated data available for research and development. This is key to a competitive healthcare and life science industry. The ultimate benefits are better healthcare in Europe and enhanced welfare outcomes, as well as an effective pandemic preparedness. EHDS is also a step towards new opportunities for B2C markets in relation to healthcare-related services such as apps, wearables, etc.

<u>DI wants to highlight the following points in particular:</u>

- ✓ The proposed definition of a data holder in **Article 2(2)(y)** needs to be further clarified.
- ✓ The EHDS legislation must be in clear alignment with existing legislation, such as the DGA, GDPR, the proposed Data Act as well as the AI act.
- ✓ DI underlines the need for a uniform interpretation and application of the GDPR across the EU – for both the primary and secondary use of health data – to ensure equal competition and opportunities across Europe.
- ✓ Transparent rules are crucial for a seamless application process for secondary use of data.

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- ✓ DI underlines the importance of ensuring data quality as well as interoperability of system. In creating the infrastructure, we encourage the Commission and Member States to draw on the highly regarded competencies and knowledge in this area that lies in Danish and European industry.
- ✓ The EHDS legislation needs to address the barriers of data sharing, promote investment in European infrastructure, and foster the adoption of interoperability standards.
- ✓ Provisions to improve data sharing require significant investments in national and European infrastructure and greater interoperability across the EU.
- ✓ The implementation of the interoperable systems should apply a race-to-the-top strategy, drawing on lessons learned from the best-in-class in the EU, in order to facilitate the full potential of the high-quality healthcare that this infrastructure can result in.
- ✓ We highly encourage that fees, compensation and other conditionalities for secondary use are further specified in the proposal.
- ✓ DI calls on EU legislators to involve industry in discussions on the secondary use of health data for research.

Chapter 1 - General Provisions (Articles 1-2)

The proposed definition of a data holder in **Article 2(2)(y)** needs to be further clarified. It is not clear why and how it links to a different definition of data holder in the recently proposed Data Act and the Digital Governance Act (DGA). Furthermore, it is not clear how companies are included in the definition in the different parts of the proposal.

According to the proposal, it is mandatory for the Member States to set up Digital Health Authorities (DHA) to deal with electronic health records, interoperability, security, standardization, etc. It is the Member States' decision whether they will establish one institution, the competent bodies dealing with primary and secondary use of data (while always separating the functions) or separate the institutions. DI is worried that this could create a fragmented landscape which in the end will put an extra burden on the industry and researchers and thereby hamper innovation. We wonder if the opportunity of a central European Authority for application for secondary use of data has been considered.

Furthermore, it is important that the EHDS legislation is in clear alignment with existing legislation, such as the DGA, GDPR, the proposed Data Act as well as the AI act. In parts of the proposal, it is not clear how the EHDS will complement the existing different legislation. Thus, this needs to be further clarified in the legislation. A consistent legal framework and clear and transparent rules for people's access to their data will provide the context for a trustworthy ecosystem that protects individuals' rights and unlocks the potential of health data. Furthermore, transparent rules are crucial for a seamless application process for secondary use of data which is of high importance in driving life science innovation.

As we read the current proposal, it is up to the individual Member States to organise the DHA. This may create very different levels of bureaucracy and efficiency in the different

DHAs, and thereby contribute further to the fragmented landscape. In addition to the legislative streamlining, we also encourage the Commission and Member State to secure that all DHAs have the necessary competences and resources.

Notes on General Data Protection Regulation (GDPR) and national regulation on the use of health data

While the GDPR has aimed at creating a level playing field for the use of personal health data, fragmentation concerning its implementation within and between Member States remains.

The Danish practice regarding authorities' handling of requests for access to health data both under the GDPR and in national health regulation is perceived as uneven from authority to authority, and often more rigorous than in other EU countries. This is partly due to the complexity of both the regulation itself and the interplay between national regulations which inhibits the authorities of competence for approval of data processing. This leads to their uneven interpretation.

The fragmented landscape gives researchers problems when health data are shared with other parties in research projects, both in public and private collaborations and between private actors. This happens, among other things, because the interpretation of the law on data sharing and the conditions for access and use of data from national and regional databases is sometimes unclear. The process-intensive approach to health data sharing means that research projects with Danish participation are often dragged into legal protracted, that could impact innovation negatively.

Therefore, we must underline the need for a uniform interpretation and application of the GDPR across the EU – for both the primary and secondary use of health data – to ensure equal competition and opportunities across Europe. This includes national efforts to reach similar interpretation of national health regulation across Denmark.

Furthermore, in view of the next evaluation report of the GDPR scheduled for 2024, EHDS should be a welcome occasion to look into the unnecessary limits GDPR sets on the use of health data for both patients, citizens, scientists and innovative companies.

Chapter 2 – Primary Use (Article 3-13)

EHDS has a potential to enable people to easily access and share their health data, while retaining greater control over them. It creates new ways of communication between health care professionals and patients and thus enables better measurement of outcomes.

User-friendliness and a high level of security are key elements to build trust among patients in Europe. It is crucial that EHDS is supported by secure technology and AI solutions that take compliance and data security for the individual citizen into account.

DI underlines the importance of ensuring data quality as well as interoperability. We encourage the interoperability of systems and data portability are objectives the EU should pursue. In creating the infrastructure, we encourage the Commission and Member States to draw on the highly regarded competencies and knowledge in this area that lies in Danish and European industry.

Chapter 4 – Secondary use (Articles 33-58)

DI highly supports the Commission's intention of enabling secondary use of data for research purposes. The vision and potential of this is unprecedented. For industries and researchers to be able to drive innovation and support the digital transformation of healthcare and to develop new solutions and treatments, the ability to access, aggregate and use health data is of critical importance.

Therefore, it is important that the legislation makes it as easy as possible for researchers and industry to access the necessary data to realize the potential of the aggregated health data collected in EHDS. Extra burdens on companies could hamper innovation and thereby risking one of the core potentials the EHDS intends to create. In the end, companies end up not having a business model driving them to use data from other markets. This is contrary to the ambition of the Commission to make EU a strong Health Union. The application process for accessing data for secondary use is not completely clear in the current proposal. Hence, further description of the – hopefully simple and transparent – process is needed.

We must make health data available for research and development purposes across all sectors of the healthcare system – including equal access for private and public research activities.

For companies to be able to participate in the data sharing system insurance is needed. The confidentiality of trade secrets and confidential information is essential for companies' business models. Therefore, the proposal must protect trade secrets. **Article 37** states that health data access bodies should take all measures necessary to preserve the confidentiality of IP rights and trade secrets. This is crucial. Thus, further clarification on the preservation of IP-rights etc. is highly needed and crucial for the exploitation of the EHDS-potential.

Interoperability

The proposed EHDS legislation needs to address the barriers of data sharing, promote investment in European infrastructure, and foster the adoption of interoperability standards. Provisions to improve data sharing require significant investments in national and European infrastructure and greater interoperability across the EU.

The implementation of the interoperable systems should apply a race-to-the-top strategy, drawing on lessons learned from the best-in-class in the EU, in order to facilitate the full potential of the high-quality healthcare that this infrastructure can result in.

Finally, DI calls on EU legislators to involve industry in discussions on the secondary use of health data for research. The life science industry relies on access to high-quality data when developing new technologies and in the roll-out of healthcare systems. In addition, the Danish and European life science sector has strong competencies in the development of interoperable data systems and infrastructures. We encourage the EU to draw on this expertise in the development and implementation of these systems in relation of EHDS.

Fees, compensation and conditionalities

To exploit the secondary use potential of EHDS it is important to secure and enable that the EHDS is used for innovation and improvement of health systems and solutions. The fees and conditionalities for accessing and using EHDS for secondary purposes must therefore be in accordance with the benefits the data provides. If the conditionalities and resources used to access data are too heavy we risk that research- and innovation opportunities are lost or that researchers take their projects to other markets. This is conflicting with the vision of the proposal.

We highly encourage that fees, compensation and other conditionalities for secondary use are further specified in the proposal.

Regarding fees **Articles 42** states that health data access bodies and single data holders may charge fees for making electronic health data available for secondary use. Any fees/compensation should at least cover the cost of making data available to data users.

Conclusion

In conclusion, DI highly supports the vision of the proposal and see great potential in its implementation. However, we find that many areas still remain to be specified, especially regarding secondary use of data and the governance model for data collection and sharing, and financing of the implementation of the EHDS.