AmCham EU
SPEAKING FOR AMERICAN BUSINESS IN EUROPE

Our position

Healthcare in a digital age

AmCham EU speaks for American companies committed to Europe on trade, investment and competitiveness issues. It aims to ensure a growth-orientated business and investment climate in Europe. AmCham EU facilitates the resolution of transatlantic issues that impact business and plays a role in creating better understanding of EU and US positions on business matters. Aggregate US investment in Europe totalled more than €3.4 trillion in 2021, directly supports more than 4.9 million jobs in Europe, and generates billions of euros annually in income, trade and research and development.

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Executive summary

The European Commission has presented a regulation to set up a European Health Data Space (EHDS). The Regulation sets out rules, common standards and practices, infrastructures and a governance framework that is key to the European Health Union.

For it to be successful, it is crucial that the EHDS ensures legal certainty and flexibility, and that it establishes open, transparent and structured engagement with all stakeholders. Moreover, the Commission must work towards fully linked EHR systems and sectoral standards for the collection and integration of patient-led data, while leveraging existing global and European Union standards and certifications. This includes taking the appropriate measures that ensure the interoperability of legal and operational requirements across organisational and geographical borders. Furthermore, international data flows for research and development purposes must be maintained, as it is key for global public health. For this, the Commission should limit hindrances on international data flows with third countries that could limit drug discovery and development.

Introduction

The digitalisation of society creates both opportunities and challenges. Europe is already seeing an increased demand for digital infrastructure as well as the need to attract investments and promote technological innovations. To unlock the possibilities and innovative solutions that the digital decade will undoubtedly bring, it is essential that the European Commission supports an innovative and research-driven digital transformation of the healthcare and life sciences sector.

As we continue to tackle the fallout of the global health crisis, it has become evident that digital solutions are critical for the resilience of healthcare systems and economic stability. AmCham EU notes the particular importance of digitalising the life sciences and healthcare sectors. In order to remain globally competitive, a European approach to a life sciences ecosystem that can capitalise on innovative health technologies is essential. With increased digitisation of health systems, research and development, care delivery and healthcare administration, we will see greater efficiency and be able to develop new treatments, therapies, medical devices and technologies that are better suited to both individual and societal needs. Better data insights will lead to more informed decisions by patients, healthcare practitioners and will also be a pre-requisite to patient-centric health policies and healthcare delivery models that will reward quality instead of quantity of treatments.

At the European level, decision makers can support the development through regulatory and legislative frameworks such as the European Health Data Space Regulation which creates a European framework for the use and re-use of health data paving the way for a European Health Union. More specially, in order for the EHDS to be a success and benefit all stakeholders the following elements are crucial – a strong framework, interoperability, a focus on citizens, an international dimension, value based healthcare and real world data/evidence and harmonisation. Please see more details on each below.

Framework

AmCham EU welcomes the European Commission's proposal to implement additional provisions and safeguards for the use and re-use of health data. These are particularly critical when handling sensitive personal data, such as health data, where security and privacy must be ensured whilst enabling access

and use. To achieve this, several technical elements need to be in place, including access request mechanisms, access procedures, secure infrastructures and common governance mechanisms.

Considering the fragmentation of the General Data Protection Regulation (GDPR) in the area of health across Member States, as well as the need for legal certainty and flexibility in the rapidly changing domain of data science, open, transparent and structured engagement with all stakeholders — patients, clinicians, researchers, the public sector and industry partners — is needed to ensure they are able to fully engage in and benefit from the EHDS.

Interoperability

Interoperability is a pre-requisite for digital health, and though AmCham EU welcomes the focus on interoperable Electronic Health Records (EHRs) and wellness apps, interoperability and standards must be addressed by the Commission in the wider digital health infrastructure to facilitate data sharing across EU Member States and beyond. Therefore, the use of fully linked EHR systems and sectoral standards for the collection and integration of patient-led data collection and must be expanded while leveraging existing global and European Union standards and certifications.

While technical and semantic interoperability are essential for data access and sharing, they should be complemented by measures that ensure the interoperability of legal and operational requirements can interoperate across organisational and geographical borders in order to avoid unintended prevention of data access and sharing.

The EU must continue to work towards interconnected and interoperable healthcare-specific computing infrastructures at the European level. Platforms such as the European Reference Networks (ERNs), which allow healthcare professionals around Europe to share expertise on diagnosis and treatment of rare or low prevalence complex diseases, must be leveraged to create robust datasets that could not be generated at national level.

Finally, all aspects of the FAIRification of data must be addressed by fully developing data quality and utility labelling.

Citizens

The European Commission should oversee the development of certification mechanisms that can enhance citizens' trust in digital health services. AmCham EU applauds the Commission's work to promote the new ISO 82304-2 standard for health and wellness apps as part of a wider initiative to promote trust in digital health.

The Commission 's ambition to improve citizens' access and control of their data, and it should support initiatives that drive citizen education on their data rights in order to foster greater comfort with the EHDS and other concepts, such as data altruism. Recent Eurostat data shows that 'people are increasingly turning to the internet to seek health information online in Europe. But the rates are uneven. In Finland, 80% of adults sought information about their health online last year; in Germany just 45%. A 2021 WHO report found that over the past seven years, despite a slight upwards bump

during the pandemic, health literacy in Germany had actually declined.'[1] Accordingly, the Commission should work with Member States to develop greater data and digital literacy amongst citizens and healthcare workers. Policymakers should also continue to work with like-minded international partners towards a standardised and robust framework for data privacy.

As the EHDS has been conceived with the interests of patients and citizens at its core, it must support the free movement of digital health goods and services across European borders. Therefore, measures that facilitate the creation of a robust single market for digital health services and products should be developed and implemented in order to improve the treatment and quality of life of European citizens.

Digital literacy, education and upskilling

Digital literacy is a requirement for digital health to reach its full potential it is essential to develop trust and to support the uptake and use of digital health technologies amongst citizens. Thus, the Commission should dedicate the appropriate resources to enhance citizens' digital literacy.

It is crucial that healthcare professionals are also properly equipped to take full advantage of new digital health innovations which enable better provision of care and reduce workloads. Supporting and training healthcare professionals is also essential for the collection of high quality, usable health data.

Finally, it is also vital that public bodies at national level are upskilled and provided with the necessary resources to fulfil the additional responsibilities which will be required by the EHDS.

International dimension

Permitting data sharing with third countries or international organisations for secondary uses (research, innovation and policy making), is welcome. This policy is in line with EU and Member States' positions at international forums (G7 and G20) and their plan to realize the benefits of Data Free Flow with Trust (DFFT) and opposition to digital protectionism.

Maintaining international data flows for research and development purposes, an area where cross-country collaboration is key for global public health. Therefore, the Commission should limit hindrances on international data flows with third countries and other barriers to cross-border digital services that could limit drug discovery and development. In order to enable international data flows, the EU-US Data Framework should be swiftly implemented, and the EU-UK data adequacy decision should be preserved. Additionally, regulatory frameworks which encourage collaborative global initiatives to prevent future pandemics should be adopted.

It is imperative that third country companies operating in Europe are able to use the EHDS to support the provision of digital health services as well as research and development of data-driven health innovations which benefit European citizens. In this respect, the Commission should work closely with industry partners which have established digital health infrastructure in Europe. Furthermore, the Commission should also work with and take learnings from the United States Department of Health and Human Services & Office of the National Coordinator for Health Information Technology, as well

[1] 'What can Europe do to bridge the digital health divide?' ***Frieda Klotz***, 17.5.2022, https://www.healthcareitnews.com/news/emea/what-can-europe-do-bridge-digital-health-divide

as industry partners with large installed bases of digital health infrastructure in Europe, including major EHR system vendors.

Finally, the Commission should engage with relevant EU agencies to ensure multi-stakeholder participation in the construction of a robust and trusted digital infrastructure for health care data, including the pilot EHDS infrastructure consortium for the re-use of health data (EHDS2), which should be operational by 2025[2].

Value based healthcare and real-world data or evidence

A connected and sustainable EDHS will enable the shift towards value-based healthcare models and systems while ensuring that the EU remains relevant for clinical research. AmCham EU supports increased access and re-use of data for scientific research, development and innovation activities.

Access to health data is critical to innovation and optimisation throughout the medicine/device and care pathway lifecycle. Specifically, the use of real-world data (RWD) and real-world evidence (RWE) for regulatory and reimbursement related purposes can address research questions about the safety and effectiveness of medicines, fill evidence gaps and complement an existing body of research. The generation and use of health data on an individual level allows for the prediction of diseases, more efficient diagnosis and more personalised healthcare interventions (eg digital therapeutics, digital twins). As such, RWD and RWE help drive new understandings of value, supporting healthcare decision-makers faced with the challenge of assessing different forms of treatments in the context of fixed healthcare budgets.

The private sector must be involved in the expected EHDS user group, along with public bodies to fully leverage RWD and RWE. The 'Darwin EU' catalogue project, relevant for the post-marketing efficacy and safety of medicines, will be crucial in this regard and should fully involve the industry as a key stakeholder whose access to the data produced could improve patients' lives.

Harmonisation

The EDHS rightly applies definitions used within the GDPR, the Data Governance Act[3], the Market Surveillance Regulation, Medical Devices Regulation and the Electronic Identification Regulation. However, the Commission should align the EHDS regulation with these and other relevant pieces of legislation, such as the AI Act and the Data Act[4] to the greatest extent possible in order to facilitate data access and use. Furthermore, additional guidelines on interconnections between these other relevant legislative pieces are needed.

[2] ' EHDS2 Pilot - A European Consortium Pilot project, candidate for the future European Health Data Space', in *Health Data Hub.* 3 July 2022, https://eupha.org/repository/EUPHA_newsletter/2022/20220307_EHDS2Pilot_JointPressRelease_En_VF.pdf

[3] 'Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on European data governance (Data Governance Act)', *European Commission,* 25.11.2020, Proposal for a Regulation of the European Parliament and of the Council on European data governance

[4] 'Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on harmonised rules on fair access to and use of data (Data Act)', *European Commission*, 23.2.2022, Proposal for a Regulation of the European Parliament and of the Council on harmonised rules on fair access to and use of data

The Commission should continue working with the European Data Protection Board in order to reduce the fragmentation of the interpretation of the GDPR, therefore enhancing legal clarity for all stakeholders.

Digitalisation of regulatory requirements

Digital innovation can be integrated in the healthcare sector in various regulatory steps, and it can improve efficiency, security and effectiveness while lowering the environmental footprint of each of these activities:

AmCham EU encourages usage of E-IFU (Electronic Instructions for Use) for both professional and consumer medical devices. Going electronic with IFUs translates into paper savings as well as packaging and transport optimisation, and thereby enhances environmental sustainability. From a safety and performance perspective, E-IFU always provides the most up-to date information and offers additional functionality such as searching for key words in a long text.

Shifting to electronic labelling also eliminates logistical and supply challenges when changes are needed, and it ensures the most up-to-date information for stakeholders. It also increases access for patients, as no country-specific inventory needs to be produced. Finally, digital labels can provide a wider range of information to the user (eg instructions for re-use, recycling or repurposing of the packaging).

AmCham EU hopes for continued dialogue with policymakers and stakeholders on the essential role of data to enact the digital transformation and achieve better health for all citizens.

Conclusion

Cross-border health preparedness is more important than ever, and the COVID 19 pandemic has made it evident that the free flow of data is key to develop novel medicines and health solutions. As such, it is essential the Commission's EDHS proposal is interoperable, builds trust among citizens, is based on international cooperation, utilises real world data for decision-making and is aligned with existing privacy regulations. If the Commission can work with citizens and the business community to implement these recommendations, we can build a more innovative, connected and healthier Europe.