AmCham EU
SPEAKING FOR AMERICAN BUSINESS IN EUROPE

Our position

Priorities for EHDS Trilogues

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 €3.7 trillion in 2022, directly supports more than 4.9 million jobs in Europe, and generates billions of euros annually in income, trade and research and development.

American Chamber of Commerce to the European Union
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Executive summary

The European Health Data Space (EHDS) can empower patients and unlock more precise and personalised healthcare for improved outcomes. Policymakers can optimise it by: ensuring sufficient input of secondary data while protecting the clinical and pre-clinical data, and intellectual property and trade secrets that companies rely on for their business models; allowing for responsible transfers of data outside the EU; and adopting a proportionate approach to conformity assessments for electronic health records.

Introduction

The EU co-legislators' hard work and commitment on the EHDS negotiations is commendable. The proposal brings considerable opportunities to empower patients and unlock more precise and personalised healthcare for improved outcomes. AmCham EU welcomes the agreements reached in both the Council and the European Parliament. Below are several critical priorities for the trilogues as they draw to a close.

Opt-out for secondary use

A significant benefit of the EHDS is the ambition to enable greater secondary use of electronic health data within the EU. The General Data Protection Regulation's (GDPR) existing provisions provide the mechanism to opt-out from inclusion of an individual's electronic heath data in the EHDS. Any additional measures under the EHDS could reduce legislative harmonisation and more importantly, would diminish the EHDS' value by creating a risk of biased population data and compromising the integrity of the datasets. Should additional privacy measures be introduced, an opt-out mechanism is preferable to an opt-in mechanism. Such a mechanism should be harmonised to the greatest extent possible across Member States to avoid fragmentation and additional burden for those accessing data for secondary purposes, especially in the case of access across multiple Member States.

Opt-in for specific data categories for secondary use

The Parliament position includes an opt-in mechanism for: genetic, genomic and proteomic data and genetic markers; data from wellness apps; and data from biobanks and dedicated databases. These are important data categories used for research and innovation, for which national legislation and the GDPR provide substantial, comprehensive and robust safeguards for individuals' privacy and rights. Data sharing practices across research organisations and university hospitals already incorporate security controls and privacy-enhancing technologies for genetic and genomic data, which effectively restrict access to trusted parties. Policymakers should extend the opt-out mechanism to genetic and genomic data, rather than the opt-in mechanism foreseen by the Parliament's position.

Clinical trial data

The co-legislators' proposal to limit secondary use of clinical trial data to data from clinical trials that have ended is welcome. This provision could be further improved by inserting into the EHDS text strong language that specifically references the Clinical Trial Regulation to ensure alignment.

Pre-clinical/exploratory data

In the context of trilogues, there are concerns around exploratory/discovery/pre-clinical trial data being within the scope of secondary use within the EHDS, specifically under Article 33.1 b, c, e, k, l and m, as well as other relevant data categories, as this would create operational challenges and risks for data holders. The institutions' objective is to include a wide range of data categories. However, Article 33(1) should take into account existing data sharing practices. Such datasets are commercially sensitive assets, which require substantial investment and are the foundation upon which the pharmaceutical business model is based. Therefore, the requirement to make such datasets available would substantially undermine incentives to invest in exploratory research in the EU, impacting the EU's research and development competitiveness, scientific excellence and innovation.

IP and trade secrets

The health industry model and investment in research and innovation are based on the protection of intellectual property (IP) and trade secret rights. Accordingly, the EHDS must protect and build upon the existing global IP and trade secrets protection framework. Therefore, the legislation should contain an explicit reference to the Trade Secrets Directive and Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) as a legislative foundation. While the co-legislators' efforts to ensure the protection of IP rights are positive, policymakers should ensure an aligned approach between the EHDS and the Data Act, which stipulates a data holder's rights to refuse access to data if a serious economic damage from disclosure can be demonstrated.

The EHDS should strengthen the role of the data holder by providing a clear framework for establishing data-sharing agreements for commercially sensitive data. This would provide data holders with clarity, oversight and greater involvement regarding the protection of their IP and trade secrets. Should there be a disagreement between a data holder and data user regarding data access, data sharing should be suspended until the issue is resolved. Additionally, the development of competing products or services should be grounds for health data access bodies to refuse data access, which would ensure that innovation is fostered in Europe.

Data localisation/international dimension

The modern healthcare and life science research landscape is highly international and interconnected, and cross-country collaboration is key for global public health. Therefore, international data flows must be maintained to nurture scientific advancement and innovation as well as facilitate regulatory fillings across different markets. The EHDS should ensure that existing mechanisms based in contract law, such as Standard Contractual Clauses (SCCs – Article 46 GDPR), which provide a basis for data sharing and processing in a GDPR-compliant manner, are maintained. This is in line with the EU and Member States' positions at international forums such as the Group of Seven (G7) and Twenty (G20), their ambitions to realise the benefits of Data Free Flow with Trust and their opposition to digital protectionism.

EHR systems and conformity assessment

The EHDS would benefit from a focused definition of the electronic health record (EHR) system that clearly delineates between what is in and what is out of scope, as in the European Parliament's position, which focuses on the *primary* functionality of the product; there are concerns with the

Council's all-encompassing approach. Although the proposal's efforts to enhance interoperability of EHR systems are welcome, policymakers should avoid the introduction of a third-party conformity assessment procedure via notified bodies before an EHR system can be placed on the market. This approach would create significant additional burden for both EHR manufactures as well as medical devices and in-vitro diagnostic devices that claim interoperability with EHRs systems, as these would also have to undergo a third-party conformity assessment procedure.

The co-legislators should take a pragmatic approach to EHR system conformity assessment and consider the lessons learned from other sectoral legislation where the procedures via notified bodies have created significant delays and deadlocks (namely the EU Medical Device Regulation). The Commission's original proposal, which allows for a self-declaration of conformity with Annex II and common specifications, is a positive solution, as this would ensure a balanced approach between fostering interoperability of EHRs across the EU, whilst ensuring the process is rolled out in a timely and implementable manner. The co-legislators should facilitate the continued use of technical International Organization for Standardization/European Committee for Standardization standards to define the EHDS Regulation's specifications, building on the experience and good practices of the industry in the field of standardisation.

Conclusion

The American business community is committed to supporting the EU's ambitions for the EHDS and its successful implementation. The incorporation of the above recommendations would help ensure that the EHDS enables digital transformation and achieves better health for all EU citizens.