AmCham EU
SPEAKING FOR AMERICAN BUSINESS IN EUROPE

Our position

European Health Data Space

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.

American Chamber of Commerce to the European Union
Speaking for American business in Europe

Avenue des Arts/Kunstlaan 53, 1000 Brussels, Belgium • **T** +32 2 513 68 92
info@amchameu.eu • amchameu.eu • European Transparency Register: 5265780509-97

Executive summary

The European Health Data Space (EHDS) has the potential to improve patient outcomes across the EU and build on Europe's innovation capabilities in the healthcare space. However, to achieve these ambitions, policymakers must ensure the initiative provides the necessary intellectual property (IP) protection, appropriate data flow possibilities and a structure for the development of a single market for digital health services and products.

Introduction

The European Commission presented its proposal to create a European Health Data Space (EHDS) on May 3, 2022. Since then, the Council of the EU and the European Parliament have been closely analysing the proposal. The American Chamber of Commerce to the EU (AmCham EU) has followed the debate on the file with interest, particularly on the issues of intellectual property (IP) rights, the international dimension, and telemedicine. More details on these issues are below.

Intellectual Property rights protection

Research and innovation (R&I) conducted by the health and life sciences industry enables the advancement of healthcare, which ultimately improves patient outcomes and the patient experience by bringing new technologies and products to market. In order to enable and support investment in R&I by the private sector, IP rights are critical. Therefore, the EHDS must protect and build upon the existing global IP and trade secrets protection framework, particularly the Trade Secret Directive and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). This is especially important for certain types of data, particularly that which has been further processed for a specific clinical or research purpose, which contains IP that must be protected when such data is made available for secondary purposes. Failure to provide companies with adequate IP rights protection would disincentivise investments in the European healthcare sector.

The co-legislators should work with innovative healthcare stakeholders to protect the IP contained in health-related data, which the EHDS would make accessible to data users through Health Data Access Bodies. To uphold IP rights holders' rights and interests, policymakers should explore establishing a data-sharing agreement between data holders/Health Data Access Bodies and data users, in order to uphold the rights and protect the interests of IP rights holders. Where a data holder is required to share data which directly or indirectly reveals IP or trade secrets, every measure should be taken to protect the interests of the IP rights holder, and if appropriate, the IP rights holder should be allowed to reject access as well as be compensated for losses caused by the exposure of IP and trade secrets.

International dimension

In the proposal, the EHDS includes provisions on international data access and transfer, which support the highly interconnected health landscape. The co-legislators should uphold such data transfers to nurture scientific advancement and innovation as well as facilitate regulatory fillings across different markets. This is in line with the EU and Member States' positions at international forums such as the Group of Seven (G7) and G20, their ambitions to realise the benefits of Data Free Flow with Trust (DFFT) and their opposition to digital protectionism.

International data flows should be maintained to further research and development, where cross-country collaboration is key for global public health. The co-legislators should, therefore, facilitate international data flows with third countries and remove other barriers to cross-border digital services that could limit the research and development of drugs, medical devices, in-vitro diagnostics and other healthcare technologies. To enable these 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.

The Commission's proposal for a purpose-based framework for the secondary use of health data, which would allow secondary use for international companies conducting research and innovation and other secondary purposes, was welcomed by AmCham EU. Although the potential for integration of third-country health data access bodies within the EHDS framework is positive, co-legislators should not create reciprocity requirements for third-country entities to access health data via the EHDS framework, especially for those that have invested heavily in building research and innovation capabilities in Europe. This would ultimately reduce research and innovation activities and delay access to new treatments and innovations for European citizens.

In particular, the EHDS should support the needs of patients with rare diseases, through both primary and secondary use of health data, by enabling global collaboration to advance research, diagnosis and treatment. It is particularly important for the EHDS to align with the Clinical Trials Regulation, especially in complex, cross-jurisdictional clinical trials.

Telemedicine

The EHDS' aim of creating a single market for digital health services and products is welcome, as this would improve the lives of citizens across Europe by enabling access to better technologies and reducing the time to market for valuable innovations. Despite the deletion of Article 8 on telemedicine in the Council compromise text, the Cross-Border Healthcare Directive's ambition to enable patients to exercise their rights to access healthcare across borders should be supported.

Therefore, Article 8 should be expanded to reflect the need for specific measures that Member States can agree on to reduce fragmentation and enable the provision and delivery of digital care services. These measures could include the explicit incorporation of telemedicine services in implementing legislation and the creation of telemedicine strategies which allow digital services to play a central role in realising European citizens' right to access care across EU borders as provided for in Directive 2011/24/EC.

Conclusion

The American business community is committed to participating in dialogue with policymakers and other stakeholders on the essential role of data in enacting digital transformation and achieving better health for all EU citizens. When adopted, the EHDS can achieve these goals by incentivising continued innovation through appropriate IP protection, enabling smooth international research and development collaboration through appropriate data flow possibilities and being ambitious in the development of a single market for digital health services and products.