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Bucharest, December 20th, 2023

TO: Ministry of Healthcare

IN ATT: Alexandru Rafila, Minister

SUBJECT: Regulation on the European Health Data Space (EHDS)

Dear Minister Rafila,

AmCham Romania supports the EU efforts to unleash the full potential of health data with the help of a European Health Data Space (EHDS). We acknowledge the fact that the European Health Data Space (EHDS) has the potential to improve patient outcomes across the European Union and build on Europe's innovation capabilities in the healthcare space. Making health data more widely available and easily accessible could result in an innovation push, which is likely to improve the EU's healthcare systems, making them more sustainable and resilient. The EHDS shall provide a consistent, trustworthy, and efficient set-up for the use of health data for research, innovation and evidence-based policy-making in the future, aiming for better healthcare delivery.

To ensure that the regulatory framework of the EHDS will act as a facilitator for those processes, it needs to provide regulatory certainty. Since the proposal is still subject to its regulatory pathway, AmCham Romania advances the below mentioned proposals that have the aim to contribute to the development of a more sustainable framework in this area, having in mind a practical approach for organizations to conform to the EU regulation. To ensure patient access to high-quality and innovative products, it is of crucial importance that market access is efficient, non-bureaucratic and that the regulatory environment is harmonized with global standards. It is also important to keep in mind that the cost of regulation should not become too high, that it does not prevent safer and better products or services from reaching the market. Maintaining an environment that is conducive to innovation is important, while striving to achieve core regulatory goals.

While advancing the below-listed proposals, AmCham Romania reinforces its commitment on sharing its expertise on the essential role of data in enacting digital transformation and achieving better health for all EU citizens.
Overall, we see room for improvement in three key areas to effectively realize the vision of the European Commission to attain a well working EHDS as part of the EU's digital transformation by 2030.

1. International data flows

Chapter IV of the European Health Data Space (EHDS) Regulation contains provisions on the third-country transfer of non-personal electronic data (Art. 61), international access and transfer of non-personal electronic health data (Art. 62), as well as the international access and transfer of personal electronic health data (Art. 63). Some MEPs have also suggested to introduce a new Article 60(a), which includes provisions on the storage, processing, and analysis of electronic health data by suggesting this should be carried out exclusively within a secure location or locations within the territory of the Union of electronic health data in

the EU. We would, therefore, welcome further alignment of EHDS requirements with the existing EU data protection regime, and in particular the Chapter V rules of the GDPR and we recommend avoiding data localisation requirements. Those rules already effectively regulate how to safeguard cross-border transfers of personal data through various data transfer mechanisms and, where applicable, with pseudonymisation and/or encryption, without imposing additional requirements on data localisation for processing or the nationality of controllers and processors. "
Healthcare products are often engineered based upon a solid, international dataset from a multitude of countries across the globe. Such datasets are the product of international cross-border data flows, in compliance with existing privacy regulations such as the GDPR. They are carefully curated to avoid bias, such as ethnically diversity in body types and shapes. Building data silos based on geographical location and hampering international data flows will impede innovation, and ultimately leave patients and healthcare providers with technologies that do not live up to their potential. The EHDS should, therefore, refrain from adding data localization requirements on the storage, access, and processing on EU territory. Data localization requirements work against the goal of the EHDS to create an environment that fosters access to health data and data sharing as they will negatively impact innovation within and for the EU. Facing new and emerging diseases (e.g., COVID 19) has clearly shown that international collaborations and global data sharing are essential to enable new and innovative treatments.

AmCham Romania supports the promotion of cross-border international data flows through the adoption of pragmatic and transparent regime following the GDPR model. It is important to protect cross-border transfer of healthcare data that allows the aggregation of data from different countries, enabling scientific advances for medical breakthroughs (especially for rare and emerging diseases) and providing more data and certainty in regulatory filings with health authorities around the world. The EHDS proposal, as it stands now, risks to further complicate an already complex framework for international transfer and access to both, personal and non-personal data.

AmCham Romania believes that international data flows require a clear legal framework. This is especially important for the research and SME communities in Europe, which are deeply intertwined with international companies. With these communities relying on international funding, expertise, and partnerships to unfold a global clout, international data flows are more important than ever. Additional barriers to international transfers of data beyond the existing legal framework (GDPR for personal data and Data Act for "highly sensitive" non-personal data) should be avoided. Yet, the ENVI/LIBE draft report introduces strict rules for data localization that go beyond the GDPR, outlining that storage processing access to electronic health data should only be allowed on EU territory. The proportionality of these measures is to be questioned.

2. Protection of trade secrets and IP rights

The proposed EHDS Regulation explicitly obliges data holders to disclose their electronic health data for secondary use (directly or through health data access bodies) to data users established in the EU. This would be required even if electronic health data entails intellectual property rights (IPRs) and trade secrets (Recital 40 and Art. 33(4)). Through these provisions, the proposed EHDS Regulation sets aside and severely impacts already established rights of data holders on intellectual property and trade secrets. If the scope of obligations to share and make data accessible is widened excessively, it disproportionately interferes with

freedom to conduct a business and the right of property guaranteed by the EU Charter of Fundamental Rights.
Under the TRIPS Agreement, IP rights such as copyright and database rights, and rights to undisclosed information also benefit from protection. The TRIPS Agreement edicts minimum standards of protection at an international level (directly or by reference). The EHDS in its current form will set aside the rights which holders of IP and Trade Secrets Rights might have on certain data sets. The EHDS needs to safeguard and enhance the established worldwide framework for protecting intellectual property and trade secrets, with a particular focus on the Trade Secret Directive and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). This is especially crucial when it comes to certain data types, especially those that have undergone additional processing for specific clinical or research purposes, containing intellectual property that must be safeguarded when such data is utilized for secondary purposes. Neglecting to offer sufficient protection for intellectual property rights to companies could discourage them from investing in the European healthcare sector.

Making health data holder, such as pharmaceutical companies or medical device manufacturers, disclose datasets that have received added value through the engineering process they underwent, contradicts existing European IP and trade secret protection. Obliging data holders to share protected data with any third party, including competing entities, would deprive them of the essence of their rights. The secondary use of electronic health data to derive insights about the economic situation, assets and production method of a competitor's product or service, as well as the use of this data to develop competing products and services, should be prohibited. **We therefore support adding unfair commercial use to the list of prohibited purposes for secondary use of data.**

Sharing datasets, to which significant R&D and engineering investments are attached, creates disincentives to collect, build, and maintain high quality datasets in the first place: past investment is lost, and further innovation stippled. The risk that investments into high-quality datasets do not return value or provide an unfair advantage for potential competitors weakens innovation attractiveness of the EU in the global setting. Instead, the EU should encourage investments in high-quality datasets by protecting their *sui generis* right. **We therefore support stronger safeguards of private enterprises through adding stronger references to existing laws on the protection of IPs/TS to the EHDS, the right for data holders to refuse the sharing of data, and the involvement of data holders in the identification of datasets that contain IP rights and trade secrets.**

AmCham Romania supports greater empowerment of private enterprises to decide which IP and trade secret data can be disclosed and under what conditions. To encourage access to and sharing of good quality data for secondary use, the EHDS needs to build on the existing trade secrets and IP rights framework. Any IP and trade secret data sharing provisions should build on voluntary disclosure models and data holder-user agreements. Data holders should have the right to refuse the sharing of their data if it threatens their IPs/TS. Adequate safeguards need to be put in place to allow protection of IP and trade secrets.

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3. Reasonable scope and clear definitions

The EHDS is not a stand-alone regulation: it is meant to interact and to complement other EU legislation. The EHDS should clarify how it intends to interact with existing secondary legislation, especially with sectoral legislation (Medical Device Regulation – MDR or In Vitro Diagnostic Device Regulation – IVDR) and the General Data Protection Regulation (GDPR) to ensure that the EHDS becomes workable in practice**.** This includes the necessary alignment with definitions and concepts of other legislation. We, therefore, suggest clarifying key terms and definitions throughout the legislation (e.g., 'electronic health data', '(non) personal electronic health data', 'electronic health record (EHR) system'), and aligning definitions with existing terms and concepts which are already established in the EU (e.g., 'data holder'). There should not be any regulatory overlap or redundancies.

The definition of **'electronic health data'** is overly broad, as it includes personal or non-personal electronic health data, that is related to health or known to influence health (professional status, behavior, environmental factors). The types of data to be shared should be narrowed down. The aim should be to ensure that only meaningful data will be available for the secondary use of electronic health data which, in turn, will be critical for the success of the EHDS. **Hence, we support the narrowing down of the scope of 'personal electronic health data'.**

Moreover, there are no clear rules to determine what **non-personal data** is, making it open to broad interpretation due to various applications of the GDPR and health data processing rules in the Member States. Contrary to the definition of 'personal electronic health data', the definition of 'non-personal electronic health data' does not contain a link to primary care, which can potentially make the definition and related obligations extremely broad. We therefore recommend **specifying the forms of data to make the data categories less broad**; **excluding non-personal electronic health data sharing**, as there are no clear rules to determine what non-personal health data constitutes; and **aligning key terms and definitions between the EHDS and the GDPR/Data Act**.

Hoping for a constructive and transparent collaboration, we reiterate our full openness and willingness to support your efforts, through the expertise of the AmCham Romania Healthcare Committee members, and we assure you of our high consideration.

Best regards,

Vlad Boeriu
President
AmCham Healthcare Committee