CONSULTATION

European Health Data Space

The proposal for a European Health Data Space (EHDS) promotes the EU-wide exchange of health data, removes access barriers and supports health research, in particular on new prevention strategies, but also for scientific research, on treatments, medicines, medical devices, as well as removing barriers to the cross-border use of digital health services and products to allow building more resilient and sustainable healthcare systems.

The German chemical and pharmaceutical industry supports the Commission's efforts and willingness to move towards a more competitive and efficient healthcare industry as well as a better provision of digital and innovative healthcare services to European citizens. In our view, it is important to emphasize the following points:

Protection of confidential business information: Intellectual property (IP) is crucial for innovation and research as well as for Europe as an industry location and should therefore be protected. The proposal should therefore introduce concrete mechanisms for IP protection.
Legal certainty needed: It should be specified how legal certainty can be created for private data holders as to which data should be brought into the EHDS in accordance with Article 33 and which remain the property of the companies in accordance with Article 33, paragraph 4.
Interaction with existing regulations: It should be avoided that application uncertainties arise as with the EU GDPR – a fragmentation of the state implementations should be prevented. Opening clauses should be avoided, otherwise cross-border research will fail due to the different technical/legal implementations. At the same time, the new regulation should be compatible with already existing acts such as Data act, AI Act, EU cybersecurity framework and more specifically the Medical Device Regulation as well as the Clinical Trials Regulation.
Avoid double regulation: With the EHDS, AI medical devices are now subject to further regulation, which should be harmonised with the other existing acts. Overregulation should be avoided, and a uniform body should be defined that is responsible for this product area.
Ensure industry participation: The proposal introduces a new EHDS Board, composed of representatives of digital health authorities and new health data access bodies from all the Member States, the Commission, and observers. As we read it, involvement of industry is not planned. In our opinion, participation of industry would give a positive effect. Should a permanent industrial participation within the board not be feasible, at least a regular involvement as "external experts" should be provided.
Prevent unnecessary bureaucracy: It is foreseen to have a so called “health data access body” in each member state. Given the fact that other legislative acts covering digital topics also foresee dedicated regulatory bodies, this would produce an unnecessary burden. The EU Commission should try to streamline these regulatory bodies to minimize the bureaucracy burden.

Creation of cross-border and EU-wide digital infrastructure: A prerequisite of a successful EHDS implementation is the functioning of electronic cross-border health services foreseen by the end of 2025 (MyHealth@EU). With this ambitious timeline the Commission needs to support Member States which are not yet ready for a timely implementation.
Cross-border data transfer with non-EU countries: While the EHDS focuses on the European Union, cross-border data transfer with non-EU countries, especially the United States, should be foreseen as well to foster research and innovation globally. It is therefore crucial that the European Union and e.g., the United States reach an agreement how data can be interchanged in a safe and legally secure manner.
Ensure a high level of cybersecurity: Cybersecurity is a crucial aspect when it comes to health data, and it is critical that every participant of the EHDS can maintain the required level of cybersecurity.

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The VCI represents the interests of around 1,900 companies from the chemical-pharmaceutical industry and related sectors vis-à-vis politicians, public authorities, other industries, science and media. In 2021, the VCI member companies realized sales of ca. 220 billion euros and employed over 530,000 staff.