

Stellungnahme des VCI zum Inception Impact Assessment der EU-Kommission zum geplanten [European Health Data Space](#).

VCI welcomes the opportunity to provide feedback on the roadmap published by the Commission on the European Health Data Space (EHDS). The current Covid-19 pandemic particularly highlights the need for such an initiative to efficiently develop vaccines and treatments while monitoring the spread of the virus. The baseline scenario describes adequately the current situation in the EU. To establish an EHDS, more needs to be done. Therefore, VCI is generally in line with the proposed policy objectives, which we consider as complementary.

Objective 1a

To enable legally secure access to and exchange of health data for healthcare provision, research, policy-making and regulatory activities an appropriate legal and governance framework is mandatory. Nevertheless, it is important that the legitimate interest of researchers as well as data protection requirements of patients are taken care of. However, every option must be compliant under GDPR, which could be realized by using anonymization or pseudonymization.

The availability of high-quality data (governmental and corporate data) is crucial for research of innovative pharmaceutical products. However, VCI emphasizes the indispensability of protecting corporate data and raises concerns regarding government intervention. Compulsory data sharing entails high risks for companies, not only for reasons of know-how protection, but also in terms of competition and antitrust law. The principle of freedom of contract in the private sector should prevail.

Objective 1b

One of the biggest hurdles for an EHDS is the interoperability of data as stated in the inception impact assessment. Common standards are crucial to boost and improve the exchange of information between researcher institutions. Additionally, a safe and secure data infrastructure is necessary, in which GAIA-X should play an important role.

VCI would like to highlight that cybersecurity is critical for an efficient health data space. The recent cyberattack which targeted the European Medicines Agency in the context of COVID-19 vaccines points out the importance of this issue. The likely economic impacts of not having adequate cybersecurity protection measures may be potentially very large (financial impact as well as damaging the competitiveness of

European companies). The impact on fundamental rights due to loss of personal and private data of patients will likely be very large as well.

Objective 1c

The objective describes the necessity of adequate protection of fundamental rights and ensuring access and control of patients and citizens over their own health data. To achieve this objective, VCI sees the necessity to have a legal framework (objective 1a) and a safe and secure data infrastructure (objective 1b).

Patients should always be able to get all relevant information about their medical treatment to optimise the match between patient's needs and treatment.

Objective 2

Cross-border movement of digital health services and products like the exchange of electronic health records or digital health applications should also be part of the EHDS. Such applications could significantly improve the provision of health services in rural areas. However, a pre-requisite is a capable data-infrastructure based on FTTH, 5G and semantic interoperability standards.

Objective 3

VCI supports that digital health products and services must be trustworthy (see comment above on cybersecurity). With respect to use of AI VCI would like to highlight that a future regulation does not hamper innovation, while considering the necessary protection of personal data.

Conclusion

VCI thanks the Commission for taking the initiative to improve the availability and interoperability of data in the health sector. The EHDS would be an important step towards a more competitive European health industry and a better provision of European citizens with digital and innovative health services. However, certain issues like cybersecurity and regulation with a sense of proportion are mandatory.

Online abrufbar unter <https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12663-Digital-health-data-and-services-the-European-health-data-space/F1566692>

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Der VCI vertritt die wirtschaftspolitischen Interessen von rund 1.700 deutschen Chemieunternehmen und deutschen Tochterunternehmen ausländischer Konzerne gegenüber Politik, Behörden, anderen Bereichen der Wirtschaft, der Wissenschaft und den Medien. 2019 setzte die Branche über 198 Milliarden Euro um und beschäftigte rund 464.000 Mitarbeiter.