



EUROPEAN COMMISSION

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Dear President,

The Commission would like to thank the Senát for its Opinion on the proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space {COM (2022) 197 final}.

Digitalisation is essential for the future of healthcare. The COVID-19 pandemic has shown the importance of digital tools and how much they improved patient care. The uptake of digital tools increased significantly during this time. The complexity of rules, structures and processes across Member States makes it difficult to access and share health data, especially across borders.

The European Health Data Space is a health specific ecosystem comprised of rules, common standards and practices, infrastructures and a governance framework that aims at empowering individuals through increased digital access to and control of their electronic personal health data and supporting their free movement, and providing a consistent, trustworthy and efficient set-up for the use of health data for research, innovation, policy-making and regulatory activities.

It brings us much closer to making health data work for patients, people and innovation

The Commission fully agrees with the Senát's views on the importance of improved access to electronic health data for natural persons. The European Health Data Space will ensure that individuals will have greater control over their health data. If they wish, they will be able to provide their data to a healthcare professional of their choice rapidly and in an easy and transparent common format. This will reduce the number of unnecessary tests and costs and increase healthcare safety. The ability to access, analyse, and share health data will make healthcare more efficient, support better medical decisions and, therefore, improve health outcomes.

When it comes to the security of health data, stakeholder consultations have shown that strengthening trust in the sharing of health data and ensuring security and privacy are key for citizens, and they must be the cornerstone of the European Health Data Space. Citizens must

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be confident that their health data is protected and that their personal health data will not be misused. The European Health Data Space will provide a trustworthy, secure setting for access to and processing of health data. Data protection and safeguarding people's privacy is an absolute prerequisite for a successful European Health Data Space.

As regards the implementation of the proposal and administrative burden especially on the primary activity of the health data processor, the Commission underlines that the proposal does not require a full redevelopment of existing systems. It will be for electronic health records systems providers and for medical facilities to assess the type and number of changes needed to make the existing system interoperable and to decide on the best interoperable IT solution to connect to the system. Some solutions may involve the addition of small software components dedicated to interoperability.

Overall, at EU level, the Commission will provide over EUR 810 million to support the European Health Data Space from the EU4Health programme, the Digital Europe Programme, the Connecting Europe Facility and Horizon Europe. Horizon Europe will continue to support the needs of the European Health Data Space through specific research projects and support actions focusing on health data interoperability and research infrastructures.

Meanwhile, Member States have already earmarked around EUR 12 billion under the Recovery and Resilience Facility for investments in digital health and secondary use of health data. The Commission is happy to see that the recovery and resilience plan of Czechia includes important actions in digital health, which focus on e-health solutions with improved data sharing between healthcare providers, greater interoperability, stronger cybersecurity, and development of telemedicine and new digital services. Also, the European Regional Development Fund and Invest EU offer complementarities for investments in digital health based on national needs. Investing in digitalisation is investing in better healthcare and the resilience of our health systems. The EU and Member States need to take this bold step, together.

Discussions between the Commission and the co-legislators, the European Parliament and the Council, concerning the proposal are now underway and the Commission remains hopeful that a timely agreement will be reached. The Opinion of the Senát will be used by the Commission to inform the discussions in the ongoing negotiations of the co-legislators.

The Commission believes that the political dialogue with national Parliaments is essential for linking the Institutions and the citizens of the European Union and looks forward to continuing it with the Senát in the future.

Yours faithfully,

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Vice-President*

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Member of the Commission*