



EUROPEAN COMMISSION

*Brussels, 9.12.2022
C(2022) 9436 final*

Dear President,

The Commission would like to thank the Camera Deputaților for its Opinion on the Communication from the Commission to the European Parliament and the Council 'A European Health Data Space: harnessing the power of health data for people, patients and innovation {COM (2022) 196 final}.

The uptake of digital tools increased significantly during the COVID-19 pandemic. At the same time, the pandemic has clearly demonstrated the importance of digital services in the health area. However, the complexity of rules, structures and processes across Member States makes it difficult to access and share health data, especially cross-border.

The European Health Data Space is health-specific and it is comprised of rules, common standards and practices, infrastructures and a governance framework that aims at (i) empowering individuals through increased digital access to and control of their electronic personal health data and support to their free movement; (ii) fostering a genuine single market for electronic health record systems; and (iii) providing a consistent, trustworthy and efficient set-up for the use of health data for research, innovation, policy-making and regulatory activities.

It makes the European Health Union stronger and places patients at its centre. It is the first common European Union data space in a specific area to emerge from the European Union strategy for data and is an integral part of the digital transition.

The Commission is pleased that the Camera Deputaților shares the view that action at European Union level as envisaged in the proposal is necessary. The Commission thanks the Camera Deputaților for the recommendations expressed and addresses them in the attached annex.

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

The Commission hopes that the clarifications provided in this reply address the issues raised by the Camera Deputaților and looks forward to continuing the political dialogue in the future.

Yours faithfully,

*Maroš Šefčovič
Vice-President*

*Stella Kyriakides
Member of the Commission*

Annex

The Commission has carefully considered each of the recommendations and considerations raised by the Camera Deputaţilor in its Opinion and is pleased to offer the following clarifications.

Point 2: The COVID-19 pandemic has revealed the urgent need and the high potential for interoperability and harmonisation, building upon existing technical expertise at national level. At the same time, digital health products and services, including telemedicine, have become an intrinsic part of the delivery of healthcare. In addition, digitalisation and data are transforming the way in which healthcare is provided, in many cases offering an alternative to traditional physical interactions, which has a particularly beneficial impact for remote and rural areas. Different reimbursement policies in Member States should, however, not constitute barriers to the free movement of digital health services such as telemedicine, including online pharmacy services. According to the European Health Data Space proposal, when digital services accompany the physical provision of a healthcare service, the digital service should be included in the overall care provision.

Point 3: One of the aims of the European Health Data Space proposal is to improve data collection, sharing, interoperability across healthcare systems in the European Union and streamlining data access for reuse. On secondary use of health data, the European Health Data Space proposal sets out a common European Union framework allowing for the use of health data for research, innovation, public health, policy-making and regulatory activities. The access to such data by researchers and innovators would require a permit from a health data access body, to be set up in all Member States. Access would only be granted if the requested data is used for specific purposes, in closed, secure environments and without revealing the identity of the individual. It would also be strictly prohibited to use the data for decisions that are detrimental to citizens, such as increasing an insurance premium or for designing harmful products or services.

Point 4: The fragmented and divergent legal and administrative rules, frameworks, processes, standards and infrastructures in Member States complicate the access to health data for individuals, healthcare providers, researchers and innovators. Health data is sensitive, and it must be protected according to the highest possible standards. The European Health Data Space proposal put forward a framework for infrastructures to efficiently and securely exchange data for primary use and to make data available for secondary use. For the latter, data can only be processed in secure processing environments that need to respect strict criteria for security of processing. For instance, no personal data can be downloaded from the secure processing environments and access is restricted to approved participants. The European Health Data Space proposal builds upon the current European Union cybersecurity legislation. At the same time, the system of data permits for secondary use would be more efficient for researchers and innovators, as it would foster harmonisation of the documentation to be submitted for obtaining a permit and facilitate multi-country requests.

Point 5: In many Member States there are substantial national, regional and local challenges to interoperability and data portability, hampering continuity of care and efficient healthcare systems. Even if health data is available in electronic format, it does not usually follow the patient when they use services of a different healthcare provider. The European Health Data Space proposal will address these challenges at European Union level, providing mechanisms for improving interoperability solutions. Member States would be required to make priority categories of data available in a common European electronic health record exchange format, such as patient summaries, e-prescriptions, e-dispensations, medical images and image reports, laboratory results and discharge reports.

Point 6: Overall, at European Union level, the Commission intends to 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. This includes earmarked investments for the European Health Data Space, as well as horizontal and complementary investments that are key for its implementation. 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.

Point 7: For policy-makers and regulators, the current limited use of health data makes it challenging to provide more efficient and effective healthcare and public health policy, which is crucial particularly for effective health crisis management. This was evident during the COVID-19 pandemic. One of the benefits of the European Health Data Space proposal is that regulators and policy-makers would have easier access to health data for the benefit of public health and the overall functioning of healthcare systems.

Point 9: The Commission intends to earmark EUR 330 million for the European Health Data Space implementation. This will come from the EU4Health Programme and the Digital Europe Programme. This includes substantial support for Member States in the form of grants, particularly for the development and rollout of cross-border infrastructures for primary and secondary uses of health data. To prepare the ground for the implementation of the European Health Data Space, the Commission is undertaking action on capacity building for Member States. This capacity building initiative aims at stimulating the developing and strengthening of skills, abilities, processes and resources working on national digital health services.

In addition, Member States have earmarked EUR 12 billion under the Recovery and Resilience Facility for investments in digital health and secondary use of health data. Additional horizontal and complementary investments will come also from the Digital Europe Programme, Connecting Europe Facility and Horizon Europe.

Point 10: Artificial intelligence has a huge potential for healthcare. The Commission agrees that, for this, the systems must be trained with high quality data. The European Health Data Space would provide access to a large array of health data categories,

while the data quality and utility label would support data quality improvement and the identification of relevant datasets. That is why establishing the European Health Data Space would also facilitate the further development of artificial intelligence systems in healthcare. The health data access bodies would be providing access to quality data that would support the training, testing and evaluation of algorithms, including for medical devices, artificial intelligence systems and digital health applications. The measures provided in the horizontal artificial intelligence Act¹ combined with the sector-specific framework set out in the European Health Data Space proposal would aid in the successful development and deployment of artificial intelligence in healthcare.

¹ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52021PC0206>