



OPINION

European Economic and Social Committee

European Health Data Space

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]

Proposal for a Regulation of the European Parliament and of the Council on the European
Health Data Space
[COM(2022) 197 final – 2022/0140 (COD)]

INT/990

Rapporteur: **Gonçalo Lobo Xavier**

www.eesc.europa.eu

EN

Referral	European Parliament, 06/06/2022 Council, 13/06/2022
Legal basis	Article 114 of the Treaty on the Functioning of the European Union
Section responsible	Single Market, Production and Consumption
Adopted in section	08/09/2022
Adopted at plenary	22/09/2022
Plenary session No	572
Outcome of vote (for/against/abstentions)	198/0/1

1. Conclusions and recommendations

- 1.1 The EESC welcomes the Commission's Communication on the European Health Data Space. After the COVID-19 crisis, and with some good examples of cooperation, such as the European COVID certificate, the EU and its citizens can benefit from safe, harmonised and shared data that could boost the Member States' health systems in all their dimensions. The EESC agrees that the digital transformation is crucial in order to provide better healthcare to citizens, build stronger and more resilient health systems, support long-term competitiveness and innovation in the EU's medical ecosystem, and help the EU recover from the pandemic.
- 1.2 From the EESC's point of view, it is crucial to use the opportunities brought by innovation and digitalisation to boost citizens' wellbeing and improve the quality of health services. At the same time, organised civil society and the social partners draw attention to the fact that there are, among the EU Member States, different levels of digital literacy, which need to be addressed as part of the strategy implementation process. When it comes to this issue, the "leave no one behind" motto is more relevant than ever.
- 1.3 For the EESC, the European Health Data Space proposal presents an excellent opportunity to empower individuals to access and control their personal health data. At the same level, the EESC believes that this strategy would ensure a consistent framework for using individuals' health data in the context of R&D policies. To achieve both goals, it is very important to guarantee confidence and safety in the process. For this reason, the EESC supports having a large-scale communication campaign to help build trust among the public. Citizens must be aware of the benefits associated with the sharing process. For the EESC, it would be interesting to highlight the direct benefits for citizens and consumers, as has been done for other stakeholders but it must be clear that mandatory quality requirements are in place, especially for authorisation and anonymity purposes.
- 1.4 The EESC considers that, as such, the European Health Data Space will have a significant positive impact on fundamental rights as regards personal data protection and free movement. If properly linked to the European Open Science Cloud (EOSC) data space and the relevant European life sciences data infrastructure¹, it will enable researchers, innovators and policy-makers to use the data more effectively, securely, and in a way that safeguards privacy. Under this idea, the EESC agrees that this proposal is another good effort to boost the internal market and its potential for improving European citizens' lives.
- 1.5 Despite supporting this agenda, the EESC draws attention to the fact that the EU cannot ask the public to support a European area for the exchange of health data if funding for healthcare is scarce. COVID-19 has been a major blow to public health systems and the EU must be aware that it must repair the damage and strengthen public health systems with an adequate budget before taking steps towards this project, which is undoubtedly positive. In the EESC's opinion, if there is a budget for an "agenda", the EU must allocate funds towards strengthening health systems and only then move towards this interesting project.

¹ The European Strategy Forum on Research Infrastructures, through its strategic roadmaps, facilitated the establishment of European research infrastructure dedicated to health research data, biobanking collection, medical imaging data, etc. Details available at: <https://roadmap2021.esfri.eu/>.

- 1.6 The EESC stresses the need to clarify the use of primary and secondary data for citizens. People must have trust and confidence in the system to cooperate and understand the benefits, both to individuals and the entire community. The EESC believes that the main fears relate to the secondary use of data. It must be very clear what the use is, what the limits are, what body will control and validate the data, and what sanctions are in place for the event of non-compliance. The EESC strongly believes that civil society organisations and social partners can help to explain and promote these messages if properly involved. Member States could truly benefit from civil society organisations on the ground to support the community in these matters, to ensure that no one misses out on this progress. In the same vein, general practitioners and treating physicians chosen by patients are key links in the chain of trust and confidence between patients and users of health data. The EESC recommends that these professionals should be particularly involved in the communication strategy.
- 1.7 The EESC, although generally in favour of this proposal, calls on the Commission to clearly reflect on the pros and cons of the initiative to reduce the risks before moving forward. One must realise that there are too many challenges ahead when we talk about the Member States' health systems. There are different paces, different views about public and private health systems and citizens must realise that this proposal means investment and public policy choices. It must be clear to citizens that it is part of a strategy and progress that will add value instead of undermining the system. Communication is needed to avoid misunderstandings by the general public.
- 1.8 With a view to promoting better access to insurance for everyone, which requires a better understanding on the part of insurers of the data evidence concerned, the EESC calls for a reflection on the relevance of having a review of the absolute prohibition on the use of secondary data by insurers. Nevertheless, given the concomitant risk involved in the individualisation of insurance premiums and risk selection, it considered it preferable to stick to the European Commission's position, which is that the secondary use of electronic health data should be restricted to the sole, perfectly legitimate objectives of improving and conducting public health policies and research. The Committee also calls for thought to be given to the possibility of opening this data up to insurers for research purposes, provided they are fully compatible with the GDPR and the public interest objectives referred to above, and are monitored by the competent authorities in cooperation with civil society.
- 1.9 The EESC firmly believes that the European Health Data Space will benefit individuals, health professionals, healthcare providers, researchers, regulators and policy-makers, but this will only happen if, in the context of this strategy, citizens and stakeholders are involved in the continuous investment in national health systems. It is not possible to get citizens involved if they do not feel they are at the heart of the process. The EESC recommends that the Commission and the Member States involve civil society organisations to make the implementation of the strategy a success and to benefit from the experience of such organisations, which can spread the word about the transparency and reliability of the initiative. Investment in these areas is crucial.

- 1.10 The EESC supports the idea that a combination of investments from the Digital Europe Programme, the Connecting Europe Facility and Horizon Europe can be used by the Member States and bodies involved in the European Health Data Space in order to implement the strategy. Furthermore, the Digital Europe Programme will support the deployment of the infrastructure needed to make health data securely accessible across EU borders and to develop common data spaces. However, the EESC also draws attention to the fact that these investments will take time and are not directly linked to the strategy timeline. Citizens' expectations must therefore be balanced within the timeline of these investments in order not to risk disappointing them and failing to gain their acceptance for the strategy and for data sharing in general.
- 1.11 Finally, the EESC urges the Commission to consistently invest in cybersecurity systems, which can prevent huge problems in all Member States. People must be able to trust in these matters and all the recent problems and examples in many different parts of the EU have created a sense of insecurity and fear regarding data protection and systems security. This must be addressed in a coordinated way by the EU and can make the difference when we address this kind of sensitive investment.

2. **General framework**

- 2.1 The European Commission has launched the European Health Data Space (EHDS), one of the central building blocks of a strong European Health Union. The EHDS is a health-specific data sharing framework establishing clear rules and practices, infrastructure and a governance framework for the use of electronic health data by patients, as well as for research, innovation, policy making and regulatory activities, while ensuring full compliance with the EU's high data protection standards.
- 2.2 It will help the EU achieve a quantum leap forward in the way healthcare is provided to people across Europe. It will empower people to control and utilise their health data in their home country or in other Member States. It fosters a genuine single market for digital health services and products.
- 2.3 The Member States will ensure that patient summaries, ePrescriptions, laboratory results and discharge reports are issued and accepted in a common European format. Interoperability and security will become mandatory requirements. To ensure that citizens' rights are safeguarded, all Member States have to appoint digital health authorities. These authorities will participate in the cross-border digital infrastructure (MyHealth@EU), which will support patients in sharing their data across borders.
- 2.4 The EHDS builds further on the GDPR, the proposed Data Governance Act, the draft Data Act and the NIS Directive. It complements these initiatives and provides more tailor-made rules for the health sector.
- 2.5 The primary use of electronic health data supports the use of data for better healthcare at national and cross-border level. Medical data is typically stored in electronic health records, containing segments of a patient's medical history (centrally or involving various healthcare providers). The European Health Data Space will allow people to access their health data and

make their data available to a health professional of their choice, including when abroad and in the language of the health professional. Thus, the patient can get a better diagnosis and treatment with fewer medical errors and avoid unnecessary diagnostics.

- 2.6 The secondary use of electronic health data takes place when health data is processed in order to inform and assess public health policies or to conduct research. This can enhance patient safety and boost the development of new medicines and medical devices, as well as personalised medicine and products relying on artificial intelligence. In the context of the European Health Data Space, the results of such research are made public in aggregated form, duly preserving data privacy.
- 2.7 The European Health Data Space is a health-specific ecosystem comprised of rules, common standards and practices, infrastructure, and a governance framework that aims at:
 - a) empowering individuals through increased digital access to and control of their electronic personal health data and support for their free movement;
 - b) fostering a genuine single market for electronic health record systems, relevant medical devices and high-risk AI systems;
 - c) providing a consistent, trustworthy and efficient set-up for the use of health data for research, innovation, policy-making and regulatory activities.

3. **The power of health data: trust as the centre of the strategy**

- 3.1 The EESC welcomes the Commission's initiative on a "European Health Data Space", which has the potential to increase citizens' quality of life, boost innovation and create a safe environment for data protection and data sharing.
- 3.2 After the COVID-19 crisis, all Member States have suffered from the pressure that their national health systems have endured, and this Commission initiative arrives at the right moment.
- 3.3 The EESC is convinced that there is a general distrust regarding the solidity of the system, in spite of some positive results seen in many different countries. General practitioners and treating physicians chosen by patients are key links in the chain of trust and confidence between patients and users of health data. The EESC recommends actively involving them in informing citizens about the value of health data exchanges for them as individuals and for all.
- 3.4 In order to unleash the potential of health data, the Commission has presented a legislative proposal to create a European Health Data Space in order to empower individuals to take control of their own health data and to allow its use to ensure the delivery of better healthcare and to enable the EU to make full use of the potential offered by the safe and secure exchange, use and re-use of health data, without the existing obstacles. The EESC supports this general idea.
- 3.5 EU citizens will be able to access and share their data in real time, while retaining greater control over it. The European Health Data Space will allow for more effective, accessible and resilient healthcare and better quality of life, while giving individuals control over their health

data and unleashing the potential of the data economy. Once again, the EESC and organised civil society believe that the EU must take advantage of the fact that people are open to such an initiative as long as they understand the project and the benefits of the concept.

4. **Challenges linked to the use of health data: risks and opportunities**

- 4.1 The EESC believes that it is crucial that Member States realise that investments are needed in order to promote this project and that there are currently several other competing strategic priorities.
- 4.2 The fact that the European Health Data Space is built on the General Data Protection Regulation (GDPR)², the Data Governance Act³, the draft Data Act⁴ and the NIS Directive⁵ provides citizens with a dimension of trust and transparency. As horizontal frameworks, these provide rules (including security measures) that apply to the health sector. However, the particularly sensitive nature of health data is a fact and must be properly addressed.
- 4.3 Over half of Member States do not have specific legislation on re-using electronic health data, for instance for research, policy-making or regulatory purposes, and rely on the general provisions of the GDPR, often using consent for processing health data⁶. This situation results in limited health data re-use. Not all Member States have a competent body for health data access, but where such a body exists, the number of requests to use health data for research or policy-making projects is rapidly increasing⁷, showing the interest in such a system and the level of suppressed demand. The EESC understands and believes that this concept also supports the need for such a strategy.
- 4.4 The European Health Data Space will open up innovative approaches to cancer registration, with potential alternatives to gather timely, geo-localised information on various types of cancers. This could provide a real-time state of play of cancers across the EU. At the same time, it could identify trends, disparities and inequalities between Member States and regions.
- 4.5 Importantly, this could make it easier to spot the challenges and specific areas of action requiring investment and other action at EU, national and regional level. It will also make cancer screening and care more targeted, more effective and more accessible, to give but one example.
- 4.6 Cybersecurity is central to people's lives. The benefits from technology are huge and when they relate to people's data, the potential is even higher, but so is the risk of losing important and

² [OJ L 119, 4.5.2016, p. 1.](#)

³ [OJ L 152, 3.6.2022, p. 1.](#)

⁴ [Proposal for a Regulation on harmonised rules on fair access and use of data \(Data Act\); COM/2022/68 final.](#)

⁵ [OJ L 194, 19.7.2016, p. 1.](#)

⁶ Hansen J. et al, *Assessment of the EU Member States' rules on health data in the light of GDPR*, available at https://ec.europa.eu/health/system/files/2021-02/ms_rules_health-data_en_0.pdf.

⁷ According to the impact assessment accompanying the proposal (p 15), forthcoming.

valuable information. The EESC is aware of the risks involved and the recent examples in different Member States call for action. A coordinated strategy to combat "*cyber piracy*" and to increase levels of cybersecurity is very important. Without this kind of investment, the proposal is useless.

5. **Governance, funding and interaction with other health policies**

- 5.1 The EESC firmly believes that this project is an opportunity to empower the EU, and to benefit from stronger rights and safeguards over EU health data. It is supposed to be easier to access and share health data with other health professionals, without having to re-do the same tests unnecessarily. At the same time, easier access to interoperable data of high quality will also facilitate innovation and the development of new treatments, new vaccines and personalised medicine. Therefore, proper coordination among all stakeholders – public health systems, governments, citizens, policymakers and communicators - is needed to achieve these goals.
- 5.2 The EESC agrees that investing in digitalisation means investing in better healthcare and the resilience of the Member States' health systems. However, the EESC also understands that there is an opportunity for the Member States to make better use of the resources provided by the European financial schemes, particularly the Recovery and Resilience Facility (RRF), as the main pillar of the European recovery plan, NextGenerationEU, aimed at providing financial aid to Member States to combat the economic and social effects of the COVID-19 pandemic and to make the European economy more resistant to future shocks.
- 5.3 The EESC draws attention to the benefits of combining investment in infrastructure that allows digitalisation and progress for all regions. It is pointless to start a project of such a dimension without the proper network or infrastructure or without investing in improving the training and digital literacy of citizens.
- 5.4 The EESC supports the idea that more than EUR 480 million from the Digital Europe Programme, the Connecting Europe Facility and Horizon Europe can be used by the Member States and bodies involved in the European Health Data Space, along with other sectors. The Digital Europe Programme will also support the deployment of the infrastructure needed to make health data securely accessible across EU borders and to develop common data spaces. The EESC states that these investments will take time and that citizens' expectations must be balanced within the timeline of these investments.

Brussels, 22 September 2022.

Christa SCHWENG

The president of the European Economic and Social Committee
