In her State of the Union address on 16 September 2020 before the European Parliament, European Commission President Ursula von der Leyen announced a new legislative proposal to create a European health data space.

Setting up a health data space is part of the European health Union. It is also a follow-up of the European data strategy adopted in February 2020, in which the Commission had stressed the importance of creating European data spaces, including on health.

The Commission, expects the European health data space to:

• promote safe exchange of patients' data (including when they travel abroad) and citizens' control over their health data;
• support research on treatments, medicines, medical devices and outcomes;
• encourage the access to and use of health data for research, policy-making and regulation, with a trusted governance framework and upholding data-protection rules;
• support digital health services; and
• clarify the safety and liability of artificial intelligence in health.

The combined evaluation roadmap/inception impact assessment was published on 23 December 2020. The feedback period ended on 4 February 2021. A public consultation ran from 3 May to 26 July 2021. The creation of a European Health Data Space was also included among the final recommendations by the Conference on the the future of Europe in 2022.

The Commission published the proposal for a regulation on the European Health Data Space on 3 May 2022. It aims at giving control to the European citizens to their health data (primary use of health data), including regarding cross borders purposes, and at facilitating the uptake of the re use of health data (secondary use) for research, innovation and public policy purposes while ensuring compliance with the EU data protection standards.

To attain these objectives, the proposal establishes a set of rules and infrastructures to support the primary and secondary use of health data, as well as a European governance framework.

On 14 of June 2022, the Employment, Social Policy, Health and Consumer Affairs Council (Health) held a first discussion on the regulation. Overall, Ministers welcomed the proposal which, once adopted, will provide a stable legal framework to facilitate the
exchange of health data within the Union. This is expected to improve healthcare and to spur research. The discussions also raised the need to ensure the relevant security and protection of health data.

During its plenary session of 22 September 2022, the European economic and social committee adopted an opinion on the European health data base. Whilst supporting the proposal and its objective, the opinion insists on several framework conditions to an effective implementation of the initiative, to the benefit of healthcare of EU citizens. Trust is a key condition: it includes technical features, such as ensuring the cybersecurity of the infrastructure, but also legal features, such as a precise definition of the scope of the secondary use. Also, skills and digital literacy is to be enhanced to allow the empowerment of EU citizens, as regards the use of their own health data. Beyond the framework conditions, the opinion also includes targeted policy advice, such as the need to provide for a proper link between the European health data space and the European open science cloud (EOSC), as well as the relevant life sciences infrastructures.

During its meeting of 9 December 2022, the Employment, Social Policy, Health and Consumer Affairs Council (Health) was informed of the progress made on the file. Under the Czech Presidency, 15 technical meetings were held on the text. In particular, the discussions focused on the articulation between the proposal and the EU legal framework on the protection of personal data. Also, several Member States outlined the need to explore the addition of an additional legal basis to the proposal: since the proposal includes provisions related to the organization, and delivery of health services and medical care in the Member States, Article 168 of the Treaty might also become a basis for the proposal. The Presidency has asked a written opinion to the Council legal service. On 23 May 2023, the Presidency presented the second compromise text to the working party on public health, following the first compromise text presented at the end of February 2023.

On 8 February 2023, the Committee of the Regions adopted an opinion on the proposal. Whilst welcoming the proposed regulation, it suggests a set of amendments to improve further the balance between privacy and the use and re-use of health data, to address the costs associated to the cybersecurity, deployment and interoperability of the digital infrastructure.

On 10 February 2023, the co-rapporteurs published their draft report. In general, the rapporteurs welcome the proposal. Their amendments aim at ensuring the alignment with the EU GDPR relevant provisions. Regarding the secondary use, they provide for an opt-out for the secondary use. Also, the amendments aim at strengthening accountability by including a judicial remedy for the natural persons, as well as the establishment of financial penalties for misuse of personal health data. The report also creates the obligation to store health data in the EU. Last, the report provides for a more inclusive governance of the European Health Data Space Board.

On 16 February 2023, the Parliament decided to refer the proposal to ENVI and LIBE, pursuant with Rule 58 of the Parliament Rules of Procedure. ITRE and IMCO were associated pursuant with the Rule 57. The report is expected to be adopted in July 2023.

On 13 June 2023, the Council (Employment, Social Policy, Health and Consumers affairs) took note of the progress achieved. Whilst delegations have welcomed favorably the two compromise texts prepared by the Swedish Presidency, there is still a need to ensure convergence over key elements, such as the scope, and modalities) of the health data to be subject to secondary use.
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