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#### NOTE

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From:	General Secretariat of the Council
To:	Council
Subject:	Proposal for a Regulation on the European Health Data Space - <i>Progress report</i>

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Delegations will find in Annex a progress report on the proposal mentioned in the subject above, due to be presented at the EPSCO (Health) Council on 9 December 2022, with a view to inviting the Council to take note of it.

The present report has been drawn up under the responsibility of the Presidency and is without prejudice to particular points of interest or further contributions of individual delegations. It sets out the work done so far in the Council's preparatory bodies and gives an account of the state of play in the examination of the above mentioned proposal.

## **Information from the Presidency on the progress achieved in the examination of the proposal for a Regulation on the European Health Data Space**

### **Background**

1. On 5 May 2022, the Commission submitted the proposal for a Regulation on the European Health Data Space<sup>1</sup> (EHDS), which was accompanied by an impact assessment and a communication. It is the first proposal for a common European data space following the communication ‘A European strategy for data’<sup>2</sup> from 2020, which announced the creation of nine sector- and domain-specific data spaces. The proposal for a Regulation on the EHDS has a legal basis in Articles 16 and 114 of the Treaty on the Functioning of the European Union and is considered a key pillar of the European Health Union.
2. The proposal aims to improve individuals’ access to and control over their personal electronic health data (primary use of data), including at national and EU level, and to facilitate data re-use (secondary use of data) for research, innovation and public policy purposes across the EU. It also aims to improve the functioning of the single market, in particular for the development, marketing and use of digital health services and products (e.g. electronic health record (EHR) systems). To that end, a health-specific data environment is proposed, with common rules, infrastructure and a governance framework.
3. On 26 September 2022, the European Economic and Social Committee adopted its opinion<sup>3</sup> on the proposal. The European Committee of the Regions was invited to deliver its opinion on the proposal on 30 June 2022, and is expected to do so in February 2023.

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<sup>1</sup> 8751/22 + ADD1 + ADD2

<sup>2</sup> [COM\(2020\) 66 final](#)

<sup>3</sup> 12883/22

4. On 13 July 2022, the European Data Protection Board and the European Data Protection Supervisor (EDPS) issued a joint opinion<sup>4</sup> on the proposal.
5. At the European Parliament, the Civil Liberties, Justice and Home Affairs Committee (LIBE) and the Environment, Public Health and Food Safety Committee (ENVI) are co-leaders for the file. The rapporteurs appointed are MEP Annalisa Tardino (IP, IT) for LIBE and MEP Tomislav Sokol (EPP, HR) for ENVI.
6. The French Presidency organised five meetings of the members of the Working Party on Public Health dedicated to the presentation of the proposal, evaluation of the impact assessment, and to beginning to examine the proposal. The first examination of the chapter regarding the primary use of electronic health data was concluded. In addition to this, during the EPSCO Council meeting on 14 June 2022, Member States exchanged views on the proposal. At the initial stage of the discussions, Member States welcomed the proposal as an important step towards better use of health data. However, several issues were identified as requiring further examination in the future, such as the implementation timelines, which many delegations consider too ambitious, how the proposal ties in with other EU regulations, including the General Data Protection Regulation (GDPR), and the necessary funding for its implementation.

### **Progress during the Czech Presidency**

7. During the Czech Presidency, 15 meetings of the Working Party on Public Health have been held, and the first examination of the proposal has been concluded. Detailed discussions have also taken place on the interlinkage with other legislation, in particular with the GDPR, on the legal basis, and the proposed European governance structure of the EHDS.

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<sup>4</sup> 11351/22

8. In addition to the work carried out by the Working Party on Public Health, the Czech Presidency organised a webinar with the participation of the Commission, experts from the capitals, and health attachés. The webinar took place on 13 July, and it allowed delegations to take a closer look at the technical implementation of secondary use of data, including national structures already in place.
9. The Presidency asked the Council Legal Service to provide a written opinion on the legal basis of the text, as several Member States deemed that the proposal might touch upon the organisation and delivery of health services and medical care in the Member States, and therefore Article 168 of the Treaty on the Functioning of the European Union should also be considered.
10. Pending the Council Legal Service's written opinion and based on the discussions in the meetings and the written comments from delegations, the Presidency tabled a revised text for Chapters II and III of the proposal, which was examined in three meetings at technical level. The document contained a number of changes to the Commission proposal, for example to align provisions with the GDPR, tackle possible interference with the organisation and delivery of health services and medical care, and make changes as regards implementing acts and delegated acts, including the substitution of an examination procedure for an advisory procedure for an in all implementing acts.

In Chapter II, in order to clarify the link with the GDPR, the Presidency proposed revising Article 3. The Presidency amended the provision allowing natural persons to insert data in their EHR systems, in order to clearly distinguish between cases where data are inserted by natural persons and by healthcare professionals. Furthermore, the Presidency strengthened natural persons' right to obtain information on any access to their personal electronic health data and added that this information is to be provided automatically and is to identify the person who has accessed their personal electronic health data. In order to ensure greater control for Member States, the Presidency suggested removing the implementing acts determining the categories of healthcare providers registering health data electronically and the categories of health data to be registered, the delegated act allowing additional tasks to be given to digital health authorities, the provision establishing the obligation for Member States to provide digital health authorities with the necessary resources, and the provision establishing the mandatory cooperation with stakeholders. The Presidency also proposed the deletion of Article 8 on telemedicine in the context of cross-border healthcare, as it was considered not to be directly related to the establishment of the EHDS. Likewise, in order to reduce the burden placed on Member States regarding the tasks of digital health authorities, the Presidency has suggested reducing the frequency of reporting, and removed the requirement to report on the level of satisfaction with MyHealth@EU services, as well as the requirement to inform complainants on the progress of complaints proceedings. As regards joint controllership of national contact points for digital health, the Presidency proposed the deletion of the word 'joint' while clarifying the interplay among processors and controllers. The decision-making process related to MyHealth@EU has also been amended by the Presidency, and the role of the joint controllership group removed. Finally, to ensure security, the Presidency has strengthened the safeguards when connecting infrastructures or bodies from third countries to MyHealth@EU.

In Chapter III, which focuses on electronic health record systems and wellness applications, the Presidency has made the requirement on the wellness applications labelling scheme mandatory if interoperability is claimed, aligning these obligations with those imposed on electronic health record system manufacturers. Moreover, the Presidency proposed changing the delegated act to an implementing act to allow manufacturers to enter specific information into the EU database of EHR systems and wellness applications as an alternative to the information sheet.

In general, the revised text was well received by delegations, who welcomed the amendments made by the Presidency, although they felt it would still benefit from further work and adjustments. Delegations widely supported the change to the examination procedure in the case of implementing acts, and several delegations, while welcoming the alignment with the GDPR, supported going further. Additionally, some delegations have asked to discuss a broader opt-out option for natural persons in the registration of electronic health data, and several delegations have also called for more centralised services to be offered by the Commission. A few delegations also emphasised the importance of including an ethical dimension.

The Presidency believes that the progress made will be a good basis for follow-up work, but would like to stress that the proposed text was the first compromise proposal, which will be further developed and amended based on the continuing discussions at the Council.

11. On the remainder of the proposal, the Presidency considers that other outstanding issues are: the list of minimum categories for secondary use of data; the tasks of health data access bodies (HDAB); HDABs' reporting duties and the fees charged by HDABs; some aspects of the issuance of data permits; joint controllership of secondary use of data and responsibilities; third countries' participation in HealthData@EU; data quality and utility labels; and the governance structure.

## Conclusions

12. The Council is invited to take note of the progress achieved so far, confirm that the Presidency's suggestions provide a good basis for future discussions, and invite the incoming Presidency to build on the progress made so far.
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