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NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee
No. Cion doc.:	8751/22 + ADD 1 - ADD 7
Subject:	Proposal for a Regulation on the European Health Data Space - <i>Preparation for the trilogue</i>

INTRODUCTION

1. On 3 May 2022, the Commission submitted to the Council and the European Parliament a proposal for a Regulation on the European Health Data Space¹ (EHDS), which was accompanied by an impact assessment and a communication. The proposal is based on Articles 16 and 114 of the Treaty on the Functioning of the European Union (TFEU) (ordinary legislative procedure). The EHDS is the first of the European common data spaces proposed in the 2020 Communication ‘A European strategy for data’², which announced the creation of nine sector- and domain-specific data spaces 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), at both national and EU levels, and to facilitate data reuse (secondary use of data) for research, innovation, regulatory and public policy purposes across

¹ 8751/22 + ADD 1 + ADD 2.

² [COM\(2020\) 66 final](#).

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 this end, the proposal provides for a health-specific data environment, including common rules, infrastructure and a governance framework.

3. The European Economic and Social Committee delivered its opinion on 26 September 2022³, while the European Committee of the Regions delivered its opinion⁴ on 8 February 2023.
4. On 13 July 2022, the European Data Protection Board and the European Data Protection Supervisor issued a joint opinion⁵ on the proposal.
5. Member States' National Parliaments were consulted on the compliance of the proposed provisions with the principle of subsidiarity and proportionality. The Portuguese Parliament submitted an opinion stating that the proposal complied with the principles of subsidiarity and proportionality and the Czech Chamber of Deputies and Senate delivered two resolutions respectively raising a number of issues.
6. In the European Parliament, the Committees on Civil Liberties, Justice, and Home Affairs (LIBE) and on the Environment, Public Health, and Food Safety (ENVI) have the lead responsibility for the file. The rapporteurs appointed are MEP Annalisa Tardino (ID, IT) for LIBE and MEP Tomislav Sokol (EPP, HR) for ENVI. The vote in the Committees took place on 28 November 2023 and in plenary on 14 December 2023.
7. On 6 December 2023, the Permanent Representative Committee agreed on its mandate⁶ for the Presidency to enter into negotiations with the European Parliament. On 26 January 2024, the Permanent Representative Committee agreed to revise this mandate⁷.

II. STATE OF PLAY

8. So far, two trilogues and 11 technical meetings have been held with the European Parliament and the Commission. These meetings have allowed to discuss and tentatively agree on a number of provisions highlighted in green in the fourth column of the four-column table in document 6155/24.

³ 12883/22.

⁴ 6403/23.

⁵ 11351/22.

⁶ 16048/1/23 REV 1.

⁷ 5173/24.

9. The discussions during the inter-institutional negotiations held so far have allowed provisionally to identify the following most relevant political issues to be discussed in the next political trilogue on 20 February 2024:

- a. **Opt-out in secondary use** (Article 33(5)/line 434 and Article 35F/lines 457an-au), including obligations of health data access bodies to provide information to natural persons on the use of the opt-out (Article 38(2)/line 504 and Article 35E/line 457ab). Where the Council makes it optional for Member States to implement the opt-out, the Parliament demands to have it mandatory.
- b. **Opt-in in secondary use** (Article 33(5a)/line 434a and Article 33(5)/line 437b). While the Council allows for Member States to introduce stricter measures to safeguard the sensitivity and value of genetic and other human molecular data, the Parliament requires consent (also referred to as opt-in) to make available genetic data and data from wellness apps and biobanks.
- c. Regulation of **electronic health record (EHR) systems** (Chapter III). In particular, the Parliament supports a third-party certification assessment while the Council has kept a self-certification procedure with limited harmonised components and with the possibility of using a digital testing environment as an aid to assess compliance.
- d. The sharing of information on **clinically significant findings** with the natural person or their treating professional (Article 38(3)/line 505 and Article 35G /line 457aw), where the Council makes it optional for Member States while the Parliament requires it to be harmonised.
- e. The introduction of **Union data access services** by the Council (Article 36A/lines 463a-d). The Parliament is unsure of the usefulness of this addition.
- f. The introduction of **intermediation entities** by the Council (Article 2(2)(ya)/line 139c and their references throughout the text). The Parliament is concerned about not having a streamlined process where health data holders are in contact directly with health data access bodies.

In addition, it is expected that the discussions from the last political trilogue will continue on:

- g. **Opt-out in primary use** (Article 7(1a)/line 196a; article 8F/lines 204ai-am): The Parliament favours a harmonised approach while the Council's right to object is optional for Member States to implement both at national and cross-border level.
- h. The use of the term **anonymous** as in Council's mandate instead of **non-personal** electronic health data as in the Parliament's text.

- i. **Telemedicine** (Article 8/lines 203-204; Article 2(2)(1)/line 125): While the Council prefers its deletion in the regulation, the Parliament prefers to keep it.
- j. The possibility for Member States to introduce **additional categories** both for **primary and secondary use**, as proposed in the Council mandate (articles 5(1A)/ line 183; article 6(1a)/line 192c; article 33(4)/line 437a).

III. PROPOSAL FOR A REVISED MANDATE

- 10. Based on the inter-institutional discussions so far, it is clear that the current mandate does not provide the Presidency with a sufficient margin to negotiate with the European Parliament. To be able to progress efficiently during the negotiations, the Presidency believes that this mandate needs to be updated.
- 11. The main political issues were discussed at the meeting of the Working Party on Public Health on 5 February 2024. Based on the conclusions of that meeting, the Presidency considers that with a view to preparing for the forthcoming trilogue, the following approach could be used:
 - a. **Opt-out in secondary use** to show a **certain degree of flexibility** by adding a “shall” with the right to object from GDPR.
 - b. On **opt-in in secondary use**, to show a **certain degree of flexibility** on which categories stricter measures can be introduced.
 - c. On the assessment of **compliance of EHR systems**, to **keep Council’s position**. Third-party assessment would be burdensome and costly for Member States.
 - d. On the sharing of information on **clinically significant findings** with the natural person or their treating professional, if needed, **show flexibility** on harmonising this element.
 - e. On the **Union data access services**, **keep Council’s position**, in order to ease the burden of national HDABs.
 - f. On the inclusion of **intermediation entities**, **keep Council’s position** as a way to lessen the burden for both health data holders and HDABs.
 - g. On the **opt-out in primary use**, to show a **certain degree of flexibility** by keeping the “may” clause with the possibility of enhancing harmonization.
 - h. On the **additional categories for primary and secondary use**, to **stick to Council’s mandate**.

12. The Presidency considers that the proposal is balanced and provides a good basis for negotiating with the European Parliament.

IV. CONCLUSION

13. In light of the above, the Permanent Representatives Committee is invited to:

- take note of the four-column table in 6155/24 as some of the text still needs to be aligned with the issues that remain open;
- take note of the main political issues referred to in point 9 above and agree on the proposed approach as outlined in point 11.