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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 and 14 February 2024, the Permanent Representative Committee agreed to revise this mandate⁷.

II. STATE OF PLAY

8. So far, three trilogues and 24 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 7050/24.

³ 12883/22.

⁴ 6403/23.

⁵ 11351/22.

⁶ 16048/1/23 REV 1.

⁷ 5173/24 and 6154/24.

9. The discussions during the inter-institutional negotiations allowed to identify the following most relevant political issues to be discussed in the next political trilogue on 7 March 2024:
- a. **Opt-out in secondary use** (Article 33(5)/line 434 and Article 35F/lines 457an-au), where the Council makes it optional for Member States to implement the opt-out, the Parliament demands to have it mandatory.
 - b. **Data localisation** in the Union (Articles 60a-60A/lines 681f-681j; lines 25a, 619a and 681d), the Parliament includes a general data localisation requirement for both primary and secondary use of data while the Council's mandate incorporates it only for core tasks in secondary use and foresees exceptions based on adequacy decisions.
 - c. **Transitional periods** (Article 70/lines 751-752; Article 72/ lines 760-764b). While the Council prefers longer implementation deadlines and a staggered approach for Chapter IV, the Parliament favours shorter transitional periods.

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 28 February 2024. Based on the conclusions of that meeting, the Presidency considers that with a view to preparing for the forthcoming discussion, the following approach could be used:
- a. **Opt-out in secondary use:** to show some **flexibility** by using Parliament's text, but with the deletion of "all or parts of" to ensure room of manoeuvre for Member States on its implementation and with the addition of justified exceptions from the opt-out for certain purposes. The Council should also insist on adding a review clause to control possible negative effects of the opt-out on the data quality, on including a specific transitional period for the opt-out aligned with the implementation timeline of Chapter IV and keeping article 1(6a) (line 104a) where it is specified that the existence of parallel systems to EHDS are allowed.
 - b. On **data localisation:** to show **limited flexibility** by adding the text that is currently in recital 15aa (line 25a) into the normative part of the Regulation.

- c. On **transitional periods**, to show **limited flexibility** by shortening selected timeframes by one year (ie. lines 751, 752, 761, 762, 764, 764a)

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 7050/24 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.
