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NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee/Council
Subject:	Proposal for a Regulation on the European Health Data Space - *Progress report*

Delegations will find in the annex a progress report on the abovementioned proposal, to be presented at the EPSCO (Health) Council meeting on 13 June 2023, with a view to inviting the Council to take note of it.

This report has been drawn up under the responsibility of the Presidency and is without prejudice to particular points of interest or further contributions from individual delegations. It sets out the work done so far by the Council's preparatory bodies and gives an account of the state of play as regards the examination of the abovementioned proposal.

ANNEX

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

I. INTRODUCTION

1. On 3 May 2022, the Commission submitted a proposal for a Regulation on the European Health Data Space[1] (EHDS), which was accompanied by an impact assessment and a communication. It 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. 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), at both national and EU levels, and to facilitate data reuse (secondary use of data) for research, innovation, regulatory 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 this end, the proposal provides for a health-specific data environment, including common rules, infrastructure and a governance framework.

[1] 8751/22 + ADD 1 + ADD 2.
[2] COM(2020) 66 final.

3. On 26 September 2022, the European Economic and Social Committee adopted its opinion[3] on the proposal, while the European Committee of the Regions delivered its opinion[4] on 8 February 2023.

4. On 13 July 2022, the European Data Protection Board and the European Data Protection Supervisor issued a joint opinion[5] 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[6] submitted an opinion stating that the proposal complied with the principles of subsidiarity and proportionality and the Czech Chamber of Deputies and Senate[7] delivered two resolutions respectively raising a number of issues.

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3 12883/22.
4 6403/23.
5 11351/22.
6 12223/22.
7 13836/22 and 13814/22.

6. At the European Parliament, the Civil Liberties, Justice and Home Affairs Committee (LIBE) and the Environment, Public Health, and Food Safety Committee (ENVI) are both responsible for the file. The rapporteurs appointed are MEP Annalisa Tardino (ID, IT) for LIBE and MEP Tomislav Sokol (EPP, HR) for ENVI. The Committee on the Internal Market and Consumer Protection (IMCO) and the Committee on Industry, Research and Energy (ITRE), as associated committees, have also been involved in the work on the file. The rapporteurs appointed are MEP Andrey Kovatchev (EPP, BG) for IMCO and Chistian-Silviu Busou (EPP, RO) for ITRE. A draft report was presented on 1 March 2023 and further amendments to the proposal were tabled until 23 March 2023 for ENVI-LIBE. The ENVI-LIBE committees are expected to vote on the file in July 2023.

II. WORK WITHIN THE COUNCIL

7. The French Presidency organised five meetings of the Working Party on Public Health dedicated to presenting the proposal, evaluating its impact assessment, and starting to examine it. The Czech Presidency devoted 17 meetings to the file, concluding the first examination of the proposal and tabling a revised text for Chapters II and III[8].

[8] The progress was reported to the Council in 14768/22 + COR 1 of 1 December 2022.

8. Building on the work done under previous presidencies, the Swedish Presidency tabled compromises in the form of revised texts for Chapter I and Chapters IV to IX[9], based on discussions held at the meetings, on written comments from delegations and on clarifications from the Commission. Nine meetings at technical level were dedicated to examining these compromises and exchanging views on specific topics that needed in-depth consideration, such as the definition and scope of EHR systems, the scope of wellness applications, the possibility of a third-party assessment instead of self-certification for EHR systems, the rights of natural persons and the possibility of an opt-out on secondary use of data, data categories for secondary use and possible reciprocity requirements for third-country data users. The compromises contained a number of adjustments to the Commission proposal, such as replacing the advisory procedure with an examination procedure in all implementing acts (as already presented in the Czech compromise on Chapters II and III), deleting delegated acts to give greater influence to the co-legislators on essential elements of the proposal, introducing the term 'health' before 'data holder' and 'data user' to specify the concepts of data holders and users defined in the Data Governance Act and the Data Act, and clarifying the links with the General Data Protection Regulation (GDPR). In particular, the following changes were made:

[9] 5302/23, 6627/23 and 7353/23.

- In **Chapter IV,** which is dedicated to the secondary use of health data, the Presidency made some structural changes to give further clarity to the text. Some provisions and articles were moved (e.g. the duties of health data holders were moved from Article 41 to Article 35b, and Article 54 on mutual recognition was incorporated into Article 46 on data permits) and three new articles were added – on the scope for clarification, on intellectual property rights and trade secrets, and on the duties of health data users – which brought together provisions that had been scattered between different articles. In Article 46, the Presidency clarified the criteria that must be met before granting access to electronic health data. The Presidency also deleted Article 48 on making data available without a permit for public sector bodies and EU institutions and bodies. In Article 49 on giving access to health data from a single health data holder, the Presidency gave greater flexibility to Member States by making it optional. Moreover, regarding joint controllership, the Presidency proposed the deletion of the term 'joint' in Article 51 while clarifying the roles of health data holders, health data access bodies (HDABs) and health data users. As for connecting third countries and international organisations to the HealthData@EU infrastructure, the Presidency made it clear that transfers resulting from such a connection must comply with Chapter V of the GDPR.

- In **Chapters V to IX**, which focus on horizontal provisions such as additional actions, governance and deferred application, the Presidency strengthened the requirements and established a clearer link with the GDPR for obtaining EU funding. In the articles related to the transfer of electronic health data to third countries, the Presidency changed the term 'non-personal data' to 'anonymous data', as it seemed more appropriate when referring to natural persons. Concerning the EHDS Board, the Presidency gave a greater role to Member States by including co-chairing and by having them adopt the rules of procedure. The Presidency also suggested replacing the joint controllership group with two steering groups and two fora for both the primary and secondary cross-border infrastructure. The two steering groups would take operational decisions regarding the infrastructure and be composed only of representatives of Member States' national contact points in order to strengthen Member States' power. The fora, on the contrary, would also include other authorised participants with the aim of exchanging information without taking decisions. The Presidency also proposed that decisions on accepting participants into and disconnecting them from the infrastructures would not be taken by the steering groups but by the Commission, through implementing acts and after a positive compliance check. Lastly, the Presidency extended the timeframes for when the Regulation would apply and its transitional provisions, and introduced a specific timeframe for the application of Chapter IV.

- In **Chapter I,** dedicated to the subject matter, the scope and definitions, the Presidency revised the subject matter and scope to clarify what the proposed Regulation covered. Additionally, the Presidency deleted some definitions, such as 'HealthData@EU', as they were already described in the articles, and made a number of clarifications, for example in the definitions of 'data permit', 'health data holder', 'electronic health data' and 'personal electronic health data'.

In general, the revised texts were well received by the delegations, who welcomed the changes made by the Presidency, though they felt the proposal would still benefit from further amendments. Some delegations appreciated the new structure as they considered it to have brought clarity to the text, and deemed that the proposal was better aligned with the GDPR. Likewise, many delegations supported the decisions to include the description of the controller role (Article 51), delete the automatic issuance of a data permit once the time limit has expired (Article 46), and give flexibility to Member States in deciding if a data permit could also be given by a single data holder (Article 49). Numerous delegations also welcomed the extension of the timeframes regarding the entry into force and application of the different provisions, and the deletion of several delegated acts. The deletion of Article 48 was widely appreciated by a majority of delegations, although some would support a fast-track procedure for EU institutions and national authorities in certain cases. Nevertheless, some delegations were still concerned about the administrative burden resulting from the HDAB reporting obligations, and the process for providing an answer to data requests and for issuing data quality labels. Furthermore, the in-depth discussions during the meetings showed that delegations were divided in their positions on a number of topics, such as what the definitions of health data user, health data holder and EHR systems should cover, whether a third-party certification or assessment should be introduced for EHR systems, whether wellness applications should be included in Chapters III and IV, what the scope of data categories and of the purposes to be included for secondary use should be, and if an opt-out (or an opt-in) procedure for secondary data should be added. As regards the possibility of reciprocity for third countries' access to data, it became apparent that further discussions were needed. As regards the priority categories of data for secondary use, some Member States were willing to keep categories such as data from clinical trials or human genetic, genomic and proteomic data in the proposal if additional safeguards were added to the text. In addition, several Member States saw a need for clarification regarding the rights of natural persons in relation to the secondary use of data in order to ensure transparency and trust.

9. Taking into account the discussions at the meetings and the written comments from delegations on the first revised texts, the Presidency has published a second compromise text encompassing the whole proposal[10]. This has been discussed at two technical meetings; two more meetings are planned for June. The Presidency has introduced substantial changes in comparison to the original proposal:

   - New articles have been added on the rights of natural persons as regards secondary use of data, covering different scopes and contexts and building on the rights under the GDPR, including an opt-out solution. For primary use, the provisions related to the rights of natural persons have been separated out into different articles with the aim of clarifying the scope of each right.
   - New articles have been added grouping together existing provisions to give a clearer structure to the text and to align the provisions on primary and secondary use, such as those relating to reporting by digital health authorities, electronic health data access services, the relationship with data protection regulation for as regards both primary and secondary use, and templates to support access to electronic health access for secondary use.
   - The order of the articles has been changed in both Chapter II and Chapter III. In Chapter II, the Presidency has started with the obligation of registration, followed by access to and exchange of priority categories; Chapter III has been rearranged to start with the scope, followed by the relationship with other regulations.
   - In Chapter I, new definitions have been added for ‘anonymous electronic health data’ and ‘contracting authorities’, for example, and further amendments have been made to existing definitions, mainly to adjust their scope.

[10] 8171/1/23 REV 1.

- In Chapter II, the possibility of adding additional priority categories by means of a delegated act has been removed.
- In Chapter III, the Presidency has introduced a new article stating that Member States remain free to regulate the use of wellness applications within their healthcare system.
- In Chapter IV, the Presidency has added the option for Member States to decide on rules for the enrichment of datasets. Prohibited uses have been added and more detail has been given on the purposes. Regarding HDABs, some tasks and reporting obligations have been removed to ease their burden. In the event of non-compliance by health data holders and health data users, the Presidency has strengthened HDABs' power to take immediate action by revoking the data permit. The Presidency has also suggested that HDABs should assess various risks when issuing a data permit or a data request in statistical format. The Presidency has also proposed that the Commission should issue guidelines on fee policies and structures instead of adopting implementing acts, and that fees may include costs related to the gathering and preparation of datasets.
- In Chapters V-IX, the article on the fora has been removed and its provisions have been integrated into the article on the steering groups. Certain elements have been added to the penalties to ensure a more harmonised implementation. Regarding the deferred application, transitional and final provisions, a specific timeframe has been set to adopt several implementing acts, and the entry into force of Chapter IV has been staggered depending on the data category.
- The links to the GDPR have been further clarified in recital 37, and those references removed accordingly from the specific articles.

Member States' initial reactions to this new compromise have been positive, indicating that the changes are going in the right direction. The Presidency believes that the progress that has been made will be a good basis for follow-up work, although it recognises the need for further fine-tuning and topical discussions on issues such as roles and responsibilities in cross-border infrastructure, the application of Chapter II to existing EHR systems, the need for European central services such as an EU HDAB, and the interplay with other legislation such as the NIS Directive and the Clinical Trials Regulation.

III. CONCLUSIONS

10. The Council is invited to take note of the progress that has been achieved in the negotiation of the proposal, confirm that the work carried out by the Presidency provides a good basis for future discussions, and invite the incoming Presidency to build on the progress made so far.