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From:	Presidency
To:	Delegations
Subject:	Presidency working document on the European Health Data Space proposal for the Working Party on Public Health on 15 September 2023

Spanish Presidency Working Document for the WPPH 2023-09-15

PUBLIC

Index of contents

PUBLIC

PUBLIC

WPPH 2023-09-15

Topics to cover

On the WPPH of the 15th of September 2023 (afternoon half-day meeting) we intend to cover the following topics:

• continuation of the discussion on the topics of the 8th of September 2023.

• creation of an EU HDAB [article 36A, article 37(1)(q), article 49(1A), article 52(1A), article 55]

• requirement for HDABs and SPEs to store health data in the EU/EEA when processing health data in the context of data access applications and data requests.

• reciprocity requirements in the secondary use of health data with third countries.

The deadline for written comments after the WPPH of the 15th of September 2023 is the 22nd of September 2023.

Versions of the EHDS text

We shall use the following terminology to refer to the different versions of the text of the Regulation:

- **Commission's original proposal:** https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52022PC0197

- **Swedish compromise text:** document number **ST8171 2023 REV1**

- **Proposal for modifications from the Spanish presidency, taking into account the comments of the delegations:** the modifications are made over the Swedish compromise text, with a ~~**double strikethrough**~~ in the case of deletions and a **double underline** in the case of additions (changes are also highlighted with a blue background and shown in **bold font**).

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Nomenclature of proposed modifications

A tag will be added to the text when the Spanish presidency introduces a proposal for the modification on the text of the Regulation. Each modification may affect one or several articles and one or several recitals.

In order to ease the identification of the changes in the text, the Spanish presidency has devised the coding scheme described below.

MOD: modification introduced in the text of:
- one or several articles
and
- one or several recitals.

Topic of the modification:
- **GA** (general aspects): definitions and articles affecting general aspects of the EHDS (some fragments of article 1 & most articles of Chapters V, VII-XI).
- **PU** (primary use): definitions affecting primary use of health data & Chapters II-III.
- **SU** (secondary use): definitions affecting secondary use of health data & Chapter IV.
- **Go** (governance): definitions affecting governance and Chapter VI.
- **TC** (third countries): definitions and articles affecting third countries, specifically.
- **XX** (other modifications).

Note: when a modification affects several topics, the main topic is chosen.

Example 1: fees in article 42 may affect secondary use and third countries, but the

Number of modification: consecutive number, within the topic.

Note: modification number 1 in topic SU would be coded as "MOD.SU.1". Modification number 2 in topic SU would be coded as

[MOD . PU . 1 . rev2]

Number of revision of this particular modification (compared to the initial compromise text of the Spanish presidency):
- ***blank***: initial version of the modification
- **rev1**: first revision of this modification
- **rev2:** 2nd revision of this modification
…
- **revN:** Nth revision of this modification

Examples:
[MOD.SU.1] = modification #1 within the secondary use of health data, initial version.
[MOD.Go.1.rev3] = modification #1 within governance, revision 3.
[MOD.PU.2.rev4] = modification #2 within the primary use of health data, revision 4

PUBLIC

Secondary use of health data

[MOD.SU.7] Creation of an EU HDAB [article 36A, article 37(1)(q), article 49(1A), article 52(1A), article 55]

Modifications in the text
1) New **article 36A** creating the EU HDAB. *Note: this would include, among others, the following institutions:* *- European Agency for Safety and Health at Work (EU-OSHA)* *- European Centre for Disease Prevention and Control (ECDC)* *- European Commission* *- European Institute of Innovation and Technology (EIT)* *- European Medicines Agency (EMA)* *- European Monitoring Centre for Drugs and Drug Addiction (EMCDDA)* *- Global Health EDCTP3 Joint Undertaking* *- Innovative Health Initiative Joint Undertaking (IHI JU)* *(see complete list of EU institutions here: https://european-union.europa.eu/institutions-law-budget/institutions-and-bodies/search-all-eu-institutions-and-bodies_en)* **2) Modification of article 37(1)(q)** which states that the EU HDAB shall also make available its dataset catalogue. **3) Article 49, paragraph 1A** (EU institutions as single data holders**) is deleted**, since all data access applications and data requests for EU institutions would now be handled through the EU HDAB. **4) Modification of Article 52: new paragraph 1A**, which clarifies that this new HDAB would act as the Union Institutions' contact point for secondary use of electronic health data and would be responsible for making electronic health data available for secondary use. **5) Modification of Article 55** clarifying that there are: - national dataset catalogues provided by the Member States, which will be made available at least in one official language of the Member State (but may also be provided in other languages, such as English to facilitate re-use). *Note: this modification was not for the EU HDAB per se, but was introduced for technical implementability reasons: the previous wording seemed to restrict national dataset catalogues to just one official language of the Member State, excluding other possibilities (several official languages in one Member State; provision of information in languages different to the official languages of the Member State, such as English).* - a dataset catalogue for EU institutions, which will be available in all official languages of the Union. **6)** The EU HDAB is also mentioned in the context of two modifications related to third countries (please, see those modifications for details): **[MOD.TC.1] Requirement for HDABs and SPEs to store health data in the EU/EEA when processing health data in the context of data access applications and data requests [article 60A, recital 63A].** **[MOD.TC.2] Reciprocity requirements in the secondary use of health data with third countries [article 47B].**
Justification for the position of the Presidency
During the WP 2023-07-14, the Presidency has tabled a proposal to create an EU HDAB. This proposal had a very strong support by the delegations. The main reasons given for this approach were the following: - It would be more efficient to have an EU HDAB than to have EU institutions as single data holders. - Even though EU institutions had (much) fewer datasets than a Member State, with the progress of European integration, more datasets will become available at the EU level. - Having an EU HDAB could help clarify the operational and procedural approach to be followed by HDABs in the jurisdiction of the Member States.

Additional explanations
One delegation raised the concern about the cost of such an entity for the Union budget. As a reference, we may use the costs of establishment an operation of a Health Data Access Body and its connection to the EU-wide infrastructures for Member States[1]: - In average, a set-up phase from a Health Data Access Body can range from EUR 0.5 million to EUR 8.5 million (depending on the size and complexity of a Member State) the maintenance costs range from EUR 0.2 million to EUR 4.0 million per year, per country. - To connect the National Health Data Access Body to the EU-wide infrastructures, the initial investment costs vary between EUR 0.8 million to EUR 2.5 million per year, per country, while maintenance costs of this connection are estimated to be between EUR 0.2 million to EUR 0.8 million. Since an EU HDAB would have a (much) lower volume of data access applications and data requests than an HDAB of a Member State, the cost of operation of an EU HDAB should be on the lower end of the estimation. However, it is up for the Member States to decide if the creation of an EU HDAB is reasonable taking the costs (described here) and the benefits (described in the "Justification of the position of the Presidency").

Modifications in article(s):

Article 36A

EU Health Data Access Body

1. The EU Health Data Access Body is hereby established as a service provided by the Commission.

2. The EU Health Data Access Body shall be responsible for fulfilling the tasks set forth in Articles 37 and 39 when Union institutions, bodies, offices and agencies process electronic health data as health data holders.

3. The Commission shall ensure that the EU Health Data Access Body is provided with the human, technical and financial resources, premises and infrastructure necessary for the effective performance of its tasks and the exercise of its powers.

***4. Unless there is an explicit exclusion, references in this Regulation to health data access bodies shall include also the EU Health* Data Access Body. [MOD.SU.7]**

Article 37

Tasks of health data access bodies

1. Health data access bodies shall carry out the following tasks:

(q) make public, through electronic means:

(i) a national dataset catalogue **referred to in Article 55** ~~that shall include details about the source and nature of electronic health data, in accordance with Articles 56 and 58, and the conditions for making electronic health data available. The national dataset catalogue shall also be made available to single~~

[1] Page 47 of https://health.ec.europa.eu/system/files/2022-05/ehealth_ehds_2022ia_2_en.pdf (Section "8.2. DIGITAL INFRASTRUCTURE") describes the "absolute costs" for a Member State for the establishment of Health Data Access Bodies. *Note: the costs provided in pages 26-27 of this document for the establishment of Health Data Access Bodies are "costs above the baseline", the "baseline" being a country which already has some kind of national infrastructure for secondary use of health data.*

~~information points under Article 8 of Regulation […] [Data Governance Act COM/2020/767 final];~~ THE DELETED PARTS MOVED TO ARTICLE 55 **The EU Health Data Access Body shall make public a catalogue detailing the scope of its duties and the electronic health data processed by Union institutions, bodies, offices and agencies:** **[MOD.SU.7]**

Article 49

*Access to electronic health data from a single **health** data holder **in Member States or Union institutions, bodies, offices and agencies***

~~**1A. Where an applicant request access to electronic health data from health data holders which are an Union institution, body, office or agency, by way of derogation from Article 45(1) or Article 47(1), that applicant shall file a data access application or a data request directly to each health data holder or when requesting electronic health data from several health data holder in several Member States or authorised participants as referred to in Article 45(5A) through the services provided in cross-border infrastructure referred to in Article 52. The data access application shall comply with the requirements set out in Article 45 and the data request shall comply with requirements in Article 47.**~~ **[MOD.SU.7]**

Article 52

~~*Cross-border infrastructure for secondary use of electronic health data (HealthData@EU)*~~

1A. The EU Health Data Access Body shall act as the Union Institutions', bodies, offices and agencies' contact point for secondary use of electronic health data and shall be responsible for making electronic health data available for secondary use. **[MOD.SU.7]**

Article 55

*Dataset description **and ~~national~~ datasets catalogue*** **[MOD.SU.7]**

1. The health data access bod~~ies~~ shall, **through a publicly available and standardised machine-readable datasets catalogue, provide** inform**ation, in the form of metadata,** ~~the data users~~ about the available datasets and their characteristics ~~through a metadata catalogue~~. **A description of** ~~E~~**e**ach dataset shall include information concerning the source, the scope, the main characteristics, **the** nature of electronic health data and **the** conditions for making electronic health data available.

1A. The dataset descriptions in the national datasets catalogue of the Member States shall be available, at least, in an official language of the Member State. The dataset catalogue for EU institutions provided by the EU Health Data Accesss Body shall be available in all languages of the Union. **[MOD.SU.7]**

1B. The ~~**national**~~ dataset**s** catalogue shall also be made available to single information points under Article 8 of **Regulation (EU) 2022/868** ~~[…] [Data Governance Act COM/2020/767 final];~~ MOVED FROM ARTICLE 37(1)(q) **[MOD.SU.7]**

First round of comments:
Does your delegation agree with the wording proposed by the presidency?
Yes/No.

Second round of comments:
Please, briefly explain your position during the WP meeting and send written comments.
If you have suggestions only for minor modifications, please, just send written comments.
Deadline for written comments: 2023-09-22

Third countries & secondary use of health data

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[MOD.TC.1] Requirement for HDABs and SPEs to store health data in the EU/EEA when processing health data in the context of data access applications and data requests [article 60A, recital 63A].

Modifications in the text
New **Article 60A** New **Recital 63A**

Modifications in article(s):

Article 60A

Prohibition of storage of personal electronic health data outside of the European Union by health data access bodies and secure processing environments

Health data access bodies designated by the Member States and the EU Health Data Access Body and secure processing environments, within the meaning of article 50, shall store personal electronic health in the European Economic Area, when performing data processing operations envisioned in articles 45-47. [MOD.TC.1]

Modifications in recital(s):
[MOD.TC.1]

(63A) The processing of large amounts of personal health data of EU citizens for the purposes foreseen in the EHDS, as part of data processing activities in the context of servicing data access applications, data permits and data requests increases the risk of unauthorized access to such personal data, as well as the possibility of cybersecurity incidents. For this reason, and in order to increase the trust of European citizens in data processing for secondary use in the context of the EHDS, it is important to establish the requirement for health data access bodies and secure processing environments that any infrastructure allowing the collection, consultation, management, access, storage or any processing of personal electronic health data for secondary use must be located in the European Union.

First round of comments:
Does your delegation agree with the wording proposed by the presidency?
Yes/No.

Second round of comments:
Please, briefly explain your position during the WP meeting and send written comments.
If you have suggestions only for minor modifications, please, just send written comments.
Deadline for written comments: 2023-09-22

[MOD.TC.2] Reciprocity requirements in the secondary use of health data with third countries [article 47B].

Modifications in the text
New **Article 47B**

Modifications in article(s):

Article 47B

Data applications and data requests from third countries **[MOD.TC.2]**

1. Without prejudice to Articles 45, 46 and 47, health data access bodies designated by the Member States and the EU Health Data Access Body data applications and data requests submitted by a data users established in a third countries shall be considered eligible if the third country concerned

a) is covered by an implementing act referred to in Article 52 (5);

or

b) allows EU applicants for access to health data for secondary use under conditions that are not more restrictive than provided for in this regulation and therefore are covered by the implementing acts referred to in paragraph (2).

2. The Commission shall adopt implementing acts establishing the list of third countries referred to in paragraph (1) point b). These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 68 (2). The Commission shall make the list of implementing acts adopted pursuant to this paragraph publicly available.

3. Health data access bodies may also consider data applications from third countries not covered by paragraph 1 eligible.

First round of comments:
Does your delegation agree with the wording proposed by the presidency?
Yes/No.

Second round of comments:
Please, briefly explain your position during the WP meeting and send written comments.
If you have suggestions only for minor modifications, please, just send written comments.
Deadline for written comments: 2023-09-22

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Abbreviations and glossary of terms

Note: these abbreviations may or may not be issued in today's discussion. It's a generic list.

International organizations

- WTO: World Trade Organization.
- WHO: World Health Organization.
- EU: European Union.
- EEA: European Economic Area. The EEA consists of the 27 European Union (EU) member states plus three non-EU member countries: Norway, Iceland, and Liechtenstein. These three non-EU countries participate in the EU's Single Market through the EEA Agreement, which ensures the free movement of goods, services, capital, and people within this area.
- COM / EC: European Commission.

Council of the European Union

- WP: working party meeting of the Council of the European Union. In the context of the EHDS discussions, we are referring to the WPs on Public Health (WPPHs).
- CLS: Council of the European Union's Legal Service.

European Health Data Space

- EHDS: European Health Data Space[2].
- EHDSB / EHDS Board: European Health Data Space Board (defined in article 64 of the current compromise text).
- "original text" (of the EHDS): Commission proposal for the EHDS[3].
- "Swedish compromise text" (of the EHDS): Swedish presidency compromise text, document number ST8171 2023 REV1.

Primary use of health data

- EHR system: Electronic Healthcare Records system (defined in article 2(2)(n) of the current compromise text of the EHDS).
- EEHRxF: European electronic health record exchange format (article 6 EHDS).
- GP: general practitioner. A general practitioner (GP), also known as a family doctor or primary care physician, is a medical doctor who provides comprehensive healthcare services to patients of all ages and genders. GPs play a crucial role in the healthcare system, serving as the first point of contact for individuals seeking medical advice, treatment, and preventive care.
- GPs: general practitioners.
- DHA: Digital Health Authority (article 10 EHDS).
- MSA: Market Surveillance Authority (article 28 EHDS).
- NCPs: National Contact Points (article 12 EHDS).

Secondary use of health data

- HDAB: Health Data Access Body (defined in articles 35D, 35F and 36-39 of the Swedish compromise text of the EHDS).
- SMEs: small and medium enterprises.
- SPE: Secure processing environment (50 EHDS).

[2] https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space_en
[3] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52022PC0197

- HDH: Health Data Holder (article 2(1)(y) EHDS).
- HDU: Health Data User (article 2(1)(z) EHDS).

Other relevant legal acts of the European Union

- TFEU: Treaty on the Functioning of the European Union[4].
- DA: Commission's proposal for a European Data Act[5].
- DGA: final text for the (European) Data Governance Act[6], i.e. *Regulation (EU) 2022/868 of the European Parliament and of the Council of 30 May 2022 on European data governance and amending Regulation (EU) 2018/1724 (Data Governance Act)*.
- Commission's proposal for the DGA[7].
- EU DCC Regulation: *Regulation (EU) 2021/953 of the European Parliament and of the Council of 14 June 2021 on a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates (EU Digital COVID Certificate) to facilitate free movement during the COVID-19 pandemic.*[8]

General Data Protection Regulation

- GDPR: General Data Protection Regulation[9], i.e. *Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation)*
- DPA: Data Protection Authority[10].

World trade organization agreements

- GATS: General Agreement on Trade in Services[11], to which the EU has made specific commitments[12].
- GATT: General Agreement on Tariffs and Trade[13].

[4] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A12012E%2FTXT
[5] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2022%3A68%3AFIN
[6] https://digital-strategy.ec.europa.eu/en/policies/data-governance-act
[7] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A52020PC0767
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