Council of the European Union

Brussels, 1 September 2023
(OR. en)

12554/23

Interinstitutional File:
2022/0140(COD)

LIMITE

SAN 497
PHARM 113
COMPET 829
MI 705
DATAPROTECT 218
CODEC 1512

WORKING DOCUMENT

From:	Presidency
To:	Delegations
On:	1 September 2023
Subject:	Presidency working document on the European Health Data Space proposal

Spanish Presidency Working Document for the WPPH 2023-09-08

Index of contents

Summary of previous discussions

- **Summary of the last WP meeting devoted to the EHDS file (2023-07-25)**

WPPH 2023-09-08

Topics to cover

We shall cover the following topics during the WPs 2023-09-08:

• clarifications about the exclusion of judicial activities from the scope of the EHDS;

• articles concerning the secondary use of health data already covered during the WPs 2023-07-04/05 & 2023-07-14 & 2023-07-20, with new wording proposals after comments from delegations;

• revision of article 33(1);

• new proposal for the fee structure in article 42 proposed by one delegation.

We shall not cover topics related to governance aspects, neither for the secondary use of health data, nor for the primary use of health data.

The deadline for written comments is:
2023-09-15

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. The modifications are highlighted with a blue background and are shown in **bold font**.

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).

Number of modification: consecutive number, within the topic.

[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

Proposed general modifications

[MOD.GA.1] Clarification of exclusion from the scope of the EHDS of certain judicial activities. [article 1(7), recital (16A), recital (41A)]

Modifications in the text
- Modification of article 1(7) **- New recital (16A)** **- New recital (41A)** **- New article 33A(c)**
Justification for the position of the Presidency & explanation of the changes introduced in the text
<u>Concerns of delegations</u> Two delegations asked for the exclusion of any health data related to "justice". Also, several delegations have expressed concerns regarding the use of health data in the context of the EHDS for two purposes related to justice: **Purpose 1:** law-enforcement entities trying to use EHDS primary use or secondary use (instead of their investigative powers set out in other laws) to obtain evidence. **Purpose 2:** health data held in the justice system being made available for secondary use (e.g. a court-ordered mental health assessment to determine whether someone can be held criminally responsible). In the view of the Presidency, **Purpose 1** for primary use was already out of the scope of the Regulation with the wording of the Swedish compromise text, article 1(7). Even without this amendment, "primary use" is processing of health data for the purpose of delivering healthcare. Law-enforcement is not healthcare. It is not clear how, if ever, law-enforcement authorities would become addressees of obligations under Chapter II even in the absence of this explanation. **Purpose 1** for secondary use is clearly not one of the allowed purposes under article 34. This is reflected in **recital (41A).** **Purpose 2** is also unviable, since courts (and other parts of the justice system) are neither entities in the health or care sector, nor do they seem to fall under the definition of data holder in another way, so they are not covered by the obligation to make electronic health data they hold available for secondary use. Therefore, courts and the like do not fall in the definition of health data holder. However, for the sake of clarity and unambiguous exclusion of such data holders, we explicitly state this exclusion in **recital (41A)** and in **article 33A(c).** Finally, in the opinion of the Presidency, a complete exclusion of "justice in general" (requested by one delegation) could lead to a situation where any health data related to administrative law, consumer law, contract law, family law, tort law, international law, etc would need to be excluded from primary and, especially, secondary use of health data. This could lead to a significant uncertainty for data users and a significant legal uncertainty and a considerable administrative burden for the HDAB, as it would be necessary to examine each dataset to decide which data could be related to "justice in general". The latter amendment was not introduced due to the reasons explained in this paragraph. However, as stated above, the "justice system" has been explicitly excluded from the obligations of a data holder. **<u>Legal clarity</u>** However, for the sake of legal clarity, it was also important to clarify that this Regulation does not affect the powers of competent authorities for the prevention, investigation, detection and prosecution of criminal offences (i.e. criminal investigations) established by law to obtain health data. Similarly, health data held by courts for the purpose of judicial proceedings (for example, data used as evidence), are out of scope of this Regulation. This is reflected in the modification of **article 7(1).**

Modifications in articles:

Article 1

Subject matter and scope

7. This Regulation shall not apply to ~~activities concerning~~ the processing of electronic health data for purposes of public security, national security, defence and law enforcement, including the prevention, investigation, detection and prosecution of criminal offences. The powers of competent authorities for the prevention, investigation, detection and prosecution of criminal offences established by law to obtain health data are unaffected. Similarly, health data held by courts for the purpose of judicial proceedings are out of scope of this Regulation.

Article 33A

Applicability to health data holders

~~The requirement in t~~This ~~article~~ **Chapter** shall not apply to**:** ~~individual researchers and~~ **[MOVED FROM ARTICLE 35B(5)]**

(…)

(c) courts and other entities of the justice system. [MOD.GA.1]

Modifications in recitals:

(16A) The processing of health data for the purpose of law enforcement should not fall within the scope of primary or secondary use of electronic health data in the meaning of this regulation. In addition, courts and other entities of the justice system should not be considered as data holders in the meaning of this regulation.

(41A) This Regulation does not create an empowerment for the secondary use of health data for the purpose of law enforcement. The prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties by competent authorities is not among the secondary use purposes covered under this Regulation. In addition, courts and other entities of the justice system are not covered under the definition of data holders, and are therefore not addressees of obligations on data holders under this Regulation.

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

Second round of comments:
If no, please, briefly explain your position during the WP meeting and send written comments.
If you have suggestions for minor modifications, please, just send written comments.
Deadline for written comments: 2023-09-15

Proposed modifications related to the secondary use of health data

[MOD.SU.1] Clarification of scope of secondary use of health data. [article 1(6A), recital (37)]

Modifications in the text

1) Modification of article 1(6) & Creation of article 1(6A)

2) Modification of recital (37)

Justification for the position of the Presidency

With the new wording, it is emphasized and clarified that the channel established in the EHDS for the access to health data for secondary use is an alternative to. Therefore, the EHDS does not affect or repeal any legally valid mechanism already in place for secondary uses of health data.

Replacing all existing channels and national / international data processing arrangements in the secondary use of health data with the "EHDS way" would have a very significant impact on health data use in the EU/EEA, and could have detrimental effects.

Given the concerns of some delegations, we have added clarifications to that effect in **article 1(6A)**. This clarification is also in line with the intention of COM in the proposal for this Regulation.

This clarification was also included in **recital (37)** for coherence purposes:

> **Without hindering or replacing contractual or other voluntary mechanisms in place, this Regulation is aimed at establishing a common mechanism to access electronic health data for secondary use.** (...)

Also, in recital (37), the following corrections are introduced specifically related to the GDPR and EUDPR, for reasons of legal technique:

1) **Wording of the Swedish compromise text:**
(...) At the same time, the data applicant should demonstrate a legal basis pursuant to Article**s** 6 **and 9** of Regulation (EU) 2016/679 **or Articles 5 and 10 of Regulation (EU) 2018/1725, where applicable**, (...)

   New proposed wording:
(...) At the same time, the data applicant should demonstrate a legal basis pursuant to Article 6 ~~**and 9**~~ of Regulation (EU) 2016/679 **or Article 5 ~~and 10~~ of Regulation (EU) 2018/1725, where applicable**, based on which they could request access to **electronic health** data pursuant to this Regulation and should fulfil the conditions set out in Chapter IV. (...)

   Justification: The intention of the proposal is that it provides the safeguards needed under Arts. 9 / 10 GDPR / EUDPR, which is why further down in the recital, when referring to what the applicant/user should explain, we only refer to Arts. 6 / 5.

2) **Wording of the Swedish compromise text:**
(...)In the case where the **health data** user has access to **personal** electronic health data (for secondary use of data for one of the purposes defined in this Regulation), the **health** data user should demonstrate its legal basis pursuant to Articles 6(1), points (e) or (f), of Regulation (EU) 2016/679 **or pursuant to Articles 5(1), points (e) or (f) of Regulation (EU) 2018/1725**(...)

   New proposed wording:
(...) In the case where the **health data** user has access to **personal** electronic health data (for secondary use of data for one of the purposes defined in this Regulation), the **health** data user should demonstrate its legal basis pursuant to Articles 6(1), points (e) or (f), of Regulation (EU) 2016/679 **or pursuant to Articles 5(1), points (e) ~~or (f)~~ of Regulation (EU) 2018/1725**
(...)

Justification: The grounds for lawful processing have a different order in EUDPR - "performance of a task in the public interest" is (a), legitimate interest doesn't exist.

3) **Wording of the Swedish compromise text:**
(…) If the lawful ground for processing by the **health data** user is Article 6(1), point (f), of Regulation (EU) 2016/679 **or Article 5(1), point (f), of Regulation (EU) 2018/1725**, in this case it is this Regulation that provides the safeguards. (...)

New proposed wording:
(...) If the lawful ground for processing by the **health data** user is Article 6(1), point (f), of Regulation (EU) 2016/679 ~~**or Article 5(1), point (f), of Regulation (EU) 2018/1725**~~, in this case it is this Regulation that provides the safeguards. (...)

Justification: Article 6(1)(f) (legitimate interest) GDPR has no equivalent in EUDPR - as the addressees of EUDPR are only the EUIBs as public sector bodies, see also 6(1), second subparagraph of GDPR explaining that public authorities when exercising their tasks cannot use (f) (… their tasks are supposed to be laid down by law, and covered under (e)).

Modifications in articles:

Article 1

Subject matter and scope

6. This Regulation shall not affect the rights and obligations laid down in Union or national law concerning **electronic** health data processing for the purposes of reporting, complying with **access to** information requests or demonstrating or verifying compliance with legal obligations~~, and is without prejudice to Union or national law providing for access to electronic health data by public sector bodies or EU institutions, bodies and agencies~~ [AMMENDED AND MOVED TO ARTICLE 6A]

6A. **This Regulation shall be without prejudice to Union or national law providing for access to electronic health data by public sector bodies of the Member States, EU institutions, bodies and agencies, and without prejudice to any access to electronic health data for secondary use for specific purposes that is based on contractual or administrative arrangements between public or private entities established in the EU or based on bilateral agreements with third countries.**

Modifications in recitals:

[MOD.SU.1] Clarification of scope of secondary use of health data.
[article 1(6A), recital (37)]

(37) **Without hindering or replacing contractual or other voluntary mechanisms in place, this Regulation is aimed at establishing a common mechanism to access electronic health data for secondary use.** For the secondary use of the ~~clinical~~ **electronic health** data for research, innovation, policy making, regulatory purposes, patient safety or the treatment of other natural persons, the possibilities offered by Regulation**s** (EU) 2016/679 **and (EU) 2018/1725** for ~~a~~ Union law**s** should be used as a basis and rules and mechanisms and providing suitable and specific measures to safeguard the rights and freedoms of the natural persons. This Regulation provides the legal basis in accordance with ~~Articles 9(2) (g), (h), (i) and (j) of~~ Regulation (EU) 2016/679 **and (EU) 2018/1725** for the secondary use of **personal electronic** health data, establishes~~ing~~ the safeguards for processing, in terms of lawful purposes, trusted governance for providing access to health data (through health data access bodies) and processing in a secure environment, as well as modalities for data processing, set out in the data permit. At the same time, the data applicant should demonstrate a legal basis pursuant to Article 6 **and 9** of Regulation (EU) 2016/679 **or Article 5 ~~and 10~~ of Regulation (EU) 2018/1725, where applicable**, based on which they could request access to **electronic health** data pursuant to this Regulation and should fulfil the conditions set out in Chapter IV. More specifically: for processing of electronic health data held by the **health** data holder pursuant to this Regulation, this Regulation creates the legal obligation in the sense of Article 6(1) point (c) of Regulation (EU) 2016/679, **in accordance with Article**

9(2)(i) and (j) of the same Regulation for disclosing ~~the~~ **personal electronic health** data by the **health** data holder to health data access bodies, while the legal basis for the purpose of the initial processing (e.g. **providing** ~~delivery of~~ **health**care) is unaffected. ~~This Regulation also meets the conditions for such processing pursuant to Articles 9(2) (h),(i),(j) of the Regulation (EU) 2016/679~~. This Regulation **also** assigns tasks in the public interest to the health data access bodies ~~(running the secure processing environment, processing data before they are used, etc.)~~ in the sense of Article 6(1)(e) of Regulation (EU) 2016/679 to the health data access bodies, and meets the requirements of Article 9(2)~~(h),(~~i),(j) of the Regulation (EU) 2016/679 **for the health data access body´s processing of personal electronic health data when the body is fulfilling its tasks to gathering, combining, preparing, including pseudonymisation and anonymisation of the data, and make those data available to the health data user for secondary use on the basis of a data permit or a data request**. ~~Therefore, in this case, this Regulation provides the legal basis under Article 6 and meets the requirements of Article 9 of that Regulation on the conditions under which electronic health data can be processed.~~ In the case where the **health data** user has access to **personal** electronic health data (for secondary use of data for one of the purposes defined in this Regulation), the **health** data user should demonstrate its legal basis pursuant to Articles 6(1), points (e) or (f), of Regulation (EU) 2016/679 **or pursuant to Articles 5(1), points (e) ~~or (f)~~ of Regulation (EU) 2018/1725** and explain the specific legal basis on which it relies as part of the application for access to electronic health data pursuant to this Regulation: on the basis of the applicable legislation~~, where the legal basis under Regulation (EU) 2016/679 is Article 6(1), point (e), or on Article 6(1), point (f), of Regulation (EU) 2016/679~~. If the **health data** user relies upon a legal basis offered by Article 6(1), point (e) **of Regulation (EU) 2016/679 or Article 5(1), point (e) of Regulation (EU) 2018/1725**, it should make reference to another EU or national law, different from this Regulation, mandating the **health data** user to process personal health data for the compliance of its tasks. If the lawful ground for processing by the **health data** user is Article 6(1), point (f), of Regulation (EU) 2016/679 **~~or Article 5(1), point (f), of Regulation (EU) 2018/1725~~**, in this case it is this Regulation that provides the safeguards. In this context, the data permits issued by the health data access bodies are an administrative decision defining the conditions for the access to the data.

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

Second round of comments:
If no, please, briefly explain your position during the WP meeting and send written comments.
If you have suggestions for minor modifications, please, just send written comments.
Deadline for written comments: 2023-09-15

[MOD.SU.2] Definition of data holder + definition of healthcare + definition of care + exclusions to the definition of data holder.

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Modifications in the text
1) No modification of 'healthcare', in **article 2(1)(b)**. **2)** New definition of 'care' in **article 2(1)(ba)** & amendment of **recital (40)**. **3)** Modification of 'data holder' in **article 2(2)(y)**. **4) Article 35B(5)** moved to **new article 33A(a)** and amended.
Justification for the position of the Presidency
Source of the modifications: verbal comments on the WPs 2023-07-04, 2023-07-05, 2023-07-14 & written comments from delegations. As a summary, 1) there was an ample agreement to use the definition of 'healthcare' from Directive 2011/24/EU. This was already in the text in **article 2(1)(b). No modifications were introduced in article 2(1)(b).** 2) there were several ideas of improvement upon the definition of 'care' proposed by the Presidency. We have tried to incorporate them in **article 2(1)(ba).** 3) there were several wording suggestions for the definition of data holder proposed by the Presidency. We have done our best to incorporate most of them in the modification of **article 2(2)(y)**. 4) there was an ample agreement to exclude natural persons. This has been reflected in **article 33A(b)**.
Detailed explanation of the wording

Definition of healthcare
article 2(1)(b) is left as itis: **(b)** the definitions of 'healthcare', 'Member State of affiliation', 'Member State of treatment', 'health professional', 'healthcare provider', 'medicinal product' and 'prescription', pursuant to Article 3 (a), (c), (d), (f), (g), (i) and (k) ~~of Article 3~~ of the Directive 2011/24/EU;
Additional explanations: The definition of 'healthcare' in Directive 2011/24/EU is as follows: *'healthcare' means 'health services provided by health professionals to patients to assess, maintain or restore their state of health, including the prescription, dispensation and provision of medicinal products and medical devices;'*

Definition of care
Article (2)(1) **(ba)** **'care' means a professional service the purpose of which is to address the specific need of a person who, on account of impairment or other physical or mental conditions requires assistance from another person or persons to carry out essential activities of daily living in order to support their personal autonomy.**
Additional explanations: This definition includes: - nursing homes,

- day-care centres,
- services for people with disabilities,
- business and technological activities related to care such as orthopaedics,
- companies providing care services.

This is reflected in the modification of **recital (40):**
Also included in the obligations category of data holders in the care sector are entities in the care sector such as nursing homes, day-care centres, entities providing services for people with disabilities, business and technological activities related to care such as orthopaedics and companies providing care services.

Definition of health data holder in article 2(2)(y)

(y) '**health** data holder' means **any natural ~~or legal~~ person, entity or body**

- ~~**any natural or legal person**~~ **developing products or services intended for the health, healthcare or care sectors,**

- **developing or manufacturing wellness applications,**

- ~~**any natural or legal person**~~ performing research in relation to the **health**, health**care** or care sector**s,**

- ~~**which is an entity or body of**~~ the **health,** healthcare or care sector**s,**

- ~~**as well as**~~ **and any** Union institution, body, office or agency;

who has theright or obligation, in accordance with this Regulation, applicable Union law or national legislation implementing Union law **either:**

(a) the right or obligation, in accordance with applicable Union law or national legislation, to process personal electronic health data for the provision of healthcare or care or for public health, reimbursement, research, innovation, policy making, official statistics, patient safety or regulatory purposes, in its capacity as a controller; or

○ **(b) the ability to make available, including to register, provide,restrict access or exchange anonymous electronic health data** non-personal data, through control of the technical design of a product and related services, the ability to make available, including to register, provide, restrict access or exchange certain data;

Additional explanations:

- In **article 33A(b)** natural persons are excluded from the obligations of being data holders , but the possibility of including them at the Member State level is also provided (some MS wish to include GPs who are natural persons or individual researchers in the scope). For that to be possible, natural persons are included in the potential scope of article 2(2)(y). The reference to 'legal persons' is removed and replaced by the more generic 'entities or bodies'[1], to avoid any loopholes for entities

[1] Note about 'entities or bodies'. In EU law, the terms "entity" and "body" are used in various contexts and their meanings can differ based on that context. Both terms can refer to organizations or units that might have specific roles or functions within the EU legal framework, but they don't necessarily imply the same thing as "legal persons" in the sense of entities that can hold rights and obligations.

- Entity: This term is broader and can encompass a wide range of organizations, units, or structures. It can refer to public entities, private entities, non-governmental organizations, and more. Depending on the context, an "entity" in EU law might refer to any organized body, irrespective of its legal personality. It's often used in contexts where the law wants to cast a wider net, encompassing all possible types of organized groups or units, without necessarily specifying their legal form or nature.

or bodies which may not be clearly a natural or a legal person, but may still be data holders[2].

- Several delegations have proposed clarifications and corrections, which do not imply a significant expansion or reduction of scope. In particular, several delegations have requested a more verbose, but more precise and consistent definition of health data holder. We thus reiterate several times 'any entity or body', 'healthcare or care sectors' in paragraph 1 of the definition.

- two delegations believe that the scope of data holder is too wide and believed that an impact assessment must be carried. Whilst this concern is very legitimate and justified, this is currently a minority position and the Presidency has chosen to move forward with the majority position which wants to expand scope compared to COM's initial proposal.

- two delegations suggested the removal of ~~*an entity or a body [performing activities] in the health or care sector;*~~, stating that it was redundant with *any natural or legal person entity or body developing products and services intended for the healthcare or care sectors*. Although there is indeed some redundancy, the Presidency has chosen to refrain from this modification. The phrase *any natural or legal person entity or body developing products and services intended for the healthcare or care sectors* mainly has the intention to include private companies developing products and services, such as software providers, providers of medical devices and pharma companies. On the other hand, the phrase *any entity or body of the healthcare or care sectors;* refers to healthcare or care providers themselves.

- one delegation proposed to expand the scope to data processors (in the case of personal data). However, the expansion to data processors does not seem feasible, as these can be unaware of the data categories they are processing (for example, a public entity may be acting as a hosting provider for another public entity in the healthcare sector. The first entity would be a data processor, most often without knowledge of the data it stores, belonging to the data controller, which would be the second entity). Also, in the GDPR logic, processors should not be making determinations about the data, but rather acting on the instructions of the controller. It is the controller who should be the addressee of the data holder's obligations. This change has not been incorporated. However, the

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- Body: In the context of the EU, when you encounter the term "body," it often refers to specific institutional structures or agencies within the European Union itself, like the European Central Bank, the European Institute of Innovation & Technology, or the various agencies and decentralized bodies. The term can also be found in national contexts when referring to specific public institutions or authorities.

Both "entity" and "body" might refer to what we think of as "legal persons" in the sense that they can hold rights, enter into agreements, or be bound by EU law. However, not every entity or body will automatically have the full scope of rights and obligations that legal persons have under civil or commercial law. There may be "entities" that do not neatly fit in the definition of "legal person" (or "natural person"). Please, see the next footnote comment for details.

[2] Note about entities which may not be legal or natural persons. From a legal perspective, both natural persons (individual human beings) and legal persons (entities like corporations, partnerships, or governmental entities) have rights and obligations under the law. However, there are constructs or entities that don't neatly fit into either of these categories. Here are some examples:

- Research groups and infrastructures: A group of researchers from several universities or insituitions may not constitute a legal person. Rather, they would, most likely, be joint controllers of a database with health data.
- Trusts: In many jurisdictions, a trust is not a legal person, but rather a relationship where assets are held by one party (the trustee) for the benefit of another (the beneficiary). The trust itself does not have separate legal personality, though the trustee does.
- Unincorporated Associations: Some groups or associations don't have a separate legal personality, even though they might have a distinct existence and specific members. They might have some rights and obligations but don't fully fit the definition of a legal person.
- Partnerships (in some jurisdictions): In some legal systems, certain types of partnerships don't have a separate legal personality, unlike corporations. This means that the individual partners are personally liable for the partnership's debts and obligations.
- Joint Ventures: Sometimes two or more entities might collaborate on a specific project without creating a new legal entity. The joint venture might have its own assets, liabilities, and operations, but it might not be a legal person.
- Digital and Artificial Entities: With advancements in technology, new questions arise about the status of digital entities or advanced AI systems. There's ongoing debate about whether such entities could or should have any legal status independent of being property of natural or legal persons.

In all these cases, while these entities might have certain rights, obligations, or roles in the legal system, they don't neatly fit into the categories of "natural" or "legal" persons. The specifics can vary widely based on the jurisdiction and the context.

current wording does *not* exclude data processors from the obligations, it's only that the addressee of the obligations of data holder should be the data controller and his processors should act upon his instructions.

- two delegations stated the need of explicitly including wellness applications, another delegation stated that the current wording did not in fact include wellness applications. We have thus explicitly included wellness applications in **article 2(2)(y)**

(y) '**health** data holder' means **any natural ~~or legal~~ person, entity or body**

(...)

developing or manufacturing wellness applications,

(...)

We have also amended **recital (40)**.
- Applicability to entities or bodies developing new products or services for the health or care sectors and those already having products and services on those markets is clarified in an amendment to **recital (40);**

Entities or bodies, such as private companies in the technological sector, developing products and services intended for the healthcare or care sectors, as well as entities of bodies developing welness applications. This obligation applies both if these entities or bodies are developing new products or services, or if they already have products on the market.

Exclusions of applicability of Chapter IV to certain data holders

Article 33A

Applicability to health data holders

~~The requirement in t~~This ~~article~~ **Chapter** shall not apply to**:** ~~individual researchers and~~

[MOVED FROM ARTICLE 35B(5)]

(a) health data holders that qualify as micro-enterprises as defined in Article 2 of the Annex to Commission Recommendation 2003/361/EC. **Member States may provide by law that this Chapter shall apply to these health data holders.**

(b) natural persons. Member States may provide by law that this Chapter shall apply to these health data holders.

(…)

Additional explanations:
Article 33A clarifies that the whole Chapter IV (not just one article) does not apply to the entities excluded from the obligations of data holders. In particular,

- natural persons are excluded, as there seems to be an ample consensus in this regard. Generally speaking, from an implementability point of view, it is rather complicated to foresee how a natural person would become aware of his/her obligations as a data holder, and how he/she would be able to comply with the obligations of a data holder. However, one important exception are individual general practitioner/medical professionals as "profession liberale". They should be able to keep abreast of regulatory developments in their field (possibly with help of professional associations) and they could be expected to share their datasets. Also, in some cases, individual researchers who are natural persons could also be included in the scope. Since some MS wish to include GPs and individual

researchers in the scope, we have allowed this possibility at the national level.

- micro-enterprises[3] are excluded. This was in COM's original proposal. Some MS have stated the desire to include micro-enterprises, and the Swedish Presidency decided to include this possibility in the text. No delegation opposed this change and the Spanish Presidency has also kept it.
- Two delegations wanted to exclude small enterprises[4] from the scope of the obligations of data holders. However, this approach would significantly limit the amount of data available, as the only entities left as data holders would be medium and large enterprises or organizations, and could -in some countries- lead to the exclusion of a sizable amount of their healthcare sector. Also, given the definition of small enterprise, it would seem that those entities should have sufficient resources to comply with their obligations as data holders.

Modifications in articles:

Article 2

Definitions

(ba) 'care' means a professional service the purpose of which is to address the specific need of a person who, on account of impairment or other physical or mental conditions requires assistance from another person or persons to carry out essential activities of daily living in order to support their personal autonomy. [MOD.SU.2]

(y) '**health** data holder' means **any natural ~~or legal~~ person, entity or body**

- ~~**any natural or legal person**~~ **developing products or services intended for the health, healthcare or care sectors,**
- **developing or manufacturing wellness applications,**
- ~~**any**~~ ~~**natural or legal person**~~ performing research in relation to the **health**, health**care** or care sector**s,**
- ~~**which is an**~~ ~~**entity or body of**~~ the **health,** healthcare or care sector**s,**
- ~~**as well as**~~ **and any** Union institution, body, office or agency; **[MOD.SU.2]**

who has the right or obligation, in accordance with this Regulation, applicable Union law or national legislation implementing Union law **either:**

(a) the right or obligation, in accordance with applicable Union law or national legislation, to process personal electronic health data for the provision of healthcare or care or for public health, reimbursement, research, innovation, policy making, official statistics, patient safety or regulatory purposes, in its capacity as a controller; or

[3] 'micro-enterprises' within the EU can be found in the Recommendation 2003/361/EC concerning the definition of micro, small, and medium-sized enterprises. According to this recommendation, micro-enterprises are defined as enterprises which:
- Have fewer than 10 employees, and
- Have either an annual turnover not exceeding EUR 2 million or an annual balance sheet total not exceeding EUR 2 million.

[4] According to Recommendation 2003/361/EC, 'small enterprises' are defined as enterprises which:
- Have fewer than 50 employees, and
- Have either an annual turnover not exceeding EUR 10 million or an annual balance sheet total not exceeding EUR 10 million.

(b) the ability to make available, including to register, provide, restrict access or exchange anonymous electronic health data non-personal data, through control of the technical design of a product and related services, the ability to make available, including to register, provide, restrict access or exchange certain data;

Article 33A

Applicability to health data holders

~~The requirement in t~~This ~~article~~ **Chapter** shall not apply to**:** ~~individual researchers and~~

(a) health data holders that qualify as micro-enterprises as defined in Article 2 of the Annex to Commission Recommendation 2003/361/EC. **Member States may provide by law that this Chapter shall apply to these health data holders.**

(b) natural persons. Member States may provide by law that this Chapter shall apply to these health data holders. [MOD.SU.2]

(…)

Modifications in recitals:

[MOD.SU.2] Definition of data holder + definition of healthcare + definition of care + exclusions to the definition of data holder.

(40) The data holders can be public, non for profit or private health or care providers, public, non for profit and private organisations, associations or other entities, public and private entities that carry out research with regards to the **healthcare or sectors, entities developing products and services intended for the healthcare or care sectors** and Union institutions, bodies, offices or agencies that process the categories of health and healthcare ~~related~~ data mentioned above. In order to avoid a disproportionate burden ~~on small entities,~~ **natural persons and** micro-enterprises are**, as a general rule, excluded from the application of Chapter IV** ~~excluded from the obligation to make their data available for secondary use in the framework of EHDS.~~ The public or private entities often receive public funding, from national or Union funds to collect and process electronic health data for research, statistics (official or not) or other similar purposes, including in area where the collection of such data is fragmented of difficult, such as rare diseases, cancer etc. Such data, collected and processed by data holders with the support of Union or national public funding, should be made available by data holders to health data access bodies, in order to maximise the impact of the public investment and support research, innovation, patient safety or policy making benefitting the society. In some Member States, private entities, including private healthcare providers and professional associations, play a pivotal role in the health sector. **Also included in the obligations category of data holders in the care sector are entities in the care sector such as nursing homes, day-care centres, entities providing services for people with disabilities, business and technological activities related to care such as orthopaedics and companies providing care services. Entities or bodies, such as private companies in the technological sector, developing products and services intended for the healthcare or care sectors, such as EHR systems, are also included in the definition of data holders, as well as entities of bodies developing wellness applications. This obligation applies both if these entities or bodies are developing new products or services, or if they already have products on the market.** The health data held by such providers should also be made available for secondary use. At the same time, data benefiting from specific legal protection such as intellectual property from medical device companies or pharmaceutical companies often enjoy copyright protection or similar types of protection. However, public authorities and regulators should have access to such data, for instance in the event of pandemics, to verify defective devices and protect human health. In times of severe public health concerns (for example, PIP breast implants fraud) it appeared very difficult for public authorities to get access to such data to understand the causes and knowledge of manufacturer concerning the defects of some devices. The COVID-19 pandemic also revealed the difficulty for policy makers to have access to health data and other data related to health. Such data should be made available for public and regulatory activities, supporting public bodies to carry out their legal mandate, while complying with, where relevant and possible, the protection enjoyed by commercial data. Specific rules in relation to the secondary use of health data should be provided. Data altruism activities may be carried out by different entities, in the context of Regulation […] [Data Governance Act COM/2020/767 final] and taking into account the specificities of the health sector.

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

Second round of comments:
If no, please, briefly explain your position during the WP meeting and send written comments.
If you have suggestions for minor modifications, please, just send written comments.
Deadline for written comments: 2023-09-15

Revision of article 33(1). Current wording & suggestions by "drafting group IV"

What follows is a discussion about the proposal made about article 33(1) by "drafting group IV", formed by experts from the Member States.

While other modification suggestions have been made by this drafting groups, they are addressed in other points of this WP meeting or shall be addressed in later discussions (such as article 72).

Option 1: **Swedish compromise text:**

Article 33

*Minimum categories of electronic **health** data for secondary use*

Option 2: **Proposal from drafting group IV:**

Article 33
Minimum categories of electronic ~~health~~ data for secondary use

Justification:
• The addition if read in the meaning of the current definition in Article 2 could exclude data on determinants of health (such as environmental factors) or related to healthcare administration/the healthcare system, as they might not be related to a person (e.g. the data now in category (dd))
• Should be aligned with the final definitions of "electronic health data". If the definition is wide, "health" could be kept. If the definition is narrow, it should be deleted in order not to exclude e.g. environmental or administrative/aggregated data.
• The drafting group would like to point out that we are aware that the provisions of Chapter IV are related to "electronic health data", starting from purposes for which these data can be used (Art. 34) to all kind of other obligations (e.g. the declaration of electronic health data in the catalogue). The group is open to use "electronic health data" rather than "electronic data" in Art. 33 81) if a wide definition of electronic health data that covers all categories in article 33(1) is used. This could also help to include legal certainty.
• Potentially, the definition of electronic health data could also relate to article 33(1)

First round of comments:
Please, choose one option:
Option 1) Swedish compromise text
Option 2) the proposal from drafting group IV
Option 3) another wording

Second round of comments:
If you choose option 3), please take the floor, and send written comments.
If you have suggestions for minor modifications, please, just send written comments.
Deadline for written comments: 2023-09-15

Option 1: **Swedish compromise text:**

- 1. **This Chapter shall apply to** ~~Data holders shall make~~ the following categories of electronic **health** data ~~available for secondary use in accordance with the provisions of this Chapter~~:

Option 2: **Proposal from drafting group IV:**

1. **Health data holders shall make** the following categories of electronic data **available for secondary use in accordance with the provisions of this Chapter**:

Justification from drafting group IV:
Based on a discussion within the drafting group, the original version of the draft regulation text is preferable:
"Data holders shall make the following categories of electronic data available for secondary use in accordance with the provisions of this chapter"

• In order to create legal certainty, the data holders should be named as the ones making data available.
• The formulation in the 2nd compromise proposal, "This Chapter shall apply to" would apply to any secondary use of health data, not just use under EHDS.
• "health" is deleted with the same reasoning as above, might be limiting too much.
• Referring to making data available for secondary use in accordance with the provisions of this chapter adds clarity when the data needs to be provided by data holders.

The addition of 'health', if read in the meaning of the definition in Article 2, could exclude data on determinants of health (such as environmental factors) or related to healthcare administration/the healthcare system, as they might not be related to a person (e.g. the data now in category (d))

First round of comments:
Please, choose one option:
Option 1) Swedish compromise text
Option 2) the proposal from drafting group IV
Option 3) another wording

Second round of comments:
If you choose option 3), please take the floor, and send written comments.
If you have suggestions for minor modifications, please, just send written comments.
Deadline for written comments: 2023-09-15

Option 1: Swedish compromise text:

(a) **health data from** EHRs **processed in a structured form**;

Comment from the Presidency:
In the Swedish compromise text, the idea of using structured data from EHRs was two-fold:
- structured data is of better quality than unstructured data.
- usage of structured data reduces the probability of accidentally and unintentionally making available for reuse data categories not included in article 33(1).

Option 2: Proposal from drafting group IV:

(a) **electronic health data from** EHRs **processed in a structured form, if available**

Justification from drafting group IV:
We recommend including this addition "if available" as Art. 33 1(a) should not introduce structuring requirements for EHR data, but should only apply to already structured data

Suggestion:
The structuring requirements for data from EHR and EHR systems and probably other data categories shall be defined by the EHDS Board as one of its tasks under Article 65 (2) and should be explicitly taken up in this paragraph.

Comment from the Presidency:
The addition of "if available " seemns unnessary. Article 33 has always been about "making available what is there". If it's not there, it can't be made available and logically doesn't have to be.

Option 3: wording proposed by some delegations (similar to COM's original proposal)

(a) **health data from** EHRs ~~**processed in a structured form;**~~

Justification from the Presidency:
Some delegations have proposed to return to the wording proposed by COM, and to include unstructured data due to its potential for different kinds of research and also the increasing possibilities offered by modern AI technologies to transform unstructured data from EHRs into structured data.

First round of comments:
Please, choose one option:
Option 1) Swedish compromise text
Option 2) the proposal from drafting group IV
Option 3) the proposal from some delegations (COM's original proposal)
Option 4) another wording

Second round of comments:
If you choose option 3), please, briefly take the floor, and send written comments.
If you choose option 4), please, briefly take the floor, and send written comments.
If you have suggestions for minor modifications, please, just send written comments.
Deadline for written comments: 2023-09-15

Option 1: Swedish compromise text:

(b) **health** data **on** ~~impacting health, including social, environmental behavioural~~ determinants **of health, such as data having an effect on the health status, healthcare needs, resources allocated to healthcare, the provision of and universal access to healthcare as well as healthcare expenditure and financing, and the causes of mortality**;

Option 2: Proposal from drafting group IV:

(b) ~~data impacting health, including social, environmental behavioural determinants~~ **aggregated data on healthcare needs, resources allocated to healthcare, the provision of and access to healthcare as well as healthcare expenditure and financing, and the causes of mortality**~~;~~

Justification from drafting group IV:
The aim is to clarify what kind of data is meant here. In the version of the 2nd compromise proposal it t is still unclear which data is meant and potentially covers a wide array of data. Moreover, personal and aggregated/non-personal data are mixed.

Hence, the addidtion "aggregated" in order to clarify that where non-personal data is meant. Some of the original data categories (behavioural data etc.) are instead added under category (l) and (i). The goal is to establish a clearer relationship between the types of data listed here and the source they should come from. This is done in order to achieve a common understanding what is meant by these data.

It is up for discussion if this data category needs to be included in EHDS at all as it only relates to aggregated data. However, an advantage could be that the relevant data holders need to be able to connect to HDABs and are obliged to provide data if an application includes category (b).

We would like to see more detail in a recital on exactly what this might mean exactly.

Remark:
Probably a definition of aggregated data (including statistical data and aggregated personal data) could be included, but is by a majority not seen as absolutely necessary, it should also be explained in the recitals

First round of comments:

Please, choose one option:
Option 1) Swedish compromise text
Option 2) the proposal from drafting group IV
Option 3) another wording

Second round of comments:
If you choose option 3), please, briefly take the floor, and send written comments.
If you have suggestions for minor modifications, please, just send written comments.
Deadline for written comments: 2023-09-15

Option 1: Swedish compromise text:

- (c) ~~relevant~~ pathogen genomic data, impacting on human health;

Option 2: Proposal from drafting group IV:

(c) ~~relevant~~ pathogen data impacting on human health

Justification from drafting group IV:
• Limitation to pathogen genomic data excluded relevant data
• It should be put in the recitals that this includes data on pathogens that potentially impact human health as well – as there might be cases where it will turn out later what will have an impact or not.

First round of comments:
Please, choose one option:
Option 1) Swedish compromise text
Option 2) the proposal from drafting group IV
Option 3) another wording

Second round of comments:
If you choose option 3), please, briefly take the floor, and send written comments.
If you have suggestions for minor modifications, please, just send written comments.
Deadline for written comments: 2023-09-15

Option 1: Swedish compromise text:

(d) health**care**-related administrative data, including claims and reimbursement data;

Option 2: Proposal from drafting group IV:

(d) health**care**-related administrative data, including **insurance status,** claims and reimbursement data **and other administrative data relating to an individual's socioeconomic status, if available in a structured form**

Justification from drafting group IV:
• The added parts were previously listed under (n) and are taken up here in order to establish the necessary relation to the healthcare system.
• It should be clarified in the recitals that "socio-economic data here is limited to what already is part of the healthcare-related administrative data, no additional data sources need to be made available (no tax records, for example). Recitals should also take up that socioeconomic status includes professional status, education.

Comment from the Presidency:
Please note that the added parts which come from n) 'and other administrative data relating to an individual's socioeconomic status, if available in a structured form' are not necessarily related to healthcare.

First round of comments:

Please, choose one option:
Option 1) Swedish compromise text
Option 2) the proposal from drafting group IV
Option 3) another wording

Second round of comments:
If you choose option 3), please, briefly take the floor, and send written comments.
If you have suggestions for minor modifications, please, just send written comments.
Deadline for written comments: 2023-09-15

Option 1: Swedish compromise text:

(e) human **genomic**, genetic, ~~genomic,~~ ~~and~~ proteomic**, transcriptomic, epigenomic, metabolomic, lipidomic and other omic** data;

Option 2: Proposal from drafting group IV:

(e) human genetic and **genomic** data
(ea) **molecular data such as** , ~~and~~ proteomic**, transcriptomic, epigenomic, metabolomic, lipidomic and other omic** data

Justification from drafting group IV:
No change to the data to be included, only a re-organization in order to facilitate any discussions on specific safeguards for human genomic data that might not be needed for the other molecular data

According to the GDPR definition of "human genetic data", the term "genomic data" falls within the definitional framework and is listed in (e) for concreteness: Per GDPR retical 34:
"Genetic data should be defined as personal data relating to the inherited or acquired genetic characteristics of a natural person which result from the analysis of a biological sample from the natural person in question, in particular chromosomal, deoxyribonucleic acid (DNA) or ribonucleic acid (RNA) analysis, or from the analysis of another element enabling equivalent information to be obtained."

Accordingly, (ee) lists the molecular data that can be derived from genomic sequence data, such as proteomics, transcriptomics, epigenomic, metabolomic, lipodomic and other omic data.

We recommend bringing up in the recital extended clarifications on how the terms genetic data, genomic data and omics data (among others) are exactly defined and differentiated with appropriate justification and with the reference to GDPR.

First round of comments:
Please, choose one option:
Option 1) current compromise text of the presidency
Option 2) the proposal from drafting group IV
Option 3) another wording

Second round of comments:
If you choose option 3), please, briefly take the floor, and send written comments.
If you have suggestions for minor modifications, please, just send written comments.
Deadline for written comments: 2023-09-15

Option 1: Swedish compromise text:

(f) person generated ~~electronic~~ health data~~, including~~ **through** medical devices, wellness applications or other digital health applications;

Note: these experts of drafting group IV have NOT made suggestions for modifications in letter f) of the Swedish compromise text.

First round of comments:
Please, choose one option:
Option 1) Swedish compromise text
Option 2) another wording

Second round of comments:
If you choose option 2), please, briefly take the floor, and send written comments.
If you have suggestions for minor modifications, please, just send written comments.
Deadline for written comments: 2023-09-15

Option 1: Swedish compromise text:

(g) ~~identification~~ data **on professional status and role of** ~~related to~~ health professionals involved in the treatment of a natural person;

Option 2: Proposal from drafting group IV:

(g) ~~identification~~ data **on professional status, specialisation and** ~~role institution of related to~~ health professionals involved in the treatment of a natural person;

Justification from drafting group IV:
None provided

First round of comments:
Please, choose one option:
Option 1) current compromise text of the presidency
Option 2) the proposal from drafting group IV
Option 3) another wording

Second round of comments:
If you choose option 3), please, briefly take the floor, and send written comments.
If you have suggestions for minor modifications, please, just send written comments.
Deadline for written comments: 2023-09-15

Option 1: Swedish compromise text:

(h) population wide health data registries (public health registries);

Option 2: Proposal from drafting group IV:

(h) population**-based** health data registries (public health registries);

Justification from drafting group IV:
Adjustment to make clear that such registries might only cover part of the population (i.e. federal states, only women…)
Could otherwise be explained in the recital

First round of comments:
Please, choose one option:
Option 1) Swedish compromise text
Option 2) the proposal from drafting group IV
Option 3) another wording

Second round of comments:

If you choose option 3), please, briefly take the floor, and send written comments.
If you have suggestions for minor modifications, please, just send written comments.
Deadline for written comments: 2023-09-15

Option 1: Swedish compromise text:

(i) ~~electronic~~ health data from medical registries ~~for specific diseases~~;

Option 2: Proposal from drafting group IV:

(i) ~~electronic~~ data from medical registries **and mortality registries** ~~for specific diseases~~;

Justification from drafting group IV:
If under (d) only aggregated data on causes of death are provided, it needs to be made clear that data from mortality registries should be provided as well

First round of comments:
Please, choose one option:
Option 1) current compromise text of the presidency
Option 2) the proposal from drafting group IV
Option 3) another wording

Second round of comments:
If you choose option 3), please, briefly take the floor, and send written comments.
If you have suggestions for minor modifications, please, just send written comments.
Deadline for written comments: 2023-09-15

Option 1: Swedish compromise text:

(j) ~~electronic~~ health data from **fully completed** clinical trials;

Option 2: Proposal from drafting group IV:

(j) ~~electronic~~ ~~**health**~~ data from ~~**fully completed**~~ clinical trials **that have ended in accordance with Article 37(4) of regulation 536/2014 and Article 77(5) of 2017/745;**

Justification from drafting group IV:
We need to refer to clinical trials that ended according to CTR and MDR, since "fully completed" is not defined in those regulations.

Option 3: Proposal from the Presidency (slight correction of option 2).

(j) ~~electronic~~ ~~**health**~~ data from ~~**fully completed**~~ clinical trials **and clinical investigations that have ended in accordance with Article 37(4) of Regulation (EU) 536/2014 and Article 77(5) of Regulation (EU) 2017/745, respectively;**

Justification from the Presidency:
"clinical investigations" is the term used in the MDR for the functional equivalent to clinical trials.

Option 4: another wording

Comment from the Presidency:
The Presidency recommends caution in changes to article (j). If the meaning is changed in such a way that ongoing clinical trials are included, this could act as a disincentive to conduct clinical trials in the EU/EEA.

First round of comments:
Please, choose one option:
Option 1) Swedish compromise text
Option 2) the proposal from drafting group IV
Option 3) the proposal from the Presidency (slight correction of option 2).
Option 4) another wording

Second round of comments:
If you choose option 4), please, briefly take the floor, and send written comments.
If you have suggestions for minor modifications, please, just send written comments.
Deadline for written comments: 2023-09-15

Option 1: Swedish compromise text:

(k) ~~electronic~~ health data from medical devices and from registries for medicinal products and medical devices;

Option 2: Proposal from drafting group IV:

(k) ~~electronic~~ health data from medical devices ~~and~~
(ka) data from registries for medicinal products and medical devices;

Justification from drafting group IV:
(k) For this category it should be clarified in a recital what is actually meant. "Health data" implies a limitation to data that is related to prevention, diagnostics and treatment, however it is not completely clear.

(ka) is separated from (k) and introduced as a new category as registries are very different from data from medical devices. Creating a new category allows for step—wise implementation according to Art. 72. Registries will most likely be easier to include into the EHDS for most member states than data from medical devices. Thus, a longer implementation period for (k) could help MS in implementation.

First round of comments:
Please, choose one option:
Option 1) Swedish compromise text
Option 2) the proposal from drafting group IV
Option 3) another wording

Second round of comments:
If you choose option 3), please, briefly take the floor, and send written comments.
If you have suggestions for minor modifications, please, just send written comments.
Deadline for written comments: 2023-09-15

(m) ~~electronic~~ health data from biobanks and **associated** ~~dedicated~~ databases;

Note: these experts of drafting group IV have NOT made suggestions for modifications in letter m) of the Swedish compromise text.

First round of comments:
Please, choose one option:
Option 1) Keep the Swedish compromise text for letter (m)
Option 2) Alternative wording

Second round of comments:
If you choose option 2), please take the floor, and send written comments.
If you have suggestions for minor modifications, please, just send written comments.
Deadline for written comments: 2023-09-15

Option 1: Swedish compromise text:

(l) **data from** research cohorts, questionnaires and surveys related to health;

Option 2: Proposal from drafting group IV:

(l) **data from** research cohorts, questionnaires **or** ~~**and**~~ surveys related to health **and potential determinants of health, such as social, environmental and behavioural factors and well-being, earliest one year after the end of the respective project collecting the data or, in case of longitudinal collections, after the first publication on the analysis of data;**

Justification from drafting group IV:

- Was previously listed under b

- Relating it explicitly to research ensures that it is (usually) collected with people's consent, with documented procedures and assessable quality

- Well-being instead of "wellness data" in order to establish a clearer connection to the health status

Remark:

- *The drafting group is also open to moving this addition: as the addition on category (j), could also be added as a new para under 35(B), duties of health data holders, as it is a temporal qualifying element.*

First round of comments:
Please, choose one option:
Option 1) Swedish compromise text
Option 2) the proposal from drafting group IV
Option 3) another wording

Second round of comments:
If you choose option 3), please, briefly take the floor, and send written comments.
If you have suggestions for minor modifications, please, just send written comments.
Deadline for written comments: 2023-09-15

[MOD.SU.3] IP rights and trade secrets. [article 35A, article 35B(1), article 35B(1.a), article 37(1)(ii), recital (40A)]

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Modifications in the text

1) Modification of article 35A(1) reinforcing the measures to be taken to preserve the confidentiality of IP rights and trade secrets. In particular, the Spanish Presidency has made a more general statement compared to the Swedish compromise text, and has explicitly included legal measures (such as non-disclosure agreements).

Swedish compromise text:
(…) they shall take all specific **organisational and technical** measures necessary to preserve the confidentiality of such data. (...)

Spanish compromise text:
(...) they shall take all specific measures, **including legal, organisational, and technical** ones, necessary to preserve the confidentiality of such data**. The data holder shall not have a veto right on the adequacy of these measures.** (...)

Additional explanations for the modification of article 35A(1), already provided in the Flash note of the WP 2023-07-04. Amendments to the explanations already provided in this WP are underlined.

1) If the measures are based on the possible veto of the data holder, most data holders with information protected by IP rights and trade secrets can easily avoid the obligation to share these data. However, the HDAB (or other public entities involved in the secure provision of these data to the data user) would be, most likely, legally liable towards the data holder if it provided an inadequate degree of protection, so the HDAB (or other public entities involved in the secure provision of these data to the data user) itself could decide not to make the data available if the risk is too high, or make it available in a very restricted form.

2) Please note that specific measures for the protection of IP rights and trade secrets are likely to depend on the type of data user, the type of data holder, the data category and the purpose of the data access application / data request. There can be many different possibilities and it does not seem feasible to list them all or to include them in the text of the Regulation. However, we can provide some examples of legal, organizational and technical measures:

   - Example of a legal measure: non-disclosure agreements (NDAs) signed between health data users and health data holders. Templates for such agreements can be defined by the HDABs at the national level, although a common structure would be desirable to streamline cross-border data access applications and requests. In some cases, NDAs may be unnecessary if the technical measures ensure the protection of IP rights and trade secrets.

   - Example of an organizational measure: HDABs should define internal procedures for handling data protected by IP rights and trade secrets.

   - Example of a technical measure: configuration of the secure processing environment (SPE) in such a way that IP rights and trade secrets data are not accessible by the data user (by means of fine-grained access control, data removal, data encryption or a combination of the aforementioned measures).

   In the current compromise text, these organizational and technical measures can be defined in non-legally binding guidelines/recommendations issued by the EHDS Board (articles 64 and 65). In the particular case of "common electronic health data access contractual arrangements" (which may include non-disclosure agreements), these can be defined in legally binding implementing acts, as per article 47A(2). Other aspects can be defined at the national level.

   Given the above, in practice, health data protected by IP rights and trade secrets can be made available, but only when the necessary technical and organizational measures are taken to preserve both. In some cases, this may lead to a very small subset of the data made available to the data user. In very specific cases, the dataset may not be made available at all due to the impossibility of sufficient mitigation of risks to IP rights and trade secrets.

3) The presidency would like to highlight that one of the points that delegations raised was the need to protect IP rights and trade secrets in data from clinical trials. Therefore, article 33(1)(j) should, generally, retain its wording: "data from *fully completed* clinical trials". If data from non-completed clinical trials is accessible, this could act as a disincentive to attempt clinical trials in the EU/EEA, as some of these data are highly sensitive from the point of view of IP rights and trade secrets.

2) In **article 35B(1)** we introduced the following amendment, for clarity and coherence purposes:
"(…) **The health data holder shall inform the health data access body of such IP rights and trade secrets when communicating to the health data access body the dataset descriptions pursuant to Article 35B(2) for datasets it holds, but at the latest following a request received from the health data access body.**"

3) In **article 35B(1.a)** we introduced the following amendment, for clarity and coherence purposes:
"(…) **If the requested electronic health data is protected by IP rights and/or trade secrets, the health data holder shall justify to the health access body why such electronic data need specific protection. The health data holder may propose specific measure in order to ensure protection of such rights.**"

4) In **article 37(1)(ii)** we introduced the following amendment, for clarity and coherence purposes:
"(…) take all measures necessary to preserve the confidentiality of IP rights and of trade secrets **of electronic health data before those data are made available for secondary use pursuant to a data permit or a data request taking into account the relevant rights of both the health data holder and health data user**; (…)"

5) New **recital (40A)**.

Justification for the position of the Presidency

In the WP 2023-07-04 there was ample support for the proposed wording of article 35A(1), which we have slightly amended following the comments of the delegations.

Then, for coherency purposes, we have also modified article 35B(1), article 35B(2), article 37(1)(ii) and have also introduced a new explanatory recital 40A.

Modifications in articles:

Article 35A

IP-rights and trade secrets

1. Where the health data access body or other P**p**ublic sector bodies or Union´s institutions, agencies and bodies obtain access to electronic health data **from health data holders** entail~~n~~ing IP rights and trade secrets in the exercise of the tasks conferred to them by ~~Union law or national law~~ **this Regulation**, they shall take all specific measures, **including legal, organisational, and technical** ones, necessary to preserve the confidentiality of such data. **The data holder shall not have a veto right on the adequacy of these measures. [MOD.SU.3]** MOVED FROM ARTICLE 34(4) AND AMENDED, SEE ALSO ARTICLE 37(1)(ii)

2. The technical and organisational measures taken to preserve the confidentiality of electronic health data entailing IP rights and trade secrets referred to in paragraph 1 shall be made publicly available.

-

*Article ~~41~~**35B***

*Duties of **health** data holders*

1. ~~Where a~~ **A health** data holder is obliged to make **the** electronic health data ~~available~~ under Article 33 **they hold available upon request to the health data access body according to a data permit pursuant to Article 46 or data request pursuant to Article 47. Such electronic health data may also entail IP rights and trade secrets**~~or under other Union law or national legislation implementing Union law, it shall cooperate in good faith with the health data access bodies, where relevant~~. **The health data holder shall inform the health data access body of such IP rights and trade secrets when communicating to the health data access body the dataset descriptions pursuant to Article 35B(2) for datasets. It holds, but at the latest following a request received from the health data access body. [MOD.SU.2]** MOVED FROM ARTICLES 41(1) AND 33(4) AND AMENDED

1a. The **health** data holder shall put the **requested** electronic health data **referred to in paragraph 1** at the disposal of the health data access body within ~~2 months from receiving the request from the health data access body~~ **a reasonable time of up to 3 months determined by the health data access body**. ~~In exceptional cases,~~ **In justified cases, such as in complex and burdensome request,** ~~that period may be extended by~~ the health data access body **may extend this period by up to 3** ~~for an~~ additional ~~period of 2~~ months. **If the requested electronic health data is protected by IP rights and/or trade secrets, the health data holder shall justify to the health access body why such electronic data need specific protection. The health data holder may propose specific measure in order to ensure protection of such rights. [MOD.SU.2]** MOVED FROM ARTICLE 41(4) AND AMENDED

Article 37

Tasks of health data access bodies

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

(ii) take all measures necessary to preserve the confidentiality of IP rights and of trade secrets **of electronic health data before those data are made available for secondary use pursuant to a data permit or a data request taking into account the relevant rights of both the health data holder and health data user [MOD.SU.2];** MOVED FROM ARTICLE 37(1)(d)

Modifications in recitals:

MOD.SU.3] IP rights and trade secrets.
[article 35A, article 35B(1), article 35B(2), article 37(1)(ii), recital (40A)]

(40A) Electronic health data protected by intellectual property rights or trade secrets should be made available for secondary use. However, this Regulation should not be used to reduce or circumvent such protection. It is for the Health Data Access Body to assess how to preserve this protection while also enabling access to such data for health data user. If it is unable to so, it should inform the health data user and explain why it is not possible to provide access to such data.

Legal, organisational and technical measures to preserve intellectual property rights or trade secrets could include common electronic health data access contractual arrangements, specific obligations in relation to such rights within the data permit and configuration of the secure processing environment so that such data is not accessible by the health data user.

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

Second round of comments:
If no, please, briefly explain your position during the WP meeting and send written comments.
If you have suggestions for minor modifications, please, just send written comments.
Deadline for written comments: 2023-09-15

[MOD.SU.4] Opt-out in the secondary use of health data

Modifications in the text
Article 35F has been completely rewritten. A recital is pending, waiting for the feedback from the delegations based on revised Article 35F.
Justification for the position of the Presidency
After the discussions of the WP 2023-07-05 and written comments, the Presidency has proposed a new wording of the article. While we have enhanced flexibility for the Member States whenever possible (if requested by delegations), a common approach is necessary for opt-out/opt-in at the Union level. Otherwise: - there would be a lack of reciprocity between Member States: some would be able to request data from other countries, but would not be obliged to share data in an equivalent manner with other Member States. For example: Member State A has an opt-in system leading to <1% of its population having data available. Member State B has an opt-out system leading to >99% of its population having data available. - dataset representativity would strongly vary between Member States and would make EU-wide research unfeasible in many situations. The Presidency has, so far, refrained from introducing an opt-in for two reasons: - in most scenarios, opt-in/consent would lead to a very small percentage of the population making their data available. This could easily lead to a situation where the Member States would be forced to build a costly infrastructure (since they are obliged to do so by the EHDS Regulation) which would see little use and provide little value, as there would be little data available. - the practical implementation of an opt-in/consent system is rather problematic, since it should be possible to retire opt-in/consent at any time, even when the research based on the data is ongoing. This can easily lead to unstable datasets, which would be a significant problem for the data user (Example: "For the last month I, as a data user, could do my research based on data of 100 persons, but today I suddenly find out that I can only use the data of 98 persons, as 2 have decided to retire opt-in/consent. I have to repeat the research I have done so far!") and could act as a significant disincentive for the affected data categories or purposes of secondary data use.
Summary of the new article
- opt-in has not been introduced (for the reasons described above). - opt-out is not allowed for the purposes of article 34 (1), points (a) to (c). - opt-out is allowed for the rest of purposes of article 34. - opt-out applies to both data access applications and data access requests. - opt-out applies to data access application or data access requests started after the opt-out. There is no retroactivity: opt-out does not apply to research based on data access applications or data access requests started before the opt-out. This is due to technical implementability reasons and, especially, due to the need to guarantee a stability of the dataset for the data users (otherwise, in ongoing research, the dataset can change every minute). - opt-out may be exercised by natural persons or legal guardians (in the conditions defined by the Member States). - It must be possible to exercise opt-out at the Health Data Access Body. Additionally, Member States may allow opt-out at individual data holders. - Health Data Access Bodies shall maintain anonymous statistics for opt-out, to inform the data users about the representativity of a dataset. If opt-out is allowed by individual data holders, they shall have the same obligation. The presidency notes that this is necessary to adequately inform the data user of the representativity (and thus usefulness) of the dataset, before the payment of fees.

Modifications in articles:

Article 35F

The right to object for natural persons

1. Natural persons shall have the right to opt-out at any time and without stating reasons from their personal electronic health data being made available for secondary use pursuant to this Regulation. Legal guardians shall be able to exercise this right on behalf of the persons whose affairs the administer, in the conditions defined by the Member States.

2. The right to opt-out under this article shall not apply regarding secondary use for the purposes listed in Article 34 (1) points (a) to (c) by public sector bodies and Union institutions, bodies, offices and agencies in the situation of Article 34 (2).

3. Natural persons shall be able to indicate their opt-out separately for each of the categories of purposes listed in Article 34 (1)(d) to (h)

4. Where a natural person has opted out and their personal electronic health data can be identified in a dataset, their personal electronic health data shall not be made available for secondary use under data permits pursuant to Article 46 which are granted after the natural person has opted out. This shall not affect the processing of that person's electronic health data for secondary use in the scope of data permits granted before the natural person has opted out. Where a natural person has opted out, their personal electronic health data shall not be processed for secondary use following request for electronic health data in a statistical format pursuant to Article 47 approved after the natural person has opted out.

5. Opt-out shall be implemented at the Member State level in the following manner:

a. The health data access body shall provide technical means enabling natural persons to exercise the right referred to in paragraph 1. Such means may be stablished within the access services referred to in Article 8G or through other means. Where a Member State has established multiple health data access bodies, they shall provide easily understandable public information on their division of competences and cooperate among each other for the effective exercise of this right, if relevant.

b. Member States may also allow the exercise of opt-out by natural persons at the level of the health data holders.

6. If the purposes for which a health data holder processes personal electronic health data do not or do no longer require the identification of a data subject by the controller, the health data holder shall not be obliged to maintain, acquire or process additional information in order to identify the data subject for the sole purpose of complying with the right to opt out under this article.

7. The health data access bodies shall keep anonymous statistics about natural persons who have exercised the right to opt-out, in order to allow an assessment of the representativity of the dataset. If Member States allow opt-out by individual data holders, they shall have the same obligation.

8. The Commission shall, by means of implementing acts, determine the implementation measures of the right referred to in paragraph 1 and the detailed elements of the statistics referred to in paragraph 7. Those measures shall take into account the requirements of data protection by design and default laid down in Article 25 of Regulation (EU) 2026/679. Those implementing acts shall be adopted in accordance with the examination procedure in Article 68 (2).

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

Second round of comments:
If no, please, briefly explain your position during the WP meeting and send written comments.
If you have suggestions for minor modifications, please, just send written comments.
Deadline for written comments: 2023-09-15

[MOD.SU.5] Fees [article 42]

Modifications in the text
1) In **article 42(1)**, the reference to DGA is removed since these did not include consulting fees, which are a very significant cost of operation of HDABs. **2)** In **article 42(1)**, for reasons of legal technique, we clarify that reduced fees may be defined for certain groups of data users. Several delegations have expressed the desire to allow discounts at the national level for certain groups of data users such as university researchers. However, this was not explicitly allowed in the Swedish compromise text, and it was important to state this. This is also reiterated in **recital (47)** **3)** References to DGA are removed from **recital (47)**, for reasons of coherence with **article 42(1)**. o **4)** A clarification is introduced regarding fees charged to data users from third countries in **recital (47)**: (…) **On the other hand, health data access bodies should be able to cover the costs of their operation with fees, and this may lead to higher fees charged to third-country data users, established in a proportionate, justified and transparent manner, if servicing their data access applications and data requests requires more work in aspects such as compliance with Chapter V of the GDPR.** (…)
Justification for the position of the Presidency
Fees have been discussed during several July WPs. Given the comments in the WPs and the written comments from the delegations, the Presidency has decided to introduce minimal changes that had sufficient support behind them and to provide a recital with further clarifications.

Modifications in the article proposed by the Presidency:

Article 42

Fees

1. Health data access bodies ~~and~~ **or** single **health** data holders **referred to in Article 49** may charge fees for making electronic health data available for secondary use. **Such fees shall be in proportion to the cost of making the data available and not restrict competition. Such**~~Any~~ fees shall **cover all or part of** ~~include and be derived from the~~ costs related to ~~conducting~~ the procedure ~~for requests, including~~ for assessing a data **permit** application or a data request, granting, refusing or amending a data permit pursuant to Article 45 and 46 or providing an answer to a data request pursuant to Article 47, ~~in accordance with Article 6 of Regulation (EU) 2022/868~~ […] [Data Governance Act COM/2020/767 final]**, as well as costs related to the gathering, preparation and providing of the electronic health data**. **Reduced fees may be established by the Member States for certain types of data users located in the Union, such as university researchers or microenterprises. [MOD.SU.5]**

2. Where the **electronic health** data in question are ~~not~~ held by **a health data holder who is not a** ~~the~~ **health** data access body ~~or a public sector body~~, the fees **charged pursuant to paragraph 1** may also include compensation **for costs incurred by the health data holder compiling and preparing** ~~for part of the costs for collecting~~ the electronic health data **to be made available for secondary use** ~~specifically under this Regulation in addition to the fees that may be charged pursuant to paragraph 1~~. **When the health data holder is a public sector body, such fees shall be in accordance with Article 6 of Regulation (EU)2022/868.** The part of the fees linked to the **health** data holder's costs shall be paid to the **health** data holder.

~~3. The electronic health data referred to in Article 33(1), point (o), shall be made available to a new user free of charge or against a fee matching the compensation for the costs of the human and technical resources used to enrich the electronic health data. That fee shall be paid to the entity that enriched the electronic health data.~~

~~4. Any fees charged to data users pursuant to this Article by the health data access bodies or data holders shall be transparent and proportionate to the cost of collecting and making electronic health data available for secondary use, objectively justified and shall not restrict competition. The support received by the data holder from donations, public national or Union funds, to set up, develop or update tat dataset shall be excluded from this calculation. The specific interests and needs of SMEs, public bodies, Union institutions, bodies, offices and agencies involved in research, health policy or analysis, educational institutions and healthcare providers shall be taken into account when setting the fees, by reducing those fees proportionately to their size or budget.~~

~~5. Where data holders and data users do not agree on the level of the fees within 1 month of the data permit being granted, the health data access body may set the fees in proportion to the cost of making available electronic health data for secondary use. Where the data holder or the data user disagree with the fee set out by the health data access body, they shall have access to dispute settlement bodies set out in accordance with Article 10 of the Regulation […] [Data Act COM/2022/68 final].~~

5A. Before issuing a data permit pursuant to Article 46 or providing an answer to a data request pursuant to Article 47, the health data access body shall inform the applicant of the expected fees. The applicant shall be informed about the option to withdraw the application. If the applicant withdraws its application, the applicant shall only be charged the costs that have already been incurred.

6. ~~The Commission may, by means of implementing acts, lay down principles and rules for the fee policies and fee structures. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2).~~ **The Commission may, in close cooperation with EHDS Board, issue guidelines on fee policies and fee structures in order to support consistency and transparency between Member States.**

Modifications in recitals:

[MOD.SU.5][Fees][article 42(1)]

- (47) Health data access bodies and single data holders should be allowed to charge fees ~~based on the provisions of Regulation […] [Data Governance Act COM/2020/767 final]~~ in relation to their tasks. Such fees may take into account the situation and interest of SMEs, individual researchers or public bodies. **In particular, Member States may establish policies for health data access bodies in their jurisdiction allowing to charge reduce fees to certain categories of data users located in the Union. On the other hand, health data access bodies should be able to cover the costs of their operation with fees, and this may lead to higher fees charged to third-country data users, established in a proportionate, justified and transparent manner, if servicing their data access applications and data requests requires more work in aspects such as compliance with Chapter V of the GDPR.**

- Data holders should be allowed to also charge fees for making data available. Such fees should reflect the costs for providing such services. Private data holders may also charge fees for the collection of data. In order to ensure a harmonised approach concerning fee policies and structure, the Commission may adopt implementing acts. ~~Provisions in Article 10 of the Regulation [Data Act COM/2022/68 final] should apply for fees charged under this Regulation.~~

Alternative text from one delegation
Article 42 **1. Health data access bodies or single health data holders referred to in Article 49 may charge fees to the data user for making the data set available for secondary use. Such fees shall cover all or part of costs related to provisioning the data and handling the data permits pursuant to Article 45 and 46 or providing an answering to a data request pursuant to Article 47, in accordance with Article 6 of Regulation (EU) 2022/868.** **2. Data holders may charge fees to cover all other costs related to building the data set, which can include collecting, gathering, compiling, enriching, preparing the data set and**

improving its quality. By way of derogation from Article 6(5) of Regulation (EU) 2022/868, this includes health data holders which are public sector bodies. Such fees can be charged directly by the data holder or through the Health data access bodies.

3. All the fees shall be transparent, objectively justified, proportionate to the costs referred to in paragraph 1 and 2, and shall not restrict competition. The specific interests and needs of SMEs, public bodies, Union institutions, bodies, offices and agencies involved in research, health policy or analysis, educational institutions and healthcare providers shall be taken into account when setting the fees. The support received by the data holder from donations, public national or Union funds, to set up, develop or update that dataset shall be excluded from this calculation.

4. Before issuing a data permit pursuant to Article 46 or providing an answer to a data request pursuant to Article 47, the health data access body shall inform the applicant of the expected fees. The applicant shall be informed about the option to withdraw the application. If the applicant withdraws its application, the applicant shall only be charged the costs that have already been incurred.

5. Guidelines on indicative fee policies and fee structures may be adopted by the EHDS Board.

6. This article shall be without prejudice to the possibility for Member States to levy fees for the activities set out in this chapter, provided that the level of the fees is set in a transparent manner and on the basis of cost-recovery principles. Member States shall inform the Commission and the other Member States at least three months before the structure and level of fees is to be adopted. The structure and level of fees shall be made publicly available on request.

Justification (with a slight editorialization, removing the name of the Member State)**:**

The application of the DGA to the specific and sensitive sector of health data re-use seems problematic.

It would be important to take into account the concept of taking into account "full costs" that could cover the investment and costs involved by healthcare professionals who are bound by professional secrecy and with a high level of expertise, before considering making data available for secondary use.

First round of comments:
Please, choose one option:
option 1) the wording proposed by the Presidency
option 2) the new wording proposed by one delegation
option 3) a different wording

Second round of comments:
If you choose option 3, please briefly explain your position during the WP and send written comments.
If you have suggestions for minor modifications, please, just send written comments.
Deadline for written comments: 2023-09-15

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.
- CLS: Council of the European Union's Legal Service.

European Health Data Space

- EHDS: European Health Data Space[5].
- "original text" (of the EHDS): Commission proposal for the EHDS[6].
- "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.

Secondary use of health data

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

Other relevant legal acts of the European Union

- DA: Commission's proposal for a European Data Act[7].

[5] https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space_en
[6] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52022PC0197
[7] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2022%3A68%3AFIN

- DGA: final text for the (European) Data Governance Act[8], 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[9].

General Data Protection Regulation

- GDPR: General Data Protection Regulation[10], 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[11].

World trade organization agreements

- GATS: General Agreement on Trade in Services[12], to which the EU has made specific commitments[13].
- GATT: General Agreement on Tariffs and Trade[14].

[8] https://digital-strategy.ec.europa.eu/en/policies/data-governance-act
[9] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A52020PC0767
[10] https://eur-lex.europa.eu/EN/legal-content/summary/general-data-protection-regulation-gdpr.html
[11] https://commission.europa.eu/law/law-topic/data-protection/reform/what-are-data-protection-authorities-dpas_en
[12] https://www.wto.org/english/tratop_e/serv_e/gatsqa_e.htm
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[14] https://www.wto.org/english/tratop_e/gatt_e/gatt_e.htm