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MEETING DOCUMENT

From:	General Secretariat of the Council
To:	Working Party on Public Health (Attachés) Working Party on Public Health (European Health Data Space)
Subject:	Working Party on Public Health on 8 September 2023 - Presentation by the Presidency on the European Health Data Space

Delegations will find enclosed the presentation given by the Presidency during the Working Party on Public Health held on 8 September 2023.

PRESIDENCIA ESPAÑOLA CONSEJO DE LA UNIÓN EUROPEA

Working Party on Public Health

Friday 8th of September 2023

10:00-13:30 & 14:30-18:00

Working Party on Public Health – EHDS (2023/09/08)

0. Summary of the last WP meeting (25th of July, 2023)	Deadline for written comments
Third countries in the context of secondary use of health data	07 / 08 / 2023
• Possible scenarios • Fees (Article 42) • Possible requirement for HDABs and SPEs to store data exclusively in the EU/EEA • Higher discretionary power of Member States for data access applications from third countries (art 46 bis)	
Third countries in the context of primary use of health data	07 / 08 / 2023
• Possible scenarios and related provisions in the EHDS proposal	
1. Topics of today's meeting (8h of September)	
• 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	15 / 09 / 2023 COB

Proposal for modifications from the Spanish presidency, taking into account the comments of the delegations: *modifications are made over the Swedish compromise text:*

~~*double strikethrough*~~ *in the case of deletions*

double underline in the case of additions.

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

Working Party on Public Health – EHDS (2023/09/08)

[MOD . PU . 1 . rev2]

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

Topic of the modification:

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

Note: when a modification affects several topics, the main topic is chosen. Example 1: fees in article 42 may affect secondary use and third countries, but the main topic of a modification in the fee structure would be secondary use (SU).

number of modification: consecutive number, within the topic

Rev2 Number of revision of this particular modification (compared to the initial compromise text of the Spanish presidency) (***blank***: initial version of the modification)

Working Party on Public Health – EHDS (2023/09/08)

Proposed general modifications
[MOD.GA.1] Clarification of exclusion from the scope of the EHDS of certain judicial activities.

- **Modification of article 1(7)**
- **New recital (16A)**
- **New recital (41A)**
- **New article 33A(3)**

Justification for the position of the Presidency & explanation of the changes introduced in the text

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 1 for primary use** => out of the scope of the Regulation with the wording of the Swedish compromise text, article 1(7); even without the proposed amendment, "primary use" = processing of health data for delivering healthcare.
- **Purpose 1 for secondary use => not one of the allowed purposes under article 34; reflected in recital (41A).**

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).

unviable, since courts (and other parts of the justice system) are not entities *in the healthcare or care sectors* & they do not fall under the definition of data holder in another way. However, for clarity, an **unambiguous exclusion is stated in recital (41A) and in article 33A(c).**

A complete exclusion of "justice in general" could lead to having any health data related to administrative law, consumer law, contract law, family law, tort law, international law, etc. excluded from primary and, especially, secondary use => legal uncertainty + administrative burden for the HDAB (examining every dataset to decide…). Instead, the **"justice system" has been explicitly excluded from the obligations of a data holder.**

For legal clarity, the modification in article 1(7) reflects 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** and that **health data held by courts for the purpose of judicial proceedings are out of scope** of the Regulation.

Working Party on Public Health – EHDS (2023/09/08)

[MOD.GA.1] Clarification of exclusion from the scope of the EHDS of certain judicial activities. (1/4)

Modification of article 1(7).

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.

Working Party on Public Health – EHDS (2023/09/08)

[MOD.GA.1] Clarification of exclusion from the scope of the EHDS of certain judicial activities. (2/4)

Modification 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.

Working Party on Public Health – EHDS (2023/09/08)

[MOD.GA.1] Clarification of exclusion from the scope of the EHDS of certain judicial activities. (3/4)

New article 33A(3)	*Article 33A Applicability to health data holders*

3. This Chapter shall not apply to courts and other entities of the justice system.

(…)

Working Party on Public Health – EHDS (2023/09/08)

[MOD.GA.1] Clarification of exclusion from the scope of the EHDS of certain judicial activities. (4/4)

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

1) Modification of article 1(6) & Creation of article 1(6A)
2) Modification of recital (37)

Justification for the position of the Presidency & explanation of the changes introduced in the text

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 **does not affect or repeal any legally valid mechanism already in p**lace 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 was also included in **recital (37)** for coherence purposes. Also, in recital (37), these corrections are introduced specifically related to the GDPR and EUDPR, for reasons of legal technique:

1) (...) 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. (...). ➔ ***This paragraph refers*** *to what the applicant/user should explain, that's only in Arts. 6 / 5, while Arts. 9 and 10 (GDPR/EUDPR) are about the safeguards needed (mentioned, further down in the recital*

2) (...) 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 Article~~s~~ 5(1), points (a) ~~points (e) or (f)~~ of Regulation (EU) 2018/1725** (...) ➔ ***This changes is due to 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) (…) 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 (a) ~~(e)~~ of Regulation (EU) 2018/1725** (…)

4) (...) 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)).*

Working Party on Public Health – EHDS (2023/09/08)

[MOD.SU.1] Clarification of scope of secondary use of health data (1/3)

Modifications in article 1

Article 1 (6)
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~~.

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.

[MOD.SU.1] Clarification of scope of secondary use of health data (2/3)

Modification in recitals (37 page 1)

(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~~.

Working Party on Public Health – EHDS (2023/09/08)

[MOD.SU.1] Clarification of scope of secondary use of health data (3/3)

Modification in recitals (37 page 2)

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 Article~~s~~ 5(1), point (a) ~~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 (a) ~~(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

Working Party on Public Health – EHDS (2023/09/08)

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

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 & explanation of the changes introduced in the text

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)**.

(*) '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;'

[MOD.SU.2] Definition of data holder + definition of healthcare + definition of care + exclusions to the definition of data holder. (1/7)

Definition of "care"

Article 2 (1)(ba)

(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.

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…

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.

[MOD.SU.2] Definition of data holder + definition of healthcare + definition of care + exclusions to the definition of data holder.(2/7)

Definition of "data holder"

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 **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, 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.

Working Party on Public Health – EHDS (2023/09/08)

[MOD.SU.2] Definition of data holder + definition of healthcare + definition of care + exclusions to the definition of data holder.(3/7)

Definition of "dataholder"

Article 2 (2)(y)

Additional explanations:

- In **article 33A(1) 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', to avoid any loopholes** for entities.
- Several delegations have proposed clarifications and corrections, which do not imply a significant expansion or reduction of scope, but a 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.
- "Any natural or legal person entity or body developing products and services intended for the healthcare or care sectors" has the intention to include private companies developing products and services (software providers, providers of medical devices and pharma companies..) "any 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), but it does not seem feasible according to GDPR. However, the current wording does *not* exclude data processors from the obligations under the instructions of data controllers
- 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.

Working Party on Public Health – EHDS (2023/09/08)

[MOD.SU.2] Definition of data holder + definition of healthcare + definition of care + exclusions to the definition of data holder.(4/7)

Modification of 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.

*The amendment to **recital (40)** clarifies the 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.*

[MOD.SU.2] Definition of data holder + definition of healthcare + definition of care + exclusions to the definition of data holder.(5/7)

Exclusions of applicability of Chapter IV to certain data holders

Article 33A Applicability to health data holders

1.The following categories of health data holders shall be exempted from the obligations incumbent on health data holders laid down in this Chapter:

(a) ~~individual researchers and~~ Natural persons;

(b) Health data holders that qualify as micro-enterprises as defined in Article 2 of the Annex to Commission Recommendation 2003/361/EC.

2. Member States may provide, by virtue of national law, that the obligations of health data holders laid down in this Chapter shall apply to the health data holders referred to in paragraph 1 which fall under their jurisdiction.

(…)

Article 33A *clarifies that in this Chapter IV micro enterprises and natural persons are exclude* ***from the obligations of data holders****.*

- ***natural persons*** ➔ *ample consensus in this regard; 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, this has been allowed at the national level.*
- ***micro-enterprises*** ➔ ***In COM's original proposal.***
- ***Two delegations wanted to exclude small enterprises,*** *but this 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.*

Working Party on Public Health – EHDS (2023/09/08)

[MOD.SU.2] Definition of data holder + definition of healthcare + definition of care + exclusions to the definition of data holder.(6/7)

Modification of recital [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 **health**care or **sector**s, 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 obligations ~~to make their data available~~ as data holders 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.

Working Party on Public Health – EHDS (2023/09/08)

[MOD.SU.2] Definition of data holder + definition of healthcare + definition of care + exclusions to the definition of data holder.(7/7)

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

Working Party on Public Health – EHDS (2023/09/08)

Revision of article 33(1). Current wording & suggestions by "drafting group IV" (1)	
Option 1: Swedish compromise text:	**Option 2: Proposal from drafting group IV:**
Article 33 *Minimum categories of electronic **health** data for secondary use*	*Article 33* *Minimum categories of electronic ~~**health**~~ data for secondary use*

- *Having "health" in the title could exclude data on determinants of health (such as environmental factors) or related to healthcare administration/the healthcare system*
- *Should be aligned with the final definitions of "electronic health data" (art 2). 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.*
- *"Electronic health data" could be used 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, 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

Working Party on Public Health – EHDS (2023/09/08)

Revision of article 33(1). Current wording & suggestions by "drafting group IV" (2)

Option 1: Swedish compromise text:	Option 2: Proposal from drafting group IV:
Article 33 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~~:	*Article 33* **1. Health data holders shall make** the following categories of electronic data **available for secondary use in accordance with the provisions of this Chapter**:

Based on a discussion within the drafting group, the original version of the draft regulation text is preferable:

- *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 (in "electronic health data") with the same reasoning as above, might be limiting too much, 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))*
- *Referring to making data available for secondary use in accordance with the provisions of this chapter adds clarity*

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

Working Party on Public Health – EHDS (2023/09/08)

Revision of article 33(1). Current wording & suggestions by "drafting group IV" (3)

Option 1: Swedish compromise text:	Option 2: Proposal from drafting group IV:	Option 3: wording proposed by some delegations (similar to COM's original proposal)
Article 33 (a) **health data from** EHRs **processed in a structured form**	*Article 33* (a) **electronic health data from** EHRs **processed in a structured form, if available**	*Article 33* (a) **health data from** EHRs ~~**processed in a structured form;**~~

1) In the Swedish compromise text, the idea of using structured data from EHRs was two-fold:

a) structured data is of better quality than unstructured data.

b) structured data reduces the probability of accidentally / unintentionally making available for reuse data categories outside art 33(1).

2) Justification from drafting group IV: *including "if available" so as not to introduce structuring requirements for EHR data and apply only apply to already structured. Structuring requirements for data from EHR & EHR systems and probably other categories shall be defined by the EHDS Board (tasks in Article 65(2))*

3) *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

Working Party on Public Health – EHDS (2023/09/08)

Revision of article 33(1). Current wording & suggestions by "drafting group IV" (4)

Option 1: Swedish compromise text:	Option 2: Proposal from drafting group IV:
(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**;	(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**;

- *Clarify the kind of data, differentiating personal and aggregated/non-personal data, with some of the original data categories (behavioural data etc.) 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, 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).*
- *More detail in a recital on exactly what this might mean exactly; 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

Working Party on Public Health – EHDS (2023/09/08)

Revision of article 33(1). Current wording & suggestions by "drafting group IV" (5)	
Option 1: Swedish compromise text:	**Option 2: Proposal from drafting group IV:**
(c) ~~relevant~~ pathogen genomic data, impacting on human health;	(c) ~~relevant~~ pathogen ~~genomic~~ data, impacting on human health;

- *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

Working Party on Public Health – EHDS (2023/09/08)

Revision of article 33(1). Current wording & suggestions by "drafting group IV" (6)	
Option 1: Swedish compromise text:	**Option 2: Proposal from drafting group IV:**
(d) health**care**-related administrative data, including claims and reimbursement data;	(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**

The added parts were previously listed under (n) and are taken up here in order to establish the necessary relation to the healthcare system.

• Clarify 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. (*)

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

Working Party on Public Health – EHDS (2023/09/08)

Revision of article 33(1). Current wording & suggestions by "drafting group IV" (7)	
Option 1: Swedish compromise text:	**Option 2: Proposal from drafting group IV:**
(e) human **genomic**, genetic, ~~genomic, and~~ proteomic**, transcriptomic, epigenomic, metabolomic, lipidomic and other omic** data;	(e) human genetic and **genomic** data (ea) **molecular data such as** ~~, and~~ proteomic**, transcriptomic, epigenomic, metabolomic, lipidomic and other omic** data;

*No change to the data, only a re-organization to facilitate any discussions on specific safeguards for human genomic data. According to the GDPR definition of "human genetic data", "genomic data" falls within the definitional framework and is listed in (e) for concreteness. Accordingly, (ee) lists the molecular data that can be derived from genomic sequence. 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 reference to GDPR.*

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

Working Party on Public Health – EHDS (2023/09/08)

Revision of article 33(1). Current wording & suggestions by "drafting group IV" (8)	
Option 1: Swedish compromise text:	**Option 2: Proposal from drafting group IV:**
(f) person generated ~~electronic~~ health data~~, including~~ **through** medical devices, wellness applications or other digital health applications;	NO PROPOSAL

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

Working Party on Public Health – EHDS (2023/09/08)

Revision of article 33(1). Current wording & suggestions by "drafting group IV" (9)	
Option 1: Swedish compromise text:	**Option 2: Proposal from drafting group IV:**
(g) ~~identification~~ data **on professional status and role of** ~~related to~~ health professionals involved in the treatment of a natural person;	(g) ~~identification~~ data **on professional status, specialisation and** ~~**role**~~ **institution of** ~~related to~~ health professionals involved in the treatment of a natural person;

<u>First round of comments: Please, choose one option</u>:

Option 1) Swedish compromise text

Option 2) the proposal from drafting group IV

Option 3) another wording

<u>Second round of comments</u>: 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

PRESIDENCIA ESPAÑOLA CONSEJO DE LA UNIÓN EUROPEA

THANK YOU