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WORKING DOCUMENT

From:	General Secretariat of the Council
To:	Working Party on Public Health (Attachés) Working Party on Public Health (European Health Data Space)
Subject:	Meeting of the Working Party on Public Health on 23 May 2023 - Flash from the Presidency

Delegations will find attached the Presidency Flash for the meeting of the Working Party on Public Health on 23 May 2023. The draft agenda is set out in CM 2778/23

Swedish Presidency of the Council of the European Union

Swedish Presidency Flash

Meeting of the Working Party on Public Health

Tuesday, 23rd of May 2023
10:00-13:00
&
14:30-18:30

Dear colleagues,

A warm welcome to the upcoming meeting in the Working Party on Public Health!

The meeting will take place between 10:00-13:00 as well as 14:30-18:30 on the 23rd of May. The agenda of this meeting will be the examination of the EHDS proposal with a focus on the following:

- **Presentation by the PRES of the second compromise with a focus on the amendments in Chapters IV and IX and in Article 70**
    - The PRES will provide a general introduction of the second compromise. A more detailed explanation and discussion is to be handled in relation to the specific articles to be examined.

- **Examination of Chapter III**

- Continue from last Working Party; examination with focus on **Articles 17, 18, 19 and 31A.**

- **Examination of Chapter IV, including the definition of health data holder**

  - Examination of the definition of health data holder in **Article 2(2)(y)** and a discussion on suggested amendments.

  - Examination of the amendments in **Articles 33, 34 and 35**, including the interplay between Article 34 and 35.

  - Examination of the amendments regarding duties for health data holders and health data users in **Articles 35B and 35C**.

  - Examination of the amendments regarding IP-rights and trade secrets; see **Article 35A, (Article 33(1)(j) on fully completed clinical trials), Article 35B(1), Article 37(1)(a)(ii), Article 46(1)(d) and Article 46(1A)(b).**

  - Examination of the procedure for access to electronic health data for secondary use, that is **Articles 44 to 47**.

  - Discussion on a **need for a fast track** for public sector bodies and EUI as Article 48 is deleted.

  - Examination of non-compliance in **Article 43**.

To facilitate the discussions, please see pages 4 to 11 in this flash for guidance.

Preliminary agenda for the upcoming working parties in June on EHDS:

- **the rights of natural persons** for both primary and secondary use, that is Articles 8A, 8B, 8C, 8D, 8E, 8F and 8G, including Article 7A(3) in Chapter II and Articles 35D, 35E, 35F and 35G in Chapter IV, including the interplay with legal bases as well as the clinical trial regulation.

- **the dataset description and data quality** in Section 5 of Chapter IV.

- **the fees** in Article 42 in Chapter IV, including a discussion on a need for differentiated fees.

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- **the governance**, as in the role of and tasks for digital health authorities, the market surveillance authority, the health data access bodies, including a discussion on the need for a health data access body for EUI, the Commission´s role as well as the role of the EHDS Board, including the interplay with other governance structure, such as NIS-directive, GDPR, DGA and DA.

- **the roles and responsibilities in a secondary use context** in Articles 49, 50 and 51.

- **the cross-border infrastructures** in Articles 12, 13 and 52.

- **the scope** of the Regulation in Article 1, **the additional provisions** in Chapter V and VII, and **the time for implementation** in Chapter IX.

In case you have any other points that you want to discuss under AOB, please don't hesitate to contact the Presidency and the Council Secretariat.

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Examination of the definition of health data holder in Article 2(2)(y)

Definition in the second compromise, option 1

The definition of health data holder is only used in a secondary use context in the second compromise and defines who will be obliged to provide electronic health data to be used for secondary use purposes, see Article 35B on the duties for health data holders.

In the second compromise **reimbursement** is included in the definition in point (a) as a result from the previous discussions.

The definition of health data holder still includes terms that is not clearly defined in EU law, such as care sector and care. This could cause legal uncertainty regarding who will be a health data holder.

This Regulation could define care and care sector, mirroring the definition of healthcare. For instance, as follows:

'Care' means services provided to natural persons to assess, maintain or restore their state of health, which are not provided by health professionals.

Suggestion for a new amendment, option 2

Member States have provided the PRES with a suggestion for an amendment of the definition of health data holder with the aim to improve 1)simplicity, 2)coherence and 3)comprehensiveness, see below.

The suggested amendment would broaden the scope of the definition and include all entities that has the right and obligation to process personal electronic health data (see definition of personal electronic health data). The PRES understanding is that the definition will include almost all entities and bodies, such as for instance schools, employers, non-profit organisations as well as public sector bodies in other sectors than the health sector, as there are many legal bases in the GDPR to process personal data concerning health.

The idea is to instead narrow the scope in separate provisions in Chapter IV and the data categories in Article 33. This work has not yet been done.

The suggested definition will exclude terms that are not defined today, such as "care" and "care sector".

'**health** data holder' means ~~any~~ **a** natural **person who is not the data subject with respect to the specific data in question** or a legal person~~, which is an entity or a body in the health or care sector, or performing research in relation to these sectors,~~ as well as Union institutions, bodies, offices and agencies 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 in its capacity as a controller; or
(b) the ability to make available or enble access to anonymous electronic health data ~~non-personal data~~, through control of the technical design **or means of access** ~~of a product and related services, the ability to make available, including to register, provide, restrict access or exchange certain data;~~

Maybe the phrase "who is not the data subject with respect to the specific data in question" is not needed as the data subjects will not be a controller (a) and the data subject will probably not control design or access of a product and related services (b). Maybe "of a product and related services" shall be included to clarify the scope of the access.

Suggestion for a new amendment, option 3

This amendment keeps the link to the health sector and focuses on entities which carries out activities in the health sector in accordance with applicable Union or national law and has the right or obligation to process the electronic health data referred to in Article 33. The suggested could cause legal uncertainty regarding the term health sector as well as entities that are targeted when it comes to anonymous electronic health data (point b in the current definition in the second compromise). Such definition could be for instance as follows:

'health data holder' means a legal person, including public sector bodies, Union institutions, bodies, offices and agencies and international organisations, or a natural person who is not a data subject with respect to the specific data in question, which carries out activities in the health sector and which, in accordance with applicable Union or national law, has the right or obligations to process electronic health data referred to in Article 33 of this Regulation;

Discussions on the definition of health data holder

1. Member States are invited to indicate their preferred option on the definition health data holder, that is options 1 to 3 above.

2. If option 2 is preferred, please provide further suggestions on amendments in Chapter IV to limit and/or clarify the scope.

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Examination of the amendments in Articles 33, 34 and 35, including the interplay between Article 34 and 35

Justifications of the amendments in Article 33

Article 33(1)(a) has been limited to only structured data based on the previous discussions where Member States were divided regarding the scope of health data from EHRs. Structured data in this regard means data that are clearly defined in the EHR and will for example exclude data that is processed in "free text field" in EHR systems that is not clearly defined. It will also exclude other data that is not health data, such as data related to criminal convictions.

The amendments in **Article 33(1)(b)** strengthen the link to public health.

The aim of the amendments in **Article 33(1)(e)** is to clarify that all omics are included.

Regarding data from clinical trial in **Article 33(1)(j)** the scope has been limit to fully completed clinical trials, see also provisions on IP-rights and trade secrets in Article 35A, 37(1)(a)(ii) and Article 46(1A)(b).

Regarding (j) and the interplay with clinical trial regulation, Member States are invited to comment in the meeting. This question will also be discussed together with the rights of natural persons and the interplay with the GDPR.

Article 33(1)(o) regarding enriched data has been deleted from para 1 as enriched data seems to be a complex matter with regard to purpose limitation and data minimisation. The requirement also needs to be analysed in a national context as the health data holder´s processing of personal electronic health data is not regulated in the proposal, only it´s disclosure of electronic health data. Therefore the PRES has made it optional for Member States to establish rules regarding enriched data in the context of each Member State, see the new para 9 in Article 33.

Discussion on the data categories in Article 33

3. Member States are invited to comments on the amendments made in Article 33. If further amendments are needed, please provide concrete text proposals.

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Justifications of the amendments in Article 34

In Article **34(1)(a)** patient safety has been included.

The scope in **Article 34(1)(b)** has been clarified and limited to policy making and regulatory activities to be more in line with recital 37.

The scope in **Article 34(1)(b)** has also been clarified and limited to only include education and teaching activities at the level of vocational or higher education.

The word personalised in **Article 34(1)(h)** has been deleted based on the scope of the purpose and the explanations made by the Commission. The procedure in Chapter IV will only enable to use the result in a healthcare context (and not personal electronic health data in clear text). The aim of the processing, as the PRES understand it, is to use the result of the processing to provide healthcare to natural persons.

The PRES see a need for further discussions regarding (h) as some Member States would like to include personalised healthcare in research and some Member States have raised questions on the contradiction between personalised healthcare and the fact that secondary use will only allow access to pseudonymised electronic health data.

Some Member States have also requested a definition of personalised healthcare. If such definition is needed, maybe this definition could work:

"Personalized healthcare (PHC) means an overarching framework for care that unifies predictive technologies with an engaged patient to coordinate care with the primary aim of promoting health and preventing disease.

PHC is tailored to the individual needs, preferences, and circumstances of each patient. This can include a wide range of interventions and approaches, from preventive measures and lifestyle changes to the use of specific treatments or therapies. (It is an approach that aims to tailor medical treatments and interventions to the individual patient's unique characteristics, such as their genetics, lifestyle, and medical history.)"

Discussion on the purposes in Article 34

4. Member States are invited to comments on the amendments made in Article 34, especially views on (h) and the interplay with research and the suggested definition. If further amendments are needed, please provide concrete text proposals.

Article 35, including the interplay with Article 34

In the compromise, the PRES has tried to clarify the interplay between Articles 34 and 35, by stating that all use and processing outside the scope of Article 34 shall be prohibited. More purposes have also been added to the list in Article 35, see **(ba),** (f) and (g) and amendments has been made in **(c)** and **(e).**

To put the provisions in a context, the PRES has also added a new para in Article 43, see **Article 43(4A)** where it states that the health data access body shall immediately revoke the data permit issued if the health data user is processing or using the electronic health data outside the scope of the data permit.

Note that the second compromise also separates the prohibited purposes – that is when the health data user has access to the data - and the assessment the health data access body shall make before issuing a data permit or answer a data request, see Article 46 and 47.

Discussions on Article 35 and the interplay with Article 34

5. Member States are invited to comment on the amendments made in Article 35. If you consider that the prohibited purposes also shall apply for the health data access body, this needs to be clarified in the Article.

Examination of the amendments regarding duties for health data holders and health data users in Articles 35B and 35C

Justifications of the amendments in Article 35A and 35C

Article 35B

In Article **35B(1)** a clarification has been added that the electronic health data may also include IP rights and trade secrets. In para 1a the time period to put the data at the disposal has been made more flexible and decided by the health data access body. In the second compromise the scope of health data holder has been limited, excluding also individual researchers as raised by Member States, see para 5. A clarification on the time period for reporting of the description of dataset has been added in para 2.

The legal bases in the GDPR for the health data holder to make the data available has been added in recital 37.

Para 1b will be examined in the upcoming meetings together with the rights of natural persons.

Article 35C

For instance, clarifications on publications in scientific journal has been added in **para 3**.

Discussions on the amendments in Articles 35B and 35C

6. Member States are invited to comment on the amendments made in Articles 35B and 35C. If further amendments are needed, please provide concrete text proposals.

Examination of the amendments regarding IP-rights and trade secrets; see Article 35A, Article 33(1)(j) on fully completed clinical trials, Article 35B(1), Article 37(1)(a)(ii), Article 46(1)(d), Article 46(1A)(b)

Justifications

Clarifications has been added in the linked Articles. To ensure transparency the measure to preserve the confidentiality shall be publicly available, see Article 35A(2). Regarding clinical trials, only data from fully completed clinical trials will be included in the scope as a safeguard related to health data holder (the sponsor).

Discussions on the amendments in the linked Articles on IP-rights and trade secrets

7. Member States are invited to comment on the amendments made in the linked articles. If further amendments are needed, such as for instance more common rules, please provide concrete text proposals.

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Examination of the procedure for access to electronic health data for secondary use, that is Articles 44 to 47

Justification of some amendments in Articles 44 to 47

The PRES has kept the provisions in Article 44, but linked the provisions to Article 46, see **Article 46(1)(b).**

In Article 45, provisions on transfer to third country has been added as well as requirements regarding data protection impact assessment, see **Article 45(4)(ba)** and **(c)**. Ethical aspects could also be relevant for access to pseudonymised data as well, see changes from **para 4 letter b**.

Regarding cross-border access to electronic health data, see added provisions in Article **46(4a).**

More elements have been added in the assessment that shall be carried out by the health data access body to also capture certain risks, see Article **46(1A).**

Article 47 is kept for now. Some elements are added in Article 47.

Discussions on the amendments in Articles 44 to 47

8. Member States are invited to comment on the amendments made in the linked Articles. If more amendments are needed, please provide concrete text proposals.

9. As discussed in previous meetings, Articles 45 to 47 could be merged into two articles; one procedure for applications and one procedure for assessment of the applications. If this is a preferred option, the PRES would like Member States to provide guidance on information to be included in the applications as well as the criteria for providing access to the electronic health data.

Discussion on a need for a fast track for public sector bodies and EUI as Article 48 is deleted

The PRES invites Member States to discuss the need for a fast track for public sector bodies and EUI as Article 48 is deleted, see the time period for access in **Article 46(3), 35B(1a)** but also the scope of this Regulation in **Article 1(6).**

10. Is there a need for additional provisions regarding fast track for public sector bodies and EUI in this Regulation?

    a. In such case, what conditions should be established?

       For instance should less information be provided in the application, less criteria be assessed by the health data access body and shorter deadlines for the health data holder to make the electronic health data available upon request?

    Please provide comments and concrete text proposal in this regard.

Examination of non-compliance in Article 43

Justifications

The PRES has changed the title to better address the content of the article.

Clarifications that the health data access body has the power to take immediate actions has been added, see **para 3 and 4A**. Also clarification on fines has been added, see **para 5**.

Discussions on the amendments in Article 43

11. Member States are invited to comment the amendments made in Article 43. If further amendments are needed, please provide concrete text proposals.

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Sweden from A to Ö – A piece of Swedish culture

If you read last week's flash, you might remember that we talked about the province Ångermanland. This week we will talk about an annual livestream that takes place in the middle of Ångermanland, called "Älgvandringen" (English: the moose walk). "Älgvandringen" is a live-broadcasted and uncommented nature program that films animals and nature around the clock for one month. The name of the show derives from it being quite common to spot moose's walking past the camera. It is being live streamed during the beginning of April until the beginning of May. In the spring of 2021, it was quite a success, since 39 moose's were spotted passing the Ångerman river.

If you are interested in watching, you can find it in the attached link. Every day, highlights are collected, so there is plenty of opportunity to spot moose's and other animals:
Den stora älgvandringen | SVT Play

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