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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: Working Party on Public Health on 06 June 2023
- Flash from the Presidency

Delegations will find attached the Presidency Flash for the meeting of the Working Party on Public Health on 06 June 2023. The draft agenda is set out in CM 3099/23.



Swedish Presidency
of the Council of the
European Union

Swedish Presidency Flash

Meeting of the Working Party on Public Health Tuesday, 6th of June 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 6th of June. The agenda of this meeting will be the examination of the EHDS proposal with a focus on the following:

- **Continuing the examination of Chapter IV**
 - Examination of the procedure for access to electronic health data for secondary use, that is **Articles 44 to 47**.
 - Examination of non-compliance in **Article 43**.
- **Examination of the rights of natural persons for primary and secondary use in Chapter II and IV**



- **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.

To facilitate the discussions, please see pages 3 to 10 in this flash for guidance.

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.

Please find our contacting details down below.

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Examination of the procedure for access to electronic health data for secondary use, that is Articles 44 to 47 (*from previous flash*)

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

1. Member States are invited to comment on the amendments made in the linked Articles. If more amendments are needed, please provide concrete text proposals.
2. 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.



Examination of non-compliance in Article 43 *(from previous flash)*

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

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

Examination of the rights of natural persons for secondary use in Articles 35D to 35G

Justifications

Articles 35D to 35F are aimed to specify and complement the rights in the GDPR with a focus on the right to be informed (being informed is a prerequisite for being able to exercise one's rights) and the right to opt out. See also the inclusion of secondary use in Article 1(2)(a).

Article 35D

Article 35D was created to ensure that natural persons are well informed of the processing of personal data and that natural person also can exercise their rights upon requests.

Article 35D(1) states that the articles in the GDPR regarding the controller's obligation to inform natural persons applies to the health data holder. In the context of the EHDS, the health data holder is obliged to inform the natural persons concerned that his or hers personal electronic health data also may be made available for secondary use (letter a), the purposes and the data included (letter b) and the right of natural persons to exercise their rights upon request (letter c) with the health data holder.

The PRES's understanding is that these letters (letters a to c) only specify what is already regulated in the GDPR on a general level, see Articles 12 to 14 in the GDPR.

As the PRES suggests for an opt-out to be placed on the health data access body, see Article 35F, the PRES also suggests that the health data holder shall inform the natural persons how to use this right - that is by contacting the health data access body.

The PRES's understanding is that letter d would complement the GDPR as there are no obligations in the GDPR to inform of the processing of personal data outside the controller's own scope.

Article 35D(2) states that the information shall be provided when the personal data are collected by the health data holder. This means for instance, when personal data are collected for the first time to be used for instance for clinical trial purposes. The controller also needs to inform that the personal electronic health data could be made available to be used for secondary use purposes in accordance with this Regulation and that the natural person could contact the health data access body if they would like to opt-out.

In accordance with good practice, the information shall also be available online, see Article 35D(3) and guidelines on transparency from EDPB¹.

Article 35E

Article 35E is replacing Article 38 and regulates the health data access body's obligations to inform natural persons. Instead of only making some information publicly available, clarifications are added stating that Article 14(5)(b) applies.

According to the GDPR, the controller is only obliged to inform natural persons of the processing of personal within its own controllership. The PRES's understanding is that some letters may also include elements that are within the health data user's controllership, see for instance letter g (having in mind that the Commission's proposal is built on a joint controllership for the health data access body and the health data user).

The PRES also suggests that the electronic health data access service for primary use could be used as a platform for the health data access body to inform natural persons concerned. The electronic health data access services for primary use will likely cover almost all citizens.

¹ Article 29 Working Party, Guidelines on transparency under Regulation 2016/67, WP260rev.01



Discussions on Articles 35D and 35E

4. Member States are invited to comment on Articles 35D and 35E, if the provisions are supported and/or if further amendments are needed. If further amendments are needed, please provide concrete text proposals.

Article 35F

This Article includes a right to object to that personal electronic health data are processed for secondary use (an opt-out right).

This right differ from an opt-in right.

Opt-out means that the processing of personal data can go on as long as the natural person has not object.

Opt-in means the processing of personal data cannot start before the natural person has given its consent or approval.

This right also differ from the right to object in Article 21 of the GDPR where the controller shall make an assessment and may come to conclusion that the processing shall continue, see Article 21(1) and 21(6) of the GDPR. The suggested right in this Article means that the health data access body do not need to make an assessment – the right to opt-out applies in any case. This could also ease the burden of the health data access body.

Article 35F(1) states that natural persons shall have the right to exercise their right in the GDPR as well as the right to opt-out. This means that natural persons still could use their right to object according to the GDPR – but they could also object to all the processing for secondary use, using the right to opt-out in this Article.

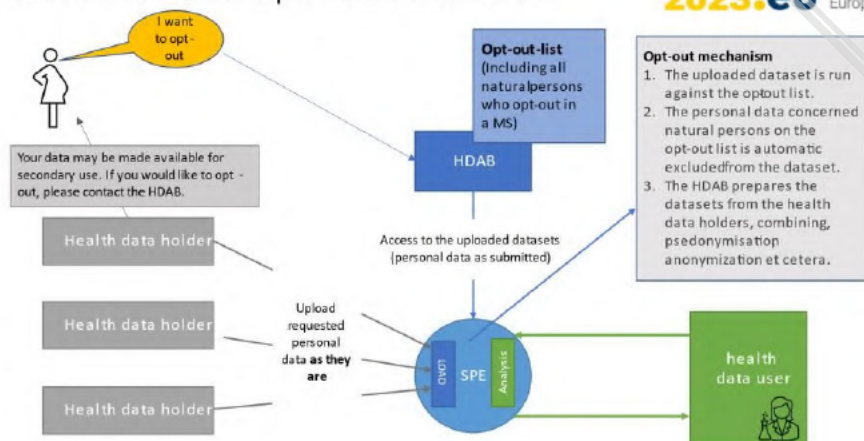
The right to opt-out is placed on the health data access body as it may be difficult and burdensome for natural persons to contact all the health data holders that may process personal electronic health data of the natural person.

Where a natural person has exercised the right to object (opt-out), the health data access body shall exclude the personal electronic health data concerning that person to be used for secondary use purposes, see para 2.

The PRES considers that this could be solved through technical means when the health data holder uploads the requested data sets in the secure processing environment, see the

picture below. The personal data concerning the natural person who opt-out could be excluded in the very early stage, that is before the electronic health data are prepared (combined with other datasets et cetera) to be accessible for the health data user.

Picture of the opt-out solution



Discussions on Article 35F

5. Member States are invited to comment on Article 35F, especially the provision regarding an opt-out, if the provisions are supported or if amendments are needed.

If amendments are preferred, please provide concrete text proposals.

Article 35G

Article 35G states the Member States may require and set out rules for handling of findings related to a natural person's health status. See also Article 35C(4). These provisions are a result from previous discussions to make it optional for Member States to establish rules in this regard.

Discussions on Articles 35G and 35C(4)

6. Member States are invited to comment on Articles 35G and 35C(4), if the provisions are supported or if amendments are needed.

If uniform rules are preferred, please provide concrete text proposals.



Examination of the rights of natural persons for primary use in Articles 8A to 8G

Justifications

The rights of natural persons in relation to primary use have been divided in separate articles as each right has a different scope. The aim has been to clarify the scope and to ease the reading. Below some of the changes are commented.

Article 8A

Changes have been done to clarify the scope by adding “at least the priority categories in Article 5”, see para 1.

In para 3, **in particular** has been added as there could be other reasons for not providing access, see Article 23 of the GDPR.

Discussions on the rights of natural persons in Article 8A

7. Member States are invited to comment on the amendments made in Article 8A, if the provisions are supported or if further amendments are needed.

If further amendments are needed, please provide concrete text proposals.

Article 8B

Regarding the possibility for the patients or their representative to insert information in their EHR, the provision states that it is up to each Member State to decide to allow this or not. If they are allowed, there are rules in this Article that need to be fulfilled.

Discussions on the rights of natural persons in Article 8B

8. Member States are invited to comment on the amendments made in Article 8B, if the provisions are supported or if further amendments are needed.

If further amendments are needed, please provide concrete text proposals.



Article 8C

If a Member State also would like to enable natural persons to exercise other rights than rectification through the patient portals, it should be possible, see subpara 2.

Discussions on the rights of natural persons in Article 8C

9. Member States are invited to comment on the amendments made in Article 8C, if the provisions are supported or if further amendments are needed.

If further amendments are needed, please provide concrete text proposals.

Article 8D

The scope of the right to data portability also includes social administrative or reimbursements services (not only the provision of healthcare), see para 1.

Para 2 only include healthcare providers (as social administrative or reimbursements services are not including in the cross-border context).

Discussions on the rights of natural persons in Article 8D

10. Member States are invited to comment on the amendments made in Article 8D, if the provisions are supported or if further amendments are needed.

If further amendments are needed, please provide concrete text proposals.

Article 8E

Para 1 is a result from the discussions of last December.

The PRES has deleted “all or part of” as the wording raised questions from Member States.

Member States shall establish rules and safeguards regarding the restrictions.



Article 8F

Para 1 is a result from the discussions of last December on an opt-out solution.

To be more in line with the right to object in secondary use it could be clarified in this Article that it is an opt-out provision.

Para 2 includes a specific right to object (opt-out) to cross-border access and exchange of personal electronic health data.

These rights shall be optional for Member States to provide.

Article 7A(3)

This para interplay with Article 8E. See also Article 1(6) regarding secondary use of electronic health data collected from primary use.

Discussions on the rights of natural persons in Articles 8E, 8F and 7A(3)

The amendments in Articles 8E and 8F(1) are a result of the discussions in December. The amendments in Article 8F(2) are new.

11. Member States are invited to comment the amendments made in Article 8E to 8F, especially the new Article 8F(2), if the provisions are supported or if further amendments are needed.

If further amendments are needed, please provide concrete text proposals.

Article 8G

Regarding the access services and the proxy services, only clarifications are added.

Discussions on the rights of natural persons in Articles 8G

12. Member States are invited to comment on the amendments made in Article 8G, if the amendments are supported or if further amendments are needed.

If further amendments are needed, please provide concrete text proposals.

Sweden from A to Ö – A piece of Swedish culture

Let's fast forward in time to the early 20th century. Here we find Ingrid Bergman who was an actress that starred in a variety of European and American films, television movies, and plays. Her career spanned over five decades, and she is often regarded as one of the most influential screen figures in cinematic history. Ingrid was born on 29 August 1915 in Stockholm to a Swedish father and a German mother. Her first film experience was as an extra in the 1932 film *Landskamp* and her first speaking role was a small part in *Munkbrogreven* (1934). Bergman appeared in eleven films in her native Sweden before the age of twenty-five. Her characters were always plagued with uncertainty, fear, and anxiety. The early Swedish films were not masterpieces, but she worked with some of the biggest talents in the Swedish film industry of the time, such as Gösta Ekman, Karin Swanström, Victor Sjöström, and Lars Hanson. It showcased her acting talent which at a later stage led to an invitation to do an English-language remake of her earlier Swedish film *Intermezzo* in the United States. The film became an enormous success and the rest is as we say history.



Credits: Herbert Dorfman / Getty images