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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 29 November 2022 - Flash from the Presidency
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Delegations will find attached the Presidency Flash for the meeting of the Working Party on Public Health on 29 November 2022.

The agenda is set out in CM 5496/22.

Czech Presidency Flash

Meeting of the Working Party on Public Health

Thursday, 29 November 2022

14:30 to 18:30

Brussels, 23 November 2022

Dear colleagues,

We are delighted to invite you to the thirty-second meeting of the Working Party on Public Health under the Czech Presidency of the Council of the European Union. It will be held in physical format from 14:30 until 18:30. The agenda has been circulated and is available in the Delegates Portal as document CM 5496/22.

I. Proposal for a Regulation on the European Health Data Space (EHDS) – continued examination of the Presidency compromise proposal on Chapters II and III

We will continue in the examination of the Presidency compromise proposal on chapters II and III of the proposal for the EHDS regulation (available as ST 13318/22) with a specific focus on several topics within chapters II and III that requires further discussion on the way forward.

Presidency has identified a number of topics based on the discussions we held so far and written comments sent by delegations. Presidency is proposing below the way forward and would like to ask delegations to provide their feedback. We will hold separate discussion rounds on each topic.

Please note that where we suggested a new text, it is not a compromise proposal, it is rather basis for discussion of the idea behind, although any specific textual proposals for specific provisions from delegations are welcomed.

- **Opt-out**

Several delegations have requested further amendments to the text to guarantee the option of **full opt-out** for natural persons (i.e. their personal electronic health data will not be made accessible using the access services under the EHDS outside the healthcare provider that provided treatment). We propose to introduce the option of a full opt-out in Article 3 by adding new paragraph 9a or by amending the existing paragraph 9 (see two options).

For both of the options, we wonder if it is more appropriate to use the word “object” or “refuse”. If the word “refuse” is used, we avoid to interfere with the GDPR’s right to object, as this right relates only to the processing of personal data based on its Article 6(1)(e) and (f) (performance of a task carried out in the public interest or the exercise of official authority

and legitimate interests), that might not be the correct legal bases for the processing of health data.

If the word “object” is used, the paragraph would probably be understood as the *lex specialis* to the GDPR.

Option 1

Natural persons shall have the right to [refuse] [object to] the access to their personal electronic health data registered in an EHR systems by electronic health data access services referred to in paragraph 5(a) of this Article and/or by health professional access services referred to in the Article 4(3). Member States shall ensure that natural persons can easily exercise this right online through these electronic health data access services.

Option 2

Member States may provide for natural persons to have the possibility to [refuse] [object to] to the access to their personal electronic health data registered in an EHR systems by electronic health data access services referred to in paragraph 5(a) of this Article and/or by health professional access services referred to in Article 4(3).

For a **partial opt-out**, we believe that the current wording of Article 3(9) is sufficient, including partial opt-out for cross-border processing of health data. However, we propose to have it explicitly stated in recital 13.

Moreover in Article 3 (9), when the patient is not disclosing certain information, is not clear if it should be visible to the treating healthcare professional or not. We propose to leave this choice to Member States.

- Responsibility of the healthcare professional in case of “hidden” information and the possibility to refuse treatment

The possibility of a full/partial opt-out might lead to a diagnosis or treatment other than that chosen by the healthcare professional, had he known all relevant data. Recital 13 explicitly states that the patient assumes full responsibility for the possible lack of data, based on which treatment is provided. However, it does not stipulate what are the options of the healthcare provider in case they know that some patient health data are not visible to them.

We also assume that possible assessment by third party, if certain healthcare was provided *de lege artis* (e. g. in case of a complaint against the healthcare professional for malpractice), will be done based on the health data at the disposal of the healthcare professional at the moment of the provision of the healthcare.

Some delegations have raised that this decision is fully a responsibility of Member States, therefore we suggest a clarification in recital 13, by adding the following sentence:

Where the healthcare provider does not have full access to a person’s electronic health data, it is the Member State’s responsibility to determine, if, or under which conditions, the healthcare provider is obliged to provide health services.

- “Breaking the glass” option

Article 3(9) of the compromise proposal refers to Article 9(2)(c) of GDPR. In a complete opt-out (data will not be registered in any EHR system), breaking the glass (i.e. access to personal electronic health data by a healthcare professional whose access is restricted) will not be possible. However, it could remain a possibility for partial opt-out. Delegations are divided in this respect.

Although everyone should be responsible for their choices, the derogation in GDPR refers to the vital interests of another natural person and it gives this option only in the specific situation of physical or legal incapacity to take an instantaneous decision.

We assume that the decision, whether or not it is the situation of vital interest, remains with the healthcare provider and should be based on the data they have at hand at the moment of taking it. We also note that GDPR allows Member States to maintain or introduce further conditions, including limitations, with regard to the processing of health data.

We propose to keep the “breaking the glass” possibility in the text.

- Protection of personal data of healthcare professionals

Article 3(10) of the proposal gives to any natural person the right to obtain information about any healthcare provider and healthcare professional (in the compromise proposal changed to “any person”) who accessed their personal data. This follows the transparency principle. However, such broad access might interfere with the rights of healthcare professionals. Therefore, the provision must strike a balance between the two.

We propose to provide automatic access to the identity of the healthcare provider (or of other authorised legal entity), having in mind that this entity is bound by GDPR provisions and would be responsible for its employees (or any other natural person to which it gave access right to the system). This would also require that the healthcare provider will have a complete log, that would allow to identify any person that accessed a specific natural person’s health data. However, in many cases it would not guarantee anonymity to healthcare professionals (e.g. employees of small healthcare providers, self-employed GPs, etc.)

In case you have any other points that you wish to raise under AOB, please do not hesitate to contact the Presidency and the Council Secretariat.

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30th anniversary of gamma knife surgery in the Czech Republic



This year, Prague's "Na Homolce" Hospital commemorates the 30th anniversary of the beginning of the unique Leksell Gamma Knife surgery, which is a radio surgical method designed to treat intracranial tumours, vascular malformations, a number of functional diseases of the central nervous system (e.g. pain, tremor) and eye diseases. More than 24,000 operations have been performed at Na Homolce during this time, which have helped patients save their lives or significantly prolong them. Thanks to its publishing and teaching activities and

international cooperation, the Department of Stereotactic and Radiation Neurosurgery ranks among the world leaders in its field

