



Council of the European Union  
General Secretariat

**Brussels, 14 June 2023**

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## **WORKING DOCUMENT**

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From:	General Secretariat of the Council
To:	Working Party on Public Health (Attachés) Working Party on Public Health (European Health Data Space)

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Subject:	Working Party on Public Health on 22 June 2023 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 22 June 2023. The draft agenda is set out in CM 3178/23.



Swedish Presidency  
of the Council of the  
European Union

# Swedish Presidency Flash

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## Meeting of the Working Party on Public Health

Thursday, 22<sup>nd</sup> of June 2023

10:00-13:00

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14:30-18:30

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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 22<sup>nd</sup> 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 the rights of natural persons for primary use in Chapter II**
  - **the rights of natural persons** for primary and secondary use, continuing with Articles 8B, 8C, 8D, 8E, 8F and 8G, including Article 7A(3) in Chapter II
  - **the deletion of Article 3(4)**

To facilitate the discussions, please see pages 3 to 5 in this flash for guidance.



Swedish Presidency  
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- Examination of amendments in the provisions on dataset description and data quality in Section 5 of Chapter IV, that is Articles 55 to 58.

Written comments following the discussions in the Meeting would be appreciated at the latest the 4<sup>th</sup> of July and should be sent to the Spanish presidency team and [LIFE.Health@consilium.europa.eu](mailto:LIFE.Health@consilium.europa.eu).

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 rights of natural persons for primary use in Articles 8B to 8G (*from previous flash*)**

### **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 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**

1. Member States are invited to comment 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**

2. Member States are invited to comment 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**

3. Member States are invited to comment 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.

4. Member States are invited to comment the amendments made in Article 8E to 8F, especially the new Article 8F(2) as well as the interplay with Article 7A(3), 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

5. Member States are invited to comment 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.

## Deletion of Article 3(4)

### Justification

Article 3(4) has been deleted in the second compromise. The reasoning is the following:

- The first sentence governs situations which arose prior to the entry into force (personal health data processed prior to the application of the regulation). Without a justification of the need for such retroactive provision, it seems that this goes against the general principle of legal certainty.
- The provision is silent about electronic health data that are not registered electronically after the entry into application of the regulation.
- The provision is purely optional for MS and has no prescriptive value.



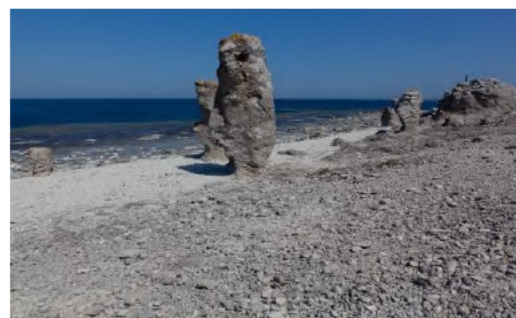
## A piece of Swedish culture

The province Gotland is the biggest island in the Baltic Sea. It has a characterful wilderness and a coastline punctuated with sandy beaches and sculptural sea stacks ('raukar' in Swedish). The sea stacks are limestone monoliths created by natural erosion during the last Ice Age. They are a common sight on the island, and the most famous ones have been given names (e.g., Lergravsporten and Hoburgsgubben). Gotland's main town is called Visby and is a Viking-era wonder and UNESCO World Heritage Site. The cobbled streets of Visby brings you back to medieval times when it was the main centre of the Hanseatic League in the Baltic. Visby is surrounded by the centuries-old 'ringmuren' (The Visby City Wall), which is complete with towers and gates, and which was built between 1250 and 1288. For the Viking enthusiasts, Gotland is dotted with burial grounds from the Viking Era, such as a 15-hectare site in Stenkyrka with some 1000 graves. If you want to experience the wingspan of history, you can do so by visiting 'Stavgård Vikingagård', which is a reconstructed Viking village.

Due to the strong fishing tradition of Gotland, seafood of all kinds is common. Besides this, a local delicacy is also to eat lamb. The rearing of sheep dates back to the Viking era, and the meat is known for its texture and flavour. Lamb meat (and wool) are the quintessential Gotland products, and the island's flag even features a sheep front and centre.



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