



Council of the European Union
General Secretariat

Brussels, 08 February 2024

Interinstitutional files:

2022/0140 (COD)

2023/0369 (COD)

WK 1609/2024 INIT

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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 12 February 2024 - Flash from the Presidency

Delegations will find attached the Presidency flash for the meeting of the Working Party on Public Health on 12 February 2024 (CM 1427/24).

EUROPEAN HEALTH DATA SPACE

12th of February 2024, 10:00 – 18:30

Introduction

The Belgian Presidency is pleased to invite you to a Public Health Working Party on the Omnibus Directive and European Health Data Space. Please find below a note on the aim of the meeting and the agenda.

Aim of the meeting

The meeting will start with information from the European Commission on the Omnibus Directive. Afterwards, the Belgian Presidency will open the discussion on European Health Data Space. First, we will give a debrief of ITMs 10 and 11 which took place on the 6th and 7th of February. Second, the Belgian Presidency aims to discuss their proposal for an opt-out for primary use and secondary use. Third, Member States will have the possibility to give feedback on preliminary greened or yellowed lines as indicated on the 4CT shared on Delegates Portal. Fourth, and in view of the Coreper meeting of the 14th of February, we would like to raise some points that will highly likely be discussed at the political trilogue on the 20th of February.

Agenda of the meeting

OMNIBUS DIRECTIVE

The European Commission will give a presentation on Article 3 of the proposed Omnibus Directive, which has the general aim to bring down 25% of administrative burden in different legislative files. In the area of Public Health legislation, it wants to amend the Cross-border Healthcare Directive (2011) with a change of reporting requirements in Article 20, paragraph 1. After the presentation, Delegations will be invited to give us their comments on the proposed amendment.

EUROPEAN HEALTH DATA SPACE

The Belgian Presidency aims to have an in-depth discussion on several topics by means of a PowerPoint presentation.

1) Discussion on the ITMs of 06/02 and 07/02

The Belgian Presidency will give an overview of the course of these ITMs.

2) Discussion on the Presidency's proposal: opt-out for primary and secondary use

As in articles 8F (Council) and 7(1a) (EP) for primary use, and articles 35F (Council) and 33(5) (EP) for secondary use.

3) Discussion on the green/yellow lines from the 4CT

Delegates will be able to give feedback on preliminary green or yellow lines from the 4CT that will be shared on Delegates Portal this Thursday. Please only indicate the lines that are highly problematic

4) Preparation for the 20/2 political trilogue – Coreper

Please find below the points that will highly likely be discussed at the 20/2 political trilogue.

- **Scope**

As in articles 1(6a) and 1(7)

- **Opt-out primary use**

As in articles 8F (Council) and 7(1a) (EP).

- **Opt-out secondary use**

As in articles 35F (Council) and 33(5) (EP).

Including;

- *Opt-out references in the obligations of HDABs (as in articles 35E (Council) and 38(2) (EP))*
- *Information of findings (as in articles 35G (Council) and 38(3) (EP))*

- **Opt-in genomic data secondary use**

As in articles 33(5) (Council) and 33(5a) (EP).

- **Union data access service**

As in article 36A.

- **Intermediation entities**

As in articles 35D (Council) and 41(7e) (EP).

- **Assessments of EHR-systems**

To discuss the principle of EHR-systems assessments, as well as the European digital test environment at political level.

- **Open points from 30/1 political trilogue**

- “Non-personal” versus “anonymous”
- Telemedicine
- Priority and additional categories

