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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)
Subject:	Working Party on Public Health on 13 November 2023 - Flash from the presidency

Delegations will find attached the Presidency Flash for the meeting of the Working Party on Public Health on 13 November 2023. The draft agenda is set out in CM 5186/23.

Spanish Presidency Flash

Meeting of the Working Party on Public Health

Monday, 13th of November 2023
14:30-18:30

Dear colleagues,

Please, find attached the agenda for the meeting of Monday, 13th of November 2023.

We will have the following point on the agenda:

Revision of compromise text for Chapters IV-VIII EHDS (excepting article 72) & related general aspects in article 1 & related definitions in article 2

More specifically, we shall review the following aspects of the compromise text:

1) Proposal to change Article 1(6A) EHDS:

Current wording: ***6A. This Regulation shall be without prejudice to Union or national law providing for access to electronic health data by public sector bodies of the Member States, EU institutions, bodies and agencies, and without prejudice to any access to electronic health data for secondary use for specific purposes that is based on contractual or administrative arrangements between public or private entities established in the EU or based on bilateral agreements with third countries.***
Proposed new wording: ***6A. This Regulation shall be without prejudice to Union or national law providing for access to electronic health data by [private sector entities or] public sector bodies of the Member States, EU institutions, bodies and agencies, and without prejudice to any access to electronic health data for secondary use for specific purposes that is based on contractual or administrative arrangements between public or private entities established in the EU or based on bilateral agreements with third countries.***

2) Proposal to remove "such as the following" from Article 34(1)(f), i.e.

(f) development and innovation activities~~, such as the following:~~

- ***(i) activities*** *for* ***the development of medicinal*** *products or* ***of medical devices*** ~~*services*~~ *contributing to public health or social security, or* ***aimed at*** *ensuring high levels of quality and safety of health-care~~, of medicinal products or of medical devices~~;*

- ~~*(g)*~~***(ii)*** *training, testing and evaluating* ***activities*** *of algorithms, including in medical devices, AI systems and digital health applications, contributing to the public health or social security~~,~~ or* ***aimed to*** *ensuring high levels of quality and safety of health-care, of medicinal products or of medical devices;*

3) Proposal to remove the reference to DGA fees from Article 42(2), in coherence with Article 42(1), i.e.

2. *Where the* ***electronic health*** *data in question are* ~~*not*~~ *held by* ***a health data holder or a data intermediation entity*** ***[MOD.SU.2.rev2]*** ~~***who***~~ ***which is not a*** ~~*the*~~ ***health*** *data access body* ~~*or a public sector body*~~*, the fees* ***charged pursuant to paragraph 1*** *may also include compensation* ***for costs incurred by the health data holder compiling and preparing*** ~~*for part of the costs for collecting*~~ *the electronic health data* ***to be made available for secondary use*** ~~*specifically under this Regulation in addition to the fees that may be charged pursuant to paragraph 1. When the health data holder is a public sector body, such fees shall be in accordance with Article 6 of Regulation (EU)2022/868.*~~ *The part of the fees linked to the* ***health*** *data holder's costs shall be paid to the* ***health*** *data holder.*

4) Proposal for a partial return to the original wording of COM's proposal in Article 45(5A).

Current text:

5A. ***Where*** ~~*Data users applicant*~~ ***an applicant*** *seeking access to electronic health data from* ***health data holders established in different*** ~~*more than one*~~ *Member State* ***or from other authorised participants in the cross-border infrastructure referred to in Article 52, the applicant*** *shall submit a single* ***data access*** *application* ***through*** ~~*to one of the concerned health data access bodies of their choice which shall be responsible for sharing the request with other health data access bodies and authorised participants in the services provided by the Commission in the cross-border infrastructure*~~ *HealthData@EU referred to in Article 52,* ***where the application shall be automatically forwarded to relevant national contact point of the Member States and other authorised participants.*** ~~*which have been*~~ *identified in the data access application.* ~~*For requests to access electronic health data from more than one Member States, the health data access body shall notify the other relevant health data access bodies of the receipt of an application relevant to them within 15 days from the date of receipt of the data access application.*~~ *MOVED FROM ARTICLE 45(3)*

Modified text:

5A. *Data users applicant seeking access to electronic health data from more than one Member States* ***or from other authorised participants in the cross-border infrastructure referred to in Article 52, the applicant*** *shall submit a single* ***data access*** *application to one of the concerned health data access bodies of their choice which shall be responsible for sharing the request with other health data access bodies and authorised participants in HealthData@EU referred to in Article 52,* ***where the application shall be automatically forwarded to relevant national contact point of the Member States and other authorised participants.*** ~~*which have been*~~ *identified in the data access application.* ~~*For requests to access electronic health data from more than one Member States, the health data access body shall notify the other relevant health data access bodies of the receipt of an application relevant to them within 15 days from the date of receipt of the data access application.*~~ *MOVED FROM ARTICLE 45(3)*

5) Proposal to change Article 46(1A): replace "market regulation authorities" by "~~market~~ regulatory authorities".
Proposal to change Article 47(2A)(c): replace "market regulation authorities" by "~~market~~ regulatory authorities".

6) Presentation of summary of the questionnaire for the transitionary periods for primary and secondary use [informative point].

7) Explanation of the proposal of the Presidency for opt-out [informative point].

8) Revision of alternative proposals for opt-out:

- deletion of Article 35F, i.e. leaving just the right to object of the GDPR, in particular Article 21(1) of the GDPR, pursuant to Article 1(3A) of the EHDS.
- other proposals.

9) Proposal to split Article 33(1)(e) into two:
- part 1: "genetic markers or comparable small amounts of genetic information."
- part 2: "whole genomes or a significant amount of genetic information"

This would allow for differentiated access conditions for part 1 (which is commonly included in EHR systems and many other repositories) and part 2.

Also, a recital should explain the difference between the two parts.