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LIMITE

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CONTRIBUTION

From:	General Secretariat of the Council
To:	Working Party on Public Health (Attachés) Working Party on Public Health (European Health Data Space)
Subject:	Proposal for a regulation on the European Health Data Space - Comments from delegations following the Working Party on Public Health of 9-10 November 2023

Delegations will find enclosed further comments from the Swedish delegation on the above mentioned subject following the Working Party on Public Health of 9-10 November 2023.

Delegations will find in Annex a draft text as prepared by the Presidency on the above-mentioned subject.

Commented [A1]: General comments.
The terms used and the wording need to be further amended as different terms is used for same things.

Changes compared to the second compromise proposal (8171/1/23 REV 1) are marked in **double underline/yellow highlight** for additions and in ~~double strikethrough/yellow highlight~~ for deletions. New movements of text fragments from one article to another are referenced in **[[blue highlight and between double brackets]]**.

ANNEX

Article 2

Definitions

(...)

2. In addition, for the purposes of this Regulation the following definitions shall apply:

- (b) ~~'non-personal electronic health data' means data concerning health and genetic data in electronic format that falls outside the definition of personal data provided in Article 4(1) of Regulation (EU) 2016/679 ;~~ **'anonymous electronic health data' means data related to health, processed in an electronic form, which does not relate to an identified or identifiable natural person or to personal data concerning health rendered anonymous processed in a such manner that the data subject is not or no longer identifiable.**
- (d) 'primary use of electronic health data' means the processing of personal electronic health data for the provision of healthcare services to assess, maintain or restore the state of health of the natural person to whom that data relates, including the prescription, dispensation and provision of medicinal products and medical devices, as well as for relevant social security, administrative or reimbursement services;

Commented [A2]: To be better in line with the GDPR

Commented [A3]: Delete as Chapter II in the third compromise only include healthcare as Article 8D has been changed.

Article 13

Supplementary cross-border digital health services and infrastructures

2. The Commission and Member States may facilitate the exchange of **personal** electronic health data with other infrastructures, such as the Clinical Patient Management System or other services or infrastructures in the health, care **or social security** fields which may become authorised participants to MyHealth@EU. The Commission shall, by means of implementing acts, set out the technical aspects of such exchanges. Those implementing acts shall be adopted in accordance with the advisory **examination** procedure referred to in Article 68(2).

The connection of another infrastructure to the central platform for digital health, **as well as disconnection**, shall be subject to a decision, **by means of implementing acts**, of the **Commission** ~~joint controllership group for MyHealth@EU referred to in Article 66~~, **based on the result of the compliance checks of the technical aspects of such exchanges as referred to in subparagraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 68(2)**

ANNEX I

MAIN CHARACTERISTICS OF ELECTRONIC HEALTH DATA CATEGORIES

Electronic health data category	Main characteristics of electronic health data included under the category
1. Patient summary	Electronic health data that includes important clinical facts related to an identified person and that is essential for the provision of safe and efficient healthcare to that person. The following information is part of a patient summary: 1. Personal details 2. Contact information 3. Information on insurance 4. Allergies 5. Medical alerts 6. Vaccination/prophylaxis information, possibly in the form of

	a vaccination card 7. Current, resolved, closed or inactive problems 8. Textual information related to medical history 9. Medical devices and implants 10. Procedures 11. Functional status 12. Current and relevant past medicines 13. Social history observations related to health 14. Pregnancy history 15. Patient provided data 16. Observation results pertaining to the health condition 17. Plan of care 18. Information on a rare disease such as details about the impact or characteristics of the disease
2. Electronic prescription	Electronic health data constituting a prescription for a medicinal product as defined in Article 3(k) of Directive 2011/24/EU.
3. Electronic dispensation	Information on the supply of a medicinal product to a natural person by a pharmacy based on an electronic prescription.
4. Medical image and image report	Electronic health data related to the use of or produced by technologies that are used to view the human body in order to prevent, diagnose, monitor, or treat medical conditions.
5. Laboratory result	Electronic health data representing results of studies performed notably through in vitro diagnostics such as clinical biochemistry, haematology, transfusion medicine, microbiology, immunology, and others, and including, where relevant, reports supporting the interpretation of the results.
6. Hospital d Discharge report	Electronic health data related to a healthcare encounter or episode of care and including essential information about admission, treatment and discharge of a natural person.