Council of the European Union
General Secretariat

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WORKING DOCUMENT

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 - Templates for written feedback from delegations after the Working Party on Public Health meeting on 4 and 5 July 2023

Delegations will find enclosed a template to provide written feedback after the Working Party on Public Health meeting on 4 and 5 July 2023.

Spanish Presidency

Request for feedback from delegations after the working parties of

Tuesday, 4th of July 2023
10:00-12:30
&
14:00-18:00

Wednesday, 5th of July 2023
10:00-13:00
&
14:30-18:30

Dear colleagues,

Please, find attached the request for feedback from the WPs of Tuesday 4th of July and Wednesday 5th of July.

If possible,

- submit the file with your comments in *both* Microsoft Word and PDF formats.

- name the file with your comments in the following manner:
  "WP_2023_07_0405_comments_< 2 digit country code[1]>"

  For example:
  "WP_2023_07_0405_comments_ES.docx"
  "WP_2023_07_0405_comments_ES.pdf"

[1] https://en.wikipedia.org/wiki/ISO_3166-1_alpha-2

Feedback about red lines

Note 1: deadline: 16th of July 2023
Note 2: the justification of red lines is fundamental for the presidency in order to take your concerns into account.

Red lines[2] in the Swedish presidency compromise text, document number ST 8171 2023 REV1 (herein after "current compromise text").
EU Member State:
Executive summary: "Red line 1." - Brief description of red line 1. - Brief justification of red line 1. "Red line 2." - Brief description of red line 2. - Brief justification of red line 2. etc **Detailed description of red lines.** "Red line 1" - Detailed description of red line 1, including text proposals. - Detailed justification of red line 1. "Red line 2" - Detailed description of red line 2, including text proposals. - Detailed justification of red line 2. etc

[2] defined as aspects of the current compromise text, which would make it unacceptable for your delegation to move forward with the proposal.

Feedback about the definition of data holder

Note 1: deadline: 16th of July 2023
Note 2: the presidency will present a new text proposal (for the definition of data holder) in the meeting of the WP of the 14th of July 2023 based on the verbal comments received during the WPs of 4th & 5th of July 2023, but additional feedback is welcome.

Wording of the current compromise text	Proposed new wording of the definition (and/or a recital)
'**health** data holder' means a~~ny~~ natural or legal person, which is an entity or a body in the health or care sector, or performing research in relation to these sectors, as well as Union institutions, bodies, offices and agencies who has~~ the right or obligation, in accordance with this Regulation, applicable Union law or national legislation implementing Union law~~ **either:** **(a) the right or obligation, in accordance with applicable Union law or national legislation, to process personal electronic health data for the provision of healthcare or care or for public health, reimbursement, research, innovation, policy making, official statistics, patient safety or regulatory purposes, in its capacity as a controller; or** **(b) the ability to make available, including to register, provide, restrict access or exchange anonymous electronic health data** ~~non personal data~~, through control of the technical design of a product and related services, ~~the ability to make available, including to register, provide, restrict access or exchange certain data~~;	
Justification of the new wording:	

Feedback for article 35A & article 47A(2)

Note: deadline: 16th of July 2023

Wording of the current compromise text	Proposed new wording of the article (and/or a recital)
Article 35A ***IP-rights and trade secrets*** **1.** **Where the health data access body or other** P**p**ublic sector bodies or Union´s institutions, agencies and bodies obtain access to electronic health data **from health data holders** entail~~i~~ing IP rights and trade secrets in the exercise of the tasks conferred to them by ~~Union law or national law~~ **this Regulation**, they shall take all specific **organisational and technical** measures necessary to preserve the confidentiality of such data. MOVED FROM ARTICLE 34(4) AND AMENDED, SEE ALSO ARTICLE 37(1)(ii) **2.** **The technical and organisational measures taken to preserve the confidentiality of electronic health data entailing IP rights and trade secrets referred to in paragraph 1 shall be made publicly available.**	
Justification of the new wording:	

Wording of the current compromise text	Proposed new wording of the article (and/or a recital)
Article 47A ***Templates to support access to electronic health data for secondary use*** 1. (…) 2. The Commission may, by means of implementing acts, adopt the necessary rules for facilitating the handling of data access applications for HealthData@EU **referred to in Article 45(5A)**, including **the single** ~~a common~~ application **template**~~form~~, a common data permit template, standard **templates** ~~forms~~ for common electronic health data access contractual arrangements, and common procedures for handling cross-border requests, pursuant to Articles 45, 46~~,~~ **and** 47 ~~and 48~~. ~~Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2)~~. MOVED FROM ARTICLE 54(3) **3. (...)**	
Justification of the new wording:	

Feedback on partial opt-out (article 35F)

Note 1: deadline: 16th of July 2023

Wording of the current compromise text	Proposed new wording of the article (and/or a recital)
Article 35F ***Exercise of rights by natural persons with the health data access body*** **1.** **In addition to the rights in Articles 15 to 18 and 21 of Regulation (EU) 2016/679, natural persons shall have the right to object (opt-out) to their personal electronic health data to be made available for secondary use with the health data access body.** **2.** **Where a natural person have exercised the right to object (opt-out), the health data access body shall exclude personal electronic health data concerning that natural person from being processed for secondary use, where possible.** **3.** **The health data access body shall provide technical means enabling natural persons to exercise their rights referred to in paragraph 1. Such means may be established within the access services referred to in Article 8G or through other means.** **4.** **In situations referred to in Article 49(1A), the single health data holder shall fulfill the obligations laid down in paragraphs 1 to 3.** **5.** **The Commission shall, by means of implementing acts, determine the implementation measures of the right referred to in paragraph 2. Those measures shall be based on the requirements of data protection by design and default laid down in Article 25 of Regulation (EU) 2016/679, including measures consisting of transparency with regard to the functions and processing of personal electronic health data for secondary use. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 68(2).**	
Justification of the new wording:	

Feedback on fees (article 42)

Note 1: deadline: 16th of July 2023
Note 2: the presidency will present a new text proposal (for fees) in the meeting of the WP of the 14th of July 2023 based on the verbal comments received during the WPs of 4th & 5th of July 2023, but additional feedback is welcome.

Wording of the current compromise text	Proposed new wording of the article (and/or a recital)
Article 42 *Fees*	
1. Health data access bodies ~~and~~ **or** single **health** data holders **referred to in Article 49** may charge fees for making electronic health data available for secondary use. **Such fees shall be in proportion to the cost of making the data available and not restrict competition. Such**~~Any~~ fees shall **cover all or part of** ~~include and be derived from the~~ costs related to ~~conducting~~ the procedure ~~for requests, including~~ for assessing a data **permit** application or a data request, granting, refusing or amending a data permit pursunat to Article 45 and 46 or providing an answer to a data request pursuant to Article 47, in accordance with Article 6 of Regulation **(EU) 2022/868**~~[…] [Data Governance Act COM/2020/767 final]~~**, as well as costs related to the gathering, preparation and provising of the electronic health data**.	
2. Where the **electronic health** data in question are ~~not~~ held by **a health data holder who 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.	
~~3. The electronic health data referred to in Article 33(1), point (o), shall be made~~	

	~~available to a new user free of charge or against a fee matching the compensation for the costs of the human and technical resources used to enrich the electronic health data. That fee shall be paid to the entity that enriched the electronic health data.~~	
~~4.~~	~~Any fees charged to data users pursuant to this Article by the health data access bodies or data holders shall be transparent and proportionate to the cost of collecting and making electronic health data available for secondary use, objectively justified and shall not restrict competition. The support received by the data holder from donations, public national or Union funds, to set up, develop or update tat dataset shall be excluded from this calculation. The specific interests and needs of SMEs, public bodies, Union institutions, bodies, offices and agencies involved in research, health policy or analysis, educational institutions and healthcare providers shall be taken into account when setting the fees, by reducing those fees proportionately to their size or budget.~~	
~~5.~~	~~Where data holders and data users do not agree on the level of the fees within 1 month of the data permit being granted, the health data access body may set the fees in proportion to the cost of making available electronic health data for secondary use. Where the data holder or the data user disagree with the fee set out by the health data access body, they shall have access to dispute settlement bodies set out in accordance with Article 10 of the Regulation […] [Data Act COM/2022/68 final].~~	
5A.	**Before issuing a data permit pursuant to Article 46 or providing an answer to a data request pursuant to Article 47, the health data access body shall inform the applicant of the expected fees. The applicant shall be informed about the option to withdraw the application. If the applicant withdraw its application, the applicant shall only be charged the costs that have already been incurred.**	
6.	~~The Commission may, by means of implementing acts, lay down principles and rules for the fee policies and fee~~	

	~~structures. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2).~~ **The Commission may, in close cooperation with EHDS Board, issue guidelines on fee policies and fee structures in order to support consistency and transparency between Member States.**	

Feedback on merging of data access application (article 45) and data request (article 47), and rewording of data permit (article 46)

Note: deadline: 16th of July 2023

Free format for feedback.