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WORKING DOCUMENT

From:	Presidency
To:	Delegations
Subject:	Presidency working document on the European Health Data Space proposal for the Working Party on Public Health on 22 September 2023

Spanish Presidency Working Document for the WPPH 2023-09-22

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Topics to cover

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General remarks about comments from the delegations

Most of the content of this particular document from the presidency is taken directly from the written comments submitted by the delegations. Minor changes are made by the Presidency:

- Some amendments may be reorganized, to keep the coherence with other amendments proposed by other delegations.

- Minor grammatical, syntactic and punctuation errors are corrected both in the justification and in the proposed amendments.

- References to the name(s) of the Member State(s) proposing the amendment are removed and minor wording changes may be introduced (such as a replacement of "name of Member State" by "our country" or "our delegation"). This may also lead to sentences being removed from the justification, when they reference specific public sector entities or bodies known to exist only in one Member State. When this happens, we usually mark such omissions with "(…)" in the text of the justification. However, we try to make sure that such omissions do not change the fundamental aspects of the justification provided by the delegation.

Additionally, in some cases the Presidency may provide "Comments from the Presidency" after the "Justifications for the amendments" provided by the delegations.

Versions of the EHDS text

We shall use the following terminology to refer to the different versions of the text of the Regulation:

- **Commission's original proposal:** https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52022PC0197

- **Swedish compromise text:** document number **ST8171 2023 REV1**

- **Proposal for modifications from the Spanish presidency, taking into account the comments of the delegations:** the modifications are made over the Swedish compromise text, with a ~~**double strikethrough**~~ in the case of deletions and a **double underline** in the case of additions (changes are also highlighted with a yellow background and shown in **bold font**).

  Note: the background has been changed to yellow to ease readability when printing the document in greyscale, after comments from delegations.

Nomenclature of proposed modifications

A tag will be added to the text when the Spanish presidency introduces a proposal for the modification on the text of the Regulation. Each modification may affect one or several articles and one or several recitals.

In order to ease the identification of the changes in the text, the Spanish presidency has devised the coding scheme described below.

MOD: modification introduced in the text of:
- one or several articles
and
- one or several recitals.

Topic of the modification:
- **GA** (general aspects): definitions and articles affecting general aspects of the EHDS (some fragments of article 1 & most articles of Chapters V, VII-XI).
- **PU** (primary use): definitions affecting primary use of health data & Chapters II-III.
- **SU** (secondary use): definitions affecting secondary use of health data & Chapter IV.
- **Go** (governance): definitions affecting governance and Chapter VI.
- **TC** (third countries): definitions and articles affecting third countries, specifically.
- **XX** (other modifications).

Note: when a modification affects several topics, the main topic is chosen.

Example 1: fees in article 42 may affect secondary use and third countries, but the

Number of modification: consecutive number, within the topic.

Note: modification number 1 in topic SU would be coded as "MOD.SU.1". Modification number 2 in topic SU would be coded as

[MOD . PU . 1 . rev2]

Number of revision of this particular modification (compared to the initial compromise text of the Spanish presidency):
- ***blank***: initial version of the modification
- **rev1**: first revision of this modification
- **rev2:** 2nd revision of this modification
…
- **revN:** Nth revision of this modification

Examples:
[MOD.SU.1] = modification #1 within the secondary use of health data, initial version.
[MOD.Go.1.rev3] = modification #1 within governance, revision 3.
[MOD.PU.2.rev4] = modification #2 within the primary use of health data, revision 4

Secondary use of health data

[MOD.SU.13] Revision of Article 46

Justification for the position of the Presidency
One delegation communicated several red lines regarding Article 46.

Revision #1: suppression of risk analysis in data permits [Article 46(1A)]

Swedish compromise text	Proposed modification
Article 46 *Data Permit* (…) **1A. The health data access body shall also take into account the following risks:** **(a) risks for national defence, security, public security and public order;** **(b) risks of undermining protected IP-rights and trade secrets and privacy of natural persons;** **(c) risk of undermining confidential data in governmental databases of market regulatory authorities;** **(d) risk of misuse, including the prohibited use in Article 35.** (…)	*Article 46* *Data Permit* (…) **1A. The health data access body shall also take into account the identified ~~following~~ risks when evaluating the data permit.** **(a) ~~risks for national defence, security, public security and public order;~~** **(b) ~~risks of undermining protected IP-rights and trade secrets and privacy of natural persons;~~** **(c) ~~risk of undermining confidential data in governmental databases of market regulatory authorities;~~** **(d) ~~risk of misuse, including the prohibited use in Article 35.~~** (…) *Justification for the new wording:* *(a) The delegation questions the practical arrangements for the HDABs to carry out an analysis of the risks listed in the revised compromise. This is a new obligation, which, on first analysis, seems disproportionate to be carried out by HDABs. It is difficult to imagine the HDAB being able to make a complete and correct assessment of such a wide range of risks. This appears to be impossible for each project and also appears to be likely to generate a burden (in terms of human resources and expert skills) and significant additional delays in the examination of applications for access authorisation.*

First round of comments:
Does your delegation agree with the proposed modification?
Yes/No.

Second round of comments:
If no, please briefly take the floor and provide detailed comments in written form.
If you have suggestions only for minor modifications, please, just send written comments.
Deadline for written comments: 2023-09-29

Revision #2: provision for a simple and recurring data permit [new para 15 in Article 46]

Swedish compromise text	Proposed modification
Article 46 *Data Permit* (Paragraph 15 does not exist.)	*Article 46* *Data Permit* **15. Health data users requesting a simple and recurring data permit may get access to electronic health data after obtaining a simplified data permit through a fast-track procedure when meeting certain criteria:** **(a) an explanation of the intended use of the electronic health data, including for which of the purposes referred to in Article 34(1) access is sought;** **(b) a description of the requested electronic health data, their format and data sources, where possible, including geographical coverage where data is requested from health data holder in several Member States or authorised participants in the cross-border infrastructure referred to in Article 52.).** **(c) a framework of security, technical and organisational requirements based on reference methodologies** **(d) the information provided in the application demonstrates sufficient safeguards to protect the rights and interests of the health data holder and of the natural persons concerned as well as to prevent misuse;** *Justification for the new wording:* *(b) EHDS regulation must avoid creating additional complexity. Therefore, the regulation must propose the possibility of providing fast track data permit procedures, with shorter deadlines, for certain recurrent processing operations that do not present any risks for the rights and freedoms of individuals. The aim is*

Swedish compromise text	Proposed modification
	not to slow down the re-use of data for research purposes and to lighten the administrative burden for data permits for HDABs. These simplified procedures will cover "simple" processing operations that meet the requirements of reference research methodologies.

First round of comments:
Does your delegation agree with the proposed modification?
Yes/No.

Second round of comments:
If no, please briefly take the floor and provide detailed comments in written form.
If you have suggestions only for minor modifications, please, just send written comments.
Deadline for written comments: 2023-09-29

[MOD.SU.14] Suppression of risk analysis in data requests [Article 47]

Justification for the position of the Presidency
One delegation communicated a red line regarding Article 47.

Swedish compromise text	Proposed modification
Article 47 (2A) **2A. The health data access body shall assess if the request is complete and take into account the following risks:** **(a) risks for national defence, security, public security and public order;** **(b) risks of undermining protected IP-rights and trade secrets;** **(c) risks of undermining confidential data in governmental databases of market regulatory authorities;** **(d) risks of misuse, including the prohibited use in Article 35.**	*Article 47 (2A)* **2A. The health data access body shall assess if the request is complete and take into account the ~~following~~ identified risks.** **(a) ~~risks for national defence, security, public security and public order;~~** **(b) ~~risks of undermining protected IP-rights and trade secrets;~~** **(c) ~~risks of undermining confidential data in governmental databases of market regulatory authorities;~~** **(d) ~~risks of misuse, including the prohibited use in Article 35.~~** *Justification for the new wording:* *Risk analysis to be carried out by the HDAB in the process to validate a request for electronic health data in a statistical format, as currently drafted in paragraph 2A, represents a disproportionate burden, especially as the data in question are anonymised, for which the risks envisaged therefore appear to be even lessened.*

First round of comments:
Does your delegation agree with the proposed modification?
Yes/No.

Second round of comments:
If no, please briefly take the floor and provide detailed comments in written form.
If you have suggestions only for minor modifications, please, just send written comments.
Deadline for written comments: 2023-09-29

[MOD.SU.15] Fast-track procedure for public sector bodies

Justification for the position of the Presidency
The fast-track existed in article 48 of the Commission's proposal, but was removed with a strong support from the delegations. Three delegations communicated the need to (re)incorporate a fast-track procedure for public sector bodies as a red line.

Option 1: Swedish compromise text

(Article 48 is deleted, no fast-track for public sector bodies)

Option 2: modification of article 46

Wording of the current compromise text	Proposed new wording
	Article 46 *Data permit* [...] 2. [...] **(3AA) Member States may provide for an accelerated application procedure for public sector bodies if the processing of the data by the public sector bodies is to be carried out for a purpose which is in the public interest.** 3. [...]
Justification for the new wording: (c) *Our delegation welcomes the deletion of Article 48 (Swedish compromise text). The special privileges it contained for public bodies were too far-reaching. These bodies can also go through an application procedure as a rule. An accelerated application procedure should be reinstated. The fast-track application procedure for public bodies should only be provided for if they want to process the data for a purpose that is in the public interest.*	

Option 3: new article 48

Proposed new wording
Article 48 ***Fast-track procedure for public sector bodies and Union institutions, bodies, offices and agencies*** **1. Public sector bodies and Union institutions, bodies, offices and agencies and national public sector bodies offices and agencies mentioned in paragraph (7) (a) can access electronic health data after obtaining a simplified data permit through a fast-track procedure under this Article.** **2. Public sector bodies and Union institutions, bodies, offices and agencies can use a simplified data access application form that shall include the following :** **(a) an explanation of the intended use of the electronic health data, including for which of the purposes referred to in Article 34(1) access is sought;**

Proposed new wording
(b) a description of the requested electronic health data, their format and data sources, where possible, including geographical coverage where data is requested from health data holder in several Member States or authorised participants in the cross-border infrastructured referred to in Article 52. The scope of the data requested shall be in accordance with paragraph 7 (b), or, for European public sector bodies and Union institutions, bodies, offices and agencies, the information mentioned in the article 45 (2), (b). **(c) a framework of security, technical and organisational requirements** **3. The health data access bodies shall decide to grant or refuse access to electronic health data on the basis of the following criteria:** **(a) the purposes followed match one or more of the purposes listed in Article 34(1) of this Regulation** **(b) the requested data is within the scope of the data that the public sector bodies, offices and agencies are allowed to access pursuant to paragraph 7** **(c) the information provided in the application demonstrates sufficient safeguards to protect the rights and interests of the health data holder and of the natural persons concerned as well as to prevent misuse;** **4. When the data permit issued covers several purposes, the data controller may undertake the various processing operations necessary to pursue these different purposes.** **5. By way of derogation from that Regulation (EU) 2022/868, a health data access body shall issue or refuse a data permit within two weeks of receiving the data access application. The health data access body may extend the period for responding to a data access application by 2 additional weeks where necessary, taking into account the urgency and complexity of the request and the volume of requests submitted for decision. In such cases, the health data access body shall notify the applicant as soon as possible that more time is needed for examining the application, together with the reasons for the delay.** **6. Following the issuance of a data permit, the health data access body shall immediately request the electronic health data from the health data holder. The health data access body shall make available the electronic health data to the public sector body within 2 months after receiving them from the health data holders, unless it specifies that it will provide the data within a longer specified timeframe.** **7. Member States shall establish:** **1. the list of its national public sector bodies and bodies with a public service mission authorised to use the fast-track procedure under this Article** **2. the definition of the scope of the data that each of its national body authorised to use the fast-track procedure is allowed to access, especially according to the depth, nature, geographic coverage of the electronic health data.**
Justification for the new wording: *This article is essential in order to ensure good public health policies. This allows simplified access to data held by the HDABs, without having to request data permits for each use (as is currently the case in our country for a number of bodies entrusted with a public service mission, under conditions governed by law).* *Such a 'fast-track' access is essential to the smooth operation of public health policies, which require simplified and frequent access to certain health data.* *(...)* *Article 48 provided for a general derogation from the principle of prior authorisation for access by public authorities. In the course of discussions, this Article, which gave rise to fears, particularly in*

Proposed new wording
countries that were less mature in the re-use of data, was deleted and does not feature in the latest Presidency compromise. To take account of these concerns while allowing public authorities to fulfil their missions, it is proposed to provide for simplified authorisations for these bodies. *Technical and organizational security guarantees for such access will have to be defined and provided for.*

First round of comments:
Please, choose one option:
Option 1: Swedish compromise text
Option 2: new wording suggested by one delegation (modification of article 46)
Option 3: new wording suggested by another delegation (new article 48)
Option 4: a different wording

Second round of comments:
If you choose option 4, please briefly take the floor, and send detailed written comments.
If you have suggestions only for minor modifications, please, just send written comments.
Deadline for written comments: 2023-09-29

Governance

[MOD.Go.1] Revision of Articles 64(1)-(5) & new para 3 in Article 65 & deletion of Article 66

Justification for the position of the Presidency

During the WP 2023-07-14 and in subsequent written comments
- 16 countries, representing ~37,5% of the EU population, supported the wording of article 64.
- 4 countries, representing ~44% of the EU population, were against the wording of article 64.

During the WP 2023-07-14 and in subsequent written comments
- 18 countries, representing 59,4% of the EU population, supported the wording of article 66.
- 2 countries, representing ~19,9% of the EU population, were against the wording of article 66.

In addition,
- several delegations have submitted text suggestions for amendments in articles 64 and 66.
- one delegation has communicated several red lines regarding the wording of articles 64, 65 and 66. This delegation made reference to the comments made by "Drafting group V", which -to the best of our knowledge- have not been formally submitted to the Presidency, but are included in the agenda with the wording provided by this delegation. Some of the amendments were supported by other delegations in written comments. When this was identified by the Presidency, we have included this in the description of the voting options. The general justification for amendments in articles 64, 65 and 66 provided by this delegation are:

EHDS success is strongly dependent on robust, agile and efficient governance involving a close collaboration between Member States and the Commission. Member States must ensure synchronization of decisions taken at EU level with their national digital health roadmaps. Moreover, EHDS governance framework may be a blueprint for the next European data spaces.

Our delegation's proposal is based on lessons learned from the on-going implementation of MyHealth@EU, the experience of the EU DCC governance as well as from other initiatives managed at European level. The proposal is articulated in order to ensure flexibility, the lowest level of complexity, and continuity of work with the current governance framework, coordination, consistency, efficiency and effectiveness of governance bodies through to operations. It includes the following key elements:
• EHDS Board, co-chaired by a Member State and the Commission, is the core governance engine of EHDS and has 3 main roles (1) as an expert being consulted by the Commission in the preparation process of delegated and implementing acts, (2) as being in charge of the coordination with Member States and other parties involved in EHDS and (3) as being involved in supervising and providing operational decisions to the Commission as operator of the infrastructures and central services.
• EHDS Board has 4 subgroups in charge of providing operational decisions to the Commission which operates central infrastructures and services supporting the functioning of EHDS.
• An executive Board is created, including the co-chairs and the chairs of the subgroups to ensure consistency and coordination within the EHDS Board.
• Specific governance modalities shall be taken for the involvement of third countries and organizations connected to EHDS.

Proposed amendments are based on the proposal made in a non-paper written by the expert group "EHDS Drafting group V" involving 13 Member States. Articles 64 and 65 are amended, and current article 66 integrated in articles 64 and 65. A clear link is established with articles 67 and 68.

Revision #1: Modification of Member States representatives in EHDS Board [Article 64(1)]

Option 1: Swedish compromise text

No changes in Article 64(1)

Option 2: proposal from 2 delegations / Drafting group V

Swedish compromise text	Proposed modification
Article 64 *European Health Data Space Board (EHDS Board)* 1. A European Health Data Space Board (EHDS Board) is hereby established to facilitate cooperation and the exchange of information among Member States **and the Commission**. The EHDS Board shall be composed of ~~the high level~~ representatives**,** **one each** of digital health authorities and health data access bodies**,** of all the Member States. ~~Other national authorities, including market surveillance authorities referred to in Article 28, European Data Protection Board and European Data Protection Supervisor, may be invited to the meetings, where the issues discussed are of relevance for them. The Board may also invite experts and observers to attend its meetings, and may cooperate with other external experts as appropriate. Other Union institutions, bodies, offices and agencies, research infrastructures and other similar structures, shall have an observer role.~~ (SECOND, THIRD AND LAST SENTENCES AMENDED AND MOVED TO PARA 1(B)-1(E)) (…)	*Article 64* *European Health Data Space Board (EHDS Board)* 1. A European Health Data Space Board (EHDS Board) is hereby established to facilitate cooperation and the exchange of information among Member States **and the Commission**. The EHDS Board shall be composed of: **1aa.** ~~the high level~~ **One or two** representative**s of national authorities with only one voting right appointed for~~ ~~**, one each of digital health authorities and health data access bodies, of all the**~~ **each** Member State~~s~~. ~~Other national authorities, including market surveillance authorities referred to in Article 28, European Data Protection Board and European Data Protection Supervisor, may be invited to the meetings, where the issues discussed are of relevance for them. The Board may also invite experts and observers to attend its meetings, and may cooperate with other external experts as appropriate. Other Union institutions, bodies, offices and agencies, research infrastructures and other similar structures, shall have an observer role.~~ (SECOND, THIRD AND LAST SENTENCES AMENDED AND MOVED TO PARA 1(B)-1(E)) (…) *Justification for the new wording (provided by one of the delegations): We are of the opinion that the Member States should be able to decide themselves from which authorities the representatives come from, not necessarily from digital health authorities or data access bodies. Two representatives from each MS creates a large group and we have concerns how the decision process would be possible in this group.*

Option 3: proposal from 2 other delegations

Swedish compromise text	Proposed modification
Article 64 *European Health Data Space Board (EHDS Board)* 1. A European Health Data Space Board (EHDS Board) is hereby established to facilitate cooperation and the exchange of information among Member States **and the Commission**. The EHDS Board shall be composed of ~~the high level~~ representatives**,** **one each** of digital health authorities and health data access bodies**,** of all the Member States. ~~Other national authorities, including market surveillance authorities referred to in Article 28, European Data Protection Board and European Data Protection Supervisor, may be invited to the meetings, where the issues discussed are of relevance for them. The Board may also invite experts and observers to attend its meetings, and may cooperate with other external experts as appropriate. Other Union institutions, bodies, offices and agencies, research infrastructures and other similar structures, shall have an observer role.~~ (SECOND, THIRD AND LAST SENTENCES AMENDED AND MOVED TO PARA 1(B)-1(E)) (…)	*Article 64* *European Health Data Space Board (EHDS Board)* 1. A European Health Data Space Board (EHDS Board) is hereby established to facilitate cooperation and the exchange of information among Member States **and the Commission**. The EHDS Board shall be composed of ~~the high level representatives, one each of digital health authorities and health data access bodies, of all the Member States.~~ **not more than two representatives of national authorities nominated by each Member State. Each Member State shall have one vote.** ~~Other national authorities, including market surveillance authorities referred to in Article 28, European Data Protection Board and European Data Protection Supervisor, may be invited to the meetings, where the issues discussed are of relevance for them. The Board may also invite experts and observers to attend its meetings, and may cooperate with other external experts as appropriate. Other Union institutions, bodies, offices and agencies, research infrastructures and other similar structures, shall have an observer role.~~ (SECOND, THIRD AND LAST SENTENCES AMENDED AND MOVED TO PARA 1(B)-1(E)) (…) *Justification for the new wording:* *Our delegation suggests to provide each Member State with more flexibility regarding the nomination of its two representatives in the EHDS Board in order to enable fruitful debates against the background of the complexity of the topics addressed by the Board.*

First round of comments:
Please, choose one option:
Option 1: Swedish compromise text
Option 2: new wording suggested by 2 delegations / drafting group V
Option 3: new wording suggested by 2 other delegations
Option 4: a different wording

Second round of comments:
If you choose option 4, please briefly take the floor, and send detailed written comments.
If you have suggestions only for minor modifications, please, just send written comments.
Deadline for written comments: 2023-09-29

Revision #2: Proposal for the modification of the number and functions of steering groups [Article 64(2)-(3) & new para 3 in Article 65 & deletion of Article 66]

Option 1: Swedish compromise text

No changes in Article 64(2)-(3)

No changes in Article 66

Option 2: new wording suggested by one delegation / drafting group V

Swedish compromise text	Proposed modification
Article 64 *European Health Data Space Board (EHDS Board)* (…)	*Article 64* *European Health Data Space Board (EHDS Board)* (…)
2. Depending on the functions related to the use of electronic health data, the EHDS Board may work in subgroups **for certain topics**, where digital health authorities or health data access bodies ~~for a certain area~~ shall be represented. **The subgroups shall support the EHDS Board with specific expertise.** The subgroups may have joint meetings, as required.	2. ~~**Depending on the functions related to the use of electronic health data, the EHDS Board may work in subgroups for certain topics, where digital health authorities or health data access bodies for a certain area shall be represented.**~~ **The EHDS Board shall create the following steering subgroups to assist by performing tasks undertaken by the EHDS Board The subgroups shall support the EHDS Board with specific expertise.** The subgroups may have joint meetings, as required. **a) One sub-group in charge of primary use issues, including supervision of the cross-border infrastructure provided for in Article 12 ; (moved from art 66A, Swedish Presidency compromise text)** **b) One sub-group in charge of secondary use issues, including supervision of the cross-border infrastructure provided for in Article 52 ; (moved from art 66A, , Swedish Presidency compromise text)** **c) One sub-group in charge of Interoperability and EHR regulation issues, including supervision of the tasks provided in Chapter III;** **d) One sub-group in charge of data protection, ethics and citizen engagement issues.**
3. The ~~composition, organisation, functioning and cooperation of subgroups shall be set out in~~ rules of procedures **of the EHDS Board shall be adopted by its members and** put forward by the Commission. (d) **The rules of procedures shall include rules pertaining to the composition, structure, operation**	**3.** The ~~composition, organisation, functioning and cooperation of subgroups shall be set out~~ **in** rules of procedures **of the EHDS Board shall be adopted by its members and** put forward by the Commission. **The rules of procedures shall include**

Swedish compromise text	Proposed modification
and cooperation of the sub-groups and shall regulate the role of invitees referred to in paragraphs 1b to 1e, taking into account the topics under discussion and the level of confidentiality involved. **Regarding voting rules, the EHDS Board shall deliberate by consensus as far as possible. If consensus cannot be reached the EHDS Board shall deliberate by a majority of two thirds of the Member States representatives. Each member shall have one vote.** (…)	**rules pertaining to the composition, structure, operation ~~and~~ cooperation and confidentiality of discussions of the sub-groups and shall regulate the role of invitees referred to in paragraphs 1b to 1e, taking into account the topics under discussion ~~and the level of confidentality~~ involved.** **Each sub-group shall be composed of:** **a. One representative per Member State** **b. One additional expert per Member State when necessary;** **c. One representative of stakeholders, including as a minimum: citizens, healthcare professionals; patient organizations; digital health industry.** **Regarding voting rules, the EHDS Board shall deliberate by consensus as far as possible. If consensus cannot be reached the EHDS Board shall deliberate by a qualified majority ~~of two thirds~~ of the Member States representatives. Each member shall have one vote.** (…)
Article 65 *Tasks of the EHDS Board* (…) *(Paragraph 3 does not exist in the Swedish compromise text)*	*Article 65* *Tasks of the EHDS Board* (…) **3. The sub-groups shall take operational decisions concerning the maintenance, operations and development of the cross-border infrastructures and services pursuant to Chapters II, III and IV in order to deliver these EHDS services ensuring interoperability with other infrastructures, digital systems or data spaces.**
Article 66 ~~*Joint controllership groups for Union infrastructures*~~***The Steering Groups for the infrastructures MyHealth@EU and HealthData@EU*** 1. **Two Steering groups are hereby established** ~~The Commission shall establish two groups dealing with joint controllership~~ for the cross-border infrastructures provided for in Articles 12 and 52**; the MyHealth@EU Steering group and the HealthData@EU Steering group. Each**	**Deletion of Article 66.**

Swedish compromise text	Proposed modification
~~The~~ group~~s~~ shall be composed of **one** ~~the~~ representative~~s~~ **per Member State** of the **respective** national contact points ~~and other authorisated participants in those infrastructures~~. **1A.** The **Steering** groups shall take **operational** decisions concerning the development and operation of the cross-border infrastructures pursuant to Chapters II and IV, on changes of infrastructure, adding additional infrastructures or services, or ensuring interoperability with other infrastructures, digital systems or data spaces. The group**s** shall also state their view on ~~take decisions to~~ accept**ing** individual authorised participants to join the infrastructures or to disconnect them~~.~~ (MOVED FROM PARA 6 AND AMENDED) **1B. The Steering Groups shall take decisions by consensus. Where consensus cannot be reached, the adoption of a decision shall require the support of members representing two-thirds majority, where each Member State has one vote.** 2. The composition, organisation, functioning and cooperation of the ~~sub-~~**Steering** groups shall be set out in the rules of procedure adopted by those groups. **3.** ~~Stakeholders and relevant third parties, including patients' representatives, may be invited to attend meetings of the groups and to participate in their work.~~ **Other authorised participants may be invited to exchange information and views on relevant matters related to the crossborder infrastructures respectively provided for in Articles 12, 13 and 52. When these participants are invited, they shall have an observer role.** MOVED FROM ARTICLE 66(1) AND AMENDED **3A. Stakeholders and relevant third parties, including patients' representatives, may be invited to attend meetings of the groups and to participate in their work.** MOVED FROM ARTICLE 66(3) 4. The groups shall elect chairs for their meetings. 5. The groups shall be assisted by a secretariat provided by the Commission. ~~6. The groups shall take decisions concerning the development and operation of the cross-border infrastructures pursuant to Chapters II and IV, on changes of infrastructure, adding additional infrastructures or services, or ensuring interoperability with other infrastructures, digital systems or data spaces. The groups~~	

Swedish compromise text	Proposed modification
~~shall also take decisions to accept individual authorised participants to join the infrastructures or to disconnect them.~~ MOVED TO PARA 1A	

Option 3: new wording suggested by one delegation

Swedish compromise text	Proposed modification
Article 64 *European Health Data Space Board (EHDS Board)* (…) 2. Depending on the functions related to the use of electronic health data, the EHDS Board may work in subgroups **for certain topics**, where digital health authorities or health data access bodies ~~for a certain area~~ shall be represented. **The subgroups shall support the EHDS Board with specific expertise.** The subgroups may have joint meetings, as required. (…)	*Article 64* *European Health Data Space Board (EHDS Board)* (…) 2. Depending on the functions related to the use of electronic health data, the EHDS Board may work in subgroups **for certain topics**, where digital health authorities or health data access bodies ~~for a certain area~~ shall be represented. **The subgroups shall support the EHDS Board with specific expertise.** The subgroups may have joint meetings, as required. **There are standing and ad hoc subgroups. The following subgroups shall be established permanently:** **(i) One sub-group in charge with primary use issues, including supervision of the cross-border infrastructure provided for in Article 12.** **(ii) O One sub-group in charge with secondary use issues, including supervision of the cross-border infrastructure provided for in Article 52.** **(iii) One sub-group in charge of overarching technical, semantic and other interoperability issues.** *Justification for the new wording:* *Our delegation suggests to set up two permanent advisory bodies to the EHDS Board as the joint coordination body of the COM and the MS – one for primary and one for secondary use of health data - as subgroups.* *In addition, our delegation suggests to establish a permanent technical working group affiliated with the Board to provide the necessary expertise for overarching technical issues.*
Article 65 *Tasks of the EHDS Board* (…) *(Paragraph 3 does not exist in the Swedish*	*Article 65* *Tasks of the EHDS Board* (…) **3. The sub-groups according to Article 64(2) shall take operational decisions**

compromise text)	**concerning the maintenance, operations and development of the cross-border infrastructures according to the Articles 12 and 52 as well as services pursuant to Chapters II, III and IV in order to deliver these EHDS services ensuring interoperability with other infrastructures, digital systems or data spaces. Decisions of sub- and working groups shall be validated by the EHDS Board.**
	Deletion of Article 66. *Justification for the new wording:* *In order to avoid the establishment of parallel groups with similar tasks, our delegations suggests to integrate the underlying intention of this Article regarding the establishment of steering bodies for the EHDS infrastructures in Article 64.*

First round of comments:
Please, choose one option:
Option 1: Swedish compromise text
Option 2: new wording suggested by one delegation / drafting group V
Option 3: new wording suggested by another delegation
Option 4: a different wording

Second round of comments:
If you choose option 4, please briefly take the floor, and send detailed written comments.
If you have suggestions only for minor modifications, please, just send written comments.
Deadline for written comments: 2023-09-29

Revision #3: Modification of adoption of rules of procedure [new para 4A in Article 64]

Option 1: Swedish compromise text

Paragraph 4A is not created in Article 64.

Option 2: new wording suggested by one delegation / drafting group V

Swedish compromise text	Proposed modification
(Paragraph 4A does not exist in the Swedish compromise text)	**4A. The EHDS Board shall adopt its rules of procedure on the basis of the proposal of the Commission. A qualified majority is required for the rules of procedures to be adopted.**

First round of comments:
Please, choose one option:
Option 1: Swedish compromise text
Option 2: new wording suggested by one delegation / drafting group V
Option 3: a different wording

Second round of comments:
If you choose option 3, please briefly take the floor, and send detailed written comments.

If you have suggestions only for minor modifications, please, just send written comments.
Deadline for written comments: 2023-09-29

Revision #4: Inclusion of additional entities which the EHDS Board shall cooperate with [Article 64(5)]

Option 1: Swedish compromise text

No changes in Article 64(5)

Option 2: new wording suggested by one delegation / drafting group V

Swedish compromise text	Proposed modification
(e) 5. The EHDS Board shall cooperate with other relevant bodies, entities and experts, such as the European Data Innovation Board referred to in Article ~~26~~ **29** of Regulation **2022/868** ~~[Data Governance Act COM/2020/767 final~~], competent bodies set up under Article 7 of Regulation […] [Data Act COM/2022/68 final], supervisory bodies set up under Article 17 of Regulation […] [eID Regulation], European Data Protection Board referred to in Article 68 of Regulation (EU) 2016/679 and cybersecurity bodies.	5. The EHDS Board shall cooperate with other relevant bodies, entities and experts, such as the European Data Innovation Board referred to in Article ~~26~~ **29** of Regulation **2022/868** ~~[Data Governance Act COM/2020/767 final~~], competent bodies set up under Article 7 of Regulation […] [Data Act COM/2022/68 final], supervisory bodies set up under Article 17 of Regulation […] [eID Regulation], European Data Protection Board referred to in Article 68 of Regulation (EU) 2016/679 and cybersecurity bodies **and the EOSC Steering Board referred to in the EU Council conclusions 14126/2021 in the effort of reaching advanced solutions for the FAIR data usage in research and innovation.**

First round of comments:
Please, choose one option:
Option 1: Swedish compromise text
Option 2: new wording suggested by one delegation / drafting group V
Option 3: a different wording

Second round of comments:
If you choose option 3, please briefly take the floor, and send detailed written comments.
If you have suggestions only for minor modifications, please, just send written comments.
Deadline for written comments: 2023-09-29

[MOD.Go.2] Revision of Article 65 & Article 64(6A)

Justification for the position of the Presidency
During the WP 2023-07-14 and in subsequent written comments - 18 countries, representing ~53% of the EU population, supported the wording of article 65. - 2 countries, representing ~19% of the EU population, were against the wording of article 65. In addition, - one delegation has communicated a red line regarding the wording of articles 65. This delegation made reference to the comments made by "Drafting group V", which -to the best of our knowledge- have not been formally submitted to the Presidency, but are included in the agenda with the wording provided by this delegation.

Revision #1: Tasks of the EHDS Board concerning cross-border infrastructures for primary and secondary use of health data, including decisions affecting third countries [new para 6A in Article 64, Article 65(1)-(2) & new para in Article 65].

Option 1: Swedish compromise text

Paragraph 6A is not created in Article 64.

No changes in Article 65(1)-(2)

No creation of paragraph 3 in Article 65

Option 2: new wording suggested by one delegation / drafting group V

Swedish compromise text	Proposed modification
Article 64 (…) *(Paragraph 6A does not exist in the Swedish compromise text)*	*Article 64* (…) **6A. EHDS Board shall take specific governance modalities regarding third countries and organizations connected to EHDS.** (…) *Comment from the Presidency:* *The wording "specific governance modalities" is unclear. Perhaps, "specific governance decisions" would be a better wording. To the best of the understanding of the Presidency, these governance decisions regarding third countries are described in the proposed modifications for Article 65(1)(f) and Article 65(2)(g), below.*
Article 65 *Tasks of the EHDS Board* 1. The EHDS Board shall have the following tasks relating to the primary use of electronic health data in accordance with Chapters II and III: (a) to assist Member States in	*Article 65* *Tasks of the EHDS Board* 1. The EHDS Board shall have the following tasks relating to the primary use of electronic health data in accordance with Chapters II and III: (a) to assist Member States in

Swedish compromise text	Proposed modification
coordinating practices of digital health authorities; (…) (e) to facilitate the exchange of views on the primary use of electronic health data with the relevant stakeholders, including representatives of patients, health professionals, researchers, regulators and policy makers in the health sector.	coordinating practices of digital health authorities; (…) (e) to facilitate the exchange of views on the primary use of electronic health data with the relevant stakeholders, including representatives of patients, health professionals, researchers, regulators and policy makers in the health sector. **(f) to issue decisions concerning:** **(i) the adoption of measures and rules set out in Article 12, paragraph 4,** **(ii) the authorisation to participate in MyHealth@EU set out in article 13, paragraph 3.** **(iii) the launch of compliance checks set out in article 12, paragraph 9 and article 13, paragraphs 2 and 3.**
2. The EHDS Board shall have the following tasks related to the secondary use of electronic health data in accordance with Chapter IV: (a) to assist Member States, in coordinating practices of health data access bodies,—in the implementation of provisions set out in Chapters IV, to ensure a consistent application of this Regulation; (…) (f) to facilitate the exchange of views on the secondary use of electronic health data with the relevant stakeholders, including **health data holders, health data users,** representatives of patients, health professionals, researchers, regulators and policy makers in the health sector.	2. The EHDS Board shall have the following tasks related to the secondary use of electronic health data in accordance with Chapter IV: (a) to assist Member States, in coordinating practices of health data access bodies,—in the implementation of provisions set out in Chapters IV, to ensure a consistent application of this Regulation; (…) (f) to facilitate the exchange of views on the secondary use of electronic health data with the relevant stakeholders, including **health data holders, health data users,** representatives of patients, health professionals, researchers, regulators and policy makers in the health sector. **(g) to issue decisions concerning :** **(i) the authorisation to participate in HealthData@EU set out in article 52, paragraph 5;** **(ii) the launch of compliance checks set out in article 52, paragraph 14.**

First round of comments:
Please, choose one option:
Option 1: Swedish compromise text
Option 2: new wording suggested by one delegation / drafting group V
Option 3: a different wording

Second round of comments:
If you choose option 3, please briefly take the floor, and send detailed written comments.
If you have suggestions only for minor modifications, please, just send written comments.
Deadline for written comments: 2023-09-29

Revision #2: Tasks of the EHDS Board concerning the adoption of delegated acts and implementing acts [new para in Article 65]

New wording suggested by two delegations / drafting group V

Swedish compromise text	Proposed modification
Article 65 *Tasks of the EHDS Board* (…) *(This paragraph 3 does not exist in the Swedish compromise text)*	*Article 65* *Tasks of the EHDS Board* (…) **(new) The EHDS Board shall be consulted by the European Commission as an expert group before adopting delegated acts by the procedure provided for in Article 67(4), or presenting implementing acts to the committee provided for in article 68.**

First round of comments:
Does your delegation agree with the proposed modification?
Yes/No.

Second round of comments:
If no, please briefly take the floor and provide detailed comments in written form.
If you have suggestions only for minor modifications, please, just send written comments.
Deadline for written comments: 2023-09-29

[MOD.Go.3] Clarification of the role of the Commission in the governance framework [new Article 66A]

Justification for the position of the Presidency
One delegation has communicated a red line regarding the need for the clarification of the role of the Commission in the governance framework.

New wording suggested by one delegation

Proposed modification (new article)
Article 66A ***Roles and responsibilities of the EU regarding EHDS functioning*** **The European Union coordinates the European Health Data Space and consequently, the**

Commission provides operational services to ensure its functioning.

1. In this role, the Commission delivers infrastructures and central services required to support the functioning of the European Health Data Space. The Commission shall provide these infrastructures and central services to Member States, third countries and organisations connected to the European Health Data Space. The central services typically include the provision, availability, maintenance and evolution of EHDS infrastructures, data and reference catalogues, technological sandboxes, testing services, central configuration services for all technical requirements, compliance assessment prior to use cases go lives or any other required coordination services. . These services are required as use cases and services provided will require to evolve and develop overtime.

2. The Commission applies operational decisions required for the functioning of EHDS taken by the EHDS Board subgroups as maintenance, operations and development of the cross-border infrastructures and services pursuant to Chapters II, III and IV. The Commission shall ensure that these services are interoperable with other infrastructures, digital systems or data spaces when required.

3. The Commission is in charge of the coordination with required European authorities, bodies, offices, agencies and institutions as EDPB-EDPS, the European Medicines Agency (EMA), the European Centre for Disease Prevention and Control (ECDC); research infrastructures involved with EHDS and eventually act as HDAB for these bodies.

4. EHDS infrastructures and services shall meet sufficient quality standards in terms of availability, security, capacity, maintenance, monitoring and evolution to ensure an effective functioning of the European Health Data Space. These standards, once defined, apply to subcontractors.

5. The Commission shall, by means of implementing acts with the examination procedure referred to in Article 68(2), set out the list of services necessary to the functioning of the European Health Data Space, as well as the modalities ensuring the quality of services provided.

6. The Commission issues a yearly public report regarding central infrastructure and coordination services supporting EHDS

Justification for the new wording:
The role of the Commission providing operational central services and infrastructures to Member States, third countries and organizations to ensure EHDS functioning is key. Central services typically refer to the provision, availability, maintenance and evolution of EHDS infrastructures, EHR translation, catalogues, sandboxes, testing, central configuration, compliance or coordination services for instance. The added article formalizes the guiding principles for delivering these services.

First round of comments:
Does your delegation agree with the proposed modification?
Yes/No.

Second round of comments:
If no, please briefly take the floor and provide detailed comments in written form.
If you have suggestions only for minor modifications, please, just send written comments.
Deadline for written comments: 2023-09-29

Abbreviations and glossary of terms

Note: these abbreviations may or may not be issued in today's discussion. It's a generic list.

International organizations

- WTO: World Trade Organization.
- WHO: World Health Organization.
- EU: European Union.
- EEA: European Economic Area. The EEA consists of the 27 European Union (EU) member states plus three non-EU member countries: Norway, Iceland, and Liechtenstein. These three non-EU countries participate in the EU's Single Market through the EEA Agreement[1], which ensures the free movement of goods, services, capital, and people within this area.
- COM / EC: European Commission.

Council of the European Union

- WP: working party meeting of the Council of the European Union. In the context of the EHDS discussions, we are referring to the WPs on Public Health (WPPHs).
- CLS: Council of the European Union's Legal Service.

European Health Data Space

- EHDS: European Health Data Space[2].
- EHDSB / EHDS Board: European Health Data Space Board (defined in article 64 of the current compromise text).
- "original text" (of the EHDS): Commission proposal for the EHDS[3].
- "Swedish compromise text" (of the EHDS): Swedish presidency compromise text, document number ST8171 2023 REV1.

Primary use of health data

- EHR system: Electronic Healthcare Records system (defined in article 2(2)(n) of the current compromise text of the EHDS).
- EEHRxF: European electronic health record exchange format (article 6 EHDS).
- GP: general practitioner. A general practitioner (GP), also known as a family doctor or primary care physician, is a medical doctor who provides comprehensive healthcare services to patients of all ages and genders. GPs play a crucial role in the healthcare system, serving as the first point of contact for individuals seeking medical advice, treatment, and preventive care. For the evidence of formal qualifications of General Practitioners in the Member States see Annex V, point 5.1.4 Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications, OJ L 255, 30.9.2005, p. 22–142.
- GPs: general practitioners.
- DHA: Digital Health Authority (article 10 EHDS).
- MSA: Market Surveillance Authority (article 28 EHDS).
- NCPs: National Contact Points (article 12 EHDS).

[1] Under the EEA Agreement, the non-EU EEA countries are bound by the majority of EU laws and regulations related to the Single Market. This includes the adoption of EU directives and the application of EU regulations, ensuring a high degree of harmonization between the EU and EEA countries' legal frameworks. For instance, the GDPR applies to the whole EEA. The intention is for the EHDS to apply to the whole EEA too. However, there are some specific EU regulations that might not apply to the whole EEA. There are instances where certain EU regulations include opt-outs or specific arrangements for certain member states, which means that these regulations might not be fully applicable in those cases. Additionally, in areas where the EEA Agreement does not cover, specific EU regulations might not automatically apply to the non-EU EEA countries.

[2] https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space_en

[3] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52022PC0197

Secondary use of health data

- HDAB: Health Data Access Body (defined in articles 35D, 35F and 36-39 of the Swedish compromise text of the EHDS).
- SMEs: small and medium enterprises.
- SPE: Secure processing environment (50 EHDS).
- HDH: Health Data Holder (article 2(1)(y) EHDS).
- HDU: Health Data User (article 2(1)(z) EHDS).

Other relevant legal acts of the European Union

- TFEU: Treaty on the Functioning of the European Union[4].
- DA: Commission's proposal for a European Data Act[5].
- DGA: final text for the (European) Data Governance Act[6], i.e. *Regulation (EU) 2022/868 of the European Parliament and of the Council of 30 May 2022 on European data governance and amending Regulation (EU) 2018/1724 (Data Governance Act)*.
- Commission's proposal for the DGA[7].
- EU DCC Regulation: *Regulation (EU) 2021/953 of the European Parliament and of the Council of 14 June 2021 on a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates (EU Digital COVID Certificate) to facilitate free movement during the COVID-19 pandemic.*[8]

General Data Protection Regulation

- GDPR: General Data Protection Regulation[9], i.e. *Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation)*
- DPA: Data Protection Authority[10].

World trade organization agreements

- GATS: General Agreement on Trade in Services[11], to which the EU has made specific commitments[12].
- GATT: General Agreement on Tariffs and Trade[13].

[4] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A12012E%2FTXT
[5] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2022%3A68%3AFIN
[6] https://digital-strategy.ec.europa.eu/en/policies/data-governance-act
[7] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A52020PC0767
[8] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32021R0953
[9] https://eur-lex.europa.eu/EN/legal-content/summary/general-data-protection-regulation-gdpr.html
[10] https://commission.europa.eu/law/law-topic/data-protection/reform/what-are-data-protection-authorities-dpas_en
[11] https://www.wto.org/english/tratop_e/serv_e/gatsqa_e.htm
[12] https://trade.ec.europa.eu/access-to-markets/en/content/general-agreement-trade-services-gats
[13] https://www.wto.org/english/tratop_e/gatt_e/gatt_e.htm