Council of the European Union
General Secretariat

Interinstitutional files:
2022/0140 (COD)

Brussels, 19 April 2023

WK 4865/2023 INIT

LIMITE

SAN
PHARM
COMPET
MI
DATAPROTECT
CODEC

This is a paper intended for a specific community of recipients. Handling and further distribution are under the sole responsibility of community members.

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 on the presidency first compromise proposal on Chapters VI to IX

Delegations will find enclosed comments of the Austrian, Czech, Dutch, Finnish, French, German, Estonian, Irish, Luxembourg, Slovak and Spanish delegations on the above-mentioned proposal.

Written contributions from delegations

Comments from the Austrian delegation

AT Written Comments on Articles Discussed in the Meeting WPPH on March 20, 2023

Presidency Compromise Proposal on Articles 66, 66A, 70 and 72 (Doc. 7353/23)	**AT Comments**
Chapter VI	**General Remarks:** **The general scrutiny reservation on Chapter VI with regard to the primary use of health data, as previously expressed, is hereby upheld:** The proposed abolition of the voluntary eHealth Network (representing the MS' competences under Art. 14 of Directive 2011/24/EU) and its proposed replacement by a "European Digital and Health Data Board" is in potential conflict with the primary Union law enshrined in Art. 168 (7) TFEU. **Although some essential changes in the compromise text of Chapter VI (especially the current amendments of Articles 66 and 66A as well as the previous amendments of Article 64) definitely go in the right direction**, a few textual changes (notably of the previously discussed Article 65) are still needed as far as the primary use of health data is concerned, in order to comply with Art. 168 (7) TFEU.
European governance and coordination	
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** ~~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~~.	The Presidency's reasoning in its explanations, namely the concerns regarding conflict of interest, lacking legal entity, especially the aim to strengthen the power of Member States and therefore also the **proposed amendments of Article 66 including a separation of Articles 66 and 66A are fully supported**.

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 shall also take decisions to accept individual authorised participants to join the infrastructures or to disconnect them.~~ (MOVED FROM PARA 6 AND AMENDED)	
1B. The Steering Groups shall, in principle, take decisions by consensus. Where consensus cannot be reached, the adoption of a decision shall require the support of members representing two-thirds majority.	
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.~~ MOVED TO ARTICLE 66A	
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 shall also take decisions to accept individual authorised participants to join the infrastructures or to disconnect them.~~ MOVED TO PARA 1A	

Article 66A	
Fora for the infrastructures MyHealth@EU and HealthData@EU	
1. Two fora are hereby established; the MyHealth@EU Forum and the HealthData@EU Forum, with a view to exchange information and views on relevant matters related to the crossborder infrastructures respectively provided for in Articles 12 and 52, excluding any decision making. These Fora shall be convened on a regular basis.	See the previous comment on Article 66: **The proposed inclusion of a separate Article 66A including its content is fully supported.**
2. The Fora referred to in paragraph 1 shall be composed of members of the Steering groups referred to in Article 66 and of other other participants in the infrastructures provided for in Articles 12 and 52.	
3. Stakeholders and relevant third parties, including patients' representatives, may be invited to attend meetings of the respective Forum and to participate in their work.	
Article 12	
MyHealth@EU	
9. The approval for individual authorised participants to join MyHealth@EU for different services, or to disconnect a participant shall be ~~issued by the Joint Controllership groups,~~ based on the results of the compliance checks **performed by the Commission**.	From the Presidency's explanations of the current amendments, it seems that Art. 12 para. 7, stating in its last version that national contact points for digital health shall act as controllers and the Commission as processor in 'MyHealth@EU, will remain and not be amended. **As previously commented on Art. 12 para. 7, the question arises whether the Commission, by virtue of its determination of the purposes and, above all, essential means of the processing under Art. 12 (especially paras. 1, 4 and 8) does effectively also act as a controller in MyHealth@EU.** **With regard to the current amendment of Art. 12 para. 9, the question of the Commission as controller in MyHealth@EU**

	becomes even more important.
Subject to the positive outcome of this compliance check the Commission shall, by means of implementing act, take decisions to connect individual authorised participants to join the respective infrastructure or to disconnect them. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 68.	See the previous comment.
Article 52	
Cross-border infrastructure for secondary use of electronic health data (HealthData@EU)	
14. The approval for individual authorised participant to join HealthData@EU or to disconnect a participant from the infrastructure shall be ~~issued by the~~ **Article 66** ~~Joint Controllership group,~~ based on the results of the compliance checks **performed by the Commission** concerning the fulfilment of the requirements **referred to in paragraph 13**.	
Subject to the positive outcome of this compliance check, the Commission shall, by means of implementing act, take decisions to connect individual authorised participants to join the respective infrastructure or to disconnect them. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 68.	

Presidency Compromise Proposal Chap. V-VIII (Doc. 6627/23)	**AT Comments**
CHAPTER VII	
Delegation and Committee	
Article 67	
Exercise of the delegation	
1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.	
2. The power to adopt delegated acts referred to in Articles 5(2), ~~10(3), 25(3),~~ 32(4), ~~33(7), 37(4), 39(3), 41(7), 45(7), 46(8), 52(7),~~ **and** 56(4) shall be conferred on the Commission for a~~n indeterminate~~ period of **XXX years** ~~time~~ from the date of entry into force of this Regulation.	The amendments, limitig the Commission's power to issue delegated acts, are (especially the deletion of the reference to Art. 10 para. 3) **fully supported, however, with one very important exception:** The **types of the processed health data (Art. 5[2])** should not be changed by the Commission through delegated acts, but **have to be already clearly regulated on the basis of the regulation**. Otherwise the processing would not be predictable for the data subject. In this way, the Commission still has the power to modify main aspects regarding some of the essential issues as it can modify and expand the scope of the regulation, in a way that also impacts data protection rights. Any restriction of fundamental rights and any processing of health data has to be forseeable on the basis of the regulation. Also, the EDPS and EDPB should be consulted when the Commission adopts delegated acts that concern data protection (see the Joint Opinion of EDPB and EDPS, page 30 and 31). In addition, a sunset clause should be inserted, limiting the delegation of power to the Commission to a specific period of time (to be determined in more detail).

3. The power to adopt delegated acts referred to in Articles 5(2), ~~10(3), 25(3),~~ 32(4)~~,~~ ~~33(7), 37(4), 39(3), 41(7), 45(7), 46(8), 52(7),~~ **and** 56(4) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.	See the previous comment.
4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Inter-institutional Agreement of 13 April 2016 on Better Law-Making.	
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.	
6. A delegated act adopted pursuant to Articles 5(2)~~, 10(3), 25(3),~~ 32(4), ~~33(7), 37(4), 39(3), 41(7), 45(7), 46(8), 52(7),~~ **and** 56(4) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of 3 months of notification of that act to the European Parliament and to the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by 3 months at the initiative of the European Parliament or of the Council.	See the previous comment.

Article 68	
Committee procedure	
1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.	

2. Where reference is made to this paragraph, Article ~~4~~ **5** of Regulation (EU) No 182/2011 shall apply.	The amendment is **fully supported**.
Chapter VIII	
Miscellaneous	
Article 69	
Penalties	
Without prejudice to Articles 30 and 43 of this Regulation and to Chapter VIII of Regulation (EU) 2016/679, Member States shall lay down the rules on penalties applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties shall be effective, proportionate and dissuasive. Member States shall notify the Commission of those rules and measures by date of application of this Regulation and shall notify the Commission without delay of any subsequent amendment affecting them.	Given the experiences with GDPR and its success mainly due to the potentially high fines to be enforced by the competent supervisory authorities, it would be highly preferable if the EHDS proposal would regulate the potential fines directly on the basis of this regulation. Otherwise, each Member State would have to define the fines within its national legislative process, potentially resulting in lower maximum fines and therefore less expected compliance with this regulation based on a positive cost-benefit-analysis by the data users and data holders. This is especially important for the secondary data use with the current uncertainty in regard to the applicability of the GDPR (incl. its fines) as well as the data protection supervisory authorities. With regards to the current amendments, we currently do not see the connex with EHDS. Also given the current legislature by the CJEU, according to which data subjects need to be given confirmation on the individual data recipients, the mentioning of the record of processing activities seems to be in clear conflict with the limited obligation for information to be provided to data subjects according to Art. 13 and 14 GDPR. Also the interplay of EHDS with certification bodies in Art. 43 GDPR remains unclear, since these may only be certified on GDPR-issues.

Presidency Compromise Proposal on Articles 66, 66A, 70 and 72 (Doc. 7353/23)	**AT Comments**
Chapter VIII	
Miscellaneous	
Article 70	
Evaluation and review	
1. After ~~5~~ **6 3** years from the entry into force of this Regulation, the Commission shall carry out a targeted evaluation of this Regulation especially with regards to Chapter III **and IV**, and submit a report on its main findings to the European Parliament and to the Council, the European Economic and Social Committee and the Committee of the Regions, accompanied, where appropriate, by a proposal for its amendment. The evaluation shall include an assessment of the self-certification of EHR systems and reflect on the need to introduce a conformity assessment procedure performed by notified bodies. **The evaluation shall also include an assessment of the costs and benefits of the implementation of the rules for secondary use laid out in Chapter IV.**	**With regard to the utmost sensitive content of the proposal under Art. 168 (7) TFEU as well as applicable data protection laws at Union and MS level, we stand by our previous position that an evaluation and review should take place earlier** than proposed by the Commission – and thus much earlier than currently suggested by the Presidency. Moreover, as also previously requested, **the secondary data use under Chapter IV should also be evaluated**.
2. After ~~7~~ **8 4** years from the entry into force of this Regulation, the Commission shall carry out an overall evaluation of this Regulation, and submit a report on its main findings to the European Parliament and to the Council, the European Economic and Social Committee and the Committee of the Regions, accompanied, where appropriate, by a proposal for its amendment.	See the previous comment.
3. Member States shall provide the Commission with the information necessary for the preparation of that report **and the Commission shall take this information duly into account in that report**.	We stand by our previous position that the proposed textual addition is indispensable to ensure that the information provided by the MS is duly taken into account by the Commission in the report.

Presidency Compromise Proposal Chap. V-VIII (Doc. 6627/23)	**AT Comments**
Article 71	
Amendment to Directive 2011/24/EU	
Article 14 of Directive 2011/24/EU is deleted.	See the General Remarks/Scrutiny Reservation on Chapter VI.

Presidency Compromise Proposal on Articles 66, 66A, 70 and 72 (Doc. 7353/23)	**AT Comments**
Chapter IX	
Deferred application and final provisions	
Article 72	
Entry into force and application	
This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.	
It shall apply from ~~12~~ **24** months after its entry into force.	The amendment is **fully supported** (only the formal question remains why counting in months here and not in years, as in the following paragraphs a-c?).
However, Articles 3, 4, 5, 6, 7, 12, 14, 23 and 31 shall apply as follows:	In view of the great variety of systems used and currently applicable laws at the MS level as well as the great differences in the respective stage of development of each MS, we stand by our previous position that **at (the very) least 3 years must be added to each of the following time indications under Art. 72.**

(a) from ~~1~~3 4 years after date of entry into application to categories of personal electronic health data referred to in Article 5(1), points (a), (b) and (c), and to EHR systems intended by the manufacturer to process such categories of data;	See the previous comment.
(b) from ~~3~~5 6 years after date of entry into application to categories of personal electronic health data referred to in Article 5(1), points (d), (e) and (f), and to EHR systems intended by the manufacturer to process such categories of data;	See the previous comment.
(c) from **3 years after** the date established in delegated acts pursuant to Article 5(2) for other categories of personal electronic health data.	See the previous comment.
Chapter III shall apply to EHR systems put into service in the Union pursuant to Article 15(2) from ~~3~~ 4 6 years after date of entry into application.	See the previous comment.
Chapter IV shall apply 36 months after date of entry into force.	The amendment is **fully supported** (only the formal question remains why counting in months here and not in years, as in the previous paragraphs a-c?).
This Regulation shall be binding in its entirety and directly applicable in all Member States.	
Done at Strasbourg,	
For the European Parliament *For the Council*	
The President *The President*	

Presidency Compromise Proposal Chap. V-VIII (Doc. 6627/23)	**AT Comments**
Chapter I	
Article 2	
Definitions	
The following definition shall be added to Article 2(1)	
(g) the definition of 'contracting authorities' laid down in Article 2(1)(1) of the Directive 2014/24/EU	
The following definition shall be added to Article 2(2)	
(af) 'anonymous' electronic health data means electronic data related to health which does not relate to an identified or identifiable natural person or personal data processed in a such manner that the data subject is not or no longer identifiable, without prejudice to Regulation (EU) 2016/679.	A reference to the GDPR should be inserted.

Comments from the Czech delegation

Comments of the Czech Republic
on Articles 2 (1) g), 2 (2) af) and 66 - 72 of Swedish Presidency compromise of draft EHDS Regulation

Chapter VI

European governance and coordination

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** ~~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~~.

Comment:
It needs to be clarified if all support and assistance (i.e. organisation of meetings of the group, including the provision of funds) regarding the functioning of the group come from the Secretariat of the European Commission?

In the compromise version of this paragraph, it has been removed that the groups consist also of other authorised participants in these infrastructures. It is not clear why the authorised participants should not join these Steering groups. CZ agrees with the concerns raised in previous discussions that authorised participants should not be involved in the decision making process in the steering groups, which will rule out the possibility to outvote Member States in the Steering groups. However, it is for further discussion whether they should be completely excluded from these groups given that they will participate fully in both 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 shall also take decisions to accept individual authorised participants to join the infrastructures or to disconnect them.~~ (MOVED FROM PARA 6 AND AMENDED)

1B. The Steering Groups shall, in principle, take decisions by consensus. Where consensus cannot be reached, the adoption of a decision shall require the support of members representing two-thirds majority.

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.~~ MOVED TO ARTICLE 66A

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

Article 66A

Fora for the infrastructures MyHealth@EU and HealthData@EU

Comment:

It is not clear who will set up those two fora and who will finance, manage and support their operation, it needs to be specified in the text.

1. Two fora are hereby established; the MyHealth@EU Forum and the HealthData@EU Forum, with a view to exchange information and views on relevant matters related to the crossborder infrastructures respectively provided for in Articles 12 and 52, excluding any decision making. These Fora shall be convened on a regular basis.

2. The Fora referred to in paragraph 1 shall be composed of members of the Steering groups referred to in Article 66 and of other other participants in the infrastructures provided for in Articles 12 and 52.

3. Stakeholders and relevant third parties, including patients' representatives, may be invited to attend meetings of the respective Forum and to participate in their work.

Article 12

MyHealth@EU

9. The approval for individual authorised participants to join MyHealth@EU for different services, or to disconnect a participant shall be ~~issued by the Joint Controllership groups,~~ based on the results of the compliance checks **performed by the Commission**.

Subject to the ~~positive~~ outcome of this compliance check the Commission shall, by means of implementing act, take decisions to connect individual authorised participants to join the respective infrastructure or to disconnect them. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 68.

Justification:

CZ leaves for consideration whether there should be reference to „positive" outcome, given that it may also be a negative outcome leading to the disconnection of authorised participants from the infrastructure. CZ proposes to delete this word.

Article 52

Cross-border infrastructure for secondary use of electronic health data (HealthData@EU)

14. The approval for individual authorised participant to join HealthData@EU or to disconnect a participant from the infrastructure shall be ~~issued by the **Article 66** Joint Controllership group,~~ based on the results of the compliance checks **performed by the Commission** concerning the fulfilment of the requirements **referred to in paragraph 13**.

Subject to the ~~positive~~ outcome of this compliance check, the Commission shall, by means of implementing act, take decisions to connect individual authorised participants to join the respective infrastructure or to disconnect them. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 68.

Justification:

See comment above

CHAPTER VII

Delegation and Committee

Article 67

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Articles 5(2), ~~10(3), 25(3),~~ 32(4), ~~33(7), 37(4), 39(3), 41(7), 45(7), 46(8), 52(7),~~ **and** 56(4) shall be conferred on the Commission for an indeterminate period of time from the date of entry into force of this Regulation.

3. The power to adopt delegated acts referred to in Articles 5(2), ~~10(3), 25(3),~~ 32(4)~~,~~ ~~33(7), 37(4), 39(3), 41(7), 45(7), 46(8), 52(7),~~ **and** 56(4) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Inter-institutional Agreement of 13 April 2016 on Better Law-Making.

5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Articles 5(2)~~, 10(3), 25(3),~~ 32(4), ~~33(7), 37(4), 39(3), 41(7), 45(7), 46(8), 52(7),~~ **and** 56(4) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of 3 months of notification of that act to the European Parliament and to the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by 3 months at the initiative of the European Parliament or of the Council.

Article 68

Committee procedure

1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article ~~4~~ **5** of Regulation (EU) No 182/2011 shall apply.

Chapter VIII

Miscellaneous

Article 69

Penalties

Without prejudice to Articles 30 and 43 of this Regulation and to Chapter VIII of Regulation (EU) 2016/679, Member States shall lay down the rules on penalties applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties shall be effective, proportionate and dissuasive. Member States shall notify the Commission of those rules and measures by date of application of this Regulation and shall notify the Commission without delay of any subsequent amendment affecting them.

Comment:
CZ has reservation on this article and will analyse in depth whether it prefers national rule setting or a common European framework, or at least common guidelines, for penalties. Indeed, the spectrum of infringements of the Regulation can be very broad and may affect many entities. This can make it difficult to reach a national consensus when drafting national legislation. At the same time, it is also possible that the individual rules in each MS will create most likely a fragmented and possibly even chaotic system that could allow penalties to be circumvented. It therefore seems that some sort of EU common framework/guidelines for penalties might be a better solution in this case.

It is also unclear whether MS are also entitled to impose penalties on research infrastructures or similar structures and Union bodies, institutions and other entities involved in research in cases of breach of this Regulation.

Article 70

Article 70

Evaluation and review

1. After ~~5~~ **6** years from the entry into force of this Regulation, the Commission shall carry out a targeted evaluation of this Regulation especially with regards to Chapter III, and submit a report on its main findings to the European Parliament and to the Council, the European Economic and Social Committee and the Committee of the Regions, accompanied, where appropriate, by a proposal for its amendment. The evaluation shall include an assessment of the self-certification of EHR systems and reflect on the need to introduce a conformity assessment procedure performed by notified bodies.

2. After ~~7~~ **8** years from the entry into force of this Regulation, the Commission shall carry out an overall evaluation of this Regulation, and submit a report on its main findings to the European Parliament and to the Council, the European Economic and Social Committee and the Committee of the Regions, accompanied, where appropriate, by a proposal for its amendment.

3. Member States shall provide the Commission with the information necessary for the preparation of that report.

Article 71

Amendment to Directive 2011/24/EU

Article 14 of Directive 2011/24/EU is deleted.

Chapter I

Article 2

Definitions

The following definition shall be added to Article 2(1)

(g) the definition of 'contracting authorities' laid down in Article 2(1)(1) of the Directive 2014/24/EU

The following definition shall be added to Article 2(2)

(af) 'anonymous' electronic health data means electronic data related to health which does not relate to an identified or identifiable natural person or personal data processed in a such manner that the data subject is not or no longer identifiable.

na

Comments from the Dutch delegation

Article 66

(The provisions in this Article are not included in the compromise)

CHAPTER VII

Delegation and Committee

Article 67

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Articles 5(2), ~~10(3), 25(3),~~ 32(4), ~~33(7), 37(4), 39(3), 41(7), 45(7), 46(8), 52(7),~~ **and** 56(4) shall be conferred on the Commission for an indeterminate period of time from the date of entry into force of this Regulation.

3. The power to adopt delegated acts referred to in Articles 5(2),~~ 10(3), 25(3),~~ 32(4)~~, 33(7), 37(4), 39(3), 41(7), 45(7), 46(8), 52(7),~~ **and** 56(4) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Inter-institutional Agreement of 13 April 2016 on Better Law-Making.

5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Articles 5(2)~~, 10(3), 25(3),~~ 32(4), ~~33(7), 37(4), 39(3), 41(7), 45(7), 46(8), 52(7),~~ **and** 56(4) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of 3 months of notification of that act to the European Parliament and to the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by 3 months at the initiative of the European Parliament or of the Council.

Article 68

Committee procedure

1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article ~~4~~ **5** of Regulation (EU) No 182/2011 shall apply.

Chapter VIII

Miscellaneous

Article 69

Penalties

Without prejudice to Articles 30 and 43 of this Regulation and to Chapter VIII of Regulation (EU) 2016/679, Member States shall lay down the rules on penalties applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties shall be effective, proportionate and dissuasive. Member States shall notify the Commission of those rules and measures by date of application of this Regulation and shall notify the Commission without delay of any subsequent amendment affecting them.

Commented [A1]: The Netherlands suggests wording to be added to ensures harmonised principles on penalties. Inspiration for these wordings can derive from the Data Act.

Article 70

(The provisions in this Article are not included in the compromise)

Article 71

Amendment to Directive 2011/24/EU

Article 14 of Directive 2011/24/EU is deleted.

Chapter I

Article 2

Definitions

The following definition shall be added to Article 2(1)

(g) the definition of 'contracting authorities' laid down in Article 2(1)(1) of the Directive 2014/24/EU

The following definition shall be added to Article 2(2)

(af) 'anonymous~~'~~ electronic health data' means electronic data ~~related to health~~ which does not relate to an identified or identifiable natural person or personal electronic health data processed in a such manner that the data subject is not or no longer identifiable.

Commented [A2]: The Netherlands suggests to use this definition of "anonymous electronic health data" throughout the proposal as opposed to "non-personal electronic health data". We suggest to delete the latter as this definition causes much discussion. Using anonymous is more in line with what is already described in the GDPR under recital 26.

Chapter VI

European governance and coordination

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** ~~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 shall also take decisions to accept individual authorised participants to join the infrastructures or to disconnect them.~~ (MOVED FROM PARA 6 AND AMENDED)

1B. **The Steering Groups shall, in principle, take decisions by consensus. Where consensus cannot be reached, the adoption of a decision shall require the support of members representing two-thirds majority.**

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 steering groups and to participate in their work. Rules concerning the participation of stakeholders and relevant third parties shall be included in the rules of procedures. ~~MOVED TO ARTICLE 66A~~

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

Commented [A3]: Deleted as the "steering" groups take not only operational decision.

Commented [A4]: We have no objections in retaining this article, however we believe that this can also be included in the Rules of Procedures set out under this Regulation.

Formatted: Font: (Default) Times New Roman, 12 pt, English (United Kingdom), Not Strikethrough

Formatted: Font: (Default) Times New Roman, 12 pt, English (United Kingdom), Not Strikethrough

~~*Article 66A*~~

~~*Fora for the infrastructures MyHealth@EU and HealthData@EU*~~

~~1. Two fora are hereby established; the MyHealth@EU Forum and the HealthData@EU Forum, with a view to exchange information and views on relevant matters related to the crossborder infrastructures respectively provided for in Articles 12 and 52, excluding any decision making. These Fora shall be convened on a regular basis.~~

~~2. The Fora referred to in paragraph 1 shall be composed of members of the Steering groups referred to in Article 66 and of other other participants in the infrastructures provided for in Articles 12 and 52.~~

~~3. Stakeholders and relevant third parties, including patients' representatives, may be invited to attend meetings of the respective Forum and to participate in their work.~~

Article 12

MyHealth@EU

9. The approval for individual authorised participants to join MyHealth@EU for different services, or to disconnect a participant shall be issued by the ~~Joint Controllership~~Steering ~~g~~Groups, based on the results of the compliance checks ~~performed by the Commission~~.

Subject to the positive outcome of this compliance check and the approval of the Steering Groups, the Commission shall, by means of implementing act, ~~take decisions~~formalise ~~to connect~~ an individual authorised participants to join the respective infrastructure or to disconnect them. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 68.

Article 52

Cross-border infrastructure for secondary use of electronic health data (HealthData@EU)

14. The approval for individual authorised participant to join HealthData@EU or to disconnect a participant from the infrastructure shall be issued by the **Article 66** ~~Joint Controllership~~Steering Ggroup~~s~~, based on the results of the compliance checks **performed by the Commission** concerning the fulfilment of the requirements **referred to in paragraph 13**.

Subject to the positive outcome of this compliance check and the approval of the Steering Groups, the Commission shall, by means of implementing act, ~~take decisions to connect~~formalise and individual authorised participants to join the respective infrastructure or to disconnect them. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 68.

Commented [A5]: The Netherlands is rather in favour in maintaining a simple governance. We believe it would be more effective in including/inviting relevant stakeholders in the Steering Group. In the practical execution of this it could be envisioned that e.g. the Steering Group will consist of 2 days of which the 1st day includes a stakeholder event/ Meet up and the 2nd day is the official steering group where decisions are taken. The Netherlands has extensive positive experience in these kind of set-up.

Considering the abovementioned comment, we suggest to delete article 66A and keep article 66(3). Perhaps in the Rules of Procedures we can include additional rules on how stakeholders can be involved.

Commented [A6]: We would suggest to replace the word "fora" with i.e. "cooperation groups" or "coordination group".

Formatted: Font: (Default) Times New Roman, 12 pt, English (United Kingdom), Not Strikethrough

Formatted: Font: (Default) Times New Roman, 12 pt, English (United Kingdom), Not Strikethrough

Formatted: Font: (Default) Times New Roman, 12 pt, English (United Kingdom), Not Strikethrough

Commented [A7]: This proposal is not in line with the current practice under MyHealth@EU, namely:
-Commission performs an audit
-eHealth Member State Expert Group (eHMSEG) makes a recommendation to the eHealth Network based on audit results
-eHealth Network approves the going live of a Member State.

The Netherlands find that under the EHDS the same governance should be maintained.

Formatted: Font: (Default) Times New Roman, 12 pt, English (United Kingdom), Not Strikethrough

Formatted: Font: (Default) Times New Roman, 12 pt, English (United Kingdom), Not Strikethrough

Chapter VIII

Miscellaneous

Article 70

Evaluation and review

1. After ~~5~~ **6** years from the entry into force of this Regulation, the Commission shall carry out a targeted evaluation of this Regulation especially with regards to Chapter III, and submit a report on its main findings to the European Parliament and to the Council, the European Economic and Social Committee and the Committee of the Regions, accompanied, where appropriate, by a proposal for its amendment. ~~The evaluation shall include an assessment of the self-certification of EHR systems and reflect on the need to introduce a conformity assessment procedure performed by notified bodies.~~

2. After ~~7~~ **8** years from the entry into force of this Regulation, the Commission shall carry out an overall evaluation of this Regulation, and submit a report on its main findings to the European Parliament and to the Council, the European Economic and Social Committee and the Committee of the Regions, accompanied, where appropriate, by a proposal for its amendment.

3. Member States shall provide the Commission with the information necessary for the preparation of that report.

Commented [A8]: The Netherlands strongly opposes any form of self-assessment for EHR-systems. We will provide concrete input to include third party certification for EHR-systems and will discuss this as well in the informal expert working group.

For now, we urge the deletion of this sentence in the review.

Chapter IX

Deferred application and final provisions

Article 72

Entry into force and application

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from ~~12~~ **24** months after its entry into force.

However, Articles 3, 4, 5, 6, 7, 12, 14, 23 and 31 shall apply as follows:

(a) from ~~1~~**3** year after date of entry into application to categories of personal electronic health data referred to in Article 5(1), points (a), (b) and (c), and to EHR systems intended by the manufacturer to process such categories of data;

(b) from ~~3~~**5** years after date of entry into application to categories of personal electronic health data referred to in Article 5(1), points (d), (e) and (f), and to EHR systems intended by the manufacturer to process such categories of data;

(c) from the date established in delegated acts pursuant to Article 5(2) for other categories of personal electronic health data.

~~Chapter III shall apply to EHR systems put into service in the Union pursuant to Article 15(2) from 3~~ 4 ~~years after date of entry into application.~~

Chapter III shall apply as follows:

- Newly introduced and to be used EHR-systems are subject to the obligations of Chapter III after the date of application of the EHDS, thus requiring an ex-ante conformity assessment by a third party.
- For existing EHR-systems that have been introduced to the market and are in use, the obligations of Chapter III will become mandatory 60 months (5 years) after the date of application of the EHDS, thus requiring an ex-post conformity assessment by a third party.

Commented [A9]: The Netherlands proposes the following concrete transition period proposal for third party assessment of EHR-systems. We understand it will still be discussed in the informal expert working group. But wish to already inform the Presidency on our proposal.

Commented [A10]: Please note that we have not yet provided the exact wording to be included in article 72.

Chapter IV shall apply 36 months after date of entry into force.

This Regulation shall be binding in its entirety and directly applicable in all Member States.
Done at Strasbourg,

For the European Parliament
The President

For the Council
The President

Comments from the Finnish delegation

FINLAND comments on the compromise proposal on Articles 66, 66A, 67, 68, 69, 70 and 72

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** ~~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 shall also take decisions to accept individual authorised participants to join the infrastructures or to disconnect them.~~ (MOVED FROM PARA 6 AND AMENDED)

1B. The Steering Groups shall, in principle, take decisions by consensus. Where consensus cannot be reached, the adoption of a decision shall require the support of members representing two-thirds majority.

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.~~ MOVED TO ARTICLE 66A

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

Article 66A

Fora for the infrastructures MyHealth@EU and HealthData@EU

1. Two fora are hereby established; the MyHealth@EU Forum and the HealthData@EU Forum, with a view to exchange information and views on relevant matters related to the crossborder infrastructures respectively provided for in Articles 12 and 52, excluding any decision making. These Fora shall be convened on a regular basis.

2. The Fora referred to in paragraph 1 shall be composed of members of the Steering groups referred to in Article 66 and of other other participants in the infrastructures provided for in Articles 12 and 52.

3. Stakeholders and relevant third parties, including patients' representatives, may be invited to attend meetings of the respective Forum and to participate in their work.

Commented [A11]: We are of the opinion that it seems that there is no value in having the Steering Groups in addition to the EHDS Board when the tasks of the Groups have been reduced. It should be clarified what is the relationship between the Board and these Groups. "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" are not necessarily the kind of tasks that we need to establish two groups of MS representatives for them.

Commented [A12]: We are of the opinion that there is added value for the word "operational". It should be clarified what these tasks mean in practice.

Commented [A13]: In principle, it is positive that voting provisions have been added. We are of the opinion that there should be one vote per member state.

Commented [A14]: In principle it is a positive thing that the authorized participants cannot influence the decisions made by the MS on the infrastructure. The MS however do not seem to have any decision power on the connecting of participants in the infrastructure in this compromise text, so this concern does not seem relevant here. In the light of this, it seems unclear what is the value of these fora. It seems these fora are only for exchanging information and views and these could already be done as part of the steering groups of the EHDS board. It is also probable that the representatives of the MS would be the same in all of the groups.

CHAPTER VII

Delegation and Committee

Article 67

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Articles 5(2), ~~10(3), 25(3),~~ 32(4), ~~33(7), 37(4), 39(3), 41(7), 45(7), 46(8), 52(7),~~ **and** 56(4) shall be conferred on the Commission for an indeterminate period of time from the date of entry into force of this Regulation.

3. The power to adopt delegated acts referred to in Articles 5(2), ~~10(3), 25(3),~~ 32(4)~~,~~ ~~33(7), 37(4), 39(3), 41(7), 45(7), 46(8), 52(7),~~ **and** 56(4) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Inter-institutional Agreement of 13 April 2016 on Better Law-Making.

5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Articles 5(2)~~, 10(3), 25(3),~~ 32(4), ~~33(7), 37(4), 39(3), 41(7), 45(7), 46(8), 52(7),~~ **and** 56(4) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of 3 months of notification of that act to the European Parliament and to the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by 3 months at the initiative of the European Parliament or of the Council.

Article 68

Committee procedure

1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article ~~4~~ **5** of Regulation (EU) No 182/2011 shall apply.

Article 69

Penalties

Without prejudice to Articles 30 and 43 of this Regulation and to Chapter VIII of Regulation (EU) 2016/679, Member States shall lay down the rules on penalties applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties shall be effective, proportionate and dissuasive. Member States shall notify the Commission of those rules and measures by date of application of this Regulation and shall notify the Commission without delay of any subsequent amendment affecting them.

Commented [A15]: We support these changes, we prefer less delegated acts. Delegated Acts should be used for technical aspects only. Finland also has reservations about the possibility of adopting delegated acts under Article 5(2).

Commented [A16]: We support this change, and this was also in the previous Compromise Proposal.

Commented [A17]: We are not sure if the added sentence has additional value in this Article. Double penalties should be avoided.

Article 12

MyHealth@EU

9. The approval for individual authorised participants to join MyHealth@EU for different services, or to disconnect a participant shall be ~~issued by the Joint Controllership groups,~~ based on the results of the compliance checks **performed by the Commission**.

Subject to the positive outcome of this compliance check the Commission shall, by means of implementing act, take decisions to connect individual authorised participants to join the respective infrastructure or to disconnect them. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 68.

Article 52

Cross-border infrastructure for secondary use of electronic health data (HealthData@EU)

14. The approval for individual authorised participant to join HealthData@EU or to disconnect a participant from the infrastructure shall be ~~issued by the **Article 66** Joint Controllership group,~~ based on the results of the compliance checks **performed by the Commission** concerning the fulfilment of the requirements **referred to in paragraph 13**.

Subject to the positive outcome of this compliance check, the Commission shall, by means of implementing act, take decisions to connect individual authorised participants to join the respective infrastructure or to disconnect them. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 68.

Commented [A18]: We do not support these changes and we are of the opinion that the MS should make the decisions to connect or to disconnect participants. It does not seem that the MS would have commented in the previous meetings that they would like to change Articles 12 and 52 in this direction. The MS do not seem to have any actual decision power in this solution. If the Article 66 Groups were not legal entities, this Regulation could have established a legal entity to make decisions on these matters. If all the MS are already participants in the infrastructures and they would make decisions on the joining or disconnecting third countries or research infrastructures, the MS would not have a conflict of interest on these decisions. We support that the Commission would perform the compliance checks. The compliance checks could be performed at the initiative of the Member States. The MS should decide on connecting participants on the results of the compliance checks and should be able to decide on disconnecting a participant.

Commented [A19]: The role of the authorised participants in this infrastructure is still unclear. We should have a clear definition of the participants and what would be their role and tasks in relation to the HDABs and Digital Health Authorities.

Chapter VIII

Miscellaneous

Article 70

Evaluation and review

1. After ~~5~~ **6** years from the entry into force of this Regulation, the Commission shall carry out a targeted evaluation of this Regulation especially with regards to Chapter III, and submit a report on its main findings to the European Parliament and to the Council, the European Economic and Social Committee and the Committee of the Regions, accompanied, where appropriate, by a proposal for its amendment. The evaluation shall include an assessment of the self-certification of EHR systems and reflect on the need to introduce a conformity assessment procedure performed by notified bodies.

2. After ~~7~~ **8** years from the entry into force of this Regulation, the Commission shall carry out an overall evaluation of this Regulation, and submit a report on its main findings to the European Parliament and to the Council, the European Economic and Social Committee and the Committee of the Regions, accompanied, where appropriate, by a proposal for its amendment.

3. Member States shall provide the Commission with the information necessary for the preparation of that report.

Commented [A20]: It is a very good idea to have an evaluation of this Regulation, but we are concerned about the time periods. Sufficient transition periods will be required for the practical implementation of the Regulation. Transition schedules must take into account the large number of systems and the actors using them, sufficient resources for their implementation and the time required for the simultaneous other ongoing national reforms.

We do not agree that the self-certification of EHR systems is enough for their security. We are of the opinion that the conformity assessment should be performed by notified bodies.

How will the targeted evaluation of this Regulation be done in practice?

How will the evaluation assessment of the self-certification of EHR systems be done in practice?

Commented [A21]: The reporting duties for MS should not be too burdensome.

Chapter IX

Deferred application and final provisions

Article 72

Entry into force and application

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from ~~12~~ **24** months after its entry into force.

However, Articles 3, 4, 5, 6, 7, 12, 14, 23 and 31 shall apply as follows:

(a) from ~~1~~**3** year after date of entry into application to categories of personal electronic health data referred to in Article 5(1), points (a), (b) and (c), and to EHR systems intended by the manufacturer to process such categories of data;

(b) from ~~3~~**5** years after date of entry into application to categories of personal electronic health data referred to in Article 5(1), points (d), (e) and (f), and to EHR systems intended by the manufacturer to process such categories of data;

(c) from the date established in delegated acts pursuant to Article 5(2) for other categories of personal electronic health data.

Chapter III shall apply to EHR systems put into service in the Union pursuant to Article 15(2) from ~~3~~ **4** years after date of entry into application.

Commented [A22]: The transitional periods for primary use have been developed in a positive direction but still we feel that our previous comments regarding realistic timeframes apply here.

The timelines should be in line with the implementing acts of the Regulation. Before MS can apply the Regulation, the implementing acts need to be drafted so that the MS can apply their requirements.

The realistic timeframes for (a) would be 5 years and for (b) 5-10 years. For EHR systems the realistic timeframe would be 5(-10) years.

The implementation of each new right and obligation requires at least 4 years and even more, if national legislation needs to be changed.

How will this Regulation and all the tasks be financed in the MS?

Chapter IV shall apply 36 months after date of entry into force.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Strasbourg,

For the European Parliament
The President

For the Council
The President

Commented [A23]: The MS were sent a questionnaire concerning the data categories of Article 33 and this included estimated times to implement different categories. Now however it seems that all the data categories will be implemented at the same time. This does not seem to reflect the reality of the member states especially considering specific data categories like genomic data. We should still discuss the need to have different implementation times for different data categories.

There should be a time-table for the implementation and more specific transitional periods for secondary use. There could be phases for introducing certain data categories to secondary use of data. For example datasets which are already of good quality and in an easily transferred form could be introduced first and for example genomic data could be introduced in a later stage, as this kind of data requires specific processing environments and expertise for processing the data.

The European-wide implementation of the dataset description, metadata catalogue, portal and the secure processing environments requirements and setting up these systems will likely need at least 5 years. Only on the basis of the implementing acts it will be possible to even start preparing these things. The implementation of the secondary use of data would be faster if the data holders would have an advisory service concerning their datasets.

Before this Regulation can be applied there should be principles concerning fees and data quality and requirements for the secure processing environments and common application forms. There should also be centralised services. It should be decided how the system functions in relation to the authorised participants.

It will be only possible to have secondary use of health data, when the HDABs have been set up, they have all the necessary resources and services like the secure processing environment, a system for handling applications, identity management system and a secure connection to receive data from the data holders, and when the data holders have dataset descriptions and there is a metadata catalogue.

If the Presidency would be willing, Finland and Findata are prepared to present their experience and views on setting up the data access bodies and how to set up these authorities in an efficient way and timely manner.

Comments from the French delegation

Objet : commentaires des autorités françaises suite au groupe de travail « Santé publique » du 20 mars 2023 relatif au règlement pour un espace européen des données de santé.

France would like to thank the Swedish Presidency for giving delegations the opportunity to submit written comments on Articles 66 (Chapter VI), 67 and 68 (Chapter VII), 69, 70 and 71 (Chapter VIII), 72 (Chapter IX) and on the definitions of "contracting authorities" in Article 2(1) and "anonymous electronic health data" in Article 2(2) of the compromises of the Presidency on EHDS proposed regulation) discussed during Public Health Working Parties.

The proposed amendments appear in blue in the body of each article reproduced below.

Regarding articles 66, 66A, 67 68, taken together with articles 64 and 65 (discussed during the Working Parties of March 6 and 7): French authorities have a scrutiny reservation on their general position regarding the governance and coordination of the EHDS regulation

Article 69 - Penalties

1. ***Without prejudice to Articles 30 and 43 of this Regulation and to Chapter VIII of Regulation (EU) 2016/679,*** *Member States shall lay down the rules on penalties applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties shall be effective, proportionate and dissuasive. Member States shall notify the Commission of those rules and measures by date of application of this Regulation and shall notify the Commission without delay of any subsequent amendment affecting them.*

Regarding Article 69,

- French authorities support part of the amendment proposed by the Presidency, concerning the interplay with the already existing regime of penalties for non-compliance with the GDPR, at European and national levels;
- French authorities acknowledge that this amendment is in line with the recommendation of the EDPS-EDPB (joint opinion, paragraph 127) to provide for harmonized rules on sanctions between the different mechanisms in order to ensure fair and safe enforcement.

Article 70 - Evaluation and review

~~*1. After 5 **6** years from the entry into force of this Regulation, the Commission shall carry out a targeted evaluation of this Regulation especially with regards to Chapter III, and submit a report on its main findings to the European Parliament and to the Council, the European Economic and Social Committee and the Committee of the Regions, accompanied, where appropriate, by a proposal for its amendment. The evaluation shall include an assessment of the self-certification of EHR systems and reflect on the need to introduce a conformity assessment procedure performed by notified bodies.*~~

*2. After ~~7~~ **8** years from the entry into force of this Regulation, the Commission shall carry out an overall evaluation of this Regulation, and submit a report on its main findings to the European Parliament and to the Council, the European Economic and Social Committee and the Committee of the Regions, accompanied, where appropriate, by a proposal for its amendment.*

3. Member States shall provide the Commission with the information necessary for the preparation of that report.

4. [Delay depending on art.72] after the entry into force of this Regulation, the Commission shall carry out an evaluation of the Union funding allocated to the establishment and operation of the EHDS, in particular with regard to the ability of Union bodies to carry out their tasks under this Regulation and of the Member States to apply the Regulation in a uniform and consistent manner. The Commission shall submit a report on its main findings to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, accompanied, where appropriate, by legislative proposals.

Regarding Article 70,

- With regard to paragraph 1, French authorities propose the deletion of the paragraph. Insofar as French authorities do not want a self-certification procedure in Chapter III to remain in the draft regulation, this paragraph, which was intended only to cover the assessment of this mechanism, should be deleted if the French proposal to adopt a conformity assessment procedure instead of the self-certification procedure provided for in Article 17 is accepted.
- With regard to paragraph 2, French authorities support the amendment proposed by the Presidency to extend the deadline to eight years.
- With regard to paragraph 4, French authorities propose to add this paragraph, suggested in the draft report of the European Parliament and aligned with the French position: "*XX years after the entry into force of this Regulation, the Commission shall carry out an evaluation of the Union funding allocated to the establishment and operation of the EHDS, concerning in particular the capacity of the Union bodies to carry out their tasks under this Regulation and of the Member States to apply the Regulation in a uniform and consistent manner. The Commission shall submit a report on its main findings to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, accompanied, where appropriate, by legislative proposals*."
- French authorities also point out that this article must be read together with article 72 in order to allow sufficient time of application before evaluation and review.

Article 71 - Amendment to Directive 2011/24/EU

Article 14 of Directive 2011/24/EU is deleted.

Regarding Article 71,

- French authorities have no comment.

Article 72 - Entry into force and application

This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

It shall apply from ~~12~~ ~~24~~ [36] months after its entry into force.

~~**However, Articles 3, 4, 5, 6, 7, 12, 14, 23, 31 shall apply as follows:**~~

~~(a)from 1 3 year after date of entry into application to categories of personal electronic health data referred to in Article 5(1), points (a), (b) and (c), and to EHR systems intended by the manufacturer to process such categories of data.;~~

~~(b)from 3 5 years after date of entry into application to categories of personal electronic health data referred to in Article 5(1), points (d), (e) and (f), and to EHR systems intended by the manufacturer to process such categories of data;~~

~~(c) from the date established in delegated acts pursuant to Article 5(2) for other categories of personal electronic health data~~.

Chapter III shall apply to EHR systems put into service in the Union pursuant to Article 15(2) from ~~3~~ 4 **5** years after date of entry into application. **This implementation period will run once the required technical specifications are validated and published via an implementing act.**

Chapter IV shall apply from 5 years after date of entry into application.

Regarding Article 72,

- French authorities welcome the Presidency's willingness to extend the deadlines for the applicability of certain provisions of the regulation.
- However, French authorities emphasize that these deadlines still seem unrealistic for all the actors in the ecosystem (professionals and institutions in the health and medico-social sectors, software publishers, medical devices manufacturers, researchers, etc.).
- French authorities testify, as an example, to the difficulties encountered in France to harmonize, structure and organize the processing of health data in a consistent way at the national level, despite a very proactive policy conducted for the past 3 years by the Ministry of Health. Many challenges have to be taken into account regarding the interoperability of information systems, the digitalization of certain sectors and the associated costs.
- Therefore, a basic deadline of two years for the application of this regulation at the level of the 27 Member States seems unachievable, not only for the actors of the ecosystem, but also in view of the time needed to adapt the national legislation.
- Firstly, French authorities propose to simplify the measures of entry into force, to make them more readable, while allowing an implementation which is at the same time voluntarist and realistic for all the actors involved. The provisions of the regulation should apply, in principle, three years after its entry into force. This corresponds to the longest period currently mentioned in the last paragraph of Article 72 concerning Chapter III, as well as the period taken into account at the time of the adoption of the GDPR regulation.
- Moreover, in reaction to the concerns raised by delegations during the Working Party of March 20th, French authorities propose to introduce targeted exceptions to this implementation period of 3 years. Deadlines for application could be extended to 5 years with respect to chapter III (which requires the compliance of existing software, medical devices and applications) and chapter IV (which also implies significant measures at the national level) of the regulation.
- French authorities would also like to add that these application periods should start to run as soon as the technical requirements are laid down in the implementing acts. They propose the following wording: « **This implementation period will run once the required technical specifications are validated and published via an implementing act.”**

Article 2(1)

(g) the definition of 'contracting authorities' laid down in Article 2(1)(1) of the Directive 2014/24/EU

Regarding this article,

- French authorities welcome the proposal of the Presidency, which refers, for the use of the term "*contracting authorities*", to the definition in Article 2.1 of the Public Procurement and Repealing Directive, which therefore refers to the State, regional or local authorities, bodies governed by public law or associations formed by one or more of these authorities or one or more of these bodies governed by public law.

Article 2(2)

af) 'anonymous' electronic health data means electronic data related to health which does not relate to an identified or identifiable natural person or personal data processed in a such manner that the data subject is not or no longer identifiable.

Regarding this article,

- French authorities welcome the proposal of the Presidency, which, in defining "*anonymous electronic health data*", is largely based on the wording of recital 26 of the GDPR, which provides, in particular, that:

"To determine whether a natural person is identifiable, account should be taken of all the means reasonably likely to be used, such as singling out, either by the controller or by another person to identify the natural person directly or indirectly.

To ascertain whether means are reasonably likely to be used to identify the natural person, account should be taken of all objective factors, such as the costs of and the amount of time required for identification, taking into consideration the available technology at the time of the processing and technological developments.

The principles of data protection should therefore not apply to anonymous information, namely information which does not relate to an identified or identifiable natural person or to personal data rendered anonymous in such a manner that the data subject is not or no longer identifiable."

Comments from the German delegation

German Comments following the WPPH on March 20, 2023

Chapter VI

European governance and coordination

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** ~~The~~ group~~s~~ shall be composed of **one** ~~the~~ representative~~s~~ **per Member State** of the **respective** national contact points, one representatives per each authorized participant under Article 52(3) and 52(4), and one represenative from the commission.. ~~and other authorisated participants in those infrastructures~~.

Commented [A24]: Since, according to Article 52(8), the Member States are to set up the infrastructure together with the Commission, the Commission should also be a member of the steering groups.

We would also like to emphasize once again that, in our view, the Commission should be included in Article 52 as a controller.

Commented [A25]: It should be clarified that this passage refers to the National Contact Points for eHealth – (NCPeH) in Art. 12 (2) and Art. 52 (1) and not, for example, the National Contact Points for cross-border healthcare.

Commented [A26]: The deletion in this form is rejected, at least authorized participants under Article 52(3) and (4) should be represented in the steering group.

In connection to that, it should be clarified in general if infrastructures like e.g. the Genomic Data Infrastrucure (GDI) that is to be built can be understood as an authorised participant under Article 52 (4) and how such infrastructures are represented in the governance of the EHDS.

Commented [A27]: The deletion in this form is rejected, at least authorized participants under Article 52(3) and (4) should be represented in the steering group.

In connection to that, it should be clarified in general if infrastructures like e.g. ELIXIR or the Genomic Data Infrastrucure (GDI) that is to be built can be understood as an authorised participant under Article 52 (4) and how such infrastructures are represented in the governance of the EHDS.

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 shall also take decisions to accept individual authorised participants to join the infrastructures or to disconnect them.~~ (MOVED FROM PARA 6 AND AMENDED)

1B. **The Steering Groups shall, in principle, take decisions by consensus. The procedure for the case that consensus cannot be reached shall be laid down in the rules of procedure referred to in Article 66(2).** ~~**Where consensus cannot be reached, the adoption of a decision shall require the support of members representing two-thirds majority.**~~

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.~~ **Health data access bodies designated by Member States under Art. 36 (1) that are not designated as national contact point unter Art. 52 (1) may be invited to attend meetings of the HealthData@EU Steering group and to participate in their work.** ~~Stakeholders and relevant third parties, including patients' representatives, may be invited to attend meetings of the groups and to participate in their work.~~ MOVED TO ARTICLE 66A

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

Commented [A28]: It should be explicitly mentioned that the Steering Groups need to closely collaborate with other relevant bodies, e.g. a Technical Subgroup of the EHDS Board (see also DEU comment, in particular on Articles 64 & 65).

Commented [A29]: Taking decisions by consensus should be the goal. How to proceed if consensus cannot be reached should be left to the steering groups to decide in their rules of procedure.

Commented [A30]: The deletion is rejected in this form. In order to be able to contribute technical expertise, Health Data Access Bodies that are not nominated as National Contact Points should be able to be involved in the work of the HealthData@EU Steering Group. Participation in the two forums under Art. 66a is not an equivalent substitute for this.

Article 66A

Fora for the infrastructures MyHealth@EU and HealthData@EU

1. **Two fora are hereby established; the MyHealth@EU Forum and the HealthData@EU Forum, with a view to exchange information and views on relevant matters related to the crossborder infrastructures respectively provided for in Articles 12 and 52, excluding any decision making. These Fora shall be convened on a regular basis.**

2. **The Fora referred to in paragraph 1 shall be composed of members of the Steering groups referred to in Article 66 and of other other participants in the infrastructures provided for in Articles 12 and 52.**

3. **Stakeholders and relevant third parties, including patients' representatives, may be invited to attend meetings of the respective Forum and to participate in their work.**

Article 12

MyHealth@EU

9. The approval for individual authorised participants to join MyHealth@EU for different services, or to disconnect a participant shall be ~~issued by the Joint Controllership groups,~~ based on the results of the compliance checks **performed by the Commission**.

Subject to the positive outcome of this compliance check the Commission shall, by means of implementing act, take decisions to connect individual authorised participants to join the respective infrastructure or to disconnect them. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 68.

Article 52

Cross-border infrastructure for secondary use of electronic health data (HealthData@EU)

14. The approval for individual authorised participant to join HealthData@EU or to disconnect a participant from the infrastructure shall be ~~issued by the **Article 66** Joint Controllership group,~~ based on the results of the compliance checks **performed by the Commission** concerning the fulfilment of the requirements **referred to in paragraph 13**.

Subject to the positive outcome of this compliance check, the Commission shall, by means of implementing act, take decisions to connect individual authorised participants to join the respective infrastructure or to disconnect them. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 68.

Commented [A31]: It remains unclear in what way these fora differ from other similar bodies, in particular the Steerings Groups (Art. 66) and the EHDS Board and its subgroups, and why these fora are necessary in addition to the mentioned bodies.

Commented [A32]: Who is responsible for organizing the fora? If these are the groups under Article 66, this should be included in their task descriptions. The objectives and powers of the forums are also not yet clear from the article in its current form.

Commented [A33]: The representation of patients in governing bodies of the EHDS should be discussed in greater detail. As a rule of thumb, patient represenatation should be permanent and strong if it is about principles and rules.

Commented [A34]: In order to ensure sufficient elaboration of the criteria here, an obligation for the Commission to elaborate should be included in Article 52(13) (« may » should be replaced by « shall »).

CHAPTER VII

Delegation and Committee

Article 67

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article~~s 5(2), 10(3), 25(3),~~ 32(4), ~~33(7), 37(4), 39(3), 41(7), 45(7), 46(8), 52(7),~~ **and** 56(4) shall be conferred on the Commission for an indeterminate period of time from the date of entry into force of this Regulation.

3. The power to adopt delegated acts referred to in Article~~s 5(2), 10(3), 25(3),~~ 32(4)~~, 33(7), 37(4), 39(3), 41(7), 45(7), 46(8), 52(7),~~ **and** 56(4) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Inter-institutional Agreement of 13 April 2016 on Better Law-Making~~.~~

5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Articles 5(2)~~, 10(3), 25(3),~~ 32(4), ~~33(7), 37(4), 39(3), 41(7), 45(7), 46(8), 52(7),~~ **and** 56(4) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of 3 months of notification of that act to the European Parliament and to the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by 3 months at the initiative of the European Parliament or of the Council.

Article 68

Committee procedure

1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article ~~4~~ **5** of Regulation (EU) No 182/2011 shall apply.

Commented [A35]: We welcome the reduction of the proposed delegated acts. However, the proposed delegated act in Article 5(2) should also be deleted here and in the following paragraph. Such a delegated act allows for changes that will have a significant impact on existing digital applications and legislation in the Member States. The decision on such essential elements cannot be delegated to the Commission.

Commented [A36]: We welcome the amendment that now provides for the examination procedure.
We also suggest that a non-opinion clause be included under Article 4(4)(b) so that an appropriate assessment by the Member States remains possible in the case of implementing acts, even if no opinion is given by the Committee during the examination procedure.

Chapter VIII

Miscellaneous

Article 69

Penalties

Without prejudice to Articles 30 and 43 of this Regulation and to Chapter VIII of Regulation (EU) 2016/679, Member States shall lay down the rules on penalties applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties shall be effective, proportionate and dissuasive. Member States shall notify the Commission of those rules and measures by date of application of this Regulation and shall notify the Commission without delay of any subsequent amendment affecting them.

Article 70

Evaluation and review

1. After ~~5~~ **6** years from the entry into force of this Regulation, the Commission shall carry out a targeted evaluation of this Regulation especially with regards to Chapter III, and submit a report on its main findings to the European Parliament and to the Council, the European Economic and Social Committee and the Committee of the Regions, accompanied, where appropriate, by a proposal for its amendment. The evaluation shall include an assessment of the self-certification of EHR systems and reflect on the need to introduce a conformity assessment procedure performed by notified bodies.

2. After ~~7~~ **8** years from the entry into force of this Regulation, the Commission shall carry out an overall evaluation of this Regulation, and submit a report on its main findings to the European Parliament and to the Council, the European Economic and Social Committee and the Committee of the Regions, accompanied, where appropriate, by a proposal for its amendment.

3. Member States shall provide the Commission with the information necessary for the preparation of that report.

Article 71

Amendment to Directive 2011/24/EU

Article 14 of Directive 2011/24/EU is deleted.

Commented [A37]: The proposed deletion of Article 14 of the Patient Mobility Directive can only be supported if the proposed arrangements for future governance (esp. EHDS Board) are adequately designed so that the cancellation of the eHealth network is compensated for. See also previous DE comments, esp. on articles 64 and 65.

Chapter IX

Deferred application and final provisions

Article 72

Entry into force and application

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from ~~12~~ **24** months after its entry into force.

However, Articles 3, 4, 5, 6, 7, 12, 14, 23 and 31 shall apply as follows:

(a) from ~~1~~**3** year after date of entry into application to categories of personal electronic health data referred to in Article 5(1), points (a), (b) and (c), and to EHR systems intended by the manufacturer to process such categories of data;

(b) from ~~3~~**5** years after date of entry into application to categories of personal electronic health data referred to in Article 5(1), points (d), (e) and (f), and to EHR systems intended by the manufacturer to process such categories of data;

(c) from the date established in delegated acts pursuant to Article 5(2) for other categories of personal electronic health data.

Chapter III shall apply to EHR systems put into service in the Union pursuant to Article 15(2) from ~~3~~ **4** years after date of entry into application.

Chapter IV shall apply 36 months after date of entry into force.

Commented [A38]: We welcome an extension of the deadlines in subparagraphs (a) and (b) and with respect to the implementation of Chapter III.
However, whether the deadlines proposed here are feasible to meet depends on the specific regulations in the respective articles and, in particular, on the definition of EHR systems. Here, we see further need for adjustment and therefore, if necessary, also for a further extension of the transition periods.

Commented [A39]: We welcome the extension of the deadline, but do not consider an application to all data categories according to Article 33 to be realistic. A step-by-step implementation should be aimed at here. For this purpose, priority data categories, with which implementation should begin, should be identified as part of the discussions on Article 33.

Chapter I

Article 2

Definitions

The following definition shall be added to Article 2(1)

(g) the definition of 'contracting authorities' laid down in Article 2(1)(1) of the Directive 2014/24/EU

The following definitions~~definition~~ shall be added to Article 2(2)

(af) 'anonymous' electronic health data means electronic data related to health which does not relate to an identified or identifiable natural person or personal data processed in a such manner that the data subject is not or no longer identifiable.

(ee-new) 'accessibility for persons with disabilities' means, according to the four basic principles of digital accessibility, such as perceivable, operable, understandable and robust, the possibility for persons with disabilities to receive, process and transmit their electronic health records in an accessible manner.

Commented [A40]: The inclusion of the definition is welcomed. In addition, it should be defined that the anonymization procedure must comply with the current state of the art. With regard to the case law of the ECJ, we also would like to get clarification on as to whether, according to this, a data subject is to be considered "not or no longer identifiable" if identification would be possible only with disproportionate effort.

Commented [A41]: We propose to include a definition on 'accessibility for persons with disabilities' in order to strengthen the rights of patients and health professionals with disabilities. That question should be considered throughout the regulation.

Comments from the Estonian delegation

Comments and proposals from Estonia following the WPPH on 20.03.2023

Article 52

Paragraph 1. Each Member State shall designate a national contact point for secondary use of electronic health data. etc

Comment: we suggests instead of designating "a contact point" to add "one contact point." So that it would align to the text that is mentioned in article 12 paragraph 2.

Article 66

Comment: In general, we are questioning the need to create a complicated governance structure and the necessity to establish two additional foras for the infrastructures (also article 66A).

Article 66A

Paragraph 3. Stakeholders and relevant third parties, including patients´ representatives, may be invited to attend meetings of the respective Forum and to participate in their work.

Comment: We find the inclusion of stakeholders and relevant third parties important, however we would like to add to the text that in some cases it can be done also electronically.

Proposed new wording: Stakeholders and relevant third parties, including patients´ representatives, may be invited, *also via electronic means*, to attend meetings of the respective Forum and to participate in their work.

Article 72

Comment: Estonia supports the prolonged deadlines suggested by the Presidency as well as the phased transition periods for implementation. However, we have to take into account the technical capacity required for implementing this Regulation. For example, the transitional period for the implementation of the provisions on secondary data use set out in Chapter IV is possible after proposed 3 years only if the final standards, conditions and requirements for secure processing environments, secondary use data categories, as well as the tasks for HDAB-s and the obligations for data holders have been established. An alternative could be to add a provision with a deadline for the Commission to prepare the relevant acts, building on examples from other Union legislative acts, f.ex Regulation 2019/6 on veterinary medicinal products (art 153).

Proposed new wording:
Chapter IV shall apply 36 months after date of entry into force. But in any case not before the date of application of the implementing acts laying down specific measures.
When adopting the implementing acts referred to in Chapter IV, the Commission shall allow sufficient time between their adoption and their start of application. The start of application shall not be less than 36 months for implementing acts specified in Articles 50, 51, 52, 53, 55, 58.

Relevant Implementing Acts needed as a prerequisite for the application of Chapter IV:
Art 50 p. 4 - technical, information security and interoperability requirements for the secure processing environments
Art 51 p. 2 - template that for meet the requirements in Article 28(3) of Regulation (EU) 2016/679 (Joint Controllership)
Art 52 p. 13 - requirements, technical specifications, the IT architecture of HealthData@EU, conditions and compliance checks for authorised participants to join and remain connected to HealthData@EU and conditions for temporary or definitive exclusion from HealthData@EU
Art 53 p. 3 - rules for facilitating the handling of data access applications for HealthData@EU, including a common application form, a common data permit template, standard forms for common electronic health data access contractual arrangements, and common procedures for handling cross-border requests
Art 55 - minimum information elements health data holders are to provide for datasets and their characteristics
Art 58 - minimum specifications for cross-border datasets for secondary use of electronic health data

Other Implementing Acts – not necessarily a prerequisite for application date
Art 42 p. 6 - principles and rules for the fee policies and fee structures
Art 43 p. 8 - architecture of an IT tool (penalties and exclusions)
Art 45 p 6 - templates for the data access application referred to in this Article, the data permit referred to in Article 46 and the data request referred to in Article 47
Art 46 p 13 - logo for acknowledging the contribution of the EHDS
Art 56 p. 5 - visual characteristics and technical specifications of the data quality and utility label + delegated act Art 56 p.4

Comments from the Irish delegation

Ireland's written comments on

Chapter IV of European Health Data Space Regulation Articles 66 – 72

Article 66A - Fora for the infrastructures MyHealth@EU and HealthData@EU

'3. Stakeholders and relevant third parties, ~~including patients' representatives,~~ may be invited to attend meetings of the respective Forum and to participate in their work.

3a. Patients representatives shall be invited to attend and participate in the work of the respective Forum.'

Rationale
Ireland is of the view that paragraph 3 of Article 66A should clearly state that patient representatives 'shall' be invited to attend the meetings of their respective forum. Including the patient in the governance structure promotes continued trust and transparency throughout the entire process. We would support a provision that requires a patient representative to be invited to the forums, separate to other relevant third-party stakeholders.

Article 12 & Article 52 (linked with Article 65 (2))

Comment

The approval structure for individual authorised participants to be connected to or disconnected from the cross-border infrastructure, following compliance checks by the Commission, should include approval by the EHDS Board. Ireland is of the view that this could be added to the list of tasks for the EHDS Board under Article 65 (2).

Article 70 - Evaluation and review

1. After 6 years from the entry into force of this Regulation, the Commission shall carry out a targeted evaluation of this Regulation especially with regards to Chapter III, and submit a report on its main findings to the European Parliament and to the Council, the European Economic and Social Committee and the Committee of the Regions, accompanied, where appropriate, by a proposal for its amendment. **~~The evaluation shall include an assessment of the self-certification of EHR systems and reflect on the need to introduce a conformity assessment procedure performed by notified bodies.~~**

Rationale
A third-party conformity assessment procedure should be included as a key component of Chapter III of the Regulation, to ensure all EHRs are suitable to be put into service.

Article 72 - Entry into force and application

Comment

Ireland continues to support longer transition timeframes to facilitate the successful implementation of the Regulation. The current timeline laid out for Chapter IV – to apply 36 months after the date of entry into force – should be extended to a minimum of 48 months after entry into force.

Comments from the Luxembourg delegation

Feedback Luxembourg on discussion of 20 March

Governance and cross-border infrastructure

Luxembourg has still scrutiny reservation on the operational governance of the cross-border infrastructure. We would like to point out that we propose a different overall governance approach that defines bodies by responsibilities rather than technical functionalities. Technical capabilities can then be defined as requirement for these bodies where applicable and / or for the countries to be provided. The proposed changes affects the definition and role of both authorised participants and national contact points in secondary use. A responsibility based definition will lead to greater clarity, can allow more flexibility in the assignment of responsibilities but will also require an adaptation inter alia of Arts 52 and Art. 66.

In any case, Luxembourg supports that decisions are taken in principle by consensus and, where this is not possible, by a two-thirds majority of members in the board.

Article 70
Luxembourg suggests that the application at least of Chapter IV should be more granular –
the implementation on the MS level will depend on the Implementing acts – those may be ready and in place at the time of entry into force. But they may not be in place and we cannot start reasonably start implementation if the "how" is not defined.
Therefore we suggest that the requirements in Chapter IV shall be applicable at minimum 3 years after the respective implementation act that is defining the specification of the requirements or that the implementing act could also suggest longer time frames for applicability depending on the complexity of requirements. An additional grace period could even be given on the level of the implementation act depending on the complexity of requirements.

Comments from the Slovak delegation

Comments of Slovak Republic to EHDS after the Working Party on 20th March

Continuing the examination of the first compromise for Chapters V to VIII
o Examination of Articles 66, 67, 68, 69, 70, 71 and 72.
o A first compromise text for Articles 66, 70 and 72 will follow shortly.

Article 66 [*based st07353.en23-1.pdf compromise*] – In general, we support the revisions in the compromise version of Article 66. However, we are not convinced about the benefits of the separation of 66 (3) as an independent article 66A. Adding "as observers" or "as non-voting members" at the end of 66 (3) could potentially alleviate the need for a new separate article 66A. The proposed Steering Groups should have the ability to hold stakeholder consultations or surveys. The explicit specification of the dedicated fora in the EHDS proposal might not be necessary.

Article 66A [*based st07353.en23-1.pdf compromise*] – As mentioned before, we are not convinced about the benefits of separating 66 (3) as an independent article 66A. If the consensus is to keep article 66A, we would recommend specifying in more detail what is meant by "participate in their work" at the end of 66A (3). The role and responsibilities of the fora are not clear at the moment, neither is their quorum requirements (for e.g., which stakeholders should be present), or what frequency is meant by convening meetings on a "regular basis" as described in 66A (1).

Article 67 We do not support delegated acts in this article. A consultation with Member States experts as described in 67 (4), does not guarantee that the potential future concerns of the Member State will be incorporated into the delegated acts (for example a sufficient implementation timeline for new priority data categories in 5 (2)). As a compromise we can support the proposed elimination of most of the delegated act clauses in the compromise version of the EHDS proposal.

Article 68 We do not have comments about the Committee procedure outlined in Article 68.

Article 69 We would appreciate a common set of guidelines (as suggested in 43(10)) or a minimum set of penalties to ensure equitable treatment and proportionality of penalties across different Member States.

Article 70 [*based st07353.en23-1.pdf compromise*] We support the extension of the mandatory evaluation period to reflect longer implementation deadlines in Article 72.

Article 71 We do not have comments on Article 71. There does not appear to be a clear consensus among Member States whether and to what extent social services data should be included (including retirement/nursing homes as outlined in the Article 14 of Directive 2011/24/EU).

Article 72 [*based st07353.en23-1.pdf compromise*] We support the longer implementation deadlines.

For 72 (c), we would like to propose that the delegated acts for priority categories of personal electronic health data for primary use should have a minimum implementation period of at least 3 years (same as in 72(a)).

We would also like to propose that secondary data uses described in Chapter IV should be operational after the primary data uses (and not before). Therefore, Chapter IV should apply not "36 months after date of entry into force" but instead "6 years after the date of entry into application". Currently, the primary uses should be operational no later than 2+3 = 5 years and 2+5 = 7 years after the EHDS will come into force, while the secondary uses should be operational only 3 years after EHDS will come into force.

o Examination of the added definitions in the compromise proposal; Article 2(1) (g) "contracting authorities" and Article 2(2) (af) "anonymous electronic health data" in Chapter I.

If the revised version of Article 60 with the term **"contracting authorities"** as defined in the Directive 2014/24/EU is more accurate than public authorities, it should be adapted into the EHDS proposal.

We are not sure if the addition of the term **"anonymous electronic health data"** in Article 2(2) (af) is necessary. The term "anonymous electronic health data" is not used consistently throughout the document (the text contains: anonymised electronic health data , anonymised form, anonymised data, anonymised statistical data, anonymised statistical format, in anonymised format, and then also anonymous data, anonymous electronic health data, etc.). Article 2(1)(a) already includes the definition of "pseudonymisation" adapted from the Regulation (EU) 2016/679. Unfortunately, GDPR definitions do not include "anonymous" or "anonymized", but perhaps inclusion of this broader term could be a better option than the proposed addition of "anonymous electronic health data".

(As an aside, the "anonymous electronic health data" in the EHDS proposal is related primarily to Article 61 and 62 for secondary use transfer of health data into third countries. In this context we would like to reiterate our position that we do not support transfer of individual health data (even in anonymous form) outside of the secure processing environment within Member States. Only aggregate values or results of analyses should be allowed to be downloaded / transferred outside – especially if patients did not provide an informed consent to sharing of their individual health data.)

Written comments and text proposal to the Articles in first compromise proposal on Chapter I, Articles 48 and 49 in Chapter IV, Articles 59, 60, 61, 62, 63, 64 and 65 in Chapter V and VI and the discussed main topics (rights of natural persons, opt-out, data categories, definitions on health data holder and health data user would be appreciated at the latest on **Tuesday the 21th of March**.

Article 48 We support the deletion of Article 48. We believe all data users should apply for a data permit and adhere to the same rules for safeguarding electronic health data and their ethical use in the public interest.

Article 49 We do not have comments related to the compromise version of Article 49. We are concerned that many (especially smaller) health data holders might not have the necessary internal resources and expertise to administer applications, permits, secure processing environment, audits, and reporting requirements. Can the data holders refuse to process individual data access requests and defer this responsibility to the relevant national health data access body? The data catalogue should specify whether data users can reach out directly to data holders or should submit their requests through the health data access body.

Article 59 We support the greater emphasis on the Member States consultation and self-assessment in the compromise.

Article 60 We do not have specific comments to the revised wording of Article 60 at this time.

Article 61 We are apprehensive about allowing transfer of individual health data to third countries. Individual health data, even in anonymized form, should only be accessible within a secure processing environment hosted in the Member States. Transfer of individual health data which could be at a risk of re-identification (especially outside of the Member States jurisdiction) should require ethical consideration and an informed consent from the affected individuals.

We are also concerned about the lack of reciprocity and lack of involvement / expertise transfer from the potential third country data users to the Member States, where the data holders reside.

We should also make sure that the “anonymous” and “anonymized” terminology is used consistently throughout the document.

Article 62 Since the revised version of Article 62 specifies anonymous electronic data, should this article still apply to digital health authorities (which are responsible for primary use of patient data)? Article 62 also does not mention health data holders, even though they may also issue data permits and provide access to health data for secondary use. Similarly to Article 61, we should make sure that the “anonymous” and “anonymized” terminology is used consistently throughout the document.

Article 63 Article 63 might also consider primary use of data and the right of patients for the portability of their personal data. If a patient moves abroad and would like to electronically move their electronic documentation to the new country, would this need to be addressed also in the revised compromise version of Article 63 (similar to its

original version). If Article 63 is only concerned with the ability of Member States to provide additional restrictions to personal data transfer to third countries, its title should be modified to better reflect this intent.

Article 64 We do not have specific comments about the revised wording of Article 64 at this time.

Article 65 If the proposed compromise of article 66A will be accepted, Article 65 (1) (e) and Article 65 (2) (f) should be revised to also include consultations with the newly proposed Fora.

Other topics (rights of natural persons, opt-out, data categories, definitions on health data holder and health data use): We do not have new submissions in addition to our previous written comments on these topics from February and March.

Comments from the Spanish delegation

Spain's comments on Chapters V-VIII and articles 2(1)(g), 2(2)(af), 12(9), 52(14) of the Proposal for a Regulation of the European Parliament and the Council on the European Health Data Space

General comments

Capacity building (article 59)

We welcome the introduction of benchmarking guidelines for the MS, as a way to help capacity-building and sharing of best practices. It would also be a good idea to introduce indicators for the monitoring of the Commission. As an example, indicators for the efficacy of Union funding could be introduced.

Requirements on public procurement and Union funding (article 60)

Regarding article 60 (Additional requirements for public procurement and Union funding),

1) in order to prevent altering free competition in public procurement procedures, we suggest the addition of a recital clarifying that article 60(1) only applies to technical specifications, but not public contract award criteria, solvency conditions, special execution conditions or any other public procurement aspects.

2) the addition of article 60(2)(b) with references to the Regulations (EU) 2016/679 ("GDPR") and Regulation (EU) 2018/1725 (GDPR for European Union Institutions / "GDPR EUIs") could introduce confusion and may be have unintended effects. Please see detailed comments for more explanations.

Governance in the EHDS (articles 64-68)

1) Regarding the definition of governance entities of the EHDS, in the proposal of the Commission, there are 5 governance groups:
- EHDS board (articles 64 and 65),
- two governance groups for operational decisions defined in article 66,
- an entity with representatives of the Member States consulted in the process of the definition of delegated acts in article 67(4),
- a committee for the approval of implementing decisions in article 68.

Comments on the compromise text of the Presidency:
- Attendance to the meetings of the aforementioned governance entities (aside from other lines of work in the context of primary and secondary use) would already imply a significant burden on the MS. We thus don't see the need for yet another governance entity in article 66A, which would have no decision-making power.

2) Regarding the functions of governance entities of the EHDS, in the proposal of the Commission
- the EHDS board (articles 64-65) somehow mirrors the functions of the eHealthNetwork (defined in article 14 of Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare) and "should provide a platform for strategic discussions" (according to the explanations provided by COM on the working party of 2022-09-28).
- the governance groups defined in article 66 are for operational decision making, including the review of authorized participants joining the MyHealth@EU and HealthData@EU infrastructures, among other tasks.

Comments on the compromise text of the Presidency:
- we support the co-chairmanship of the MS and COM in the EHDS Board (article 64).
- we don't support the removal of the MS from the onboarding process of authorized participants (third countries and international organizations) in MyHealth@EU and HealthData@EU in articles 64, 12(9) and 52(14). We believe that MS should be "in the driving seat" when assessing the readiness of new authorized participants and not be completely removed from the process.
- we'd suggest an addition: the entities of article 66 ("Steering groups") must be involved in the drafting of implementing acts and in the definition of delegated acts. This would be coherent with the *Inter-institutional Agreement of 13 April 2016 on Better Law-Making*[1], as long as, in the case of implementing acts, this approach does not interfere with the procedure defined in Regulation (EU) No 182/2011. (Why just the steering groups and not the EHDS board? Please, see our general comments on articles 67 and 68.)

3) Regarding composition of the governance entities defined in articles 64 and 66, we believe several topics should be defined in the text of the Regulation:
- In general, any other EU stakeholders aside from EU MS and COM may be invited to the meetings, but not attend them on a general basis.
- In particular, we believe that EDPB/EDPS could be invited to some of the meetings, but their presence is not necessary on a permanent basis, since many discussions will not require advice on data protection matters.
- In this sense, it is important to consult relevant stakeholders (such as representatives of healthcare professionals or patients' organizations), but it must be clearly stated that they may be invited to join some of the meetings, but not participate on a permanent basis, since the discussion will not always require this kind of stakeholder involvement.

4) Regarding the decision-making process of the governance entities defined in articles 64 and 66, we believe several topics should be defined in the text of the Regulation:
- it must be clearly stated that EEA countries which are not part of the EU (Norway, Iceland and Lichenstein), third countries (which are not part of the EU and EEA) and international organizations (which are authorized participants in MyHealth@EU and HealthData@EU) cannot have a vote in the decision-making process. They may be observers to the meetings, if so decided by the co-chairs (i.e. MS and COM), but must not be part of the meetings on a permanent basis.
- for Member States, the decision-making process should take into account the population of the country, since these decisions, although technical, will affect the population of the EU as a whole, and it would be important to guarantee representativity.

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L:2016:123:FULL&from=EN

Delegation and committee (articles 67 and 68)

1) In articles 67 and 68, we believe that it must be explicitly stated that the steering groups (article 66) must be involved in the drafting process of implementing and delegated acts, as well as in the analysis of impact assessment. In our opinion, this would be coherent with the Inter-institutional Agreement of 13 April 2016 on Better Law-Making[2], already referenced in article 67(4) EHDS in the proposal of the Commission.
Why should the steering groups (article 66) participate in the drafting of implementing and delegated acts but not the EHDS board (articles 64-65)? Because, after the trilogues, the EHDS board may end up with a very long list of stakeholders (including lobbies, such as industry representatives) with a permanent presence in all meetings, which may hinder or introduce unwanted effects in the drafting process of implementing decisions and/or delegated acts. Of course, the opinions of these stakeholders should be taken into account if possible, but these entities should not directly participate in the drafting of implementing and delegated acts, as they are not legislators.

On the other hand, the steering groups (article 66) would be the most qualified governance entity to participate in the drafting process of implementing and delegated acts, since they would be composed by experts from the Member States.

2) In article 67(2), in the drafting of the Commission, delegated powers are given for an indefinite period of time. In the proposal of the Presidency this wording is kept, but with a much smaller scope. We welcome this change. However, perhaps, delegation powers could be given for a more limited period of time.

Transitionary periods in the EHDS (article 72)
We believe that transitionary periods should be realistic. Our position in this regard has already been stated in the survey sent by the CZ Presidency. If the opinion of the Council is to restrict article 33(1)(a) to the data categories of article 5(1) -which in our opinion would be a very significant mistake[3]-, then the transitionary periods for article 33(1)(a) must be completely aligned with the transitionary periods for article 5(1).

[2] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L:2016:123:FULL&from=EN

[3] We have explained this in detail in our previous written comments on Chapters I and IV of the EHDS proposal. As a summary, linking article 33(1)(a) and article 5(1) would: (i) lead to significant problems for data users in the secondary use as this approach would leave almost devoid of content the most relevant data category of secondary use (article 33(1)(a) / EHRs); (ii) lead to significant problems for data holders, as it is much easier to provide data of article 33(1)(a) as-is than in the structured format of article 5(1); (iii) can lead to unforeseen consequences in the legislative process with the creation of a previously non-existing link between primary and secondary use of health data, such as the incoherence between transitionary periods (i.e. a data holder may not be able to comply with article 33(1)(a) since, in order to do that, he would also need to comply with article 5(1), and transitionary periods may end up being different for article 33(1)(a) and article 5(1)).

Detailed comments on specific articles

Chapter I	
Article 2 Definitions (…) The following definition shall be added to **Article 2(1)** **(g)** the definition of 'contracting authorities' laid down in Article 2(1)(1) of the Directive 2014/24/EU	
The following definition shall be added to **Article 2(2)** **(af)** 'anonymous' electronic health data means electronic data related to health which does not relate to an identified or identifiable natural person or personal data processed in a such manner that the data subject is not or no longer identifiable.	

Spain's comments:
We support the changes made in article 2(1)(g) and article 2(2)(af).

Chapter V
Additional actions

Article 59
Capacity building

The Commission shall support sharing of best practices and expertise, aimed to build the capacity of Member States to strengthen digital health systems for primary and secondary use of electronic health data. To support capacity building, the Commission shall **in close cooperation and consultation with Member States** ~~draw up~~ **establish indicators for self assessment** ~~benchmarking guidelines~~ for the primary and secondary use of electronic health data. These indicators will include monitoring of the central services provided by the Commission in MyHealth@EU and HealthData@EU and funding offered by the Commission.

Justification:
We suggest the inclusion of indicators for monitoring not just the MS, but also COM.

2. **The criteria for obtaining funding from the Union** ~~The ex-ante conditionality for Union funding~~ shall take into account**:**
a) the requirements developed in Chapters II, III and IV**;**
~~**b) the requirements laid down in Regulations (EU) 2016/679 or (EU) 2018/1725, where applicable, in particular:**~~
~~**(i) the requirements laid down in Article 35 or 39 respectively of these Regulations by requiring a documented data protection impact assessment, including where Chapter V of these Regulations apply, an assessment of the impact of the transfer to third countries or international organisations. (ii) where Article 28 or 29 respectively of these Regulations is applicable, by requiring a contract or other legal act between the controller and the processor pursuant to Article 28 paragraph 3 or Article 29 paragraph 3 respectively.**~~

Justification:
Regulations (EU) 2016/679 (GDPR) and Regulation (EU) 2018/1725 (GDPR for European Union Institutions / "GDPR EUIs") apply even if article 50(2)(b) is deleted. We thus see no need for the explicit reference to this inclusion. In general, we don't see the added value of stating that the application of the GDPR is necessary to obtain Union funding (the GDPR is a separate legal obligation, which always applies).

In particular,

1) the reference to article 35 GDPR (*Data protection impact assessment / DPIA*) as a requirement for Union funding is rather confusing. In a simplified manner, a DPIA is required in the following cases[4]:
• a systematic and extensive evaluation of the personal aspects of an individual, including profiling;
• processing of sensitive data on a large scale;
• systematic monitoring of public areas on a large scale.

However, Union funding for the EHDS may not even imply personal health data processing in most cases (or much personal data processing at all), much less a DPIA. For instance, if the funding is for technical / functional specifications or the implementation of technical components (which covers most of the existing lines of funding for the EHDS), there will be almost no personal data processing in the context of the funding call, and even less so a data processing operation which would require a DPIA. Therefore, article 60(2)(b) would seldom apply in the context of Union funding.

2) the references to article 28 GDPR and article 29 GDPR EUIs (data processors) and the need for a contract between controllers and processors (or other legal act) would be challenging to implement in practice. Let's see this example. In an EU funding call there is an applicant which is a public-sector entity which receives the Union funding in several tranches and can only launch a public procurement procedure after receiving the first batch of funding. If this is the case, this public-sector entity cannot know the contractor in advance, and thus cannot present a legal proof for the controller-processor relationship. Therefore, this requirement is rather hard to foresee as an *ex ante* conditionality for funding.

Given the above, even though some references to GDPR and GDPR for EUI are welcome as a reminder, we don't see the need for their inclusion here.

Article 61

*~~Third country~~ **T**transfer **to a third country** of **anonymous electronic health data** ~~non personal electronic data~~ **presenting a risk of re-identification***

1. ~~Non personal~~ **Anonymous** electronic data made available by health data access bodies **to a health data user in a third country according to a data permit pursuant to Article 46 or a data request pursuant to Article 47 or to an authorised participants in a third country or an international organisation**, that are based on a natural person's electronic **health** data falling within one of the categories of Article 33 ~~[(a), (e), (f), (i), (j), (k), (m)]~~ shall be deemed highly sensitive within the meaning of Article 5(13) of Regulation **(EU) 2022/868**~~[…] [Data Governance Act COM/2020/767 final]~~, provided that their transfer to third countries presents a risk of re-identification through means going beyond those **reasonably** likely ~~reasonably~~ to be used, **in particular** in view of the limited number of natural persons involved in that data, the fact that they are geographically scattered or the technological developments expected in the near future.
2. The protective measures for the categories of data mentioned in paragraph 1 shall depend on the nature of the data and anonymization techniques and shall be detailed in the Delegated Act under the empowerment set out in Article 5(13) of Regulation **(EU) 2022/868** ~~[…] [Data Governance Act COM/2020/767 final]~~.

Comment:
We agree with the changes introduced by the Presidency.

[4] https://commission.europa.eu/law/law-topic/data-protection/reform/rules-business-and-organisations/obligations/when-data-protection-impact-assessment-dpia-required_en#:~:text=References-,Answer.rights%20and%20freedoms%20of%20individuals.

Article 62

~~International access and~~ T~~t~~ransfer of anonymous ~~non-personal~~ electronic health data to a third country or an international organisation

1. The digital health authorities, health data access bodies, the authorised participants in the cross-border infrastructures provided for in Articles 12 and 52 and **health** data users shall take all reasonable technical, legal and organisational measures, including contractual arrangements, in order to prevent ~~international~~ transfer **to a third country or an international organisation, including** ~~or~~ governmental access **in a third country** **of** ~~to~~ **anonymous** ~~non-personal~~ electronic health data held in the Union where such transfer ~~or access~~ would create a conflict with Union law or the national law of the relevant Member State, without prejudice to paragraph 2 or 3 of this Article.

2. Any judgment of a third-country court or tribunal and any decision of a third-country administrative authority requiring a digital health authority, **a** health data access body or **a health** data user~~s~~ to transfer ~~or give access to~~ **anonymous** ~~non-personal~~ electronic health data within the scope of this Regulation held in the Union shall be recognised or enforceable in any manner only if based on an international agreement, such as a mutual legal assistance treaty, in force between the requesting third country and the Union or any such agreement between the requesting third country and a Member State.

3. In the absence of an international agreement as referred to in paragraph 2 of this Article, where a digital health authority, a health data access body, **a health** data user~~s~~ is the addressee of a decision or judgment of a third-country court or tribunal or a decision of a third-country administrative authority to transfer ~~or give access to~~ **anonymous** data within the scope of this Regulation held in the Union and **in** compliance with such a decision would risk putting the addressee in conflict with Union law or with the national law of the relevant Member State, transfer **of** ~~to or access to~~ such data **to** ~~by~~ that third-country authority shall take place only where:
   (a) the third-country system requires the reasons and proportionality of such a decision or judgment to be set out and requires such a decision or judgment to be specific in character, for instance by establishing a sufficient link to certain suspected **natural or legal** persons or infringements;
   (b) the reasoned objection of the addressee is subject to a review by a competent third-country court or tribunal; and
   (c) the competent third-country court or tribunal issuing the decision or judgment or reviewing the decision of an administrative authority is empowered under the law of that third country to take duly into account the relevant legal interests of the provider of the data protected under Union law or the national law of the relevant Member State

4. If the **criteria** ~~conditions~~ laid down in paragraph 2 or 3 are met, **a** digital health authority, a health data access body or a **health data user** ~~data altruism body~~ shall provide the minimum amount of data permissible in response to a request, based on a reasonable interpretation of the request.

5. The digital health authorities, health data access bodies, **health** data users shall inform the **health** data holder about the existence of a request of a third-country administrative authority to access its data before complying with that request, except where the request serves law enforcement purposes and for as long as this is necessary to preserve the effectiveness of the law enforcement activity.

Comment on article 62, paragraphs 2-6:
Although it is a good idea to provide legal certainty to third countries by the EU/EEA, the same guarantees should be obtained from third countries when accessing data from the EU/EEA. These conditions should be specified in the implementing acts for joining the MyHealth@EU and HealthData@EU infrastructures, defined in article 13(3) EHDS and articles 52(5) EHDS respectively.

The need for general reciprocity and recognition of certain legal decisions by Member States in third countries and/or international organizations in the context of implementing decisions in articles 13(3) and 52(2) EHDS should be mentioned in a recital.

Article 63

*~~International access and~~ **T**~~t~~ransfer of personal electronic health data **to a third country or an international organisation***

In the context of ~~international access and~~ transfer of personal electronic health data **to a third country or an international organisation,** Member States may maintain or introduce further conditions, including limitations, in accordance with and under the conditions of **A**~~a~~rticle 9(4) of Regulation (EU) 2016/679, **in addition to the requirements set out in Articles 13 paragraph 3 and 52 paragraph 5 of this Regulation and the requirements laid down in Chapter V of Regulation (EU) 2016/679**.

Comment:

It should be made clear that Article 13(3) applies to potential international data transfers in the context of MyHealth@EU (primary use), while article 52(5) applies to potential international data transfers in the context of HealthData@EU (secondary use). With the current wording, it may seem that both article 13(3) and article 52(2) apply to all international data transfers, while this is not necessarily the case (for example, a third country may be part of MyHealth@EU but not HealthData@EU and, in this case, only article 13(3) should apply, but not article 52(5)).

Chapter VI European governance and coordination

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. 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))

1a. **A representative of** ~~T~~the Commission **and a representative of the Member States** shall **co-**chair the meetings of the EHDS Board. (MOVED FROM PARA 6)

Justification:

We support this change. Following the comments made by HU, if this is given up in the trilogues as a concession (thus making the Commission the sole chair), it would be important to specify in the rules of procedure (of the EHDS board) that points in the agenda can be added upon request by two or more Member States.

1b. ~~Other national authorities, including~~**M**~~m~~arket surveillance authorities referred to in Article 28, European Data Protection Board and European Data Protection Supervisor, ~~**shall**~~ ~~may~~ may be invited to the meetings, where the issues discussed are of relevance for them. (MOVED FROM PARA 1 AND AMENDED)

Justification:

We believe that the EDPB and EDPS may be invited to some of the meetings (specifically, those that need their exertise on personal data protection), but should not be invited to all the meetings, since not all discussion topics will require expertise on personal data protection.

1c. The Board may also invite **other national authorities,** experts and observers to attend its meetings, and may cooperate with other external experts as appropriate. (MOVED FROM PARA 1 AND AMENDED)

1d. Other Union institutions, bodies, offices and agencies, research infrastructures and other similar structures ~~**shall**~~**may** have an observer role **when invited to participate in the meetings**. (MOVED FROM PARA 1 AND AMENDED)

Justification:
We believe that these entities could be obervers, but should not be given a permanent observer status, as this may be counter-productive. Depending on the topic, only certain entities may be invited to the meetings, if so decided by the co-chairs.

1e. Stakeholders and relevant third parties, including patients' representatives, **may** ~~shall~~ be invited to attend meetings of the EHDS Board and to participate in its work, depending on the topics discussed and their degree of sensitivity. (MOVED FROM PARA 4)

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 may have joint meetings, as required.

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. **They shall include rules pertaining to the composition, structure, operation 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 confidentiatlity involved. Countries belonging to the European Economic Area which are not part of the European Union, third countries and international organizations which are authorized participants in MyHealth@EU or HealthData@EU will not have a vote in the EHDS Board or its sub-groups, but may be invited as observers to their meetings.**

Justification:
We believe that it is important to clarify that the following entities, after becoming authorised participants of MyHealth@EU or HealthData@EU, cannot have a vote in the decision-making process in the EHDS Board:
- EEA contries which are not part of the EU (Norway, Iceland and Lichenstein).
- third countries.
- international organizations.
However, they may be invited as observers if so decided by the co-chairs.

~~4. Stakeholders and relevant third parties, including patients' representatives, shall be invited to attend meetings of the EHDS Board and to participate in its work, depending on the topics discussed and their degree of sensitivity.~~ MOVED TO PARA 1E

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.

~~6. The Commission shall chair the meetings of the EHDS Board.~~ MOVED TO PARA 1A

7. The EHDS Board shall be assisted by a secretariat provided by the Commission.

8. The Commission shall, by means of implementing acts, adopt the necessary measures for the establishment~~,~~ **and** management ~~and functioning~~ of the EHDS Board. Those implementing acts shall be adopted in accordance with the ~~advisory~~ **examination** procedure referred to in Article 68(2).

Comment:
We welcome the change to examination procedure.

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 coordinating practices of digital health authorities;
   (b) to issue written contributions and to exchange best practices on matters related to the coordination of the implementation at Member State level of this Regulation and of the delegated and implementing acts adopted pursuant to it, in particular as regards:
      (i) the provisions set out in Chapters II and III;
      (ii) development of online services facilitating secure access, including secure electronic identification, to electronic health data for health professionals and natural persons.~~;~~
      ~~(iii) other aspects of the primary use of electronic health data~~.
      (iii) other aspects of the primary use of electronic health data.

Justification:
We'd prefer not to delete "(iii) other aspects of the primary use of electronic health data", since there may be other topics to discuss aside from (i) and (ii) in the EHDS Board. We should not be too restrictive in this regard.

   (c) to facilitate cooperation between digital health authorities through capacity-building, establishing the structure for **biennial** ~~annual~~ activity reporting, **and exchange of information in those reports** ~~peer review of annual activity reports and exchange of information~~;
   (d) to share information concerning risks posed by EHR systems and serious incidents as well as their handling;
   (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.

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;
   (b) to issue written contributions and to exchange best practices on matters related to the coordination of the implementation at Member State level of this Regulation and of the delegated and implementing acts adopted pursuant to it, in particular as regards:
      (xi) implementation of rules for access to electronic health data;
      (xii) technical specifications or existing standards regarding the requirements set out in Chapter IV;
      (xiii) incentives policy for promoting data quality and interoperability improvement;
      (xiv) policies concerning fees to be charged by the health data access bodies and **health** data holders;
      (xv) the establishment and application of penalties~~;~~
      ~~(xvi) other aspects of the secondary use of electronic health data~~.
      (xvi) other aspects of the secondary use of electronic health data.

Justification:
We'd prefer not to delete "(xvi) other aspects of the secondary use of electronic health data", since there may be other topics to discuss aside from the ones explicitely mentioned in the list. We should not be too restrictive in this regard.

(c) to facilitate cooperation between health data access bodies through capacity-building, establishing the structure for **biennial** ~~annual~~ activity reporting, **and** ~~peer review of annual activity reports and~~ exchange of information **in those reports**;

(d) to share information concerning risks and data protection incidents related to secondary use of electronic health data, as well as their handling;

~~(e) to contribute to the work of the European Data Innovation Board to be established in accordance with Article 29 of the Regulation […] [Data Governance Act COM/2020/767 final];~~ (SEE ARTICLE 65(5))

(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.

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** ~~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~~. **Countries belonging to the European Economic Area which are not part of the European Union, third countries and international organizations which are authorized participants in MyHealth@EU or HealthData@EU will not have a vote in the Steering Groups or its sub-groups, but may be invited as observers to their meetings.**

Justification:

We believe that it is important to clarify that the following entities, after becoming authorised participants of MyHealth@EU or HealthData@EU, cannot have a vote in the decision-making process in the EHDS Board:
- EEA contries which are not part of the EU (Norway, Iceland and Lichenstein).
- third countries.
- international organizations.

However, they may be invited as observers to the meetings.

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 shall also take decisions to accept individual authorised participants to join the infrastructures or to disconnect them.~~ (MOVED FROM PARA 6 AND AMENDED)

Comment:

We'd prefer to keep the original wording in article 66(6) and the original wording of articles 12(9) and 52(14), since the MS should be involved in the onboarding of authorized participants in MyHealth@EU and HealthData@EU.

1AA. The steering groups will participate in the drafting process of delegated acts as per article 67 and the implementing acts of article 68, in accordance with the Inter-institutional Agreement of 13 April 2016 on Better Law-Making. **(NEW PARAGRAPH)**

Justification:

he entities of article 66 ("Steering groups") must be involved in the drafting of implementing acts and in the definition of delegated acts. This would be coherent with the Inter-institutional Agreement of 13 April 2016 on Better Law-Making , as long as, in the case of implementing acts, this approach does not interfere with the procedure defined in Regulation (EU) No 182/2011.

Why should the steering groups (article 66) participate in the drafting of implementing and delegated acts but not the EHDS board (articles 64-65)? Because, after the trilogues, the EHDS board may end up with a very long list of stakeholders (including lobbies, such as industry representatives) with a permanent presence in all meetings, which may hinder or introduce unwanted effects in the drafting process of implementing decisions and/or delegated acts. Of course, the opinions of these stakeholders should be taken into account if possible, but these entities should not directly participate in the drafting of implementing and delegated acts, as they are not legislators.
On the other hand, the steering groups (article 66) would be the most qualified governance entity to participate in the drafting process of implementing and delegated acts, since they would be composed by experts from the Member States.

1B. The Steering Groups shall, in principle, take decisions by consensus. Where consensus cannot be reached, the adoption of a decision shall require the support of members representing two-thirds majority.

Comment:
We believe that, for Member States, the decision-making process should take into account the population of the country, since these decisions, although technical, will affect the population of the EU as a whole, and it would be important to guarantee representativity.

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.~~ MOVED TO ARTICLE 66A
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 shall also take decisions to accept individual authorised participants to join the infrastructures or to disconnect them.~~ MOVED TO PARA 1A

Comment:
We'd prefer to keep the original wording in article 66(6) and the original wording of articles 12(9) and 52(14), since the MS should be involved in the onboarding of authorized participants in MyHealth@EU and HealthData@EU.

~~**Article 66A**~~

~~***Fora for the infrastructures MyHealth@EU and HealthData@EU***~~

~~**1. Two fora are hereby established: the MyHealth@EU Forum and the HealthData@EU Forum, with a view to exchange information and views on relevant matters related to the crossborder infrastructures respectively provided for in Articles 12 and 52, excluding any decision making. These Fora shall be convened on a regular basis.**~~

~~**2. The Fora referred to in paragraph 1 shall be composed of members of the Steering groups referred to in Article 66 and of other other participants in the infrastructures provided for in Articles 12 and 52.**~~

~~**3. Stakeholders and relevant third parties, including patients' representatives, may be invited to attend meetings of the respective Forum and to participate in their work.**~~

Justification:

Regarding the definition of governance entities of the EHDS, in the proposal of the Commission, there are 5 governance groups:
- EHDS board (articles 64 and 65),
- two governance groups for operational decisions defined in article 66,
- an entity with representatives of the Member States consulted in the process of the definition of delegated acts in article 67(4),
- a committee for the approval of implementing decisions in article 68.

Comments on the compromise text of the Presidency:
- Attendance to the meetings of the aforementioned governance entities (aside from other lines of work in the context of primary and secondary use) would already imply a significant burden on the MS. We thus don't see the need for yet another governance entity in article 66A, which would have no decision-making power.

Article 12
MyHealth@EU

9. The approval for individual authorised participants to join MyHealth@EU for different services, or to disconnect a participant shall be ~~issued by the Joint Controllership groups,~~ based on the results of the compliance checks **performed by the Commission**.
Subject to the positive outcome of this compliance check the Commission shall, by means of implementing act, take decisions to connect individual authorised participants to join the respective infrastructure or to disconnect them. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 68.

Article 52
Cross-border infrastructure for secondary use of electronic health data (HealthData@EU)

14. The approval for individual authorised participant to join HealthData@EU or to disconnect a participant from the infrastructure shall be ~~issued by the **Article 66** Joint Controllership group,~~ based on the results of the compliance checks **performed by the Commission** concerning the fulfilment of the requirements **referred to in paragraph 13**.
Subject to the positive outcome of this compliance check, the Commission shall, by means of implementing act, take decisions to connect individual authorised participants to join the respective infrastructure or to disconnect them. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 68.

Comment:
We'd prefer to keep the original wording in article 66(6) and the original wording of articles 12(9) and 52(14), since the MS should be involved in the onboarding of authorized participants in MyHealth@EU and HealthData@EU.

CHAPTER VII
Delegation and Committee

Article 67
Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The power to adopt delegated acts referred to in Articles 5(2), ~~10(3), 25(3),~~ 32(4), ~~33(7), 37(4), 39(3), 41(7), 45(7), 46(8), 52(7),~~ **and** 56(4) shall be conferred on the Commission for an indeterminate period of time from the date of entry into force of this Regulation.
3. The power to adopt delegated acts referred to in Articles 5(2), ~~10(3), 25(3),~~ 32(4)~~,~~ ~~33(7), 37(4), 39(3), 41(7), 45(7), 46(8), 52(7),~~ **and** 56(4) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Inter-institutional Agreement of 13 April 2016 on Better Law-Making.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
6. A delegated act adopted pursuant to Articles 5(2)~~, 10(3), 25(3),~~ 32(4), ~~33(7), 37(4), 39(3), 41(7), 45(7), 46(8), 52(7),~~ **and** 56(4) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of 3 months of notification of that act to the European Parliament and to the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by 3 months at the initiative of the European Parliament or of the Council.

Comment:
We support the changes made by the Presidency.

Article 68
Committee procedure

1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.
2. Where reference is made to this paragraph, Article ~~4~~ **5** of Regulation (EU) No 182/2011 shall apply.

Comment:
We support the changes made by the Presidency.

Chapter VIII
Miscellaneous

Article 69
Penalties

Without prejudice to Articles 30 and 43 of this Regulation and to Chapter VIII of Regulation (EU) 2016/679, Member States shall lay down the rules on penalties applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties shall be effective, proportionate and dissuasive. Member States shall notify the Commission of those rules and measures by date of application of this Regulation and shall notify the Commission without delay of any subsequent amendment affecting them.

Comment:
We support the changes made by the Presidency.

Article 70
Evaluation and review

1. After ~~5~~ **6** years from the entry into force of this Regulation, the Commission shall carry out a targeted evaluation of this Regulation especially with regards to Chapter III, and submit a report on its main findings to the European Parliament and to the Council, the European Economic and Social Committee and the Committee of the Regions, accompanied, where appropriate, by a proposal for its amendment. The evaluation shall include an assessment of the self-certification of EHR systems and reflect on the need to introduce a conformity assessment procedure performed by notified bodies.
2. After ~~7~~ **8** years from the entry into force of this Regulation, the Commission shall carry out an overall evaluation of this Regulation, and submit a report on its main findings to the European Parliament and to the Council, the European Economic and Social Committee and the Committee of the Regions, accompanied, where appropriate, by a proposal for its amendment.
3. Member States shall provide the Commission with the information necessary for the preparation of that report.

Comment:
We support the changes made by the Presidency.

Article 71
Amendment to Directive 2011/24/EU

Article 14 of Directive 2011/24/EU is deleted.

Article 72
Entry into force and application

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.
It shall apply from ~~12~~ **24** months after its entry into force.
However, Articles 3, 4, 5, 6, 7, 12, 14, 23 and 31 shall apply as follows:

(a) from ~~1~~**3** year after date of entry into application to categories of personal electronic health data referred to in Article 5(1), points (a), (b) and (c), and to EHR systems intended by the manufacturer to process such categories of data;
(b) from ~~3~~**5** years after date of entry into application to categories of personal electronic health data referred to in Article 5(1), points (d), (e) and (f), and to EHR systems intended by the manufacturer to process such categories of data;
(c) from the date established in delegated acts pursuant to Article 5(2) for other categories of personal electronic health data.

Chapter III shall apply to EHR systems put into service in the Union pursuant to Article 15(2) from ~~3~~ **4** years after date of entry into application.
Chapter IV shall apply 36 months after date of entry into force.

Comment:
We believe that transitionary periods should be realistic. Our position in this regard has already been stated in the survey sent by the CZ Presidency.