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From: General Secretariat of the Council
To: Delegations
Subject: Proposal for a Regulation on the European Health Data Space
- First Presidency compromise proposal on articles 66, 66A, 70 and 72

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

Changes compared to the Commission proposal are marked in **bold/underline** for additions and in ~~strikethrough~~ for deletion.

Justifications

The Presidency's explanations of amendments made in the articles in the first compromise proposal for Articles 66 and 66A.

ARTICLES 66 and 66A

After the last meeting the Presidency has provided delegates with slides on the cross- border infrastructure for secondary use, HealthData@EU. The cross-border infrastructure for primary use, MyHealth@EU, has been examined during the CZ Presidency.

According to the Commission's proposal and the first compromise proposal for Articles 12, 13 in Chapter I and Article 52 in Chapter IV the Commission will act as a processor and the authorised participants will act as controllers for the processing of personal data in the cross-border infrastructures. The word joint has been deleted in the first compromise proposals for both Articles 12 and 52.

According to Article 66 in the Commission's proposal the Commission shall establish two groups dealing with joint controllership for the two cross-border infrastructures provided for in Articles 12 and 52. Representatives from national contact points and other authorised participants are to be included in these groups. The two groups shall not only take operational decisions concerning the infrastructures but also decisions on accepting individual authorised participants and to disconnect them.

Regarding the groups' roles in taking decisions on accepting and disconnecting participants in the two infrastructures the Presidency would like to make Member States aware of the following. The first concern is the possible conflict of interest if the groups should be taking decisions on their own participations in the infrastructures. The second concern would be, as these decisions have legal effect, and these groups do not seem to be legal entities, it is not clear which authorised participants should be addressed with a legal claim.

Therefore the Presidency have proposed the following in Articles 66, 66A, 12 and 52:

1. The Commission, through implementing acts (examination procedure), takes decisions on accepting and disconnecting individual authorised participants in the two cross-border infrastructures, see amendments to Articles 12 and 52. According to the Commission's proposal the Commission may or shall, by means of implementing acts, set out several criteria regarding the cross-border infrastructure, see Articles 52(13) and 52(6) on the secondary use and Article 12(4) on the primary use. The Commission shall also perform compliance check before decision on joining or disconnecting shall be issued, see Article 12(9). This could also be clarified in Article 52(14)

2. The two groups referred to in Article 66 take only operational decisions regarding the means of the infrastructure, such as development and operation of the cross-border infrastructures in accordance with Chapters II and IV, on changes of infrastructure, adding additional infrastructures or services, or ensuring interoperability with other infrastructures and digital systems or data spaces. The decisions on accepting and disconnecting authorised participants are not included in the tasks of these groups. Instead the Presidency propose that this should be a task for the Commission, see amendments to Article 12 and 52.

3. The groups in Article 66 only include Member States to strengthen the power of Member States. To also include other authorised participants the Presidency propose to create two Forum in Article 66A, where also other authorised participants in the cross-border infrastructures are included.

There are of course other ways to arrange the roles and responsibilities in the infrastructures, including keeping the Commission's proposal for Article 66.

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 groups shall be composed of **one** ~~the~~ representatives **per Member State** of the **respective** national contact points ~~and other authorised 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.

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 Controllershship 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 Controllershship 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.

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.

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 ~~13~~ 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 ~~35~~ 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.

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
