Council of the European Union

Brussels, 28 February 2023
(OR. en)

6627/23

Interinstitutional File:
2022/0140(COD)

LIMITE

SAN 90
PHARM 29
COMPET 126
MI 127
DATAPROTECT 48
CODEC 222

WORKING DOCUMENT

From:	General Secretariat of the Council
To:	Delegations
Subject:	Proposal for a Regulation on the European Health Data Space *- First Presidency compromise proposal (Chapters V-VIII)*

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 Chapter V, VI, VII and VIII.

Articles 61 and 62

Articles 61 and 62 shall complement the rules on transfer to a third country or an international organisation in Regulation (EU) 2016/679 regarding anonymous data (or non-personal data). Regulation (EU) 2022/868 contains similar rules.

To our understanding a transfer is made already when the electronic health data is made available to an entity in a third country or an international organisation. Hence the rules regarding transfer to a third country apply already when electronic health data is made available to an entity in a third county or an international organisation pursuant to a data permit or a data request.

Our amendments in Articles 61 and 62 are made to clarify the link to the rules in Regulation (EU) 2016/679 by using the same word.

Further information on transfer to a third country can be found in EDPB´s Guidelines 05/2021 on the interplay between the application of Article 3 and the provisions on international transfers as well as in Chapter V of the GDPR.

Anonymous data instead of non-personal data

In Articles 61 and 62 the term anonymous data is used instead of non-personal data. The reason behind is that this Regulation set out rules for processing of electronic health data. In the vast majority of cases, the electronic health data will originally come from and concern natural persons, either as anonymous or as personal data. The word anonymous is also used and described in Regulation (EU) 2016/679, see recital 26 in the same Regulation.

Article 66

Article 66 is excluded from the compromise proposal, since the Presidency see a need for further discussion and mapping regarding the data flow and the responsibilities and roles in the cross border infrastructure provided in Article 12 and 52, before presenting a compromise proposal.

Article 70

Article 70 is also excluded from the compromise proposal and put on hold at this stage, because of the strong link to Article 72.

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.

Article 60

Additional requirements for public procurement and Union funding

1. **Contracting authorities** ~~Public procurers, national competent authorities~~, including digital health authorities and health data access bodies and **Union institutions, bodies, offices or agencies, including** the Commission**,** shall make reference to the applicable technical specifications, standards and profiles as referred to in Articles 6, **12,** 23, 50, **52,** 56, **as well as to the requirements laid down in Regulations (EU) 2016/679 and (EU) 2018/1725,** as relevant, as points of orientation for public procurements and when formulating their tender documents or calls for proposals, as well as when defining the conditions for Union funding regarding this Regulation, including enabling conditions for the structural and cohesion funds.

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.

Article 61

*~~Third country~~ **T**~~t~~ransfer **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 authorisated 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]~~.

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.

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**.

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

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~~ be invited to the meetings, where the issues discussed are of relevance for them. (MOVED FROM PARA 1 AND AMENDED)

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** have an observer role **when invited to participate in the meetings**. (MOVED FROM PARA 1 AND AMENDED)

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.**

~~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).

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~~.

   (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~~.

(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

(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.

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 data processed in a such manner that the data subject is not or no longer identifiable.