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MEETING DOCUMENT

From:	General Secretariat of the Council
To:	Working Party on Public Health (Attachés) Working Party on Public Health (European Health Data Space)
Subject:	Working Party on Public Health on 25 July 2023 - Presentation by the Presidency on the European Health Data Space

Delegations will find enclosed the presentation given by the Presidency during the Working Party on Public Health held on 25 July 2023.

PRESIDENCIA ESPAÑOLA CONSEJO DE LA UNIÓN EUROPEA

Working Party on Public Health on 20 July 2023

Thursday 25th of July 2023

10:00-13:00 & 14:30-18:30

Working Party on Public Health – EHDS (2023/07/25)

0. Summary of the last WP meetings (4th, 5th, 14th, 20th of July, 2023)	Deadline for written comments
Proposal for article 2 (2) (y); art 35 A, 35 F, 42, merging of 45 and 47 + rewording 46	17 / 07 / 2023 COB
Governance at the national level: art 10, 36, 37; proposal for a HDAB for EU institutions. Governance at EU level: art. 64, 65, 66 Procurement, reimbursement & financing of EHR systems, art 16A; Public procurement & EU funding, art 60 Reporting at national level: art 10A (DHA) and art 39 (HDAB) Art 11 (Right to lodge a complaint with a digital health authority) Art 11 A (Relationship with data protection regulation)	31 / 07 / 2023 COB
Art 42 (Fees) Art 58 (Minimum dataset specifications)	07 / 08 / 2023 COB
A. Rights of natural persons in the secondary use of health data (articles 35D, 35E, 35G), excepting opt-out, i.e. article 35F **B. Primary use**: definition of an EHR system [article 2(2)(n) + article 5 + Annex I], revision of the European electronic health record exchange format [article 6], possibility of defining additional specifications for EHR at the national level, assessment of compliance by manufacturers of EHR systems to EU-wide EHDS-requirements, testing environment provided by the EU Commission.	07 / 08 / 2023 COB
1. Continuation of discussion of topics of the previous meetings	
• **Proposal for an implementing act to define technical specifications [article 8E(2) Right to restrict access and information on access]** • **Should wellness applications be in the scope of harmonization in the primary use of health data in the EHDS?**	07 / 08 / 2023 COB
2. Topics of today's meeting (25th of July) Third countries in the context of secondary use of health data	
• Possible scenarios • Fees (Article 42) • Possible requirement for HDABs and SPEs to store data exclusively in the EU/EEA • Higher discretionary power of Member States for data access applications from third countries (art 46 bis)	15 / 08 / 2023 COB
3. Backup topics (25th of July, 2023) Third countries in the context of primary use of health data	
• Possible scenarios and related provisions in the EHDS proposal	

Working Party on Public Health – EHDS (2023/07/25)

1. Topics from previous meetings: Proposal for an implementing act allowing the definition of technical specifications [article 8E(2) *Right to restrict access and information on access*]

Wording of the current compromise text	Proposed new wording
1. ~~Notwithstanding Article 6(1), point (d), of Regulation (EU) 2016/679,~~ ~~n~~**N**atural persons shall have the right to restrict access of health professionals **and healthcare providers** to ~~all or part of~~ their **personal** electronic health data. **Such restriction of access may be derogated from under the conditions laid down to in Article 7A(3).** Member States shall establish the rules and specific safeguards regarding such restriction mechanisms. 2. Natural persons shall have the right to obtain information on ~~the healthcare providers and health professionals that have accessed~~ **any access to** their **personal** electronic health data in the context healthcare. The information shall be provided ~~immediately~~ **without delay** and free of charge through electronic health data access services. **The information shall include at least the following:** **(**a) the healthcare provider who accessed the personal electronic health data; (b) the date and time of access; (c) the personal electronic health data that was accessed.	1. ~~Notwithstanding Article 6(1), point (d), of Regulation (EU) 2016/679,~~ ~~n~~**N**atural persons shall have the right to restrict access of health professionals **and healthcare providers** to ~~all or part of~~ their **personal** electronic health data. **Such restriction of access may be derogated from under the conditions laid down to in Article 7A(3).** Member States shall establish the rules and specific safeguards regarding such restriction mechanisms. 2. Natural persons shall have the right to obtain information on ~~the healthcare providers and health professionals that have accessed~~ **any access to** their **personal** electronic health data in the context healthcare. The information shall be provided ~~immediately~~ **without delay** and free of charge through electronic health data access services. **The information shall include at least the following:** **(**a) the healthcare provider who accessed the personal electronic health data; (b) the date and time of access; (c) the personal electronic health data that was accessed. **3. The Commission shall, by means of implementing acts, determine the requirements concerning the technical implementation of the format defined in paragraph 2.**

First round of comments: Yes/No

Second round of comments: If NO, please briefly explain your position during the meeting and send written comments (deadline: 7th of August 2023).

Working Party on Public Health – EHDS (2023/07/25)

1. Topics from previous meetings: Should wellness applications be in the scope of harmonization in the primary use of health data in the EHDS?

After the comments of the delegations of the WP 2023-05-23, there seems to be a desire of some delegations of removing harmonization of wellness applications from the primary use of the EHDS:

- Concerns about the reliability and cybersecurity of such applications
- The added value in primary use would be to add patient-provided data/patient comments (article 8B EHDS) to EHR systems from wellness applications; could be useful in certain medical conditions…
- However, these benefits would seem to be best provided (in a more secure and verified way) by medical devices, rather than wellness applications…

Article 31A in the current compromise text states that "*Member States shall remain free to regulate the use of wellness applications* (…)"; perhaps, it would be clearer to simply remove article 31 (Article 31 *Labelling of wellness applications*) and Article 31A (*Wellness applications within Member States´ healthcare systems*), avoiding harmonization at the EU level and placing 31A in a recital.

First round of comments: Would your delegation support the removal of wellness applications from the primary use of health data? (i.e. deletion of articles 31 and 31A) Yes/No.

Second round of comments: If YES, please briefly explain your position during the meeting and send written comments. If you have an alternative proposal, please send written comments too. (deadline: 7th of August 2023).

Working Party on Public Health – EHDS (2023/07/25)

2. Topics of today's meeting (25th of July): Third countries in the context of secondary use of health data

General approach

- Political decision
- Preliminary iinformation on the matters at hand to help the discussion
- Opinions during the WP, and will try to provide sufficient time for written feedback

Outline of the analysis

Several **concerns have been raised by MS**, grouped around the following topics:

1. General comments about the cooperation with third countries in the context of the secondary use of health data.
2. Risks of more restrictive measures with third countries in the context of the EHDS (in secondary use of health data).
3. Executive summary of risks of a very open approach to third countries in the context of the EHDS (secondary use)
4. Proposals for solutions to the risks of a very open approach
    a) Possibility of higher fees for data access applications / data access request for data users in third countries.
    b) Possible requirement for HDABs and SPEs to store data exclusively in the EU/EEA.
    c) Higher discretionary power of Member States for data access applications from third countries.

Working Party on Public Health – EHDS (2023/07/25)

2. Topics of today's meeting (25th of July): Third countries in the context of secondary use of health data

1. **General comments about the cooperation with third countries (secondary use of health data) (1/2)**

- The EHDS **does not prevent alternative data transfer mechanisms** at the EU/EEA level or with third countries (within the secondary use of health data)

- What **could be the constraints** from a legal point of view in the introduction of more restrictive measures towards third countries in the context of the EHDS?
  - EU law cannot establish barriers to **international trade in products and services**, **unless there are specific exceptions** in the international trade legal framework, mainly composed by World Trade Agreements of which the EU is part of, in particular, the General Agreement on Trade in Services (GATS) to which the EU has made specific commitment.
  - EHDS could be seen as a 'service' => GATS could apply in the context of secondary use of health data in the EHDS.
  - **GATS has several exceptions** (situations where it does not apply):
    1. The 'services in the exercise of government authority' (herein after 'SSEGA') exception; Article I(3). SSEGA services are supplied (a) neither on a commercial basis, nor (b) in competition with one or more service suppliers. SSEGAs are out of scope of GATS.
    2. The data protection exception. Article XIV(c)(ii) (*as long as these measures do not constitute arbitrary or unjustifiable discrimination between countries or a disguised restriction on trade in services)*

Working Party on Public Health – EHDS (2023/07/25)

2. Topics of today's meeting (25th of July): Third countries in the context of secondary use of health data

1. General comments about the cooperation with third countries (secondary use of health data) (2/2)

How does GATS apply in the context of **secondary use** of health data in the EHDS?

Two different aspects:

1) **the activities of the HDABs themselves**. The permitting and data request process is something that only the HDABs can do (no competition) and they don't do it commercially (there can be fees, but only for cost-recovery). Those processes thus **appear to be covered under the SSEGA exception in GATS**.

2) **possible subcontracting by HDABs**. On the other hand, for the task of providing a SPE (and in that process possibly relying on subcontractors providing data processing services), there can be other entities who provide SPEs as well. **This function would not appear to qualify as a SSEGA**. However, restrictions to subcontracting activities by the HDABs **may be defined under the aforementioned** 'data protection exception'.

These exceptions in the context of the EHDS **may be subject to interpretation**, but they might establish a legal justification for specific conditions to apply more restrictive conditions for third countries.

Working Party on Public Health – EHDS (2023/07/25)

2. Topics of today's meeting (25th of July): Third countries in the context of secondary use of health data

2, Risks of more restrictive measures with third countries in the context of the EHDS (secondary use)

The compromise text has a very open model with third countries:

- **any natural or legal person from any third country, in principle, may request personal or anonymous healthcare data from the EU/EEA.**
- If there is access to personal health data, this data user would need to be compliant with the GDPR and (in particular, Chapter V GDPR and article 9(4) GDPR.
- when accessing anonymous health data which may be subject to re-identification, protective measures may be defined, as mentioned in article 61 EHDS.
- aside from this, the data user from a third country is, largely, on equal terms compared to data users from the EU/EEA.

- Risks of imposing restrictive measures on third countries
  - Retaliatory measures by third countries (it might not be as EHDS, by itself, would not affect previously existing data flows); however, in the future it could come to that…
  - Very restrictive measures in the data exchanges with third countries may lead to a certain isolation of research in the EU/EEA, if this research evolves towards the 'EHDS model of secondary use of health data'.
  - Indirect benefit in openness with data users from third countries. Data users from third countries will contribute to scientific research based on health data and development of products
    - *Scientific research (Art 34 (1) (e)), development of commercial products and services (article 34(1)(f)). In the original proposal of the Commission, the results of all data access applications and data requests had to be made publicly available, for transparency purposes and to benefit to 'society at large'. (proposal of the Presidency 20/07/2023 going back from 35E(1) to the original proposal of art 38.*

Working Party on Public Health – EHDS (2023/07/25)

2. Topics of today's meeting (25th of July): Third countries in the context of secondary use of health data

3. Summary of risks of the a very open approach to third countries in the context of the EHDS (secondary use)

Risk in the current compromise text	Proposal for a solution
Data users in third countries may require more resources from HDABs to process data access applications / data access requests. .	Possibility of establishing higher fees for data access applications / data access request made by data users in third countries.
Personal health data is of a particularly sensitive nature and it needs to be properly protected, to ensure trust of citizens in the EHDS. Personal health data of a sizeable amount of the population of an EU/EEA country is temporarily stored in an SPE. If these SPEs store raw personal health data outside of the EU/EEA, this may lead to higher risks of unauthorised access to these health data.	Establish a requirement for HDABs and secure processing environments to store data exclusively in the EU/EEA. Data users from third countries would still be able to access personal health data through an SPE, and in compliance with Chapter V of the GDPR. However, the SPEs themselves and the HDABs would always have the requirement of storing personal health data in the EU/EEA.
HDABs and data holders in the EU are supposed to recoup the costs of data access applications / data access requests. However, in practice, they may not be able to fully do so, and thus will operate 'at a loss', similarly to most public services provided by EU/EEA countries. This will be most probably the case if they have to provide services to the whole world Third countries offer no guarantees of reciprocity. In this case, reciprocity means the ability to request data from third countries. Since EU/EEA countries have some of the best datasets in the World, there should be reciprocity guarantees, if possible. Politically, it may be challenging to explain and justify to EU/EEA citizens why their personal health data can be used in third countries in a very open manner, especially if there is a lack of reciprocity.	This leads to a situation wherein EU Member States may need some discretionary power when answering data requests and data access applications from third countries. The conditions for data access applications by third countries could be defined in implementing acts. In this context, reciprocity with third countries would need to be negotiated at a political level. In particular, there would to be a unilateral recognition of particular rights for third countries by the EU/EEA in the context of the EHDS, accompanied by a reciprocal unilateral recognition of similar rights by the EU/EEA in the national legislation of the third country.

Working Party on Public Health – EHDS (2023/07/25)

2. Topics of today's meeting (25th of July): Third countries in the context of secondary use of health data

4. Proposals for solutions to the risks of a very open approach (1/6)

a) Possibility of higher fees for data access applications / data access request for data users in third countries.

- Against the international trade commitments of the EU to charge more third country data users **just based on their localization**
- Not against the international trade commitments of the EU, ***if*** **it is justified based on requirements of data users from third countries**
- FINDATA fees as an example. Therein, applicants from non-EU countries **may** be subject to higher fees.

Article 42 Fees	Article 42 Fees
Health data access bodies ~~and~~ **or** single **health** data holders **referred to in Article 49** may charge fees for making electronic health data available for secondary use. **Such fees shall be in proportion to the cost of making the data available and not restrict competition. Such**~~Any~~ fees shall **cover all or part** ~~**of** include and be derived from the~~ costs related to ~~conducting~~ the procedure ~~for requests, including~~ for assessing a data **permit** application or a data request, granting, refusing or amending a data permit pursuant to Article 45 and 46 or providing an answer to a data request pursuant to Article 47, in accordance with Article 6 of Regulation **(EU) 2022/868** ~~[…] [Data Governance Act COM/2020/767 final]~~**, as well as costs related to the gathering, preparation and provisioning of the electronic health data**.	Health data access bodies ~~and~~ **or** single **health** data holders **referred to in Article 49** may charge fees for making electronic health data available for secondary use. **Such fees shall be proportionate to the cost of making the data available and not restrict competition. Such**~~Any~~ fees shall **cover all or part** ~~**of** include and be derived from the~~ costs related to ~~conducting~~ the procedure ~~for requests, including~~ for assessing a data **permit** application or a data request, granting, refusing or amending a data permit pursuant to Article 45 and 46 or providing an answer to a data request pursuant to Article 47, in accordance with Article 6 of Regulation **(EU) 2022/868** ~~[…] [Data Governance Act COM/2020/767 final]~~**, as well as costs related to the gathering, preparation and provisioning of the electronic health data**. **Reduced fees may be established by the Member States for certain types of data users, such as university researchers or microenterprises. Such reductions shall also apply for data users from Member States and third countries.** **Fees may be higher for data users from third countries if justified by higher resources for servicing their needs. These shall be proportionate and a justification shall be provided.**

Working Party on Public Health – EHDS (2023/07/25)

2. Topics of today's meeting (25th of July): Third countries in the context of secondary use of health data

4. Proposals for solutions to the risks of a very open approach (2/6)

b) **Possible requirement for HDABs and SPEs to store data exclusively in the EU/EEA.**

- Personal health data is of a particularly sensitive nature and it needs to be properly protected, to ensure trust of citizens in the EHDS.
- the personal health data of a sizeable amount of the population of an EU/EEA county could be temporarily stored in an SPE. If these SPEs store raw personal health data outside of the EU/EEA, this may lead to higher risks of unauthorised access to these health data.
  .
- some delegations have proposed that the data shared within the context of the EHDS is either restricted to the jurisdiction of their specific country or to the EU/EEA. i.e. it would be possible to view the data from other countries (even third countries), but the data must be stored in a specific jurisdiction.
- This could be interpreted as a 'data localization requirement
  - Statements in EU law stating that data may not leave the EU/EEA, or may be specifically bind to a certain jurisdiction are against the 'digital trade chapter of EU trade arrangements
  - BUT
    - the GDPR by itself is often considered a 'conditional data localization requirement
    - article XIV(c)(ii) GATS establishes a clear exclusion from this agreement of *'the protection of the privacy of individuals in relation to the processing and dissemination of personal data and the protection of confidentiality of individual records and accounts;'* as long as these measures do not constitute arbitrary or unjustifiable discrimination between countries or a disguised restriction on trade in services.
    - according to recent academic references, '*so far, data protection has not been subject to dispute settlement proceedings at the WTO*
    - there is a recent precedent in EU law imposes a data localization requirement, specifically article 10(8) of *Regulation (EU) 2021/953 of the European Parliament and of the Council of 14 June 2021 on a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery*

Working Party on Public Health – EHDS (2023/07/25)

2. Topics of today's meeting (25th of July): Third countries in the context of secondary use of health data

4. Proposals for solutions to the risks of a very open approach (3/6)

b) **Possible requirement for HDABs and SPEs to store data exclusively in the EU/EEA.**

- Using this precedent, and using the 'data protection exception' in GATS, SPEs (which would be data processors) could have a requirement to store (raw) personal health data in the EU/EEA. However, obviously, data users from third countries would still be able to access the data from their own jurisdiction through SPEs.
- HDABs could also have this requirement based both on the 'data protection exception' and the 'services in the exercise of government authority exception' in GATS.
- Given the above, considering the sensitivity of health data and the need to protect these data, we would like to open the debate for **the requirement for HDABs and SPEs to store personal health data in the EU/EEA.**

First round of comments: Does your delegation agree with the need for defining a requirement for HDABs and SPEs to store personal health data in the EU/EEA? (data users from third countries would still be able to access the data from their own jurisdiction through SPEs.) Yes/No.

Second round of comments: Please **briefly explain your YES position during the meeting** and send written comments.

Third round of comments: Please **briefly explain your NO position during the meeting** and send written comments.

(deadline: 15th of August 2023).

Working Party on Public Health – EHDS (2023/07/25)

2. Topics of today's meeting (25th of July): Third countries in the context of secondary use of health data

4. Proposals for solutions to the risks of a very open approach (4/6)

c) Higher discretionary power of Member States for data access applications from third countries.

- HDABs and data holders in the EU are supposed to recoup the costs of data access applications / data access requests. However, in practice, they may not be able to fully do so, and thus will operate 'at a loss', similarly to most public services provided by EU/EEA countries. If EU/EEA countries operate 'at a loss', providing this service to data users from any country in the World seems rather challenging due to the resources required to service all possible data requests and data applications.

- Third countries offer no guarantees of reciprocity. In this case, reciprocity means the ability to request data from third countries. In other words, since third countries can request data from EU/EEA countries, EU/EEA countries should be able to do the same. Since EU/EEA countries have some of the best datasets in the World, there should be reciprocity guarantees, if possible.

- Politically, it may be challenging to explain and justify to EU/EEA citizens why their personal health data can be used in third countries in a very open manner, especially if there is a lack of reciprocity.

- This leads to a situation wherein EU Member States may need some discretionary power when answering data requests and data access applications from third countries.

Working Party on Public Health – EHDS (2023/07/25)

2. Topics of today's meeting (25th of July): Third countries in the context of secondary use of health data

4. Proposals for solutions to the risks of a very open approach (5/6)

c) Higher discretionary power of Member States for data access applications from third countries.

The conditions for data access applications by third countries could be defined in implementing acts. In this context, reciprocity with third countries would need to be negotiated at a political level. In particular, there would to be a unilateral recognition of particular rights for third countries by the EU/EEA in the context of the EHDS, accompanied by a reciprocal unilateral recognition of similar rights by the EU/EEA in the national legislation of the third country.
A possible wording that could, potentially, accommodate this approach has been suggested by the delegations:

Article 46bis Data applications from third countries

(1) Without prejudice to Article 46, Member States shall receive data applications submitted from third countries
a) that are covered by an implementing act referred to in Article 52 (5); or
b) that allow EU applicants for access to health data for secondary use under conditions that are not more restrictive than provided for in this regulation and therefore are covered by the implementing acts referred to in paragraph (2).

(2) The Commission shall adopt implementing acts establishing the list of third countries referred to in paragraph (1) point b). The implementing acts shall also indicate the eventual data categories referred to in Article 33 (1) if the specific third country applies in relation to a corresponding data categories more restrictive conditions than those set out in this regulation and therefore paragraph (1) of the Article applies with restrictions. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 68 (2). The Commission shall make the list of implementing acts adopted pursuant to this paragraph publicly available.

(3) Member States may receive data applications from third countries not covered by paragraph (1).

Working Party on Public Health – EHDS (2023/07/25)

2. Topics of today's meeting (25th of July): Third countries in the context of secondary use of health data

4. Proposals for solutions to the risks of a very open approach (6/6)

c) Higher discretionary power of Member States for data access applications from third countries.

The Regulation should not guarantee unconditional access to health data for secondary use without any reciprocity. Therefore, the regulation should provide for rules under which third country entities or individuals can submit data request. This possibility should be guaranteed in relation to third countries which are authorised participants in HealthData@EU and to those countries that allow access to health data for secondary use under conditions that are not more restrictive than provided for in this regulation.
In order to allow for uniform implementation at the level of Member States the Commission should adopt implementing acts.
Member States should remain free to decide to grant access to applicants from third countries not mentioned above.

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

Second round of comments: Please briefly explain your **YES** position during the meeting and send written comments.
Third round of comments: Please **briefly explain your NO position during the meeting** and send written comments.

(deadline: 15th of August 2023).

Working Party on Public Health – EHDS (2023/07/25)

3. Backup topics: Third countries in the context of primary use of health data (1/3)

In regards to Chapter II of the EHDS

- In the *default scenario*, the new citizen rights (arts 8A-8G) only apply in EU Member States and European Economic Area countries which are not part of the EU (i.e. Norway, Iceland and Lichtenstein).
- In the *default scenario*, healthcare professionals from a third country cannot directly (or indirectly) access health data belonging to a citizen (or legal resident) of an EU/EEA area country.
- A citizen (or legal resident) of an EU/EEA area country who travels to a third country can provide health data to a healthcare professional in a third country intentionally, and in an 'off-line presentation'.
- Conversely, in this *default scenario*, healthcare professionals form the EU/EEA cannot access health data from citizens in third countries by means of an 'on-line presentation'. However, citizens from said third countries may choose to provide their health data to a healthcare professional in the EU/EEA by means of an 'off-line presentation'.

Working Party on Public Health – EHDS (2023/07/25)

3. Backup topics: Third countries in the context of primary use of health data (2/3)

In regards to Chapter II of the EHDS

- Going beyond the *default scenario*
  - To exchange health data of citizens with healthcare professionals in third countries with an 'on-line presentation' the third country (for example, the United Kingdom) would need to join MyHealth@EU (**articles 12 and 13 EHDS**).
  - The procedure for third countries joining MyHealth@EU is described in article 13(3).
  - If a third country joins the MyHealth@EU infrastructure, transfer of personal health data of EU/EEA citizens would imply an international personal data transfer and Chapter V of the GDPR would apply => that third country would also need to *some* GDPR transfer tool in place.
- In principle, **there would be no legal guarantees of reciprocity**, i.e. healthcare professionals from third countries would be able to view data of EU/EEA citizens travelling to those third countries, but the reverse would not necessarily be true. In order for the reverse to happen, that third country would need to explicitly allow this in their national legislation

Working Party on Public Health – EHDS (2023/07/25)

3. Backup topics: Third countries in the context of primary use of health data (3/3)

In regard to Chapter III of the EHDS

- EHR systems would be considered a 'computer product' in terms of international trade agreements, of which the EU is a participant.
- Due to the legal commitments of the EU to the international trade agreements within the WTO, generally speaking, as long as third country manufacturers are compliant with the technical requirements set forth in Chapters I, II and III of the EHDS regulation (discussed in detail during the WP of the 2023-07-20), their EHR could be put in the EU market.

First & second round of comments:
Please, explain your position regarding third countries in the context of primary use of health data during the meeting and send written comments, if necessary. (*Possible participants in*

(deadline: 15th of August 2023).

PRESIDENCIA ESPAÑOLA CONSEJO DE LA UNIÓN EUROPEA

THANK YOU