Council of the European Union
General Secretariat

Interinstitutional files:
2022/0140 (COD)

Brussels, 24 April 2023

WK 5288/2023 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.

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 24 April 2023 - Presentation by the Presidency on the second compromise proposal.

Delegations will find enclosed the presentation given by the Presidency during the Working Party on Public Health held on 24 April 2023


Welcome.
sweden 2023.eu
Swedish Presidency of the Council of the European Union

Second compromise on EHDS

Chapter I

Scope

- Keping most provisions from the first compromise

- Clarification that this Regulation is without prejudice to Union or national law providing for access to electronic health data by public sector bodies or EU institutions, bodies and agencies (see Art 1(6))
- Exclusion from scope of “law enforcement, including the prevention, investigation, detection, and prosecution of criminal offences” (see Art 1(7))
- Need for further discussions, for example this regulation´s interplay with the NIS directive and interplay with national procedures for access to electronic health data

Definitions

- More definitions from other regulations; **public health**, **contracting authorities**
- New definitions specific to the EHDS regulation; **putting into service** and **risk**
- Addition of definition of **anonymous electronic health data**
- Deletion of definitions to avoid duplication, for example;
  - national contact point,
  - European exchange format
- Amendments made on other definitions, for example;
  - EHR systems (narrowed the scope),
  - Primary use (broaden the scope to include all kinds of social reimbursements services),
  - health data holder (the process of reimbursement to be included)
  - Data quality to also applies to primary use

Second compromise on EHDS

Chapter II

- Change of order of articles
  - Starting with the obligation of **registration**
  - Continuing with the purposes of Chapter II: **access** and **exchange** of the priority categories
  - Separate articles for each **right of natural persons** as each right also seems to have different scope and context
  - **Access services**; both for health professionals and natural persons has its own article

- As some provisions relates only to provision of healthcare while other also includes social reimbursements services, we have tried to do necessary clarifications

- **Deleted the possibility of delegated act** to add additional priority categories

- Clarification of relation to the **GDPR** and **the role of the data protection authority** related to the primary use

- Deleted reference to Eidas Regulation in Article 9 to allow more flexibility and ease of administrative burden

- Separate article on the reports by the Digital Health Authority (as for the Health Data access Body)

- Need for further discussions
  - The role for the digital health authorities
  - The roles and responsibilities in the cross-border infrastructure (horizontal issue)

Second compromise on EHDS

Chapter III

- Changed order of articles
  - starting with the scope
  - continuing with the relationship with other regulations (added in vitro medical devices)

- Clarification that MS remain free to use wellness applications within their healthcare systems
- Time frame for reporting serious incident changed from 15 days to 3 days
- Increased the power of market surveillance authority by being able to take immediate actions

- Need for further discussions
  - third party assessment
  - the relation to the NIS Directive
  - Clarifications on and when this Chapter will be applicable for existing EHR system (EHR system that is in use or marketed)

Second compromise on EHDS

Chapters V-VIII

- Kept Article 59-63, mainly no changes from the first compromise
- Kept 64 and 65, included voting rules, otherwise only minor changes
- Deleted Article 66A and integrated the provisions in Article 66
- Kept the decision making on the Commission to join or disconnect authorised participants (as the steering groups are not legal entities)
- Added element regarding penalties in Article 69 to help harmonised implementation

Survey results regarding the content of the **digital health authority´s** and **the health data access body´s reports**

Content of the digital health authority´s report

Article 10(2)(o)	Content	Rating (1-5) (based on 14 MS replies)
(i)	Measures taken to implement this Regulation	**4,43**
(ii)	Percentage of natural persons having access to different data categories of their electronic health records	**4,29**
(iii)	Information on the handling of requests from natural persons on the exercise of their rights pursuant to this Regulation	3,43
(iv)	Number of healthcare providers of different types, including pharmacies, hospitals and other points of care, connected to MyHealth@EU calculated in absolute terms, as share of all healthcare providers of the same type and as share of natural persons that can use the services	**4,14**
(v)	Volumes of electronic health data of different categories shared across borders through MyHealth@EU	3,93

Content of the digital health authority´s report

Article 10(2)(o) New Article 10A	Content	Rating (1-5) (based on 14 MS replies)
(vi)	Level of natural person satisfaction with MyHealth@EU services	3,00
(vii)	Number of certified EHR systems and labelled wellness applications enrolled in the EU database	3,79
(viii)	Number of non-compliance cases with the mandatory requirements	3,14
(ix)	A description of its activities carried out in relation to engagement with and consultation of relevant stakeholders, including representatives of natural persons, patient organizations, health professionals, researchers, and ethical committees	2,57
(x)	Information on cooperation with other competent bodies in particular in the area of data protection, cybersecurity, and artificial intelligence.	2,79

Content of the health data access body´s report

Article 39	Content	Rating (1-5) (based on 14 MS replies)
(a)	Information relating to the data access applications for electronic health data access submitted, such as the types of applicants, number of data permits granted or refused, purposes of access and categories of electronic health data accessed, and a summary of the results of the electronic health data uses, where applicable	**4,55**
(b)	A list of data permits involving access to electronic health data processed by the health data access body based on data altruism and a summary description of the general interests purposes pursued, where applicable, including the outcomes of the data permits granted	3,18
(c)	Information on the fulfilment of regulatory and contractual commitments by data users and data holders, as well as penalties imposed	**3,77**
(d)	Information on audits carried out on data users to ensure compliance of the processing with this Regulation	3,50
(e)	Information on audits on compliance of secure processing environments with the defined standards, specifications and requirements	**3,93**
(f)	Information on the handling of requests from natural persons on the exercise of their data protection rights	3,54

Content of the health data access body´s report

Article 39	Content	Rating (1-5) (based on 14 MS replies)
(g)	A description of its activities carried out in relation to engagement with and consultation of relevant stakeholders, including representatives of natural persons, patient organisations, health professionals, researchers, and ethical committees	2,86
(h)	Information on cooperation with other competent bodies in particular in the area of data protection, cybersecurity, data altruism, and artificial intelligence	2,93
(i)	Revenues from data permits and data requests	3,36
(j)	Satisfaction from applicants requesting access to data	2,57
(k)	Average number of days between application and access to data	**3,71**
(l)	Number of data quality labels issued, disaggregated per quality category	2,55
(m)	Number of peer-reviewed research publications, policy documents, regulatory procedures using data accessed via the EHDS	2,79
(n)	Number of digital health products and services, including AI applications, developed using data accessed via EHDS	3,21