

Maxime Morren

Attaché Health and Pharma, Permanent Representation of Belgium to the European Union

DEPARTMENT OF **CARE**

EHDS

EUROPEAN HEALTH DATA SPACE

1. The proposal

In short

"The European Health Data Space is a health-specific data sharing framework establishing clear rules, common standards and practices, digital infrastructures and a governance framework for the use of electronic health data by patients and for research, innovation, policy making, patient safety, statistics or regulatory purposes."

(European Commission website)

- A key pillar of the strong European Health Union
- The first of more common EU data spaces to emerge from the European strategy for data
- An answer to healthcare challenges that emerged after COVID-19
- Innovative: EHDS is essential for digital transformation in healthcare

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2. The negotiation process

Council vs EP text

- November 2023:
  - MS voted in favor of the general approach and gave a mandate to start negotiations with the EP
  - EP voted in favor of their amended text
- Most divergent points:
  - Opt-out (primary: amendment 555, secondary: obligatory vs optional)
  - Opt-in
  - EHR-systems (difference in scope)
  - TPA and European digital test environment
  - HDABs
  - Implementation period

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Trilogues process

- December 2023 – March 2024:
  - 4 Working Parties
  - 28 Interinstitutional Technical Meeting (ITMs)
  - 5 political trilogues
- Voting:
  - Coreper supported the provisional agreement on 22/3
  - EP voted in favor in Committee on 9/4, and in favor in plenary on 22/4
- Corrigendum procedure

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3. The final agreement

Some key elements

- Opt-out:
  - Opt-out primary: Council's text, with the deletion of the split between cross-border and national situations
  - Opt-out secondary: obligatory with the possibility for exceptions for the purposes of public interest, policy making, statistics and research purposes in the public interest
- Sensitive data:
  - MS may add extra measures at the national level.
- Restricted information:
  - If the patient restricts information, HCPs will only be able to access restricted health data in situations of vital interest.
- Trusted data holders:
  - To reduce the administrative burden, MS may establish trusted data holders that can securely process requests for access to health data
- Data localization:
  - Normative text for both primary and secondary use.
  - Exception to store data in third countries (adequacy decision)

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Concretely

- Greater control over your health data:
  - Immediate and free access to your health data in electronic form
  - Possibility to share your data with HCPs
  - Possibility to add information, rectify errors, restrict access and obtain information on which health professional accessed your data
  - have certain categories of health data issued and accepted in a European EHR exchange format
- Ensuring your privacy and security:
  - Researchers, industry or public institutions will be able to access to your health data only for specific purposes
  - They can only access data that do not reveal your identity;
  - Data can only be accessed and processed in closed, secure environments and only anonymized data can be downloaded.
  - Possibility of opt-out

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EHDS will allow you to go to a German pharmacy with a Belgian prescription

Or

If you get sick abroad (in the EU), you will be able to get treatment faster and easier thanks to the sharing of health data

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A balanced agreement

- Good and efficient use of data
- Secure use of data
- Data as a possible solution to face healthcare challenges

Futureproof. High-quality. Trustworthy.

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