

EHDS – General overview

Infosession

“Impact of the EHDS-Regulation on secondary use for health-data”

8 may 2023



Flanders
State of
the Art

Agenda

- 1. EHDS**
- 2. Secondary use of Health Data**

1. EHDS

- ▶ = proposal of a Regulation (in negotiation – Second Compromise Text)
- ▶ -timeline: in the year 2024 → implementation 1 year (mostly) or 3 years.
- ▶ 4 main objectives:

Empower individuals to control their health data



Foster a single market for digital health services and products



Ensure interoperability and security of health data and a level playing field for manufacturers



Ensure a consistent and efficient framework for the reuse of health data for research, innovation, policy-making and regulatory activities



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1. EHDS

- part of Digital Europe Programme (DEP) – Data Spaces
- building block of the European Datastrategy
- Foundation of the European Health Union

→ Challenge for ethics, data, privacy, legal.

- 3 essential chapters in the EHDS-proposal:

1) **Primary use (Chapter 2 EHDS)**

2) **Legal framework for the Healthcare-ICT market (EHR-systems + wellness-apps) (Chapter 3 EHDS)**

3) **Secondary use (Chapter 4 EHDS)**

1. EHDS

▶ 1.1. primary use

= processing of personal electronic health data for healthcare to assess, maintain or restore the state of health of the natural persons to whom that data relates (incl. prescription, provision of medical devices, social, administrative or reimbursement services (see Art. 2, 2, d) EHDS).

Principles:

-Healthcare providers will register personal electronic health data (min. 5 priority categories- Art. 5 EHDS) in an EHR-system.

-Access by health professionals to health data.

-Healthcare providers will update the data.

1. EHDS

▶ 1.1. primary use

-idea: civilian should be in control.

→more rights of access and processes of health electronic data (> GDPR)

f.e. - right of person to access his/her personal electronic health data;

- right of person to insert info in their own EHR;

- right to rectification;

- right to data portability for persons;

- right to restrict access and information on access;

- right to object.

1. EHDS

▶ 1.1. primary use

-° **Digital health AUTHORITY:**

Enforcement, ensure implementation of the EHDS-rights and obligations of Chapter II and III EHDS + collaboration with other supervisory institutions.

-National Contact Point (1 in MS) provides cross-border access/exchange health data through the European data-infrastructure My Health@EU.

f.e. treatment of a Belgian in Greece (MS of treatment)

“My Health@EU” = cross-border exchange of following data:

1) Patiënt summaries;

2) Electronic prescriptions;

3) Electronic dispensations;

4) Medical images and related image reports;

5) Laboratory results and related laboratory reports;

6) Hospital discharge reports.



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1. EHDS

▶ 1.2. Legal Framework for the Healthcare-ICTmarket

1) Electronic Health Records (EHR-systems)

2) wellness-apps

→ focus on requirements and obligations for importers/distributors and the manufacturers of EHR-systems.

→ °European internal market

- Market-surveillance authorities
- System of self-certification (EHR-systemen)
- Label of wellness-applications

2. Secondary use

2.1. scope of Secondary use

= use of electronic health data for re-use (other societal purposes than only healthcare):

- Research, innovation**
 - policy-making, statistics, policy-evaluation**
 - personalised medicine,**
- Check the correct Purpose for secondary use(Art. 34)**
- Scope of Health(care) Data is very broad (Art. 33, 1 a tot en met o)**

Purposes for electronic health data-secondary use (Art. 34 EHDS)

► **Purposes** for which electronic health data can be processed for secondary use

1. Health data access bodies shall only provide access to electronic health data referred to in Article 33 to a health data user if the purpose of processing complies with:
 - (a) activities for reasons of public interest in the area of public and occupational health, such as protection against serious cross-border threats to health, public health surveillance or ensuring high levels of quality and safety of healthcare and of medicinal products or medical devices;
 - (b) to support public sector bodies or Union institutions, agencies and bodies including regulatory authorities, in the health or care sector to carry out their tasks defined in their mandates;
 - (c) to produce national, multi-national and Union level official statistics related to health or care sectors;
 - (d) education or teaching activities in health or care sectors;
 - (e) scientific research related to health or care sectors;
 - (f) development and innovation activities for products or services contributing to public health or social security, or ensuring high levels of quality and safety of health care, of medicinal products or of medical devices;
 - (g) training, testing and evaluating of algorithms, including in medical devices, AI systems and digital health applications, contributing to the public health or social security, or ensuring high levels of quality and safety of health care, of medicinal products or of medical devices;
 - (h) providing personalised healthcare consisting in assessing, maintaining or restoring the state of health of natural persons, based on the health data of other natural persons.



Categories of data under the scope of 'Healthdata' (Art 33, 1 a) till o) EHDS) (1)

Data holders shall make the following categories of electronic data available for secondary use in accordance with the provisions of this Chapter:

- (a) Electronic Health Records;
- (b) data impacting on health, including social, environmental behavioural determinants of health;
- (c) relevant pathogen genomic data, impacting on human health;
- (d) health-related administrative data, including claims and reimbursement data;
- (e) human genetic, genomic and proteomic data;
- (f) person generated electronic health data, including medical devices, wellness applications or other digital health applications;
- (g) identification data related to health professionals involved in the treatment of a natural person;

Categories of data under the scope of 'Health Data' (Art. 33, 1a) till o) EHDS (2)

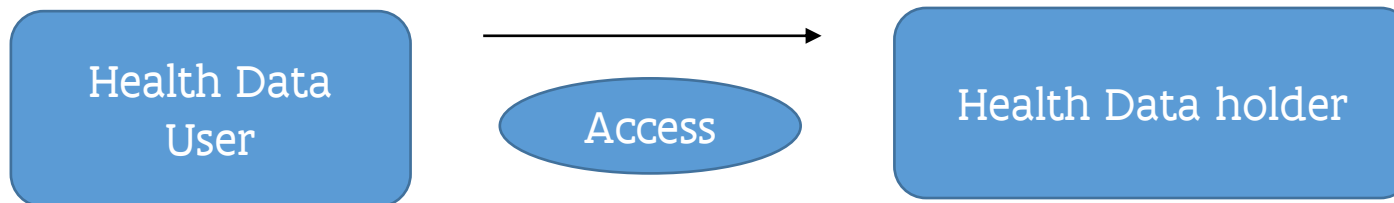
- (h) population wide health data registries (public health registries);
- (i) electronic health data from medical registries for specific diseases;
- (j) electronic health data from clinical trials;
- (k) electronic health data from medical devices and from registries for medicinal products and medical devices;
- (l) research cohorts, questionnaires and surveys related to health;
- (m) electronic health data from biobanks and dedicated databases;
- (n) electronic data related to insurance status, professional status, education, lifestyle, wellness and behaviour data relevant to health;
- (o) electronic health data containing various improvements such as correction, annotation, enrichment received by the data holder following a processing based on a data permit.

2. Secondary use

2.2. Principles:

- 1) **Data holder** must hold available upon request to the Health Data Access Body (HDAB) according to data permit/data request.
 - exception: micro-entreprises
 - (3 months to deliver data from Data holder to HDAB).

- 2) **Data user shall only have** access and processes only in accordance with a data permit/data request.



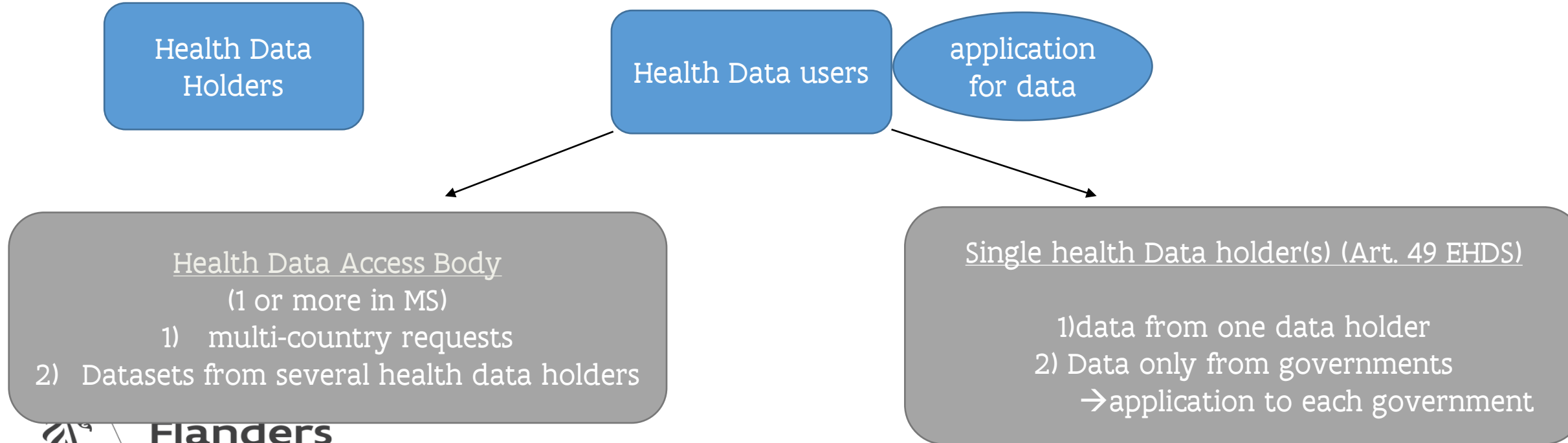
2. Secondary use

2.3. Functioning of data application

-list of forbidden secondary use to access and process data: advertising, insurance premiums,

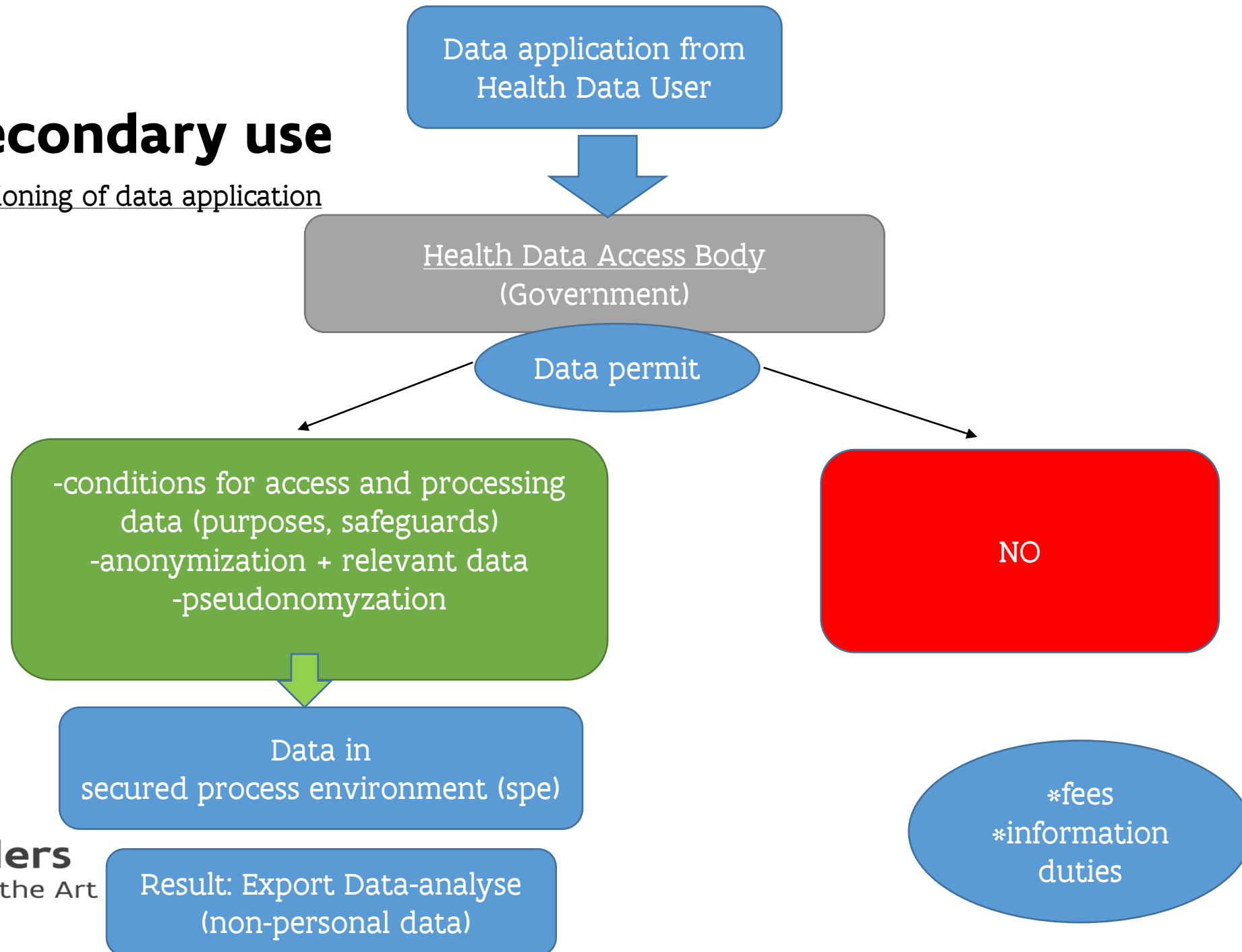
...

-data application: **data permit** Art. 47 EHDS or data request Art. 48 EHDS (anonymised statistical answer + no access to data)



2. Secondary use

2.3. Functioning of data application



2. Secondary Use

- ▶ 2.3. Functioning of data application
- ▶ **“HDAB”** = KEY PLAYER in secondary use

tasks:

- decide on data permits/requests
- anonymization and pseudonymization (ID-Key)
- monitor + supervise users and holders (penalties)
- provide access to Users in a SPE
- national dataset catalogue (metadata catalogue)
- ...

-data quality and utility label

2. Secondary Use

- ▶ 2.4. Cross-border access to electronic health data
- ▶ In practice: HDAB's will be in the game.
- ▶ **National Contact Point** = organisational and technical gateway for making data cross-border accessible.
- ▶ Cross-border EU-infrastructure **"Health Data@EU"**
 - Authorised participants (Research infrastructures)
 - Third Countries/international organisations
- **EU Datasets Catalogue** (connecting the national metadata catalogues)

Primary use

Secondary use

Governance MS-level:

- **Digital Health Authority**
(1 or more)

- **Health Data Access Body**
(1 or more)
(recently °federal HealthData-Agency)

EHDS-BOARD

Facilitating collaboration Digital
Health Authorities + Health
Data Access Bodies

Governance cross-border:

- National contact person

EU- Infrastructure:

- My Health@EU** (steering group)

- National contact person

- Health Data @EU** (steering group)



Questions and Answers?

Thank you for your attention !