EHDS
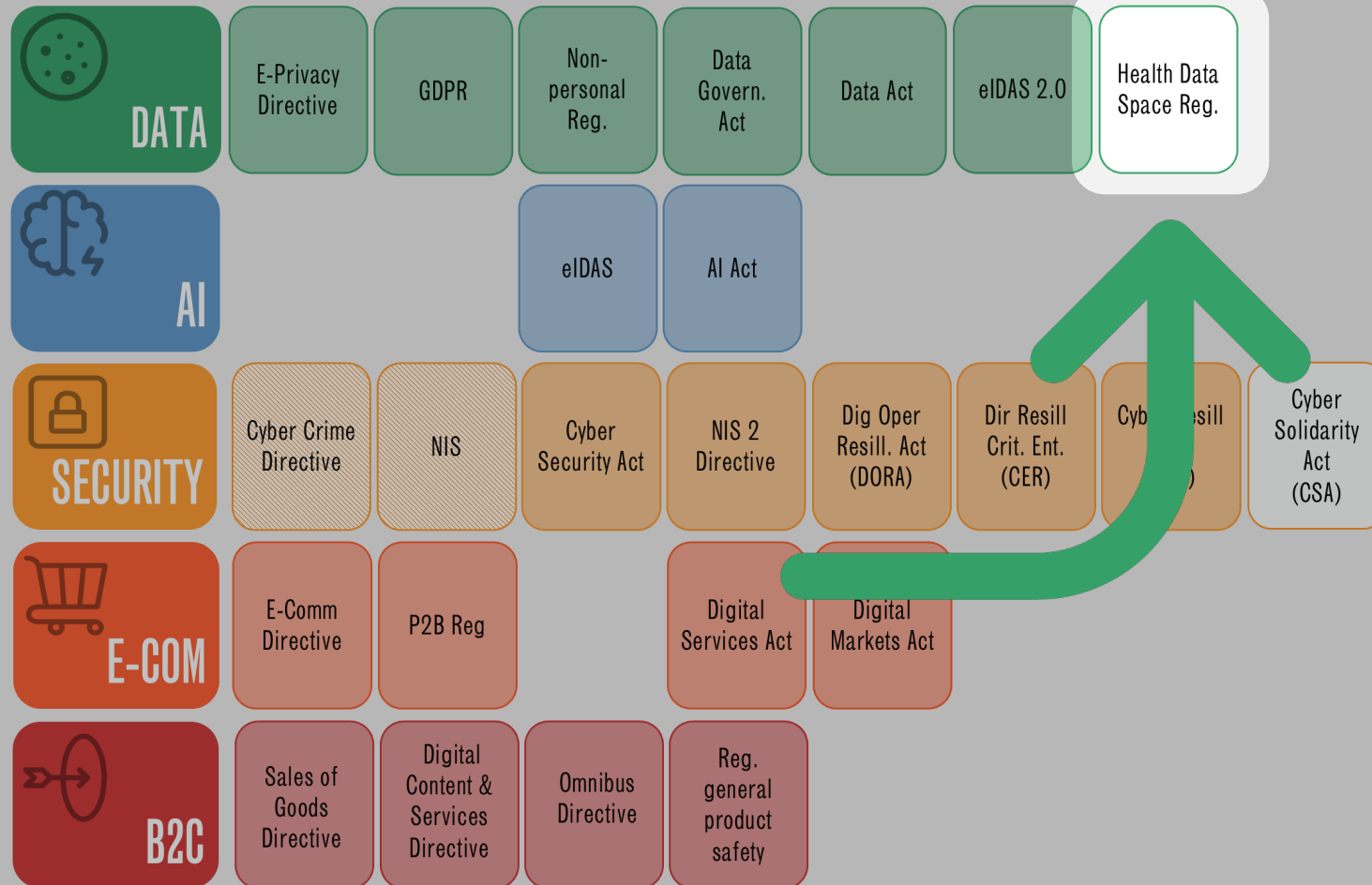## IN A NUTSHELL

Subject matter

The European Health Data Space (**EHDS**) is the first sector specific data space proposed as part of the EU's digital strategy re health data

Aim

Improve availability of health data

Key objectives

- Improve natural persons' control over their health data for healthcare purposes (primary use)

- Advance and facilitate re-use of health data (secondary use)

- Create a single market for electronic health record (EHR) systems

Natural persons have the <u>right</u> to:

- <u>opt-out</u> to access by healthcare professionals to personal electronic health data

  ! **Optional** for Member States to implement

- <u>restrict</u> access to personal electronic health data

- <u>access and download</u> priority categories of personal electronic health data in EU exchange format

- <u>add</u> information into EHR-system

- lodge a <u>complaint</u> with digital health authority

- obtain <u>access logs</u>

Priority categories of personal electronic health data
Patient summary, electronic prescriptions & dispensations, medical imaging studies, medical test results, discharge reports

Most of these rights should be exercisable via an <u>electronic health data access service</u>

WHAT?
PRIMARY USE

Healthcare professional
Individual exercising a regulated profession in the healthcare sector, such as a doctor or nurse

Right to access priority categories of personal electronic health data necessary for treatment

! Also to restricted electronic personal health data if necessary to protect the vital interests of the natural person

Via a health professional access service

Cross-border access via MyHealth@EU

WHAT?
PRIMARY USE

Healthcare Provider
Natural or legal person or entity legally providing healthcare

- <u>Facilitates</u> rights of natural persons and healthcare professionals
- Ensures electronic <u>registration</u> of <u>priority categories</u> in EHR-system
- Ensures <u>up-to-date</u> personal electronic health data
- <u>Accepts</u> and <u>is able to read</u> data in <u>EU exchange format</u>
- <u>Receives no compensation</u> for making personal electronic health data available

WHAT?
SECONDARY USE

Natural persons may opt-out to secondary use of their personal electronic health data

Provides a national dataset catalogue, manages data access applications, issues data permits for secondary use (such as research, innovation, and public policy) and informs natural persons

Health Data Access Body (HDAB)

Health data holder

Must make certain data available for secondary use and must provide a description of its dataset to HDAB

secure processing environment

Health data user

Can apply for access to electronic health data for permitted secondary use under certain conditions

Contractual arrangements

(for example, on protection of IP and trade secrets)

WHAT?
EHR-SYSTEMS

Electronic Health Record (EHR) systems that are intended by their manufacturer for primary use (e.g., storing, intermediating, importing, exporting, converting, editing or viewing) of priority categories of electronic health data must comply with strict requirements, including:

Conformity requirements

- CE-marking
- technical documentation & declaration of conformity
- common specifications
- information sheet
- prohibited claims
- registered in EU database

Essential requirements on security, interoperability & data portability

- suitable for intended purpose
- reliable identification & authentication mechanism
- logging
- retention
- access
- compatibility with EU infrastructure
- ability to process, receive and access data in EU exchange format

Manufacturers, importers & distributors
have (different) responsibilities to ensure compliance of EHR-systems with requirements

Also applicable to (in-vitro) medical devices, high-risk AI systems, and wellness apps claiming interoperability with EHR-systems

AND?
SUPERVISION & ENFORCEMENT

Supervisory authority responsible for the implementation and enforcement of requirements on:

- primary use: national digital health authority

- secondary use: HDAB

- EHR-systems: national market surveillance authority

- processing of personal data: national Supervisory Authority

Penalties

- HDAB may impose administrative fines upon data holders and data users for non-compliance up to EUR 20 mio or 4% of annual worldwide turnover

- Data protection-related violations are subject to penalties under GDPR

- For other infringements of EHDS, penalties are to be determined by Member States

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