European Health Data Space

Harnessing the value of health data

EC DG SANTE C1
18/02/2024

EHDS webinar series

1. **Primary Use and Requirements for EHR systems**
2. Secondary Use 27/02
3. Implementation and Governance – who does what? 06/03

European Commission

Agenda

1. EHDS in a nutshell
2. Primary Use
3. Requirements for EHR systems
4. Transition
5. Q&A

Target audience: healthcare providers, EHR systems manufacturers, patient groups, digital health authorities

European Commission

1 EHDS in a Nutshell

Why this Regulation (now)?
Three legs of the Regulation

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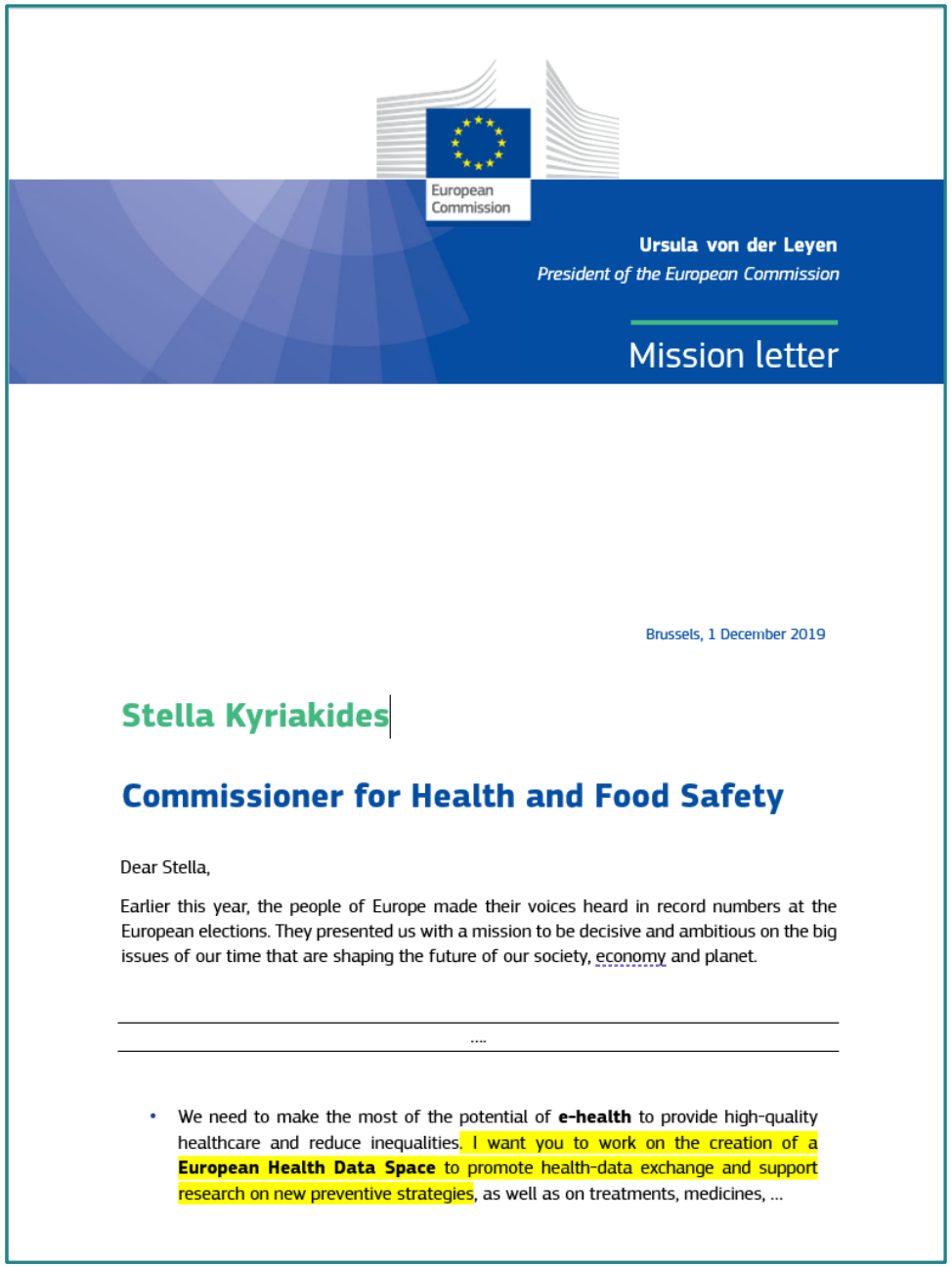


European Commission

Ursula von der Leyen
President of the European Commission

Mission letter

Brussels, 1 December 2019

Stella Kyriakides

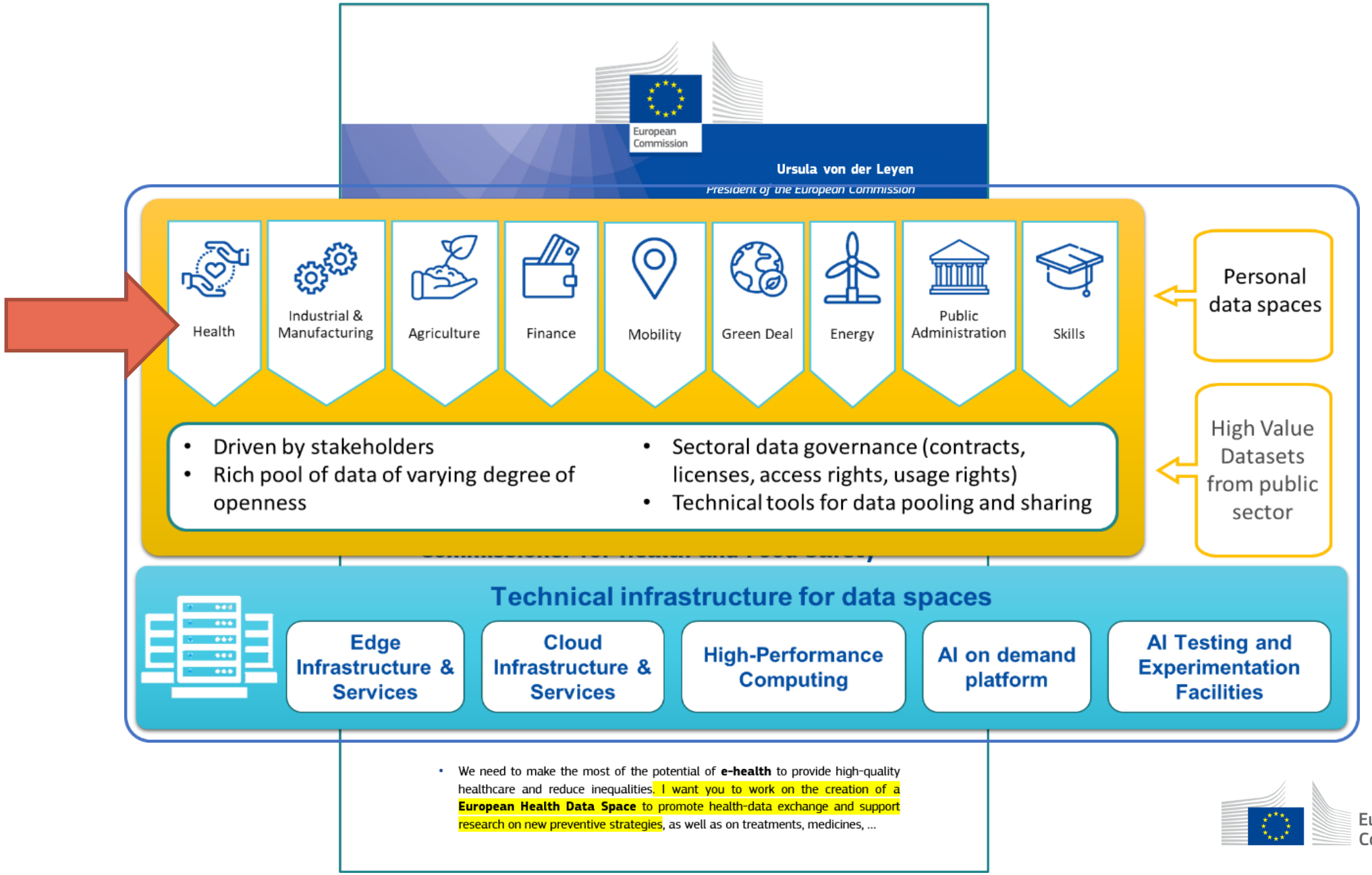
Commissioner for Health and Food Safety

Dear Stella,

Earlier this year, the people of Europe made their voices heard in record numbers at the European elections. They presented us with a mission to be decisive and ambitious on the big issues of our time that are shaping the future of our society, economy and planet.

....

- We need to make the most of the potential of **e-health** to provide high-quality healthcare and reduce inequalities. I want you to work on the creation of a **European Health Data Space** to promote health-data exchange and support research on new preventive strategies, as well as on treatments, medicines, ...


European Commission
Ursula von der Leyen
President of the European Commission
Health
Industrial & Manufacturing
Agriculture
Finance
Mobility
Green Deal
Energy
Public Administration
Skills
Personal data spaces
High Value Datasets from public sector
• Driven by stakeholders
• Rich pool of data of varying degree of openness
• Sectoral data governance (contracts, licenses, access rights, usage rights)
• Technical tools for data pooling and sharing
Technical infrastructure for data spaces
Edge Infrastructure & Services
Cloud Infrastructure & Services
High-Performance Computing
AI on demand platform
AI Testing and Experimentation Facilities
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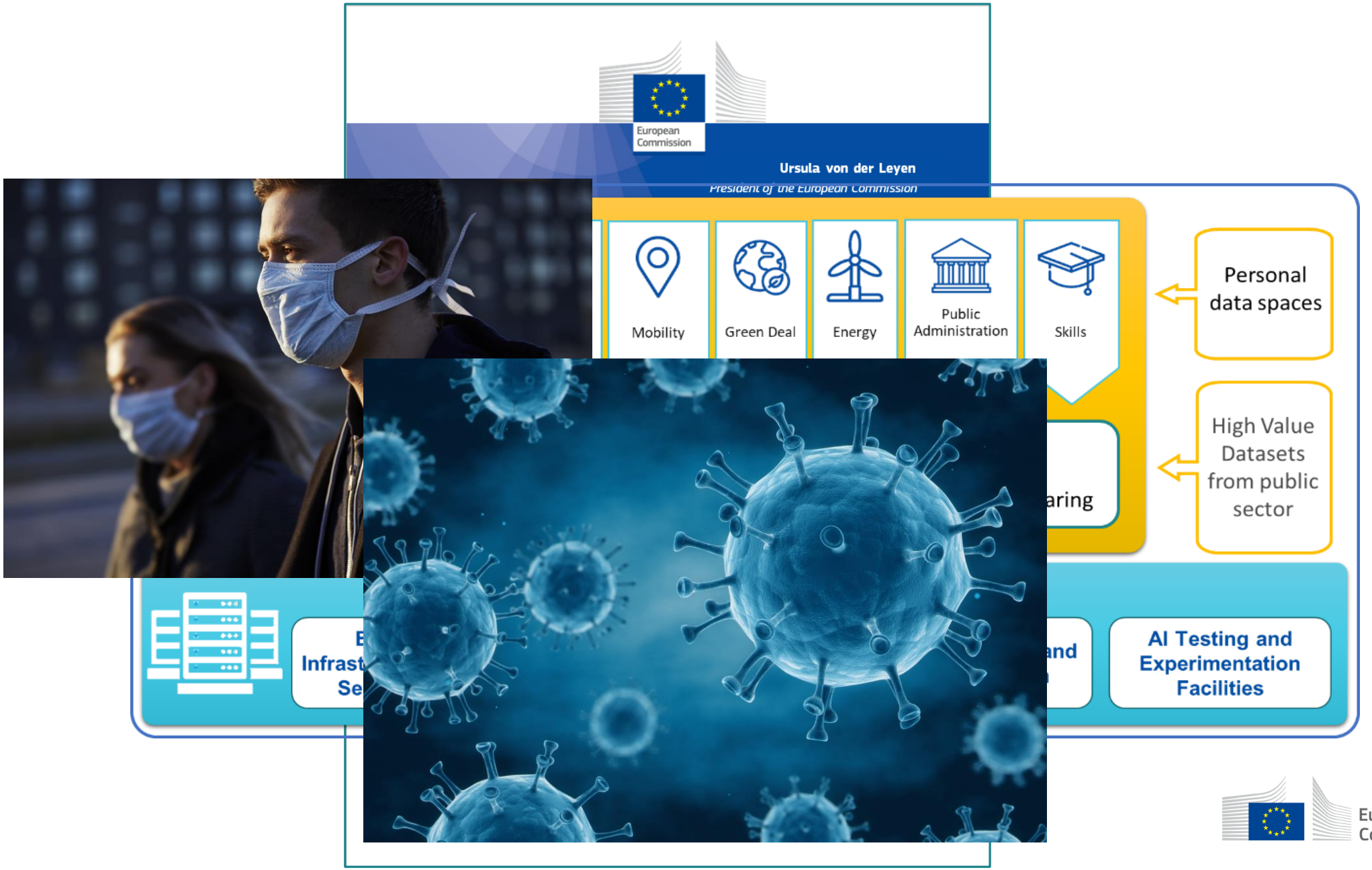

European Commission

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EHDS in a Nutshell – what is it about?

1. Primary use = use of data for the delivery of healthcare
   - Improving patients' access to their health data;
   - Ensuring seamless exchanges for continuity of healthcare.

2. Secondary use = use of data for research and public interest purposes
   - Making data available for research, policy-making etc. in a safe and secure way.

3. Requirements for electronic health record (EHR) systems
   - Creating a single market for electronic health records systems, supporting both primary and secondary use.

EHDS in a Nutshell – Primary Use

How?

- Strengthening patients' rights on defined categories of their own data;
- Patient- and health professional-facing services to access data;
- Building on existing voluntary MyHealth@EU infrastructure, not touching upon national rules on provision of care / management of healthcare systems.

EHDS in a Nutshell – EHR systems

How?

- Product legislation for two components of EHR systems: interoperability and logging;
- Full harmonisation for those two components;
- Approach based on new legislative framework for product legislation, incorporating recent developments from other product legislation.

EHDS in a Nutshell – Secondary Use

How?

- Common European rules on who has to make which data available for which purposes and under which conditions
- Common infrastructure
- Health Data Access bodies as orchestrators
- Permits for data use, common safeguards
- Data catalogues of available datasets

2 Primary Use

What’s in it for patients and health professionals?
What infrastructures will provide support?

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Benefits – who/what for?

For patients

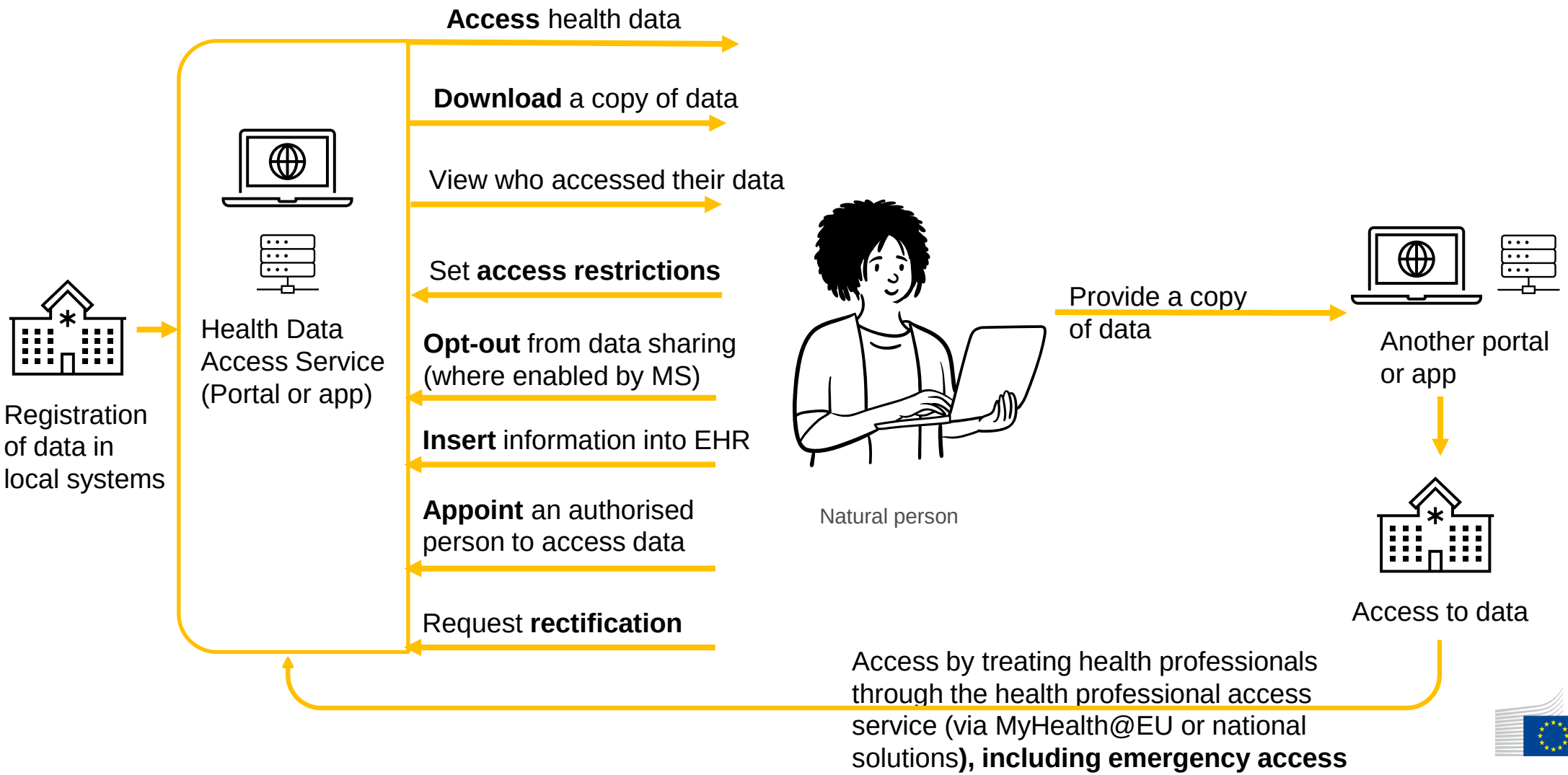
- Quick, easy, and free of charge access to their own electronic health data in the priority categories.
- Easy sharing of data with health professionals, including cross-border.
- Easy ways to to add data, restrict access, see who accessed data, ask for rectification of errors.

For health professionals

- Easier and quicker access to their patients' data, including cross-border.
- European electronic health record exchange format will facilitate data sharing across systems by increasing interoperability.

Articles 3 to 13, 16 to 18

Rights of natural persons in primary use



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Articles 14, 15

Priority categories

Group 1

- Patient summaries
- Electronic prescriptions
- Electronic dispensations

Detailed specifications for the European Electronic Health Record Exchange Format (EEHRxF) via implementing act, building on work done following 2019 recommendation, several projects etc. => strong Member State involvement

Group 2

- Medical imaging studies and related imaging reports
- Medical test results, including laboratory test and related reports
- Discharge reports

Article 3

Rights of natural persons: access

Right to obtain access to own data

- To priority categories, through health data access service;
- Free of cost for patient, immediate answer;
- Scope: priority categories;
- ➢ Complementing right of access under GDPR: narrower scope, ‘better’ modalities.

Limitations

- Data may have a slight lag for technical reasons;
- Possibility to restrict, in particular for protection of patient.

Article 7

Rights of natural persons: data portability

- ‘Data follows the patient’ in EEHRxF
- Complements GDPR portability right
- Additional possibility of one-way export for reimbursement purposes

Pull

- Treating health professional fetches data through MyHealth@EU or equivalent national solutions.
- Access is logged.

Push

- Data downloaded in EEHRxF can be sent or uploaded to a selected healthcare provider.

Article 9

Rights of natural persons: access logs

Who accessed what when?

- Implemented through health data access services;
- Logs must be available for at least 3 years;
- Must support automatic notifications – patient choice to switch on/off.

Article 8

Rights of natural persons: restrict access

- Right to restrict access
  - Can set access restrictions on all or parts of data (e.g. data deemed by the person as more sensitive). Such data will not be accessible through health professional access services.
  - Restrictions are not visible to healthcare providers – not even the fact of their existence.
  - Healthcare providers can use ‘breaking the glass’ function if necessary to protect vital interests.
- How to place restrictions on parts of health data?
  - This may depend on digital health infrastructure in every MS. Could be based on the selection of documents, episodes of care, specific datasets, etc.
  - The mechanisms should allow for sufficient granularity to restricts parts of datasets, such as components of the patient summaries.

Article 10

Rights of natural persons: opt out (primary)

- Member States *may* (by law) provide for an opt-out from exchanges under EHDS for primary use; detailed rules and safeguards to be set out by MS;
- Exercise of the right is reversible;
- Data not available at all through EHDS primary use services.

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Restrictions

- All or parts of data – as chosen by the person
- Natural person can access the data
- ‘breaking the glass’

Opt-out

- Complete opt-out (but MS rules possible)
- Natural person may not be able to access the data using EHDS services
- By default, no ‘breaking the glass’ (but may depend on MS)

Article 5

Rights of natural persons: insert data

- Right to insert information in EHR
  - Such information will be separately marked.
  - What information? The main scope is priority data categories, MS can define more detailed rules.
  - Implemented through data access services or apps connected to them.

Rights of natural persons: appoint representative

Article 4(2)

- People can appoint representatives to act on their behalf

- Appointing representative
  - Use cases: spouse, other trusted person…
- Legal guardians
  - Use cases: parents-children; guardians of persons with limited legal capability;
  - Link to national rules: parents/legal guardians should see everything for a baby, but not necessarily for a teenager…
- Proxy services
  - To manage such appointments – integrated into health data access service
  - Persons can also submit on paper

Rights of natural persons: request rectification

Article 6

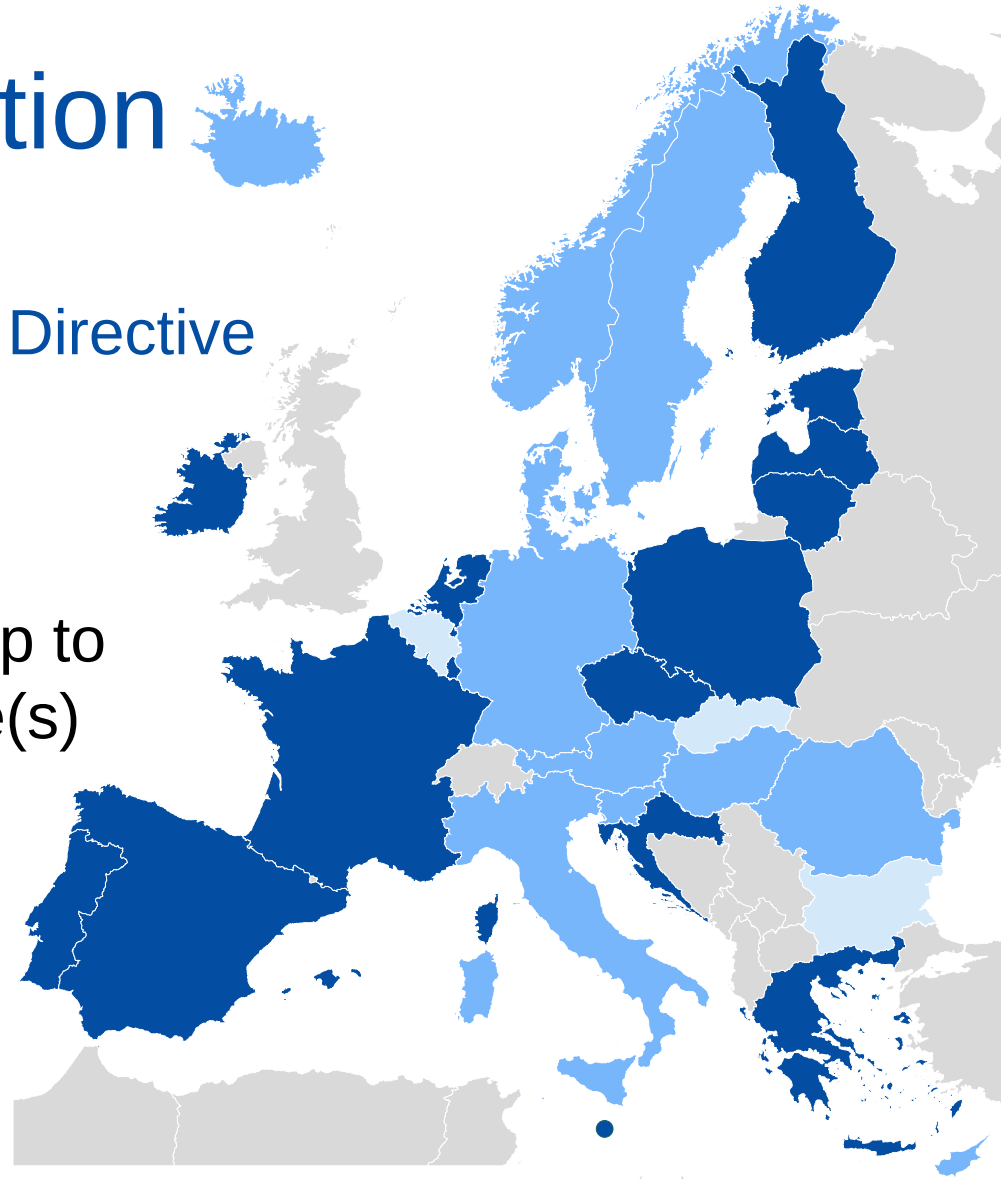
- Request rectification of data online (again through data access services).
- Requests are processed by the initial data controllers – involving health professionals where appropriate.
- A new channel to exercise GDPR right to rectification, not a new right.

Articles 4,11, 12, 16

Access services

- Patient-facing
  - MS to establish one or more (their choice depending on organisation of healthcare system);
  - Agnostic regarding centralised or decentralised storage;
  - Interoperable among MS (COM to provide technical specs).
- Health professional-facing
  - Access to priority categories of patients *under their treatment;*
  - Authentication: Art. 6 eIDAS-recognised or other electronic identification that meet Art. 36 common specs

Building on existing cooperation



MyHealth@EU under Cross-border Healthcare Directive

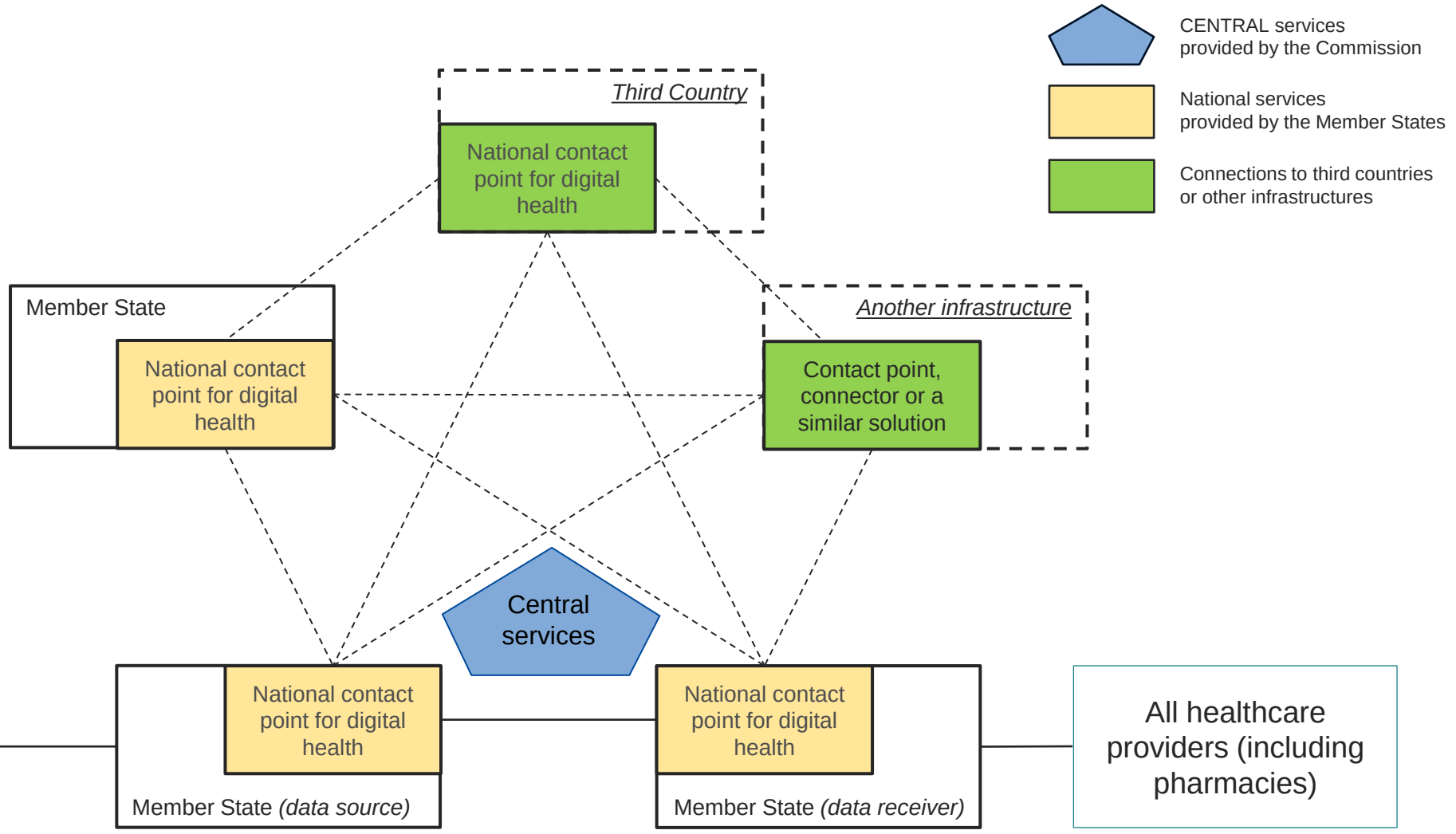
- Voluntary system for exchanging patient summaries, prescriptions and dispensations (= first group of priority categories)
- **15 countries** live with at least one service, up to **10 more** expected to go live with first service(s) this year

Evolution of MyHealth@EU for the EHDS

- Voluntary => mandatory
- New services
- New data categories

MyHealth@EU high-level architecture

Article 23



Data categories

Priority group 1:
- Patient summaries
- ePrescriptions and eDispensations

Priority group 2:
- Medical test results: laboratory, other diagnostics, related reports
- Medical imaging: studies and reports
- Discharge reports

Additional data categories:
May be exchanged where supported

Data suppliers:
all healthcare providers.

3 Requirements for EHR Systems

What functions will EHR systems have to support?
What does it mean for manufacturers?
What does it mean for health professionals?

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Benefits of requirements on EHR systems

For manufacturers

- Easier market access across Member States due to harmonised requirements for interoperability and logging components.
- Increased interoperability reduces switching costs, making market entry easier.

For patients

- Increased interoperability facilitates data sharing, saving time and money.

For healthcare providers

- Can be assured that any EHR system they buy enables them to comply with interoperability requirements.
- Increased interoperability:
  - saves time and money by not uselessly repeating tests;
  - reduces switching costs, decreasing vendor lock-in effects.

Article 2(2)(k)

What is (and is not) an EHR system?

Elements of the definition:

- combination of hardware of software or software only;
- allows the storage, intermediation, export, import, conversion, editing, or viewing of priority categories of electronic health data
- Not necessary to provide all of storage, intermediation, export, import, conversion, editing, or viewing functionalities to be considered as an EHR system;
- intended by their manufacturer to be used:
    - by healthcare providers when providing patient care; or
    - by patients when accessing their electronic health data.

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Systems that only processes other kinds of data, e.g. appointment booking systems, are not EHR systems.

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e.g. systems used by clinicians for recording notes, test results etc., up to a patient management system

E.g. an app that connects to the electronic health data access service for patient will count as an EHR system.

Articles 26, 29, 36

Scope of harmonisation

EHR systems must contain two harmonised components, starting early 2029 / early 2031 for 1st / 2nd group of priority categories:

Interoperability component

- Provides capability to import/ export data in EEHRxF as per Art. 15

Logging component

- Provides capability to generate the logs of access as per Art. 9

Detailed specifications to be set out by COM in implementing act.

Member States remain free to have requirements on other parts of EHR systems, provided they don't interfere with the harmonised components.

Articles 39 to 41

How to demonstrate compliance?

- Self-declaration of conformity by manufacturer – no third-party conformity assessment as in MDR;
- However: EHR systems must pass an automated test in the *digital testing environment* before being placed on the market.;
- Test report becomes part of product documentation;
  - Final ‘all fine’ report – no obligation to disclose failed reports;
- COM to develop software package for testing environments, MS to deploy;
- What to expect from the testing environment?
  - Details to be developed, but expect simulated actions on the system:
  - Import/export transactions – checking if presentation / translation of test data is correct;
  - Logging of actions – checking if logs are generated in the right format.

Article 27

Interaction with other relevant product rules

- EHR systems may have additional functions that make them also qualify as e.g. a medical device
  - ➢ Both sets of requirements apply
- Medical devices, in-vitro devices, and high-risk AI systems (which are not medical devices at the same time) that claim interoperability:
  - ➢ Have to comply with common specifications as well

Article 49

Registration of EHR systems

- EHR systems will have to be *registered* in a public EU database;
- Aim: provide overview of systems available on the market, transparency for buyers;
- Self-service system for use by manufacturers and other relevant actors;
- Product registration requirements: do it once, information gets forwarded between databases;
- Detailed content of registration to be set out by COM in delegated act.

Articles 47 to 49

Wellness apps

- Wellness apps that *claim interoperability* with EHR systems to be registered and labelled;
- Apps must provide possibilities to set details of sharing (what, how often, triggers…);
- Registration in same database as EHR systems;

4 Transition

By when will all of this happen?
How do we get there?

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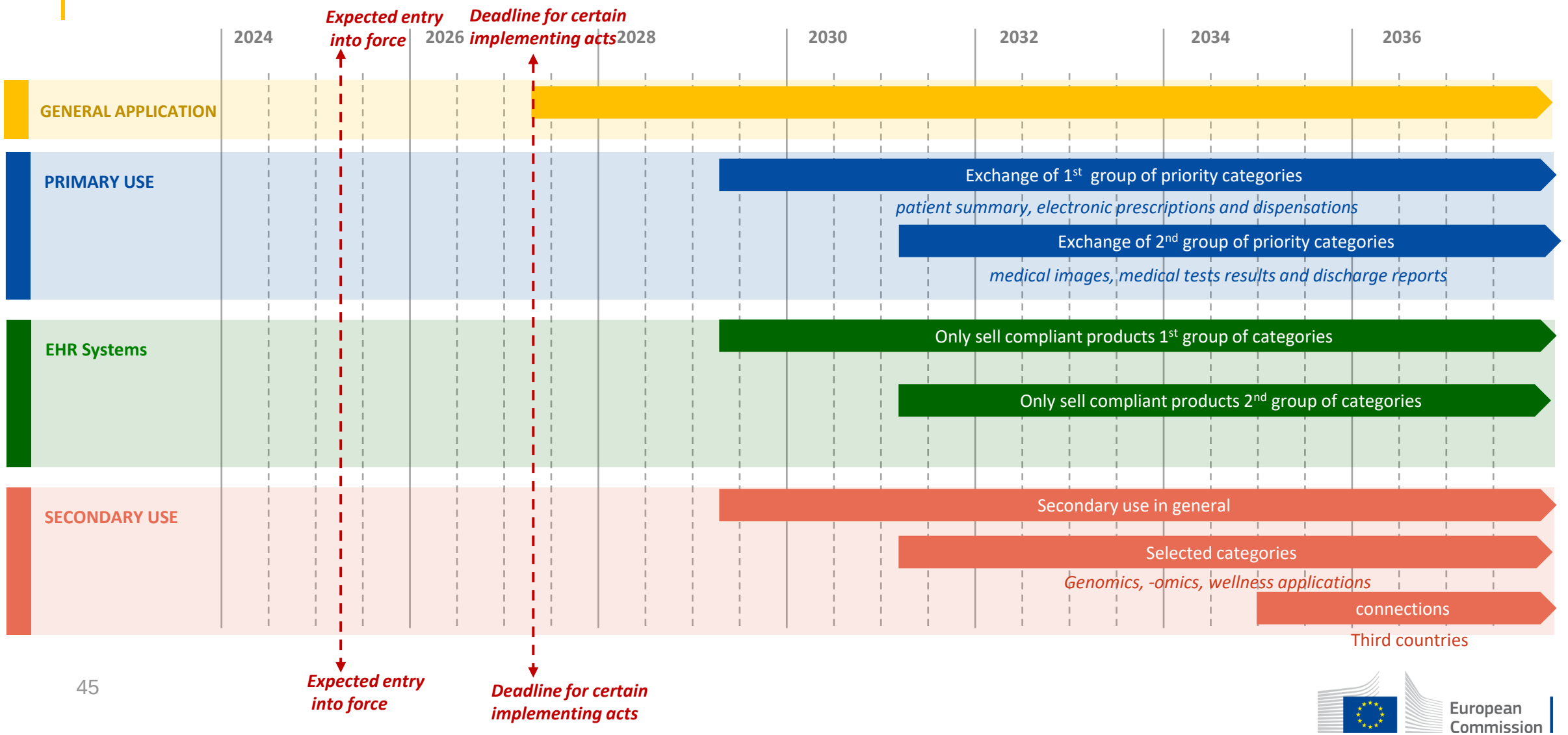
Next steps?

- Formal signature was on 11/02/25, procedure is finished, waiting on publication in the Official Journal;
- Official Journal publication is expected for first half of March – that's when the clock for implementation will start ticking.

Article 105

EHDS – Overall timeline for application



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Article 105

What will happen when?

- For patients:
  - March 2029: can use health data access services and exercise rights for 1st group of priority categories
  - March 2031: go-live for 2nd group of priority categories
- For healthcare providers:
  - March 2029: for 1st group of priority categories, connect to NCP, can use health professional access services
  - March 2031: same for 2nd group of priority categories

Article 105

What will happen when?

- For manufacturers of EHR systems:
  - March 2029: only sell compliant systems for 1st group;
  - March 2031: only sell compliant systems for 2nd group;
- For Member States:
  - March 2027: designate digital health authority
  - March 2029: for 1st group, ensure they're connected to MyHealth@EU and that healthcare providers are connected to NCP; ensure that access services are up and running; provide testing environments;
  - March 2031: same for 2nd group.

Thank you!
Questions? Answers!

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