



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

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

1 EHDS in a Nutshell

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



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



- 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

Personal data spaces

High Value Datasets from public sector

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

Ursula von der Leyen

President of the European Commission



Mobility



Green Deal



Energy



Public Administration



Skills

Personal data spaces

High Value Datasets from public sector

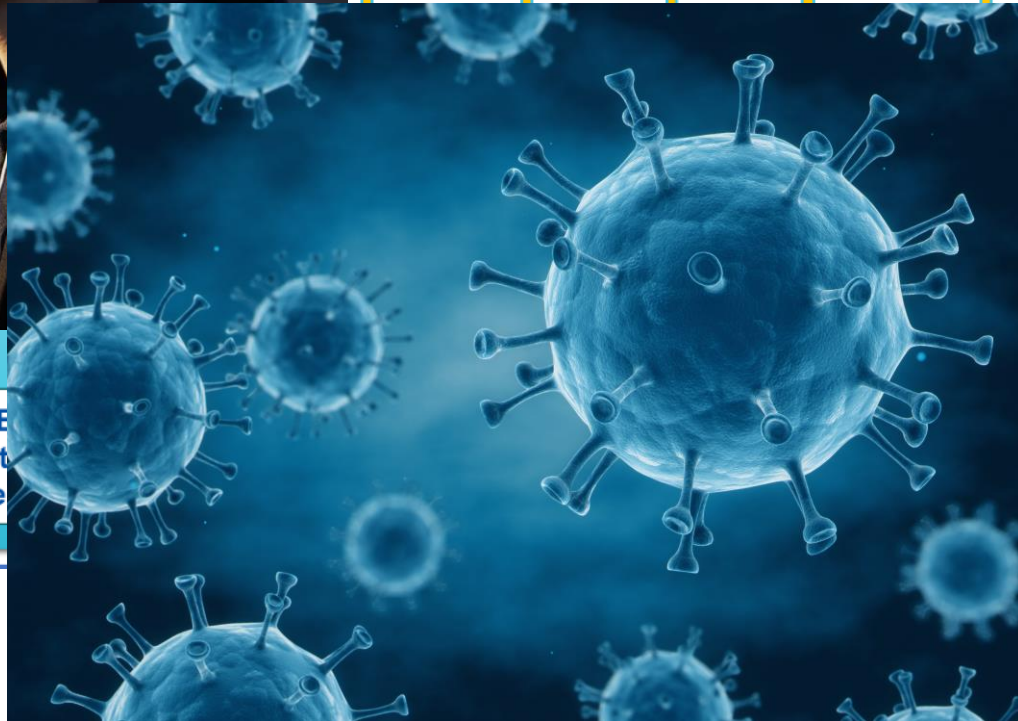
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AI Testing and Experimentation Facilities



European Commission




EUROPEAN CENTRE FOR
DISEASE PREVENTION
AND CONTROL

Heating, ventilation and air-conditioning systems in the context of COVID-19: first update

10 November 2020

Key messages

- It is now well-established that COVID-19 transmission commonly occurs in closed spaces;
- If well-maintained and adapted for use in the COVID-19 pandemic, heating, ventilation and air-conditioning (HVAC) systems may have a complementary role in decreasing potential airborne transmission of SARS-CoV-2;
- Four bundles of non-pharmaceutical interventions (NPIs) should be considered to reduce potential airborne transmission of SARS-CoV-2 in closed spaces: the control of COVID-19 sources in closed spaces; engineering controls in mechanically ventilated (by HVAC systems) and naturally ventilated closed spaces; administrative controls; and personal protective behaviour.

Scope of this document

This document provides guidance on heating, ventilation and air-conditioning (HVAC) systems in closed spaces in the context of the COVID-19 pandemic.

Changes to the current update

The first update of the ECDC ventilation guidance document contains:

- key new findings that emphasise four bundles of NPIs to reduce the risk of SARS-CoV-2 transmission in closed spaces;
- updated references on the evidence of transmission in closed spaces;
- recommendations based on the new evidence and on national and international guidance; and
- an overview of national guidance ventilation documents in the context of COVID-19 based on an inquiry sent to ECDC's National Focal Points (NFPs) for Preparedness and Response and NFPs for Influenza and other respiratory diseases.

Target audience

Public health authorities in the European Union and European Economic Area (EU/EEA) and the United Kingdom (UK).

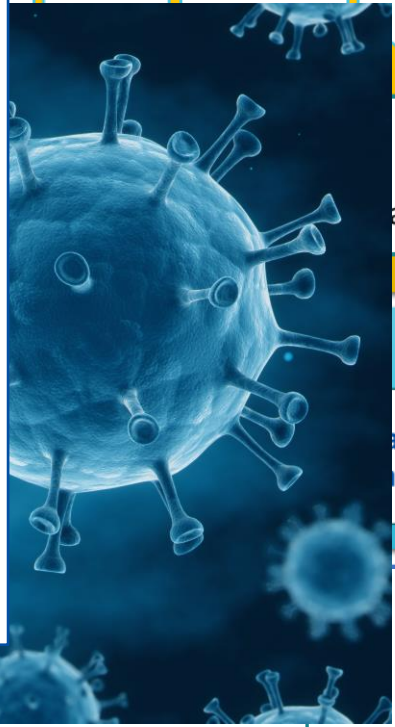
Suggested citation: European Centre for Disease Prevention and Control. Heating, ventilation and air-conditioning systems in the context of COVID-19. 10 November 2020. Stockholm: ECDC; 2020.
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rsula von der Leyen
European Commission

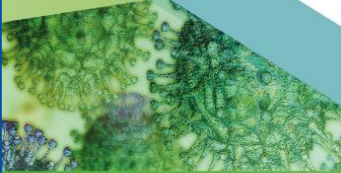


Personal data spaces

High Value Datasets from public sector



AI Testing and Experimentation Facilities

Heating, ventilation systems in the context of COVID-19: update

10 November 2020

Key messages

- It is now well-established that COVID-19 transmission can occur in indoor spaces with mechanical ventilation (HVAC) systems; these systems may have a role in the transmission of SARS-CoV-2;
- Four bundles of non-pharmaceutical interventions to reduce the risk of airborne transmission of SARS-CoV-2 in mechanically ventilated spaces: engineering controls in mechanically ventilated spaces; administrative controls; and personal protective equipment.

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This document provides guidance on heating, ventilation and air conditioning (HVAC) systems in the context of the COVID-19 pandemic.

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Target audience

Public health authorities in the European Union and other countries.

Suggested citation: European Centre for Disease Prevention and Control. Heating, ventilation systems in the context of COVID-19. 10 November 2020. Stockholm: ECDC; 2020. © European Centre for Disease Prevention and Control.



Strasbourg, 3.5.2022
COM(2022) 197 final
2022/0140 (COD)

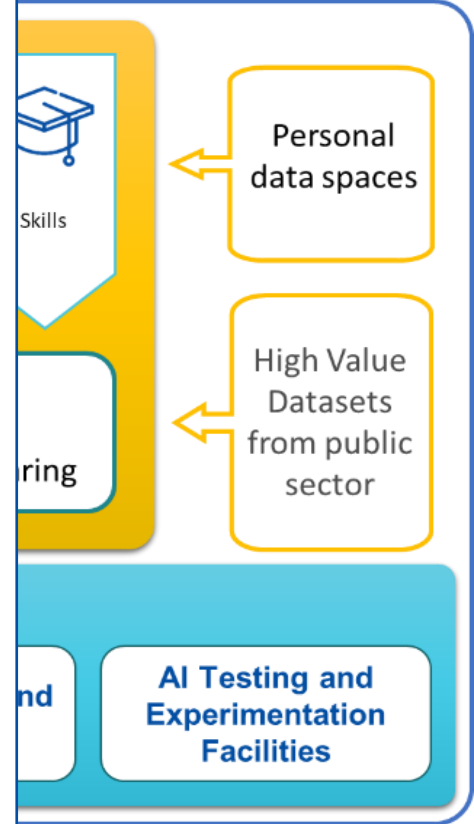
Proposal for a
REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
on the European Health Data Space

(Text with EEA relevance)

{SEC(2022) 196 final} - {SWD(2022) 130 final} - {SWD(2022) 131 final} - {SWD(2022) 132 final}

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European Commission - Press release



Commission welcomes European Parliament's adoption of the European Health Data Space and regulation on substances of human origin

Brussels, 24 April 2024

The Commission welcomes the adoption by the European Parliament today of the [European Health Data Space \(EHDS\)](#) and new rules to **increase the safety and quality of substances of human origin (SoHO)**. These are two cornerstones of a **strong European Health Union** which protects the health of citizens and improves the resilience of healthcare systems.

The European Health Data Space (EHDS)

This groundbreaking initiative, put forward by the Commission in May 2022, has two main aims:

- to place citizens at the centre of their healthcare, granting them full control over their data, with the goal of achieving **better healthcare across the EU**;
- to allow the use of health data for **research and public health** purposes, under strict conditions.

Thanks to the new rules, **citizens will benefit from immediate and simple access to their digital health data when in the EU, regardless of their location**. For instance, when a patient seeks healthcare abroad, healthcare professionals will be able, when necessary, to access key information from the patient's home Member State. This will **improve evidence-based decision making, reduce repetition of tests and examinations and enhance patient care**.

The EHDS also establishes a **strong legal framework for the re-use of health data** for research, innovation and public health purposes in full compliance with strict EU data security and access criteria, fundamental rights and cybersecurity rules. The data will help **develop life-saving treatments and personalised medicines** and improve European crisis **preparedness**.

Substances of human origin

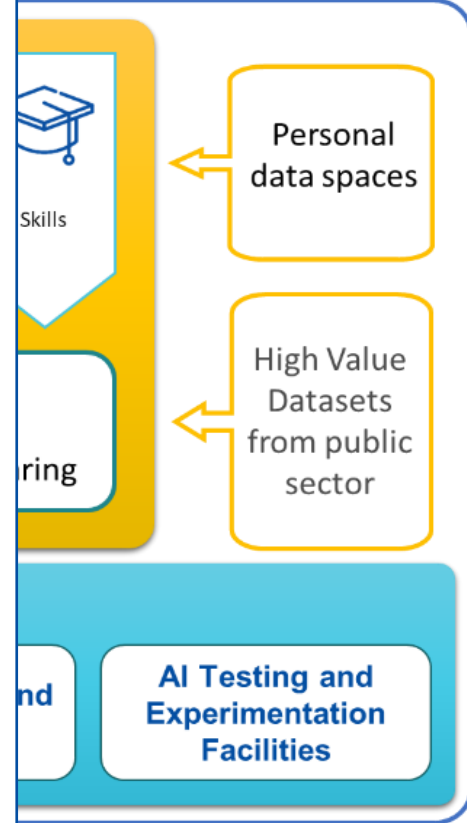
The new regulation, proposed by the Commission in July 2022, provides a holistic approach for the regulation of substances of human origin. The new rules notably **include better protection of recipients and donors of substances of human origin, as well as children born from medically assisted reproduction**. The new framework foresees:

- Clear rules covering **all substances of human origin** except solid organs, such as faecal microbiota and human breast milk;
- **Registration of all entities** that carry out activities that could affect the safety and quality of SoHO;
- **Reinforced expertise**, building on existing technical bodies, notably [the European Centre for Disease Prevention and Control \(ECDC\)](#) and the [European Directorate for the Quality of Medicines & HealthCare \(Council of Europe\)](#), to keep technical guidelines up to date;
- **More innovation**, with a common procedure to assess and authorise SoHO preparations, proportionate to the risks these bring;
- Strengthened **national oversight**, and EU support for national authorities (such as training and IT);
- New measures supporting **supply continuity** that will help Member States to take action when the supply of critical SoHO is threatened;
- A **SoHO Coordination Board (SCB)** will be established, with and for Member States. It will support the implementation of the new regulation and provide legal clarity;
- Finally, the **digital EU SoHO Platform** will be created, to gather all required information, streamline reporting and increase visibility to citizens.

Next steps

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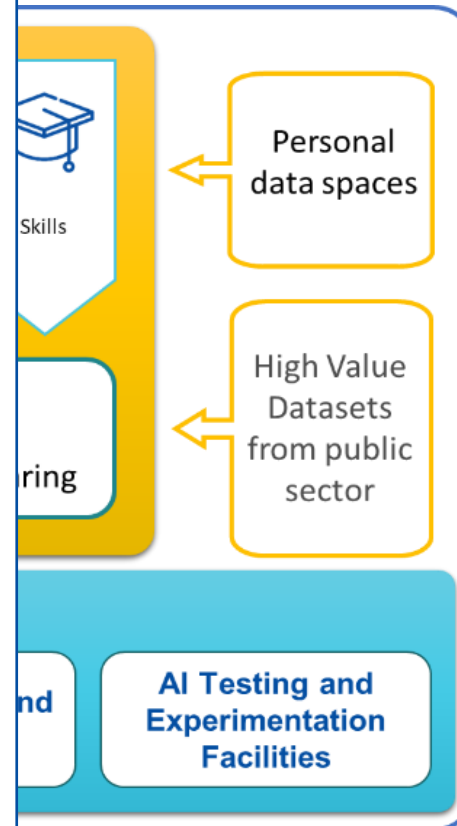
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Next steps



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?

Benefits – who/what for?

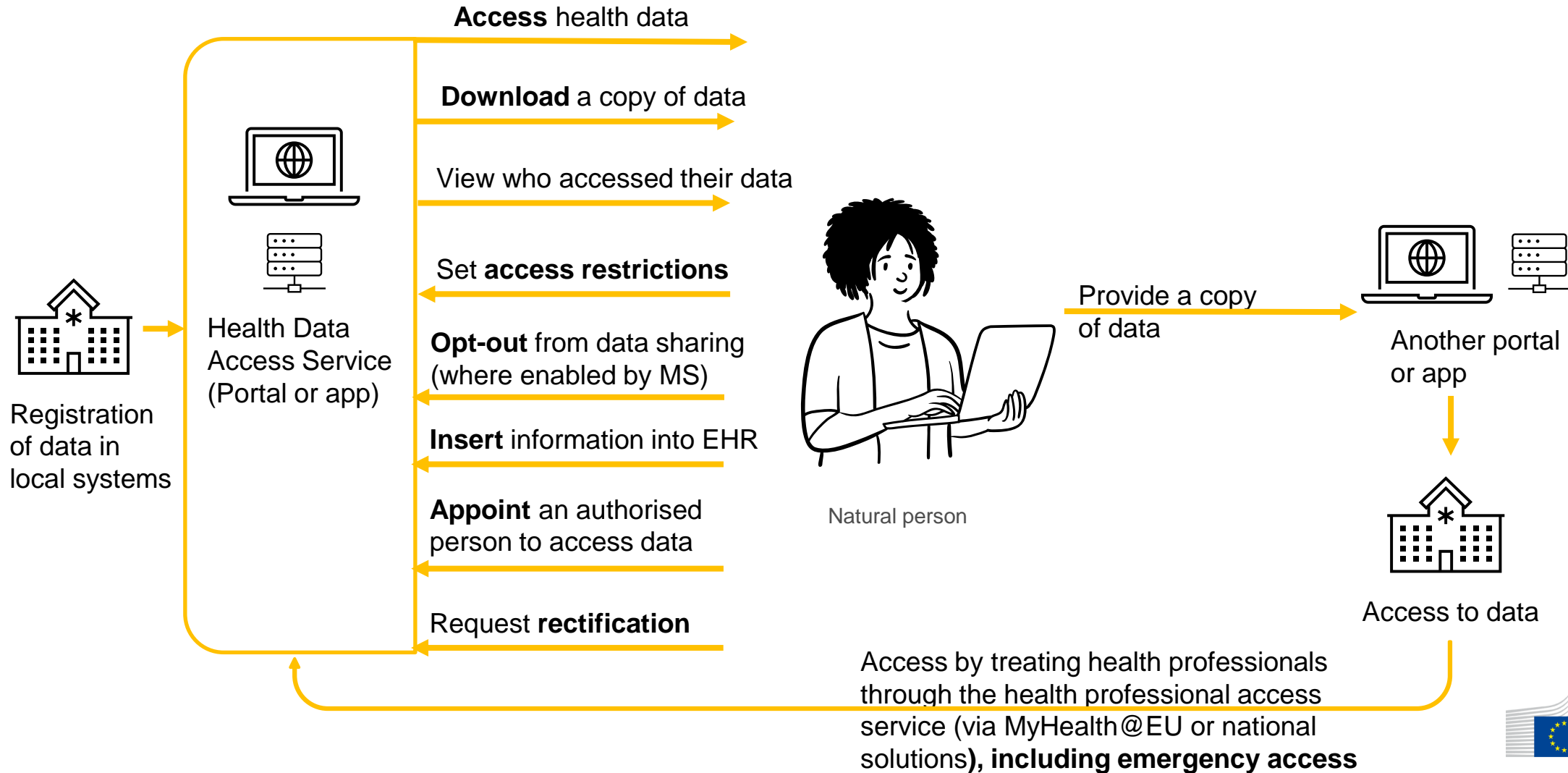
For patients

- 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.

Rights of natural persons in primary use



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

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.

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.

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.

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 restrict parts of datasets, such as components of the patient summaries.

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)

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

- 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.

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

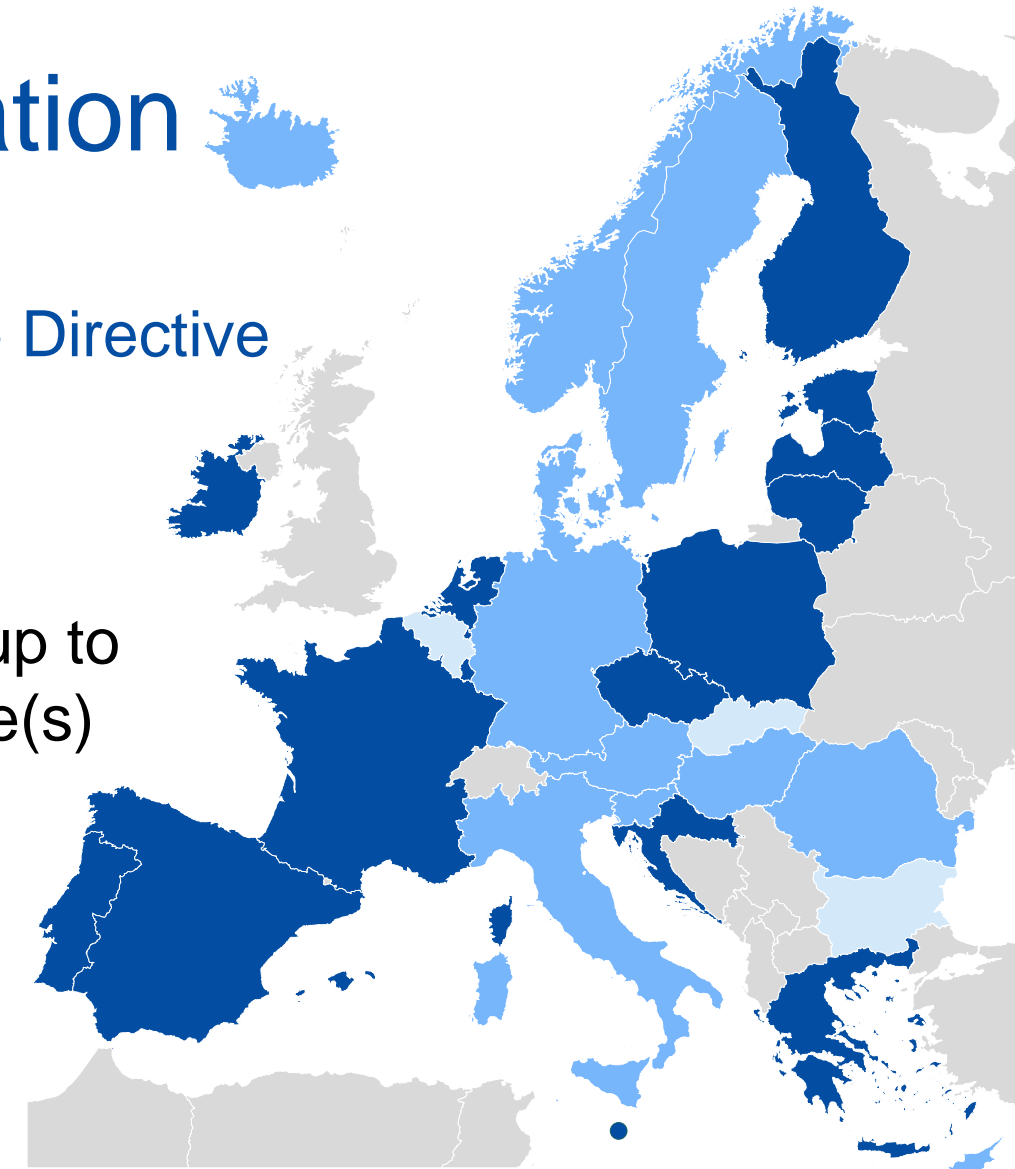
Building on existing cooperation

MyHealth@EU under Cross-border Healthcare Directive

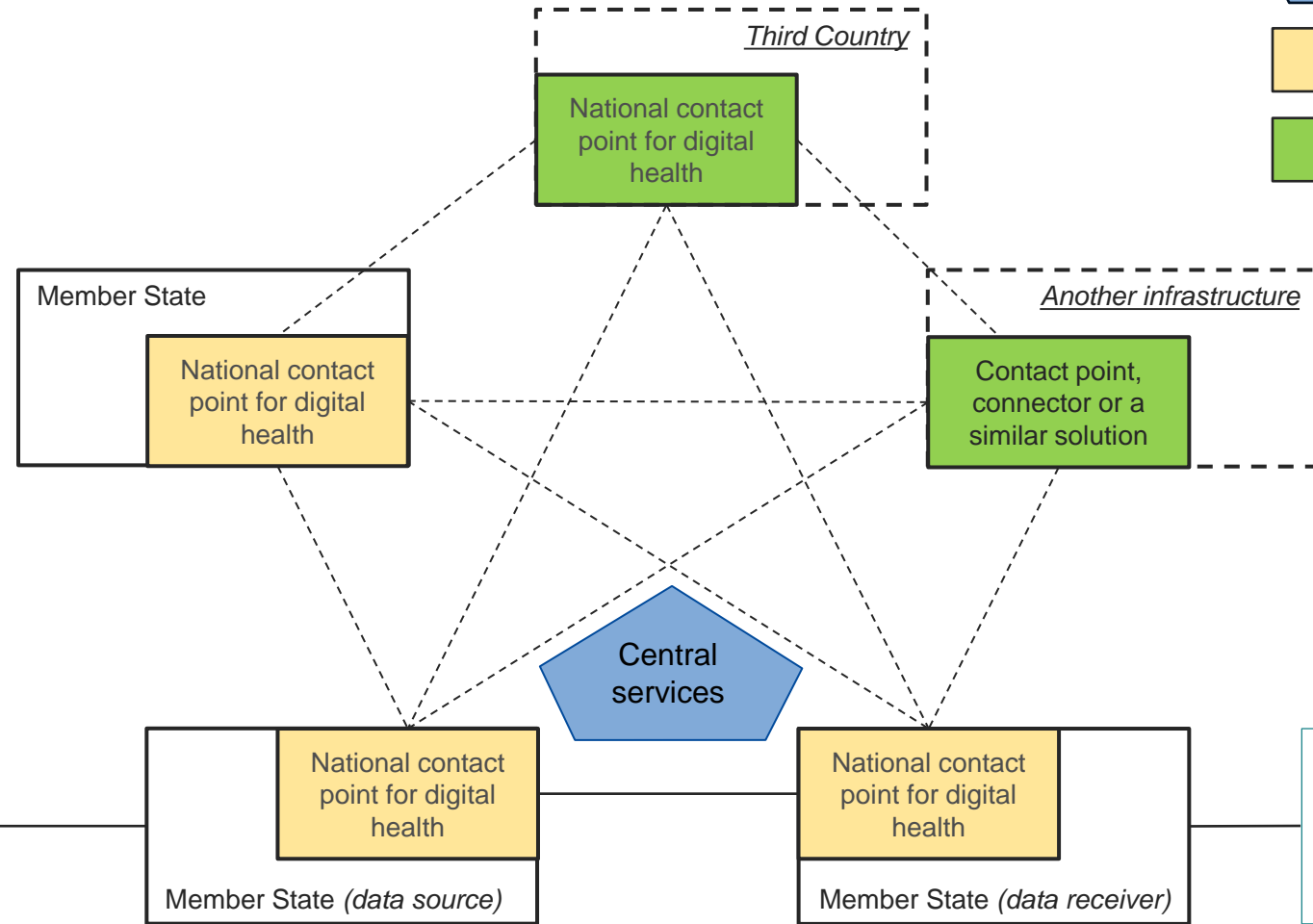
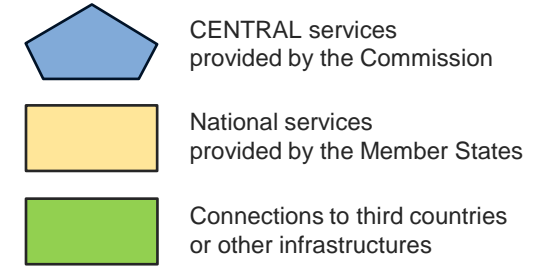
- Voluntary system for exchanging patient summaries, prescriptions and dispensations (= first group of priority categories)
- **15 countries** live with at least one service, up to **10 more** expected to go live with first service(s) this year

Evolution of MyHealth@EU for the EHDS

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



MyHealth@EU high-level architecture



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?

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.

What is (and is not) an EHR system?

Elements of the definition:

- combination of hardware or 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

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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.

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.

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.

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

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.

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;

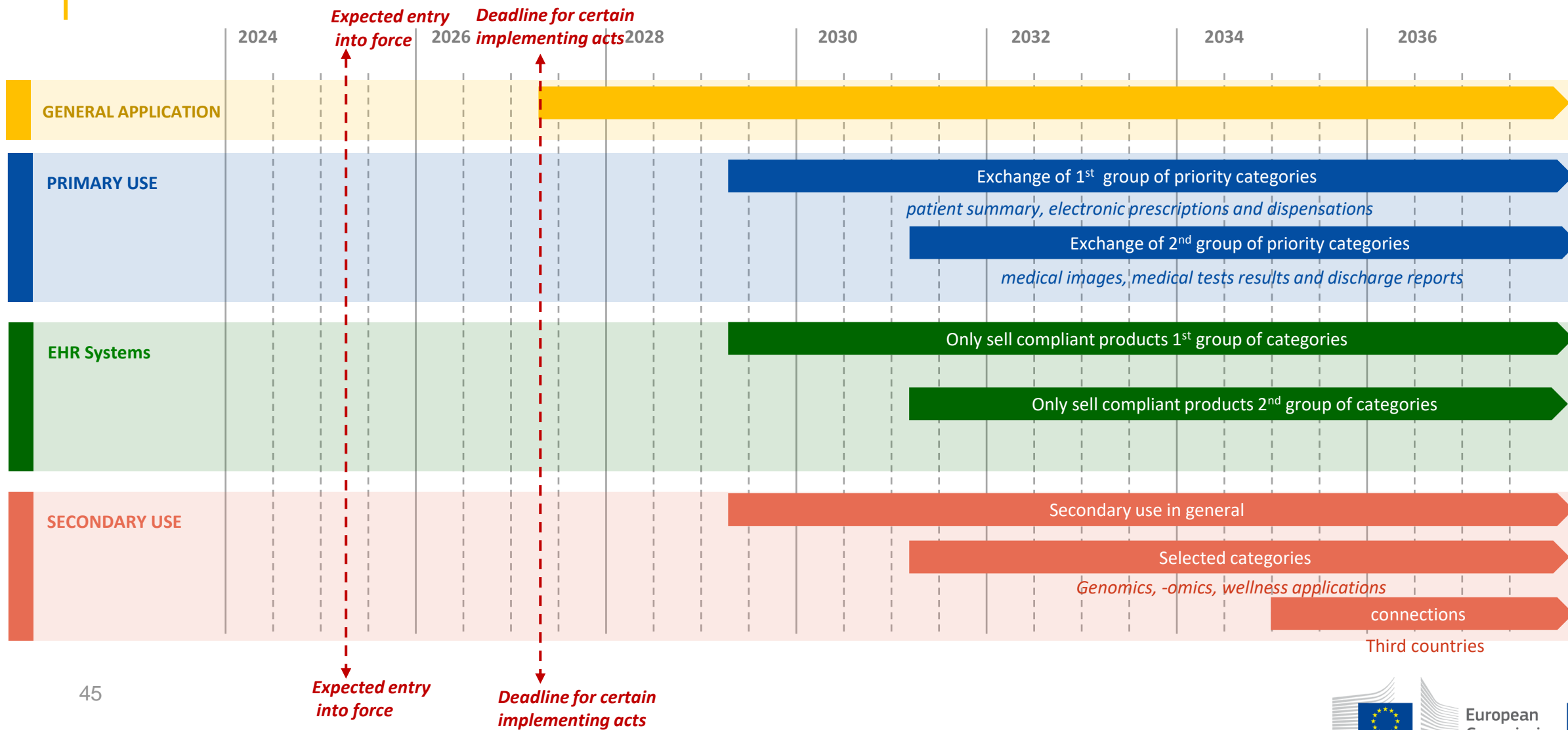
4 Transition

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

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.

EHDS – Overall timeline for application



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

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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