



European Health Data Space

Harnessing the value of health data

06/03/2025

EHDS webinar series

1. Primary Use and Requirements for EHR systems
2. Secondary Use
- 3. Implementation and governance – who does what?**

Agenda

1. EHDS in a nutshell
2. Tasks in primary use
3. Tasks regarding EHR systems
4. Tasks in secondary use
5. Tasks relating to governance
6. Q&A

Target audience: digital health authorities, health data access bodies, Member State authorities in general, data holders

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

- 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



Mobility



Green Deal



Energy



Public Administration



Skills

Personal data spaces

High Value Datasets from public sector

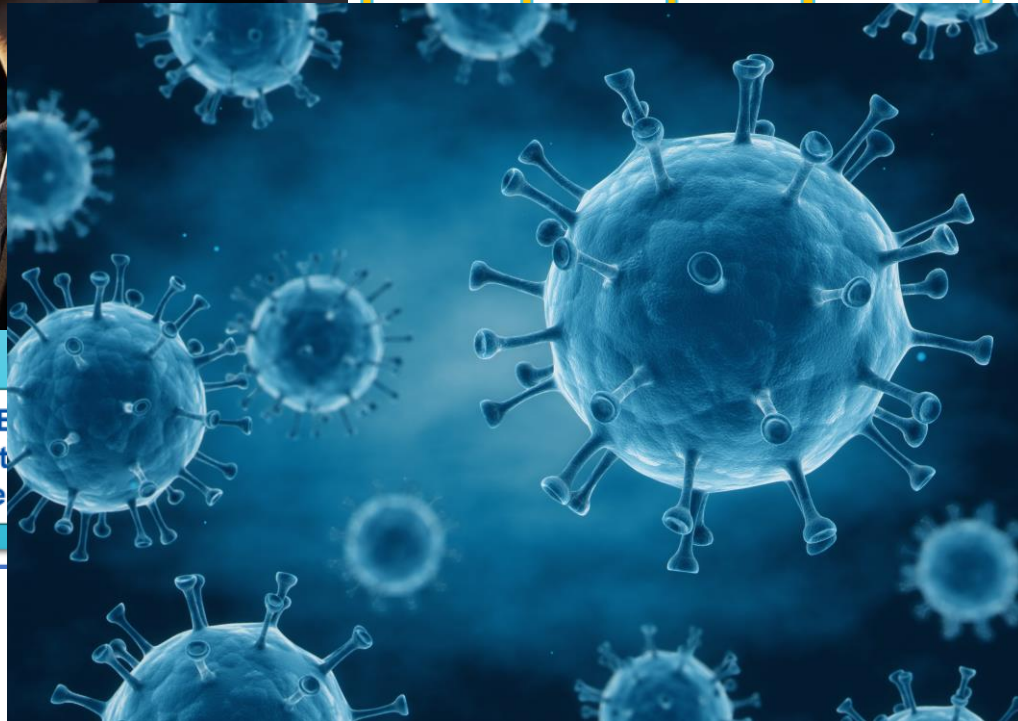
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AI Testing and Experimentation Facilities






EUROPEAN 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).

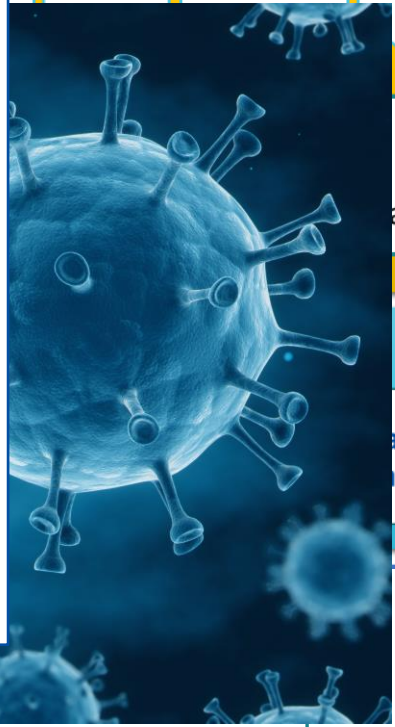
Suggested citation: European Centre for Disease Prevention and Control. Heating, ventilation and air-conditioning systems in the context of COVID-19. 10 November 2020. Stockholm: ECDC; 2020.
© European Centre for Disease Prevention and Control, Stockholm, 2020.

rsula von der Leyen
European Commission

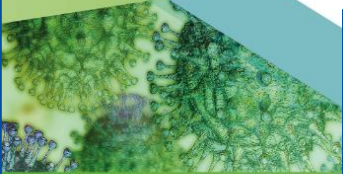


Personal data spaces

High Value Datasets from public sector



and
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 (MV) systems.
- If well-maintained and adapted for use in the context of COVID-19, MV systems may have a role in reducing the transmission of SARS-CoV-2.
- Four bundles of non-pharmaceutical interventions (NPIs) 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 (PPE).

Scope of this document

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

Changes to the current guidance


The first update of the ECDC ventilation guidance includes:

- key new findings that emphasise four bundles of NPIs in closed spaces;
- updated references on the evidence of transmission in indoor spaces;
- recommendations based on the new evidence on the role of MV systems;
- an overview of national guidance ventilation to ECDC's National Focal Points (NFPs) for PPE in respiratory diseases.

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.



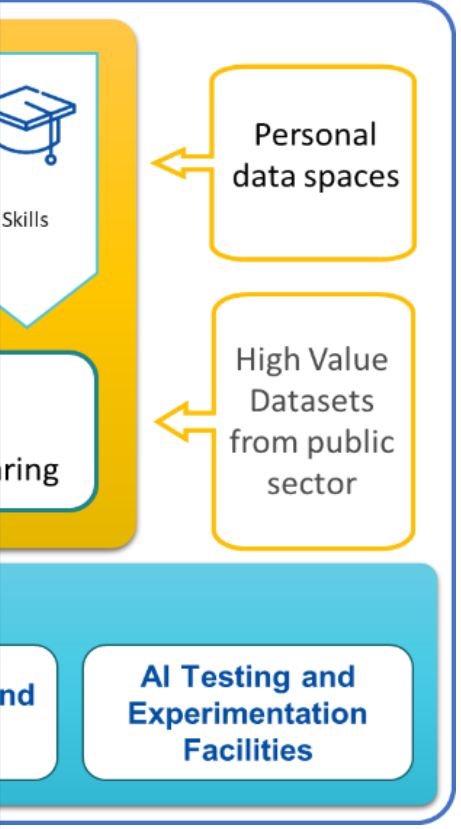
Strasbourg, 3.5.2022
COM(2022) 197 final
2022/0140 (COD)

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

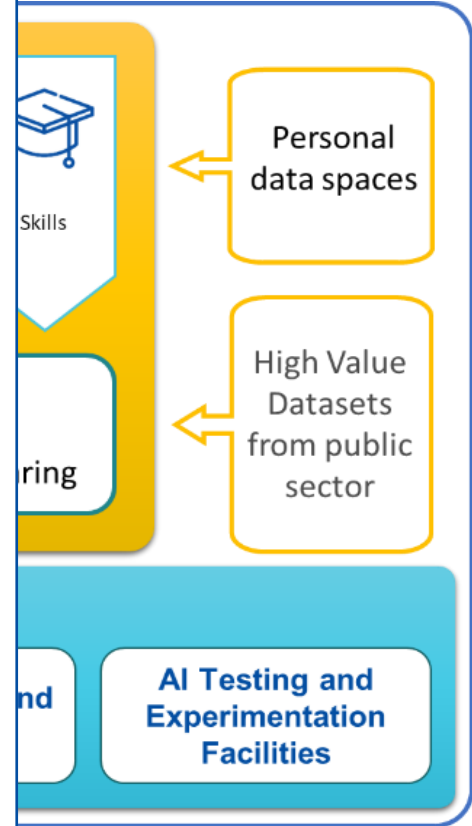
The new regulation, proposed by the Commission in July 2022, provides a holistic approach for the regulation of substances of human origin. The new rules notably **include better protection of recipients and donors of substances of human origin, as well as children born from medically assisted reproduction**.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

COUNCIL

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

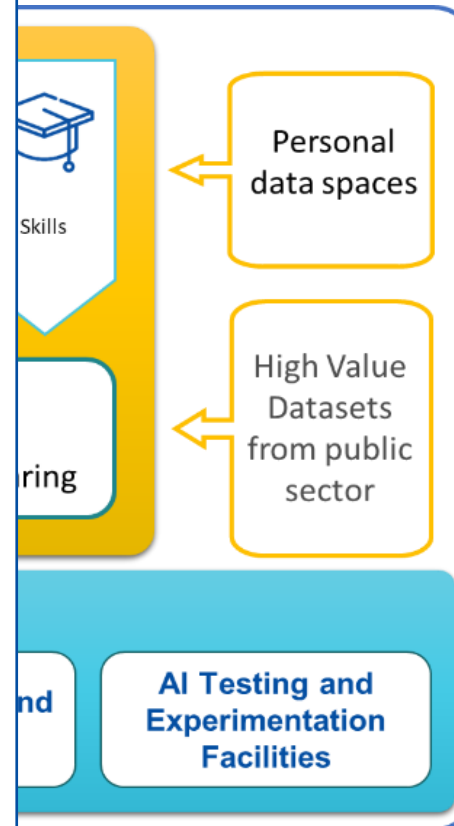
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- technical guidelines up to date;
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Next steps



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

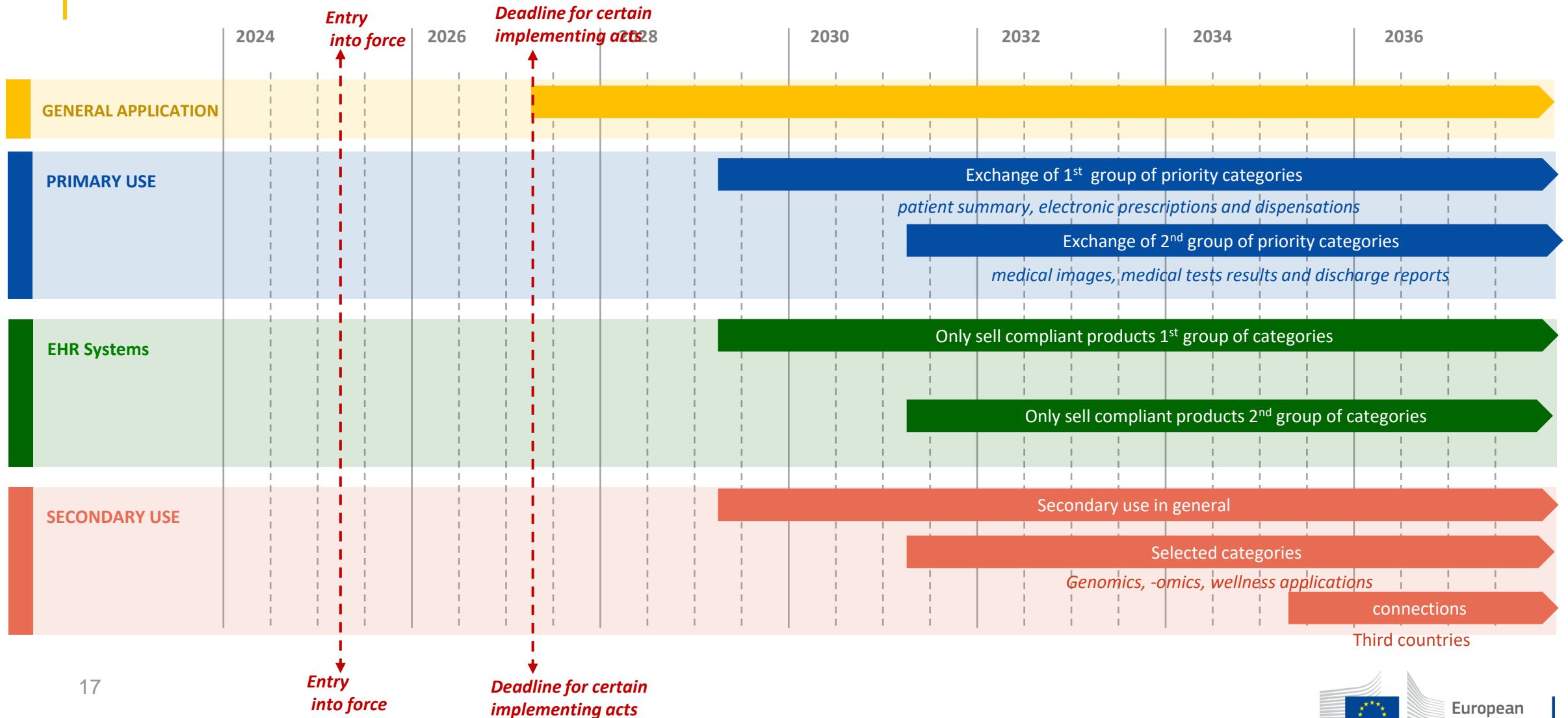
How?

- 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

Governance – MS and EU level

- MS to set up Digital Health Authorities (primary use) and Health Data Access Bodies (secondary use)
- Coordination on EU level in EHDS Board for exchanging best practices, coming up with guidelines etc.
- COM to provide MyHealth@EU and HealthData@EU infrastructures and certain other services for MS
 - MS Steering groups for guidance

EHDS – Overall timeline for application



2 Tasks in Primary Use

What organisation and services do MS have to set up?

What infrastructures will MS use?

What do healthcare providers need to do?

What does COM need to do?

Establish Digital Health Authority

- What: MS to designate Digital Health Authority
- When: 26/03/2027
- Dependencies: n/a
- Background: evolution of current tasks

Defining EEHRxF

- What: COM to lay down specifications for European Electronic Health Record Exchange Format (EEHRxF)
- When: DL for COM 26/03/2027
- Dependencies: n/a
- Background: see Commission Recommendation (EU) 2019/243 of 6 February 2019 on a European Electronic Health Record exchange format

Ensure setup of access services

- What: Member States to ensure that one or more electronic health data access services (patient-facing) and health professional access services are set up. This includes connecting healthcare providers.
- When: services must be up and running by 26/03/2029 for first group of priority categories, by 26/03/2031 for the second group
- Dependencies: implementing acts for Arts. 4(4), 15 (DL for COM: 26/03/2027), 16(2), 17

Registration of electronic health data

- What: Member States to ensure that priority category data are kept in EEHRxF
- When: by 26/03/2029 for first group of priority categories, by 26/03/2031 for the second group
- Dependencies: implementing act Art. 13(4) (DL)

Connect to MyHealth@EU

- What: MS to designate national contact point (NCP) for MyHealth@EU, connect NCP to central services, connect healthcare providers to NCP
- When: 26/03/2029 for first group of priority categories, 26/03/2031 for second group.
- Dependencies: implementing acts for Art. 23(4) and (8) (DL)

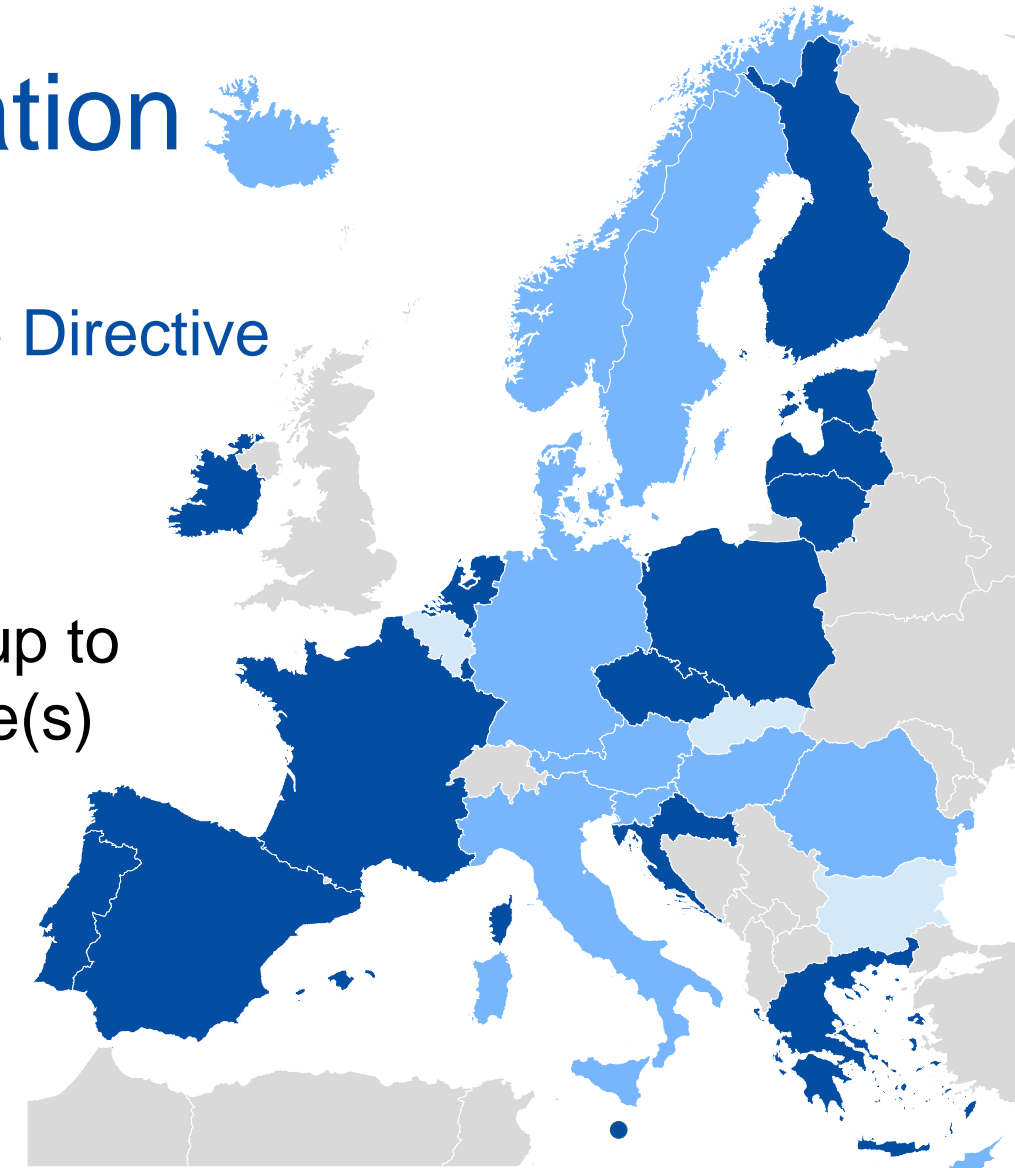
Building on existing cooperation

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



3 Tasks relating to EHR Systems

Market surveillance
Testing environment

Designate Market Surveillance Authority

- What: MS to designate Market Surveillance Authorities
- When: 26/03/2027 for designation
- Dependencies: n/a
- Background: COM to provide cooperation tools, e.g. ICSMS

Deploy and operate testing environment

- What: MS to deploy and operate testing environments
- When: no defined deadline, but should be up and running before key obligations of Chapter 3 become applicable, so before 26/03/2029
- Dependencies: implementing act for Article 40(4) (DL), development of testing environment by COM
- Background: COM to develop software package for testing environment and make it available to MS

Tasks for manufacturers of EHR systems

- What: only place on the market EHR systems with the two harmonised components that comply with the common specifications under Art. 36, passed the testing environment, are CE-marked and registered in the Art. 49 database
- When: 26/03/2029 for products processing first group of priority categories, 26/03/2031 for second group
- Dependencies: Art. 36 implementing act (DL)
- Background: similar obligations for healthcare providers ‘putting into service’ in-house systems – but 26/03/2031 as target date, for both groups of data categories

Tasks for manufacturers of wellness apps

- What: when they claim interoperability with EHR systems, label them, comply with Art. 48, register them in the Art. 49 database
- When: 26/03/2029 for apps processing first group of priority categories, 26/03/2031 for second group
- Dependencies: implicitly Art. 36 implementing act (DL)

4 Tasks in secondary use

Health Data Access Bodies
Connection to HealthData@EU

Establish and designate Health Data Access Body

Article 55 and following

- What: MS to designate one or more HDABs and set up all functions – e.g. application management, transparency portal...
- When: 26/03/2027 for designation, 26/03/2029 for receiving applications
- Dependencies: Art. 70 implementing act (DL) for templates, Art. 73(5) IA (DL) for SPE specs
- Background: UHDAS to be set up by 26/03/2029 as well

Connecting to HealthData@EU

- What: MS to connect their NCPs to HealthData@EU – federating catalogues, forwarding applications.
- When: 26/03/2029 for most Art. 51 categories, 26/03/2031 for last ones
- Dependencies: IA for 75(12) (DL)

Building secure processing environments (SPEs)

- What: HDABs need to ensure that they can provide a SPE to make data available in.
- When: 26/03/2029 for most Art. 51 categories, 26/03/2031 for last ones
- Dependencies: IA for Art. 73(5) (DL)
- Background: additionally, COM can provide SPE for cross-border cases – see Art. 75(9)

Tasks for holders

- What: provide dataset descriptions to HDAB, be ready to provide data pursuant to permit/request.
- When: 26/03/2029 for most of Art. 51 categories, 26/03/2031 for the remaining ones
- Dependencies: implementing act for Art. 77(4) (DL)

Tasks for users

- What: can apply for permits/requests
- When: 26/03/2029 for most of Art. 51 categories, 26/03/2031 for the remaining ones
- Dependencies: none for the users

4 Tasks relating to governance

EHDS Board
Steering Groups

Transition from eHealth Network to new governance mechanisms

- In short: EHDS Board succeeds eHealth Network (plus extension to secondary use)
- Starts to apply 26/03/2027
- Expectation:
 - gradual replacement over time, finalised by repeal of Art. 14 CBHCD 26/03/2031.
 - eHN subgroups to be succeeded EHDS Board subgroups
- Parallel existence for some time: MS can use existing voluntary eHN cooperation as staging ground for getting ready for EHDS.

Governance (1) : EHDS board



Objectives

- Facilitate cooperation and exchange of information between MS and Commission.
- Competence for both primary and secondary use of electronic health data.

Composition

2 representatives per MS : one for primary use, one for secondary use.

Each MS has 1 vote.

Decision-making by consensus or, failing that, by a 2/3 majority of MS.



The members act in the public interest and independently.

Functioning

Co-chairing by a representative of COM and one MS.

Adoption of procedural rules and a code of conduct proposed by COM. Secretariat provided by COM.

Invites supervisory authorities, market surveillance authorities, EDPB, EMA, ECDC, ENISA as relevant.

Possible sub-groups for specific subjects with representation of digital health authorities and health data access bodies.

Governance (2) : Steering groups for infrastructures

Objectives

- Guiding the development and operation of MyHealth@EU and HealthData@EU cross border infrastructures.

Composition

1 representative per MS each.

Each MS has 1 vote.

Decision-making by consensus or, failing that, by a 2/3 majority of MS.

Functioning

Elect their own chairs

Adopt their own rules of procedures, can create subgroups.

Secretariat provided by COM

Possibility to invite observers to exchange on subjects of interest (other authorized participants, representatives of patients, health professionals, and industry).

Governance (3) : Stakeholder Forum

Objective

- Platform for the exchange of information and cooperation with stakeholders.

Composition

Representatives of patients' organisations, health professionals, industry, consumer organisations, scientific researchers and academia

Appointed by COM following public call for interest and a transparent selection procedure

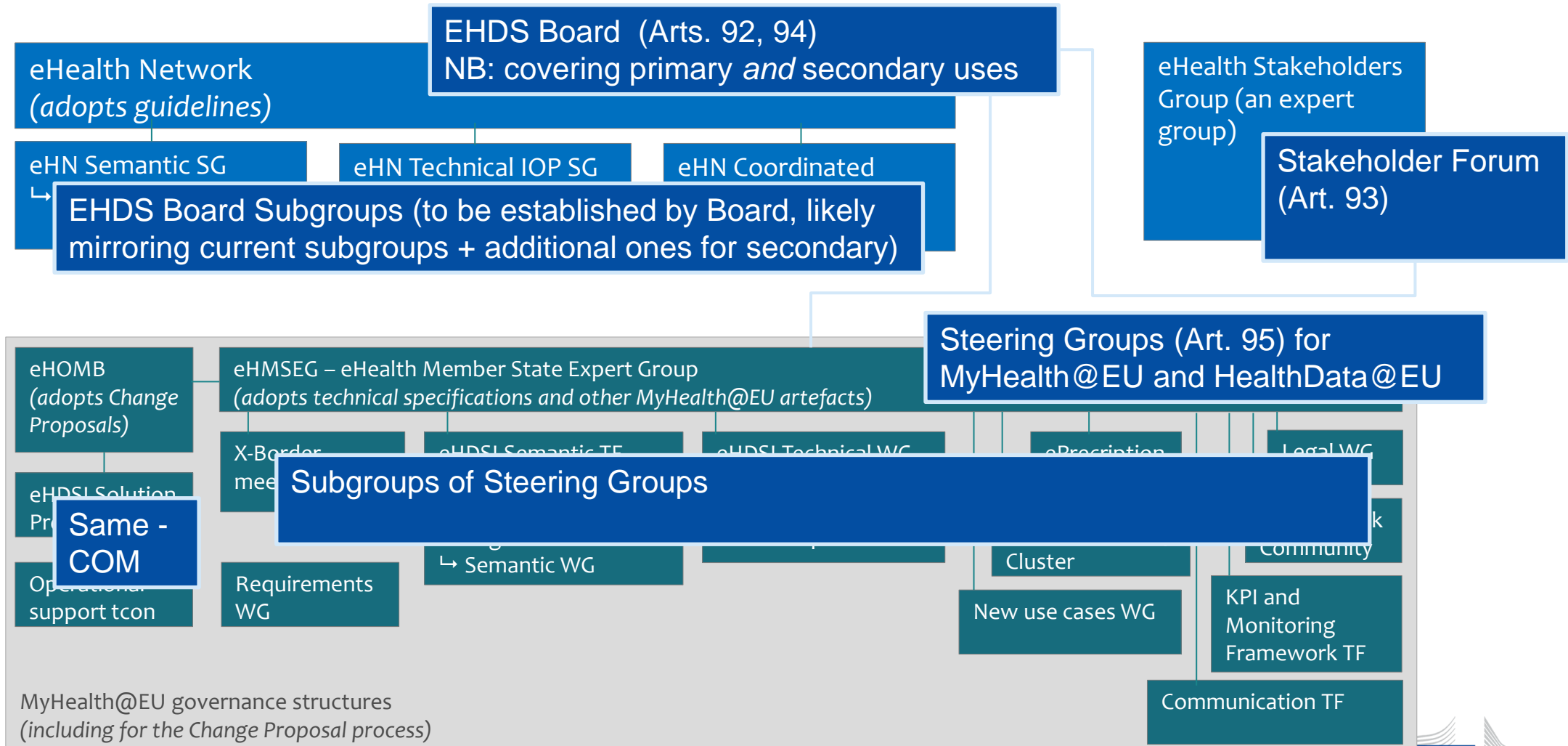
Functioning

Chaired by COM

Adopts its own rules of procedures, can create subgroups.

Secretariat provided by COM

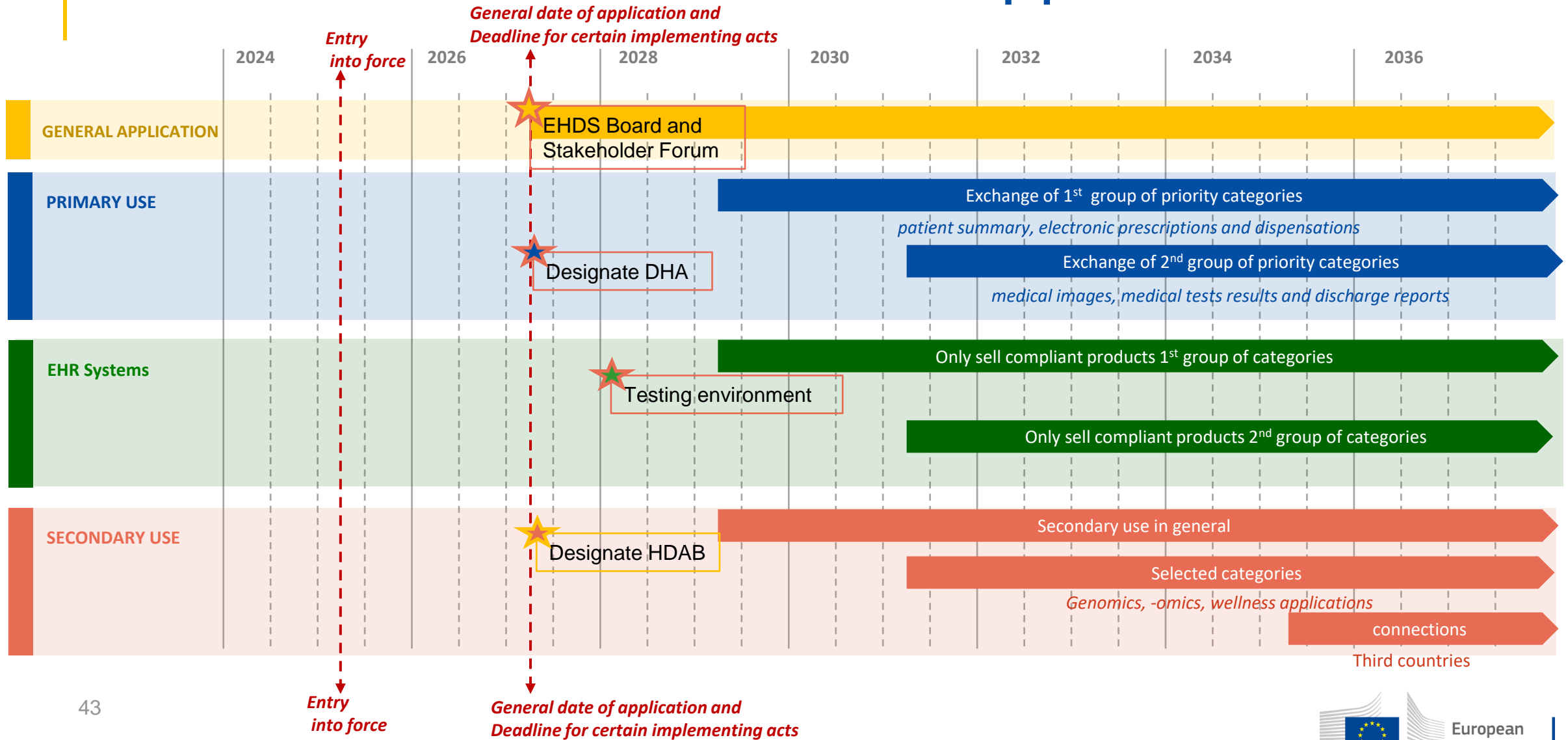
Comparison to eHealth Network, subgroups, current MyHealth@EU governance



4 Transition & Conclusion

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

EHDS – Overall timeline for application



Thank you!

Questions? Answers!



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