



An Roinn Sláinte
Department of Health

Ireland – Getting Ready for the European Health Data Space

10 February 2025

EHDS Regulation

The EHDS Regulation aims to to establish a **common framework for the use and exchange of electronic health data** across the EU.

It will:

- empower individuals and healthcare providers to access, control and share electronic health data within and across borders for healthcare delivery (**primary use of data**),
- enable the secure and trustworthy reuse of health data for research, innovation, policy-making, and regulatory activities (**secondary use of data**),
- foster a single market for **electronic health record (EHR) systems**, supporting both primary and secondary use.



EHDS Regulation

Primary Use

- Builds upon and establishes key patient rights in respect of personal electronic health data
- Mandates priority categories of data for EHRs and standard, interoperable EHR format
- Electronic access services for patients and HCPs
- Establishment of **Digital Health Authority**
- Mandatory participation in **MyHealth@EU** infrastructure

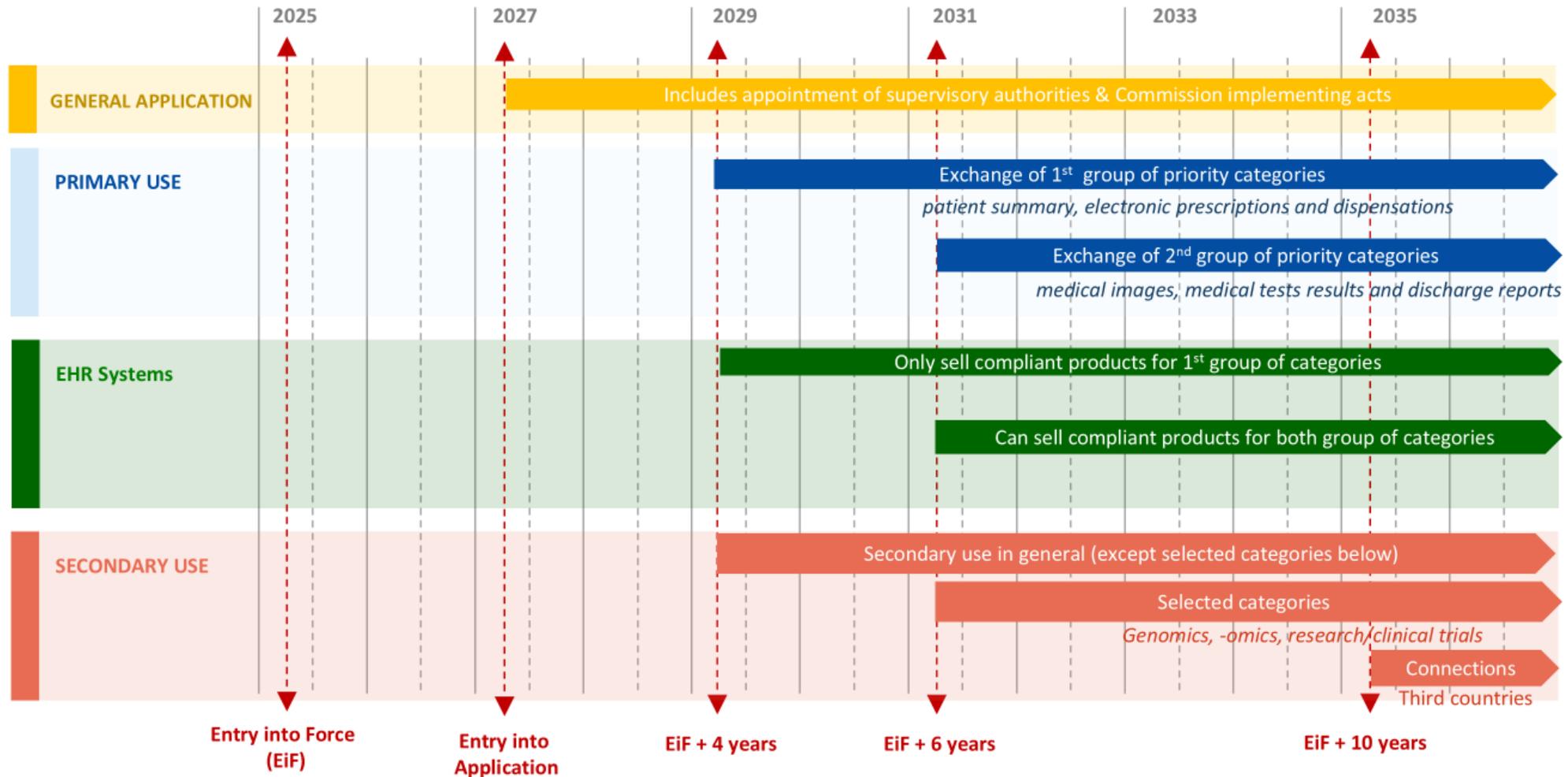
Secondary Use

- Minimum categories of data for secondary use
- Allowed and prohibited purposes
- Establishment of **Health Data Access Body**
- Duties of health data holders and users
- Safeguards and enforcement
- Health data access process
- **HeathData@EU** infrastructure

EHR Systems

- Standardised requirements for vendors in respect of interoperability and compliance
- Establishment of **Market Surveillance Authority**

Implementation Timeline



Implementation of the EHDS Regulation

Legislative Landscape

The Health
Information Bill

A Statutory Instrument
on the EHDS

Expansion of health
information legislation

Primary Health Data Landscape

Digital for Care: A
Digital Health
Framework for
Ireland, 2024-2030

HSE Digital Roadmap

National Engagement
on Digital Health &
Social Care

MyHealth@EU & the
eHealth Network

Secondary Health Data Landscape

HealthData@IE Direct
Grant

EU Community of
Practice

TEHDAS2

Quantum Joint Action



Data Holders and Users under the EHDS

Art 60 & 61

Data Holders

- **Who?**
 - Have the **right or obligation to process personal electronic health data as controller / joint controller or the ability to make non-personal data available.**
- **What?**
 - Provide description of datasets to feed into **national dataset catalogue**
 - Include **data quality & utility label** (mandatory for publicly funded data collection)
 - Provide **data requested** by HDAB (penalties for non-compliance)
- **How?**
 - Fees collected from data users

Data Users

- **Who?**
 - Natural or legal person **granted lawful access** to electronic health data for secondary use
- **What?**
 - Can only use data according to access granted
 - Make public **results/output of secondary use** within 18 months
 - Inform HDAB of **significant findings**
- **How?**
 - Apply through HDAB for **data permit** or **data request**

Categories of data available for secondary use

Art. 51

By 2029		By 2031
Data contained in Electronic Health Records	Wellness app generated data	Socioeconomic, behavioural, environmental determinants of health data
Aggregated data on healthcare needs, resources, access, expenditure	Data on professional status and institution of HCPs	Genetic and genomic data
Pathogen data	Data from registries (including public health, medical, mortality, medical products/devices)	Other human molecular data (e.g., proteomic)
Healthcare-related administrative data (e.g., reimbursements)	Biobanks and databases	Clinical trial data (after completion)
Medical device-generated data		Data from research cohorts/surveys (after first publication of results)

Allowed & Prohibited Purposes

Art. 53 & 54



- **Public interest** in the area of public & occupational health, including public health surveillance and patient safety
- **Policy making** and **regulatory** activities
- Developing **statistics** at national or multi-national levels

[reserved for public sector bodies]



- **Educational or teaching activities** in health/care sectors
- **Scientific research** related to health or care, contributing to public health
- **Improvement of delivery of care**, optimisation of treatment, & providing healthcare, based on EHR data from other individuals



- Taking decisions **detrimental to individuals or groups** based on electronic health data (legal, social, or economic impacts)
- Making **employment-related decisions** based on health data, including discriminatory decisions affecting insurance, credit, or loans
- **Advertising or marketing** activities.
- **Developing products or services that could harm** individuals, public health, or society (e.g., illegal drugs, alcohol, tobacco, weaponry, or addictive products)
- Engaging in activities that **conflict with ethical standards** set by national law.

Safeguards for Accessing Data



- Strictly **prohibited** purposes
- An **Access Review Committee** will review applications for and determine whether access will be granted
- Research applicants may need to secure **ethical approval** (where required) through a research ethics committee
- Data can only be accessed in **anonymised or pseudonymised** (where required) format
- Data can only be accessed through a **secure processing environment** (activities monitored, download of personal data strictly prohibited)
- **Penalties** may be applied for non-compliance (e.g., attempts to re-identify individuals)
- **Opt-out** mechanism – any time, reversible, and no reason needed
- **Public transparency** on data processing activities and outcomes

Health Information Bill

(published 19
July 2024)

Foundational legislation: a key enabler of *Digital for Care: A Digital Health Framework for Ireland 2024-2030* and support for EHDS national implementation.

Part 1: Preliminary and General

Part 2: A **'duty to share'** health information for care and treatment, spanning public, private and voluntary settings.

Part 3: A legal framework for the development of **digital health records** in Ireland and **enhanced patient access** to their digital health records.

Part 4: **Enhanced provision of information to HSE for its secondary use.**