Policy Briefing on the European Health Data Space (EHDS)

EHDS in a Nutshell

- In May 2022, the European Commission published a legislative proposal to set up the EHDS to unleash the full potential of health data in the EU to make healthcare systems more sustainable and resilient.
- The EHDS is a health specific ecosystem comprising rules, common standards and practices, infrastructures and a governance framework for primary use of health data to improve care delivery (EHDS 1) and for secondary use to support research, innovation and policies (EHDS 2).
- It supports individuals to take control of their health data so that health data follow people within and across the EU borders.
- The proposal is backed by a substantial budget: €12 billion for Member States to digitise healthcare under the Recovery and Resilience Facility and €810 million to support the EHDS at EU level.
- The proposal is now in negotiation with the European Parliament and the Council, the co-legislative bodies of the EU.

This briefing consists of 4 guidance notes:

Notes 1 & 2: the purpose of the EHDS
1. Primary use of Electronic Health Data
2. Secondary use of Electronic Health Data

Notes 3 & 4: the infrastructure of the EHDS
3. Data interoperability, accessibility and quality
4. Data access bodies and governance

EUROPEAN HEALTH DATA SPACE

**EHDS 1**
MyHealth@EU

**Facilitate**
- Patient access
- Patient control
- Patient contribution

**Support**
- Local care
- Cross border care
- Telemedicine
- Connected health

**Interoperable Data**
Based on
- Standardised EHR
- "FAIR" principles
- Quality label
- Anonymised / Pseudonymised data

**Common Infrastructure & Governance**
Through
- Health data access bodies
- Reporting requirements
- Single permit model
- Centralised access points for: MyHealth@EU & HealthData@EU

**EHDS 2**
HealthData@EU

**Facilitate**
- Scientific research
- Clinical trials

**Support**
- Planning
- Policy-making
- Regulation

**Allow**
- Reuse of enhanced datasets
- Citizen data altruism

Sustainable and resilient healthcare systems across the EU and beyond
Purpose of the EHDS: Primary Use of Electronic Health Data

Within the scope of primary use of health data, the objective of the EHDS is to support EU Citizens in exercising their rights to data access, control and portability, and to allow them to more easily add data from wellness apps, devices and other digital health information sources. Better data availability will improve access to diagnosis and treatment, patient safety, continuity of care and healthcare efficiency.

The EHDS will facilitate much needed health data sharing between EU Member States for the purposes of care provision (primary use) that can also be used further within the secondary use provision (see page 3). Focusing on developing the MyHealth@EU infrastructure it also seeks to increase uptake of cross-border telemedicine to allow medical expertise to move without patients having to travel to another country.

With respect to cross care, it builds on the 2011 Cross Border Care Directive that created the European Reference Networks for Rare Diseases (ERNs) as well as the eHealth Digital Service Infrastructure (eHDSI). Within the framework of the MyHealth@EU initiative, eHDSI currently supports exchanges of ePrescriptions and Patient Summaries among 10 EU Member States on a voluntary basis. ‘MyHealth@EU’ will become the cross-border infrastructure for primary use of electronic health data, as the EHDS proposal foresees upgrading the current infrastructure to be mandatory for all Member States (see page 5).

The EHDS proposal creates the concept of priority categories of personal electronic health data for primary use. Where data is processed in electronic format, Member States shall implement access to and exchange of data falling under the categories of ePrescriptions and Patient Summaries - both currently in use across EU borders - as well as medical images and reports, laboratory results and discharge reports to be rolled out gradually (see page 4).

The EHDS will empower EU citizens through better digital access to their personal health data and support free movement by ensuring that health data follow the people. It ensures more actionable rights for individuals enshrined in GDPR with respect to data concerning them, including:

- **Access** to health data in electronic form immediately and without any cost
- **Share** health data with health professionals nationally and cross-border
- **Add** to information, **rectify** errors, and **restrict** access including in relation to healthcare professionals
- **Obtain information** on how data is shared
- **Have a right to health data**, issued and accepted in a **common European format**

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Purpose of the EHDS: Secondary Use of Electronic Health Data

Within the scope of secondary use, the objective of the EHDS is to facilitate the re-use of health data to support the development and assessment of health policies and regulation, and drive research and innovation.

EHDS 2 will set up strict rules for the use of anonymised or pseudonymised health data for research, innovation, policy-making and regulatory activities. Facilitating secondary use of health data, both in terms of introducing EU wide rules and infrastructure, is a new feature at EU level. It will be linked to EHDS 1 (see page 2) for scientific purposes to allow re-use of data that was collected during the course of care.

A new decentralised EU-infrastructure for secondary use health data will be created called HealthData@EU. It will connect health data access bodies which all Member States will be required to set up (see page 5). These bodies will be required to ensure transparency by publishing information on datasets and data access applications (see page 4).

Both public and private sector organisations may make secondary use of health data through HealthData@EU, by applying for a permit from a health data access body. Non-public sector bodies may make secondary use of data for scientific research or educational activities related to health and care, as well as innovation of products and services for public health or social security including medicines and medical devices, training Artificial Intelligence systems and providing personalised healthcare. Public sector bodies may in addition make use of data for public health and research of public interest. The importance of making health data available for the development of artificial intelligence (AI) algorithms and AI training data sets is called out in the draft legislation as a particular objective of secondary use.

As the general rule, data access bodies will provide permits to access anonymous data in the secure processing environment. Where data users can justify access to personal electronic health data, the data access body may provide access to pseudonymised data, with the information necessary to reverse the pseudonymisation available only to the health data access body. It will be forbidden to use data to make decisions detrimental to individuals. Data users must make public the results of their health data use and return enriched datasets for further use.

EU citizens’ security and privacy will be ensured by making sure that:

- Researchers, industry, and public institutions will have access to health data only for scientific purposes that benefit individuals and society
- Researchers, industry and public institutions may only have access to data that do not reveal the identity of the individual

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**Infrastructure of the EHDS: Interoperability, accessibility, quality**

The EHDS proposal supports sharing electronic health data that are findable, accessible, interoperable and reusable (‘FAIR principles’), and ensuring that electronic health data are as open as possible and as closed as necessary. It gives a wide definition of electronic health data as personal and non-personal data related to the physical or mental health of an individual which is processed in electronic form.

**Improvement of interoperability** and data sharing across the Member States will be gradual due to the fact that various categories of electronic health data achieved different levels of maturity in standardisation across the EU. The proposal requires Patient Summaries, ePrescriptions, eDispensations to be available within 1 year of entry into force of the legislation and Medical Images and Reports, Laboratory Results, Discharge Reports within 3 years.

All EHR systems, including ‘in house systems’ using data of these priority categories need to go under mandatory self-certification to demonstrate that they comply with essential requirements related to interoperability and security. Whereas certification for EHR systems will be mandatory, wellness applications that claim interoperability with an EHR system will be subject to voluntary labelling. This will enhance transparency by supporting users in their choice of appropriate wellness applications with high standards of interoperability and security.

Datasets with electronic health data collected and processed with the support of EU or national public funding shall have a data quality and utility label. This will inform data users about the quality and characteristics of a dataset and enable them to choose the datasets that best fit their needs for secondary use (see page 3). Health data access bodies and single data holders may charge fees, which need to be transparent and proportionate, for making electronic health data available for secondary use.

Data holders will be required to make available wide varieties of data, including: EHRs, data related to social determinants of health, pathogen and genomic data, claims and reimbursements, person-generated data from devices and apps, disease registries and biobanks, clinical trial data and data related to insurance status, education and lifestyle.

Manufacturers of EHR systems need to provide documentation to show interoperability by design, including capability to be operated together with other products in such a way that interoperability and compatibility are reliable and secure, and personal electronic health data can be shared between them. All EHR systems must be capable of using the European EHR Exchange Format.

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Infrastructure of the EHDS: Data access bodies and governance

The EHDS proposal includes the expansion and rollout of the cross-border digital infrastructures

• for primary use of electronic health data (see page 2) called ‘MyHealth@EU’ and

• for secondary use of electronic health data (see page 3) called ‘HealthData@EU’

It will be mandatory for all EU Member States to participate in both infrastructures, including designating in each country

• a national digital health authority and a national contact point for digital health for primary use

• a health data access body and a national contact point for secondary use of electronic health data

‘MyHealth@EU’ will be upgraded to deal with all priority categories of electronic health data for primary use (see pages 2 and 4). It will be formed by the combination of national contact points under the supervision of digital health authorities and central interoperable services provided by the European Commission to support and facilitate data exchanges. Member States need to make sure that all healthcare providers, including pharmacies, are connected to the national contact points and able to perform two-way data exchanges.

‘HealthData@EU’ will be established for secondary use, connecting the national contact points for secondary use of electronic health data of all Member States and authorised participants in that infrastructure. Member States shall also designate one or more health data access bodies and entrust them with powers to take decisions on access to and secondary use of health data. The European Commission will develop, deploy and operate a core platform for HealthData@EU to provide a secure processing environment for secondary use.

A European Health Data Space Board (EHDS Board) will be established to facilitate cooperation between digital health authorities and health data access bodies, in particular the relation between primary and secondary use of electronic health data. Stakeholders and relevant third parties, including patients’ representatives will be invited to participate in its work.

At national level, digital health authorities dealing with the primary use may be different to the health data access bodies dealing with the secondary use of electronic health data. Therefore these functions are different and need distinct cooperation in each of these areas, including separate EHDS subgroups as well as networks and links at national and EU level.

Data permits (see page 3) issued by a health data access body in one Member State could be used across the EU on the bases of mutual recognition within the specific conditions applicable for the data user such as types of data, purpose and duration of use.

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