

The European Health Data Space

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Background

In May 2022, the European Commission (EC) presented [a proposal for regulation to set up a European Health Data Space](#) (EHDS). The EHDS will be a key pillar of the strong [European Health Union](#) and is the first common EU data space in a specific area to emerge from the [European Strategy for Data](#).

What is the European Health Data Space?

The EHDS proposal aims to create data infrastructures for the use and re-use of health data. In particular, it puts forward a regulation for primary use (by individuals and healthcare providers) and secondary use of health data (for research, innovation, policy-making and regulatory activities). The EHDS should enter into place one year after the Regulation goes into force.

Below is a short overview of the proposed measures. The pages that follow set out the proposal chapter by chapter.

<p>Primary data: the direct control/use of health data by patients and doctors for (cross-border) care purposes. The proposal includes</p> <ul style="list-style-type: none">● The creation of MyHealth@EU: a common cross-border digital infrastructure for the primary use of data● The establishment of national digital health authorities for monitoring the rules associated with the primary use of data● Provisions related to the interoperability of datasets● Establishing national contact points tasked with enforcing the obligations related to interoperability and privacy associated to primary health data	<p>Secondary data: re-use of health data for research, innovation and policy-making. The proposal includes</p> <ul style="list-style-type: none">● Creation of HealthData@EU, a decentralised EU-infrastructure for (cross-border) secondary use of data● The establishing of a national health data access body for monitoring rules associated to the secondary use of data● The definition of a set of data types that can be used for defined purposes, as well as prohibited purposes, and anonymisation requirements● Provisions on data altruism (providing consent to make available data– voluntarily and without reward)● Provisions on transparency of fees calculation and conditions for data requests● Provisions related to dataset description and their quality
<p>Other relevant issues included in the proposal:</p> <ul style="list-style-type: none">● The establishment of 'European Health Data Space Board'● The implementation of a self-certification scheme for Electronic Health Records systems● Voluntary labelling for wellness applications	

A closer look at the EHDS regulation

[The Proposal](#) is structured in eight main chapters. Chapter II and IV are most relevant to our Members:

- I. **Chapter I (General provisions)** presents the subject and the scope of the regulation.
- II. **Chapter II (Primary use of electronic health data)** sets out the **additional rights and mechanisms** designed to complement the individual's rights provided under the General Data Protection Regulation (GDPR), relating to their electronic health data.

In addition, it describes the **obligations of various (health) professionals** in relation to electronic health data. Some types of electronic health data are identified as priorities to be integrated in the EHDS. These include patient summaries, electronic prescriptions, electronic dispensations, medical images and image reports, laboratory results, and discharge reports. This integration will take place in a staged process with a transition period. It will be in line with targets to provide 100% of EU citizens with access to their electronic health records by 2030. This is one of the [digital targets for 2030](#), part of Europe's Digital Decade.

Member States will have to set up **digital health authorities** responsible for **monitoring these rights and mechanisms**, and for ensuring that these additional rights of individuals are properly implemented.

Chapter II also includes provisions related to the **interoperability** of certain health-related datasets. Member States will also have to **designate national contact points** tasked with enforcing the obligations and requirements of this Chapter. Finally, a **common infrastructure (MyHealth@EU)** is designed to provide the infrastructure to facilitate cross-border exchange of electronic health data.

Chapter II in a nutshell:

- ✓ Additional **data protection** rules complementary to GDPR
- ✓ Creation of **MyHealth@EU** common cross-border digital infrastructure for primary use of data
- ✓ Establishment of national **digital health authorities** for the monitoring of rules associated to the primary use of data
- ✓ Provision related to the **interoperability** of datasets
- ✓ Establishment of **national contact points** tasked with enforcing obligations

- III. **Chapter III (Electronic Health Records systems and wellness applications)** focuses on implementing a mandatory **self-certification scheme for Electronic Health Records (EHR)** systems. Such systems must comply with essential requirements related to interoperability and security.

Chapter III defines the (1) **obligations of each economic operator of EHR systems**; (2) the requirements related to the conformity of such EHR systems; as well as the (3) **obligations of market surveillance** authorities responsible for EHR systems in the context of their market surveillance activities. This chapter also includes provisions on the **voluntary labelling** of wellness applications.

IV. Chapter IV (Secondary use of electronic health data) facilitates the secondary use of electronic health data, for instance **for research, innovation, policy making, patient safety or regulatory activities**. It **defines a set of data types** that can be used **for defined purposes, as well as prohibited purposes** (e.g., use of data against persons, commercial advertising, raising insurance fees, and developing dangerous products). Only data necessary for the requested purpose will be provided (not the whole datasets) and for a limited amount of time.

Member States will have to set up a **health data access body for secondary use of electronic health data**, and ensure that electronic data is made available by data holders for data users. This chapter also contains provisions on the implementation of **data altruism in health**, which occurs when individuals give their consent for sharing data, voluntarily and without reward, to be used in the public interest. The duties and obligations of the health data access body, the data holders and the data users are also set out.

This chapter includes general provisions on **transparency of fees calculation**. On a practical level, requirements focus on the security of the processing environment.

This chapter also contains provisions on setting up and fostering **cross-border access to electronic health data**. The cross-border infrastructure designed to enable such a process and its operation are also described (**HealthData@EU**). Finally, the chapter contains provisions related to **dataset descriptions and their quality**.

Chapter IV in a nutshell:

- ✓ Define a **set of data** types that can be used for **defined purposes**, as well as **prohibited purposes**
- ✓ Establishment of national **health data access body** for secondary use of electronic health data and ensuring that electronic data is made available by data holders for data users
- ✓ Provisions on the implementation of **data altruism in health**
- ✓ Provisions on **transparency of fees calculation**.
- ✓ Setting out the conditions and the information needed in a **data request form** for obtaining access to electronic health data for secondary use
- ✓ Provisions on setting up and fostering **cross-border access** to electronic health data for secondary use
- ✓ Provisions related to dataset descriptions and their quality

- V. **Chapter V (Additional actions)** puts forward other measures to promote **capacity building** by the Member States to accompany the development of the EHDS. The Commission will support sharing of best practices and expertise, aiming to build the capacity of Member States to strengthen digital health systems for primary and secondary use of electronic health data. To support capacity building, the Commission will draw up benchmarking guidelines for primary and secondary use of data.
- VI. **Chapter VI (European governance and coordination)** regulates the establishment of **'European Health Data Space Board'** ('EHDS Board'), managed by the European Commission. Dedicated sub-groups such as on primary use and secondary use of electronic health data may be formed to focus on specific issues or processes.
- VII. **Chapter VII (Delegation and Committee)** allows the Commission to adopt delegated acts on the EHDS. Following the adoption of the proposal, the Commission intends to create an expert group to advise and assist it in the preparation of delegated acts.
- VIII. **Chapter VIII (Miscellaneous)** contains provisions on cooperation and penalties and sets down final provisions. Five years after the Regulation enters into force, the Commission will carry out a targeted evaluation. After seven years, it will carry out an overall evaluation.

EuroHealthNet's recommendations

The digitisation of our health systems is inevitable, and it is important to be ready for this transformation. Indeed, if applied in effective and equitable ways, this process could have many benefits, including the potential of reducing gaps in health outcomes and improving the sustainability of our health systems¹. However, there is a risk that the most vulnerable people are left behind in this transition. Ensuring that they benefit from the digital transition requires action within health and other sectors; innovation within states and companies; the establishment of new professions and services; and wider, complementary and enabling improvements in education, and social justice and inclusion.

A large part of the implementation of such digital transformation will be through the management of digital data. In this context, the **European Health Data Space (EHDS)** represents one of the most important initiatives put in place at EU level for the deployment of digital health systems across Europe. The EHDS aims to “*make the most of the potential of digital health to provide high-quality healthcare and **reduce inequalities***”. EuroHealthNet has supported the establishment of the EHDS, as it could improve monitoring and prevention systems for public health and health equity, as well as enhance the ability of people to better understand and engage in their own wellbeing via applications and tools.

Throughout the development process of the EHDS, EuroHealthNet has participated in all consultation processes, including public consultations, requests for feedback and the work organised within the eHealth Stakeholder Group.

Previous related work:

- [2nd feedback on the European Health Data Space \(July 2022\)](#)
- [Consultation on the European Health Data Space \(September 2021\)](#)
- [1st feedback on Feedback to the European Health Data Space \(February 2021\)](#)
- [Consultation on the European Strategy for Data \(June 2020\)](#)
- [Consultation on Europe's digital decade – 2030 digital targets \(March 2021\)](#)
- [Annual Seminar: Promoting Digital Health Literacy for Europe's Digital Future \(December 2021\)](#)
- [2020 Webinar series – Digital challenges and opportunities: best uses of data and artificial intelligence to promote health and equity](#)
- [Policy Précis on digital health literacy: how new skills can help improve health, equity and sustainability \(September 2019\)](#)

Digital Health Literacy

The creation and implementation of the European Health Data Space will imply a more widespread use of health data, and associated digital health apps/technologies, across the EU. Along with a multitude of implied benefits, this could also bring a number of challenges relating to how such health data is managed, both in terms of trust and safety and whether it is used in an appropriate wayⁱⁱ. We recommend that the EHDS Proposal **gives significant importance to the development of digital/data health literacy programmes** as action targets at both EU and national levels.

Such programmes should be targeted toward relevant stakeholders, such as:

- **Citizens/patients:** the implementation of the EHDS will imply a more frequent use of digital portfolios, electronic health records, and associated services. People will need to adapt their habits to benefit from such technologies. **Improving digital/data literacy across the population** will therefore be fundamental to ensure the adoption and spread of new digital health technologies associated with the EHDS. It would allow people to not only actively manage their own personal health and care, but also to increase their understanding of the quality and suitability of apps (including mHealth apps), their marketing, what their data is being used for, how they can control it and other relevant issues. Improved data/digital health literacy would also increase trust in digital innovation in health, care and related sectors.
- **Health and non-health professionals:** The deployment of the EHDS should go hand in hand with **training and capacity building programmes** for professionals (including through up- and re-skilling). The proposal will require health professionals to adapt their way of working to incorporate new digital health infrastructures. At the same time, new non-health professionals will be hired in health settings for the management and treatment of this data. Action must be taken to help all of these professionals to improve their digital/data health literacy and digital competencies. Due to the sensitive nature of health data, particular attention should be given to trainings focused on how to **safely**

manage health data in the respect of confidentiality and privacy rules. This would help professionals deliver better quality of care and also create a safer environment, generating trust with citizens/patients. For instance, a large part of cyber threats to health systems begin with phishing events at workstations, which could be prevented using better data and digital literacy.

- **New health authorities:** The EHDS foresees the establishment of several new health authorities in charge of the coordination and management of health data for primary and secondary use as well as for the monitoring and surveillance of its implementation. Professionals employed in such authorities should have **sufficient technical skills, bringing together experts from different backgrounds**. Capacity building activities should be foreseen on a regular basis for continuous staff training and education .

Other relevant European policies on this issue include:

- [European Skills Agenda](#)
- [EU digital skills targets](#)
- [Regional digital health action plan for the WHO European Region 2023–2030](#)

Empowering public health

The collection and availability of large volumes of health data under the EHDS infrastructures represents an important opportunity to boost public health, health promotion and disease prevention policies across the European Union. In line with WHO flagship on digital health, the EHDS should support countries to **leverage the use of digital health data to improve health system performance and strengthen public health functions**, including disease surveillance, early warning systems, and risk assessmentⁱⁱⁱ.

The accessibility to health data at different territorial levels would facilitate close monitoring of population health trends, especially across the social gradient, and allow implementation of tailored public health programmes as well as more efficient resource planning^{iv}.

Secondary use of health data

The secondary use of data can be key to bringing innovation to health settings as well as provide significant support for policy-making. However, the EHDS Proposal should **provide more detailed information regarding the purposes for which electronic health data can be processed for secondary use**. The purposes listed under article 34 are too broad and vague. A more specific definition of the expected benefits for citizens and society as a whole should be provided, backed by studies and sound evidence. The Proposal should also bind the secondary use of health data to principles of inclusivity, equity and anti-discrimination.

Secondary data will be issued by national health authorities via “data permits”. The data permit will set out the **general conditions applicable to the data user**, in particular types and format of electronic health data accessed, duration, fees to be paid by the data user, etc.

EuroHealthNet recommends that such elements, in particular fees and duration, are **proportionate to the scope of the use of secondary data**, namely if it implies directly or indirectly profitable uses.

Inclusive digital infrastructure and standardisation

The development of sound digital infrastructures should ensure the collection of high-quality data that adds value to health systems in a non-discriminatory way. **Infrastructure and governance need to be reliable, ethical, safe and inclusive** to ensure that data sharing will effectively and equally benefit people's health. This includes ensuring that AI algorithms used in such processes are designed, reflecting the needs, preferences and expectations of people in vulnerable circumstances and according to priority needs^v. This means that people with lower digital or health literacy, less education, low income, migrants, disadvantaged older people, people with physical or mental disabilities etc., should systematically and meaningfully be included in the underpinning research and planning.

In addition, standardisation, as a core aspect of the EHDS proposal and its deployment, should ensure high levels of **data protection and anti-discriminatory principles**. Digital tools collecting this data should also be standardised and regulated to ensure they are safe, comprehensible, easy to use and (therefore) accessible to everyone, everywhere.

Other relevant EU policies on this issue include the [European AI Strategy](#).

Labelling and certification

The introduction of voluntary labelling of wellness applications should **support equitable access and safe use of health apps**. The use of health apps is indeed not yet inclusive^{vi}. The greatest users of such apps are found predominantly among younger, more educated and more digitally literate populations, leaving others underserved and unaware of the benefits they provide^{vii}.

The use of a **trustworthy label** would help in fostering quality health apps and ensure that the data these apps produce is well protected and safely managed. As part of the Horizon Europe project "[Label2Enable](#)", EuroHealthNet and other 14 organisations from across the EU joined forces to promote the uptake of the CEN-ISO 82304-2 label. The label will help users understand the extent to which health apps (1) are healthy and safe; (2) are easy to use (3) handle data in a secure way; and (4) have a robust build.

Governance

The governance of the EHDS will be carried out through its EHDS board. Under article 64, the current Proposal states that "*Stakeholders and relevant third parties, including patients' representatives, shall be invited to attend meetings of the EHDS Board and to participate in its work, depending on the topics discussed and their degree of sensitivity*". EuroHealthNet recommends that the **involvement of Civil Society Organisations and citizens representatives** to be systematic and meaningful, as integral part of the decision making of the EHDS board.

References

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