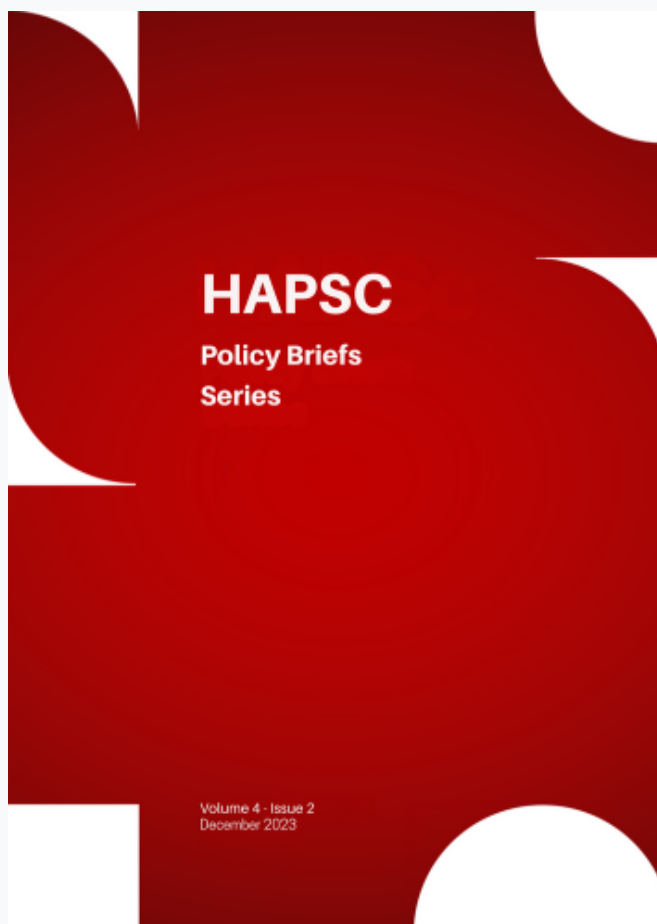


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### European Health Data Space: A New Era in EU Health

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# European Health Data Space: A New Era in EU Health<sup>1</sup>

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## Abstract

After the COVID-19 pandemic, the European Union (EU) put in action the plan to create a European Health Union, the structural pillar of which is the creation of the European Health Data Space (EHDS). In 2022, the European Commission presented the proposal for a regulation for its creation. Its purpose is to enable European citizens to control their health data and to strengthen health research and innovation in the EU. The EHDS is a key step in the transition to digital health in the EU. Digital health is the means to enhance the resilience of healthcare systems in the EU as it will strengthen healthcare. For this reason, the "MyHealth@EU" platform is being created, which will contribute both to the transfer of primary data and to checking the validity of digital health documents. On the research and innovation side, the "HealthData@EU" platform is being developed, which will bring together a plethora of health data. The EHDS Board will play a coordinating role in the EHDS project. The policy brief concludes with the need for an immediate adoption of the proposed EHDS Regulation, which will contribute to improving healthcare provision while completing the single internal market and achieving the free circulation of health data.

**Keywords:** European Health Data Space, European Health Union, Resilience, Digitalization, Health Data, Single Market.

## Introduction

The COVID-19 pandemic highlighted the weaknesses of the health systems of EU Member States and brought health policies into focus to strengthen them. The EU and its Member States realized that to deal more effectively with health threats they need to establish more resilient health systems and strengthen their health cooperation (European Commission, 2020).

In this context, the European Commission presented a Proposal for a Regulation on 11 November 2020 to create a European Health Union. At the core of the European Health Union is the strengthening of Member States' cooperation in tackling serious cross-border health threats, the development of a new pharmaceutical strategy, the strengthening of the role of the European Center for Disease Prevention and Control (ECDC) and European Medicines Agency (EMA), the cancer response plan and a holistic approach to mental health (European Commission, 2020). At the same time, the EU is setting the ambitious goal of creating a European Health Data Space, which will be a structural pillar of the European Health Union (European Commission, 2020).

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In this Policy Brief we will analyze the European Health Data Space and establish its importance, its role in building a European Health Union and the enlargement of the single market.

On 3 May 2022, the European Commission presented its Proposal for the creation of the EHDS. According to the Commission, this proposal serves a dual purpose, on the one hand to create a European Health Union and on the other hand to strengthen the effort to digitalize the Union (European Commission, 2022). Its aim is to enhance the healthcare of EU citizens by providing them with free digital control of their personal health data and the possibility to transfer this data to other Member States, to strengthen health research and innovation in the EU and to create a single market for health data in the EU (European Commission, 2022). This Proposal, although published in May 2022, is still in the process of consultation between the Council and the European Parliament, as required by the ordinary legislative procedure.

### **Primary Use of Health Data**

The proposal for a Regulation on the European Health Data Space implements the objective of strengthening the resilience of health systems through their digitalization in the context of the Digital Transformation of the Union by 2030, as set out in the Strategic Compass. The digitalization of health data will include the patient's medical history, electronic prescription of medicines, results of medical examinations, hospital discharges and medical opinions (Article 5(1) of the proposed EHDS Regulation).

Taking into account both Article 168 of the Treaty on the Functioning of the European Union (TFEU), which sets out the obligation of each Member State to provide a high level of healthcare while respecting the right of Member States to shape their national health policies, and the fact that the health systems of each Member State have different needs, the Commission has proposed the creation of a digital health authority in each Member State. The aim of the authorities is to coordinate the work of digitization in each Member State, while respecting what will be decided through the ordinary legislative procedure and promoting cooperation between Member States and the Union. In addition, they are given the right to intervene to deal with any problems. It is very important that the regulation provides that the task of both digitalization and data exchange will be undertaken by a national authority. This means that the Member States have the first word, with the EU acting in a supportive way by providing certain guidelines that strengthen national health systems throughout the Member States of the Union for the benefit of European citizens. Moreover, according to Article 6 TFEU, public health is a supporting competence of the EU.

To achieve the objective of exchanging health data between the Member States of the EU and the European Economic Area, a central platform "MyHealth@EU" is created to which the relevant national health platforms are connected (Article 12 of the proposed EHDS Regulation). At its core is the secure exchange of data while enhancing the safety and level of healthcare provision. Thus, it will help to achieve the exchange of health data referred to in Article 5 of the proposed EHDS Regulation, but also to facilitate the provision of complementary services such as telemedicine, mobile health, citizens' access to their data and the storage and verification of health certificates and vaccination certificates. This platform is an outgrowth of the need to check the validity of health-related documents. This was most evident during the pandemic period with the creation and verification of the European digital health certificates for COVID-19. The platform therefore protects both the health of the individual who may be at risk and, in some cases, public health in general.

### **Secondary Use of Health Data**

The EHDS aims to study and process health data to support health research and innovation at European level. It is essentially a secondary use of health data that aspires to lead to the prevention of cross-border health threats and the development of new treatments, medicines, vaccines, and medical equipment (Article 34 of the proposed EHDS Regulation). Access to data will be determined by authorities designated by Member States, which in turn will be responsible for assessing requests for access and data processing by other authorities. The assessment and granting of access will be carried out in accordance with security and privacy protocols (Articles 36, 37, 45 of the proposed EHDS Regulation). It is important to note that research and innovation are key to creating more resilient health systems (European Commission, 2022). Resilience has been brought into focus already in 2016 through the EU Global Strategy. Resilience is the means for the Union to achieve a common and coherent approach towards the issues of concern (Joseph et Junicos, 2019). At the societal level, resilience implies the ability of communities to resist "external shocks" through innovation (Adger 2000, p. 361). The EHDS could therefore serve as a tool to prevent and respond to future external shocks, such as a pandemic.

To achieve the objective of secondary data use, the Commission proposes the creation and use of the HealthData@EU platform (Article 52 of the proposed EHDS Regulation). Member States will authorize the bodies that will be able to make electronic health data available on the platform, provided that the body communicates its data to the Commission. Access to the platform will also be available to Union institutions and bodies that research, formulate policy or analyze developments in the health sector. It is noteworthy that third countries and international organizations can also participate in the platform, provided they respect the rules set by the EU. We note that in this platform,

too, the primary role is played by the Member States, as they are responsible for formulating public health policies and therefore decide which bodies will have access to and upload data on the HealthData@EU platform. The Commission, on the other hand, in its role, supports the Member States by providing them with both incentives and guidelines to digitalize their health systems, which is in line with its primary objective of providing a high level of quality of health services.

### **European Health Data Space Board**

Considering that the initiative to create a European Health Data Space is based on cooperation and information exchange, the Commission proposes to set up a new Board, the European Health Data Space Board (EHDS Board), which will bring together representatives of digital health authorities, health data access bodies from each Member State and other national authorities. Depending on the topic to be discussed, observers, experts, research groups and patient representatives may participate in the meetings. The EHDS is chaired by the Commission (Article 64 of the proposed EHDS Regulation). The responsibilities of the EHDS Board include coordinating Member States' digital health authorities, making recommendations to coordinate Member States for the optimal implementation of this Regulation, promoting cooperation between the digital health authorities of each Member State, taking preventive action to avoid risks and consulting with interest groups. These responsibilities relate to both primary and secondary use of health data (Article 65 of the proposed EHDS Regulation). This Board is a new intergovernmental cooperation framework that aims to better coordinate Member States around the goal of digitalizing healthcare. Digital health is gradually emerging as a tool to enhance the resilience of healthcare systems which will help improve healthcare services and strengthen the competitiveness of the EU medical sector by introducing innovations, such as telemedicine, which have the aim of improving the quality of life of EU citizens (European Commission, 2022). In the context of European integration theory, the EHDS Board as an intergovernmental cooperation framework constitutes an aspect of Spillover Effect and more specifically Spill Around<sup>4</sup> (Schmitter, 1970:846).

### **Recommendations**

- **Need for immediate adoption**

Considering the results of the public consultation on the European Health Data Space, which took place in 2021, it is significant to expedite the procedures for the vote and implementation of the EHDS Regulation. In particular, 88% of participants to the public consultation supported the use of digital

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<sup>4</sup> Spill Around is interpreted, as increasing competences in intergovernmental institutions or creating new intergovernmental cooperation frameworks (Schmitter 1970:846).

tools in order to check their health data. 83% were in favor of simplifying healthcare procedures at cross-border level between EU Member States. Finally, 89% emphasized that EU research should be strengthened on public health issues. It is noteworthy that 87% of participants argued that obstacles to the circulation of health data increase the cost of healthcare. This is confirmed by the Commission which estimates the cost at €25-30 billion/year. This cost is estimated to be doubled over the next decade. Moreover, according to Article 168 TFEU, a high level of care must be provided to citizens. In this light, EHDS comes to serve this purpose as 84% of the respondents to the public consultation consider that problems in the free movement of health data cause delays in providing the required therapy (European Commission, 2022). For all these reasons, it is deemed necessary within the first half of 2024 to have the procedures for the adoption of the proposal for a regulation on the European health data space completed, especially considering that it takes 4 years to become fully operational.

- **Exchange of good practices**

To expedite the digitalization of health services and data in the EU, it is proposed that countries with a high digitalization rate of their public services, such as Estonia, Finland, Malta and the Netherlands, contribute to the exchange of good practices with EU countries with a low digitalization rate, such as Romania, Greece and Bulgaria (European Commission, DESI 2022). This exchange of good practices can take place through the EHDS Board in which independent experts can participate in addition to Member State representatives. Thus, this Board can be a tool to accelerate digitalization in the EU health sector.

**Figure 1: Digital Economy and Society Index**



Source: European Commission, DESI 2022, Available at: <https://digital-strategy.ec.europa.eu/en/policies/desi-digital-public-services>

## Conclusions

In a nutshell, the European Health Data Space is intended to resolve the problems that existed in the access, free circulation, and use of primary and secondary health data in the EU. Its importance lies in the fact that it completes the single internal market, which has so far allowed the free movement of goods, services, capital, and people. Thus, with the creation of the European Health Data Space, the free circulation of health data will be achieved.

This proposal for a regulation should be seen as an effort to protect public health on the one hand and to strengthen the prevention and response to health threats through the effective use of primary and secondary health data on the other. At the same time, the adoption of this regulation will be another important step towards the creation of a European Health Union. Consequently, the Council and the European Parliament should proceed to the immediate adoption of the regulation, which strengthens the welfare state in the EU.

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