EU Health Union: Legal Aspects and Digital Health

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Abstract

Recurrent health crises and outbreaks of infectious diseases of international concern have created a specific EU public health policy. Its role was further strengthened by the COVID-19 pandemic, which triggered the next stage in the integration process of the Member States: the European Health Union. The research is carried out using a literature review method (a review of literature and documents in the field of public health policy and the European Health Union) and a comparative-legal method for comparing EU legal acts on which the Health Union is based (endogenous comparison) and the legal acts of EU and the Republic of Slovenia (exogenous comparison). The findings are examined using a qualitative content analysis method, which allows for meaningful aggregation and use of the data under study to answer the research questions. The European Health Union builds on and extends existing areas of public health and requires greater integration between Member States. One of its most essential pillars is a single information system with a single database to improve the health of individuals, resilience to cross-border health crises, patient mobility, and joint research on the most severe diseases. Member States, including Slovenia, must follow EU public health commitments. As the Slovenian legislative proposal analysis on the digitalization of healthcare shows, this challenging task will also require respect for the institute (safeguards) of other areas of law.

Introduction

A German proverb says that health is our greatest asset. Unfortunately, we usually only realize this when it is too late, both at the individual level and at the level of respective countries or communities of countries. Health crises and scares in the past have highlighted the importance of health and health policy, and it is only when individual crises occur that initiatives for greater cooperation to better protect against future crises begin to emerge.

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In an era marked by intertwined global relationships, the pace at which diseases emerge and spread has accelerated to unprecedented levels. Factors such as the appearance and dissemination of novel disease agents, the forces of globalization, extensive travel, the rise of drug-resistant pathogens, and the looming specter of bioterrorism all contribute to the array of potential risks in today's world. Since viruses pay no attention to national borders, safeguarding public health necessitates collaborative efforts among various countries, organizations, and institutions (European Commission, 2022). Given the gravity of these threats, it is imperative that we not only contemplate but also actively implement healthcare strategies at the individual country, community of nations, and global scales.

When the European Economic Community was established in 1957, public health was not initially recognised as one of its fundamental pillars. Over time, however, the need for health policy at the Community level became increasingly apparent. Bucher (2022) highlights that the political recognition of public health as a goal of European integration began to emerge alongside the creation of the common market. As integration progressed, there was a growing demand to integrate different aspects of public health into EU policies. While individual Member States initially sought to retain exclusive control over healthcare, many health policy components gradually became more 'Europeanised' over time. This change was driven by the single market and the free movement of goods, people, services, and capital, which required national health systems to comply with European rules. These regulations covered areas such as the safety of medicines, the quality of blood products, health technology assessment, the digitalization of healthcare, and more. Back in 1986, the Single European Act mandated that all European policies should maintain a high level of protection for people's health.

European health policy is built on a solid collaboration between the EU institutions and the Member States, respecting the diversity of national health systems that have developed over time. As clarified by the Treaty on the Functioning of the EU, complete harmonization of health legislation at the EU level is not feasible. Instead, the EU can offer support when needed.

According to Bucher (2022), the most straightforward way to conceptualize health policy is through two key pillars: public health and healthcare. Public health encompasses many areas, including health information systems for monitoring people's well-being, health promotion, disease prevention, handling health crises, and health protection through regulation. In the European Union, public health serves a dual role, addressing the care and treatment of individuals' health and preventive measures (such as joint procurement of vaccines, epidemic surveillance and response, and the secure supply of blood products). Therefore, it covers both curative and preventive aspects. Public health activities are promoted by the European Commission and the Directorate-General for Health (DG Sante). They are a mixture of binding legal acts in specific areas (e.g., control of substances of human origin), supporting activities (e.g., joint procurement such as vaccine procurement during the pandemic), and health recommendations (Greer et al., 2022).

The second pillar, healthcare, covers the organization of national health systems (hospitals, public health organizations), the financing of health services for citizens, the organization of access to these services, and the conditions for training and employment of health professionals. Health systems in each Member State are part of the social protection system, which has evolved and reflects the cultural, economic, and social characteristics of each Member State. As a result, they differ significantly from one Member State to another in terms of financing, service structure, and regulation (Federal Ministry of Health, 2016). Given these differences, the growing inequalities in access to health services, the lack of agreed funding, etc., the EU could achieve much more through greater integration in the field of health. The need for cooperation was further stimulated by the COVID-19 pandemic, which showed that no single country can tackle such cross-border challenges and problems alone (Fraundorfer & Winn, 2021). This is why the call for a European Health Union (European Commission, 2022) was first highlighted in the speech of the President of the European Commission in October 2020. Historically, this represents the next stage in the integration process of the Member States.

As the central research question, we emphasize the impact of healthcare reform or the establishment of the European Health Union on EU health policy and, consequently, healthcare systems within Member States. To address this, we will examine the EU's legislative framework, which laid the foundation for the European Health Union. The latter primarily relies on regulations which, in the classification of legal sources in the European Union, fall under secondary sources of law. Regulations are acts of unification, meaning they bring uniformity to the law in member states, as opposed to directives, which merely harmonize it (Bratina et al.,

2018). This highlights the EU's dedication to the importance of reforming health policy. We will specifically focus on one of the main pillars of the Health Union - the European Health Data Space. Therefore, as our second research question, we have posed the question of how Slovenia is adhering to the requirements of the European Health Union in the digitalization of healthcare systems or whether it is following the requirements for creating the European Health Data Space. To find the answer, we will compare the EU acts with the Healthcare Digitalisation Bill in Slovenia, which is currently under consideration in the National Assembly of the Republic of Slovenia.

Literature Review

This section overviews key literature, research, and policy documents on public health in the EU and the European Health Union.

The idea of a health union emerged in 1952 when the first European Coal and Steel Community was established. Still, it did not develop further because of security and economic union priorities. Health remained on the sidelines, and the EU has no standard body or institution in public health (Nabbe & Brand, 2021).

The scope of public health for which the EU is responsible has evolved over the years (Greer & Jarman, 2021). The Maastricht Treaty of 1992 established that the EU should be more competent in health, and environmental and consumer protection legislation was introduced accordingly. The Amsterdam Treaty of 1997 (which came into force in 1999) established new EU competencies in public health, the supply of blood products, and animal and plant health policies that affect public health. The next step in public health protection was the control of agriculture and the food system, and in 2002, the European Food Safety Authority was established. The Lisbon Treaty of 2007, according to Bucher (2022), set essential parameters in the field of public health and requirements for the unification of safety standards in specific areas.

European public health law and policy began to develop as a distinct field about 20 years ago. Fraundorfer & Winn (2021) note in their study that the development of a common European public health policy has been strongly influenced by emerging health crises and outbreaks of infectious diseases (anthrax, SARS) of international proportions. Nabbe & Brand (2021) also note that past health crises have demonstrated the importance of joint action to prevent health crises. As a result, the European Centre for Disease Prevention and Control (ECDC) was established in 2005 to operate at the EU level. The European Commission has taken on an informal role as the focal point for public health protection, coordinating communication and activities to improve pandemic preparedness.

Between 2007 and 2017, the EU started promoting cross-border healthcare cooperation through various projects. Schmidt et al. (2022) analyzed 400 incentives and projects from this period. They found that in most cases, geographical and cultural-social factors, rather than economic ones, were decisive for cooperation and that further cooperation between Member States would positively impact the development of the Health Union and the improvement of public health policy. The need to develop an information system that enables sustainable and integrated health data in the EU was highlighted in a study by Bogaert & Van Oyen (2017). eHealth can benefit patients, doctors, and the health system (Ardielli, 2020). A common information system would allow better and more extensive data sharing, enabling better and more comparable research, international comparisons, and national and European health surveillance (Bogaert & Van Oyen, 2017).

In responding to the pandemic, the EU has already acted as a supranational organization, bringing together the leading institutions in positive cooperation. Pre-existing crisis response and communication programmes were used, and significant policy decisions were made without lengthy public consultations. Quaglia & Verdun (2023) assess that the EU response was highly successful in terms of three criteria - perception of potential threats, mobilization of scarce resources, and legitimacy of the response - and could lead to greater integration. The pandemic demonstrated that such shocks can contribute to further progress in developing the EU and its institutions.

The Bucher study (2022) also pointed out that the EU could benefit significantly from greater integration in public health. The EU has increased the scope for intergovernmental cooperation on public health threats by establishing the European Health Emergency Preparedness and Response Authority (HERA). The study suggests that this cooperation should be further strengthened to include issues like the fight against antimicrobial resistance. The study also indicates that the EU should better organize, coordinate, and unify knowledge on health protection measures and more systematically introduce legislation on public health policies. Support for developing digital services in public

health or developing a European Health Data Space is highlighted as very important, as this will be the central infrastructure for future health research.

Fraundorfer & Winn (2021) emphasize that the European Health Union aims to strengthen preparedness for pandemics and international health crises. This includes improving and reinforcing existing measures developed in response to past crises, supporting the European Medicines Agency (EMA) and the ECDC authorities, and establishing a new agency called HERA. These three organizations will focus on improving pandemic preparedness, surveillance, and control and ensuring medical countermeasures under the supervision of the European Commission. Nabbe & Brand (2021) also emphasize that to build a robust health union, it is essential to strengthen existing agencies' roles (ECDC and EMA) and establish a new one to cover preparedness for future crises, improved response, surveillance, and data exchange.

A common health information system and a single health data space are also crucial to the European Health Union. In 2021, the EU launched a joint action for a European health data space - Towards the European Health Data Space (TEHDAS). The effort brings together 22 Member States and four other European countries. The joint action aims to support the European Commission in establishing the European Health Data Space. To realize the full potential of health data, in May 2022, the EU presented the Proposal for a Regulation on the European Health Data Space (COM(2022) 197/2), in which it

- supports individuals to take control of their health data;
- supports the use of health data for better healthcare, research, innovation, and policy-making;
- enables the EU to fully exploit the potential of secure and reliable exchange, use, and secondary use of health data (European Commission, 2023).

The European Health Data Space (EHDS) is one of the key foundations of the European Health Union and the first EU common data space in a specific domain. It is based on strict requirements for data protection, interconnectivity, and security, including cybersecurity, which are crucial for the trust of EU citizens and the stability of the project. It brings together national organizations responsible for eHealth and tasks related to patient access to health data. The European Health Data Space proposal would replace Article 14 of the CBHC Directive with an entirely new set of binding rules for using and reusing health data. Given the highly sensitive nature of data relating to an individual's health, the European Health Data Space must fully comply with all the requirements of the General Data Protection Regulation (GDPR) and the EU Data Protection Regulation (EUDPR) (European Commission, 2023).

Slovenia also follows the trend of digitalizing healthcare and unifying information systems to make EU data more consistent and accessible. In January 2023, the Ministry of Health (2023) presented the Strategy for the Digitalisation of Healthcare in Slovenia for 2022–2027. Through the strategy, Slovenia aims to enable better control of the digital healthcare system and simplify the flow of data for better patient care. The main goal is that by 2027, eHealth will be patient-centered and enable better health for all Slovenian citizens. Patients are placed at the centre; work is being done to enhance the connectivity of existing information systems and databases, ultimately leading to greater efficiency and better control and management of the healthcare system. This has been followed by the Healthcare Digitalisation Bill of June 2023, which brings essential innovations for patients and healthcare professionals to make the healthcare system work more efficiently (Ministry of Health, 2023).

The final steps towards the completion of the European Health Union will be the legislative acts adopted at the end of 2022 (presented in more detail in the next section), which will provide the legal framework for improving the EU's capacity in the key areas of prevention, preparedness, surveillance, risk assessment, early warning and response to current health problems and the health of EU citizens, as well as to cross-border health crises (European Commission, 2022).

Methodology

The study will use qualitative research methods. Data collection will be carried out using the technique of reviewing existing literature and documents to provide an overview of the literature, the legal framework, and the opinions of individual researchers on the European Health Union and the development of EU public health policy. We will examine the EU legal framework through a comparative legal analysis, comparing the EU legal acts on which the Health Union is based (Pavcnik, 2020). The comparison will be twofold, with an endogenous aspect, as it will take place within the framework of EU law, and an exogenous dimension, as we will also make comparisons of the Proposal for a Regulation on the European Health Data Space of 3 May 2022, resulting from the European Data Strategy, with Slovenian

legislation, more specifically with the Slovenian Healthcare Digitalisation Bill of June 2023. We will further explore the findings using the qualitative content analysis method, which allows for a meaningful synthesis and use of the data studied to provide answers to the research questions (Yin, 2009). In addition, we will synthesize the findings to provide solutions to the research questions. Data are collected from official and public EU (Eur-lex) and Slovenian (gov.si and pisrs) websites.

Results and Discussion

Our literature review has revealed that EU legislators have enacted various legislative acts to strengthen the European Health Union, as outlined in Table 1. Notably, these legislative measures primarily aim to enhance the authority of existing health agencies, thus emphasizing the EU's engagement in public health and reinforcing its preparedness for potential future health crises.

Table 1
Basic legal acts for the establishment of the European Health Union

Title of the act	Date of adoption	Main orientations
Regulation on a reinforced role for the European Medicines Agency	1/3/2022	Build a strong European Health Union; Enhance the role of the EMA in crisis preparedness and management for medicines and medical devices; Facilitate a coordinated response to public health crises at the EU level; Enable faster authorization of medicines.
Regulation on serious cross-border threats to health	23/11/2022	A preparedness planning system and a more comprehensive threat monitoring system; Establishing an early warning and response system; Improving capacity for accurate risk assessment and targeted response; Establishing mechanisms for joint procurement of medical countermeasures; Common action at the EU level is possible to address future cross-border health threats.
Regulation amending the Regulation establishing a European Centre for Disease Prevention and Control (ECDC)	23/11/2022	The primary purpose is to enable the ECDC to identify, assess, and report on current and emerging threats to human health promptly; To make recommendations on measures to control disease outbreaks; To provide state-of-the-art epidemiological surveillance of infectious disease outbreaks based on common standards and definitions; To operate an early warning and response mechanism; To establish a network of reference laboratories for crisis consulting on emerging pathogens.
Regulation on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at the Union level	24/10/2022	Improve the EU's rapid response capacity to crises; Establish a Health Crisis Board; Rapidly coordinate the supply of and access to medical countermeasures at the EU level; It enables the activation of the instruments of the network of 'ever-warm' production capacities for vaccine and medicine manufacturing (EU FAB) and emergency research and innovation plans, as well as access to their funding; Ensure the development and equitable distribution of key medical countermeasures to fill gaps in their availability and accessibility.

Source: Authors' own elaboration

Table 2 shows the main areas of public health policy before and after the creation of the European Health Union. We can see that all areas will be strengthened, with particular emphasis on developing information systems and databases to allow the free flow of health data and thus better patient mobility, joint research on the most severe diseases, increased resilience to cross-border health crises, etc.

Table 2
Overview of public health policy areas

Public health area	Before the Health Union	After the creation of the Health Union
Healthcare information systems	eHealth; voluntary database; no links between Member States' systems	A common European health data space; A better basis for public health policy-making; Benefits for human health
Use of health data for research purposes (secondary use)	Very poorly or not used	In our opinion, developing the common health data space will significantly enhance this potential.
Health promotion and disease prevention	Common databases for communicable disease surveillance; Screening tests	further strengthened by the Cancer Plan; More integrated options to fight non-communicable diseases, antimicrobial resistance, and health inequalities; Reinforced by increased powers for the ECDC; Included in at least 20% of the resources of a new health programme
Prevention and control of cross-border threats		Strengthened by the new authority HERA and increased powers for ECDC
Prevention and management of health crises		Strengthened by the new authority, HERA
Patient mobility	It is also supported through eHealth; it is not 100% operational due to poor connectivity between eHealth systems	It will be improved through better information flow within the common health data space
Free movement of healthcare personnel	Secured through the free movement of workers	Secured through the free movement of workers
Ensuring standards for quality and safety in the field of health (human samples, organs, animals, plants, medical products, and devices)	Unified EU standards based on the Lisbon Treaty	Common standards of healthcare will further enhance this to reduce health inequalities.

Source: Authors' own elaboration

As shown in Table 2, the common health information system will be an essential part of the European Health Union. It will be based on the common Health Data Space, which the EU intends to establish through a regulation proposed by the Commission in May 2023. Slovenia follows the EU requirements for the digitalization of healthcare through its Healthcare Digitalisation Bill.

Table 3 shows the main highlights of the Proposal for a Regulation on the European Health Data Space and the Healthcare Digitalisation Bill. We note that the Healthcare Digitalisation Bill follows the Proposal for a Regulation on the European Health Data Space in several areas. It aims to put in place a central collection of all health data, promotes the exchange of health data for healthcare (patients and healthcare professionals will have access to the data), and provides access to health data for secondary use. In particular, there is a strong emphasis on strengthening the right of individuals to access their health data and facilitating the free flow of such data, which is also one of the priorities of the Proposal for a Regulation on the European Health Data Space.

The Legislative and Legal Service and the Information Commissioner provided their opinions on the Bill. The Legislative and Legal Service (2023) assessed the Bill for its compliance with the constitution, legal system, and legislative and technical aspects. At the same time, the Information Commissioner expressed various concerns regarding the Bill.

The Bill is characterised by ambiguity, uncertainty, and even unconstitutionality in some parts. In the opinion of

Table 3
Comparison between the Proposal for a Regulation on the European Health Data Space and the Healthcare Digitalisation Bill

Proposal for a Regulation on the European Health Data Space	Healthcare Digitalisation Bill
It is based upon: General Data Protection Regulation (GDPR), proposed Data Governance Act, draft Data Act, Directive on the security of network and information systems	Transposition of Directive 2011/24/EU on the application of patient's rights in cross-border healthcare, as last amended by the Regulation on Health Technology Assessment in December 2021
To establish a single market for digital health services	Setting up a wholly state-owned company to develop and maintain the central electronic health system
To strengthen the rights of individuals to control their health data and to support the free flow of such data	Putting the patient at the centre of healthcare, enabling individuals to access their health data, special care for digitally illiterate persons
To promote the exchange of health data for healthcare purposes	All health records will be collected in digital form in a national single health card, an obligation of all providers to transmit documents to a central electronic health record
To facilitate access to health data and promote secondary use for research, innovation, and policy-making purposes.	Data is accessible through a central health information system; access will be available to patients and healthcare professionals
To allow for innovative health products and services based on health data use and secondary use of health data.	Data control facilitates health policy planning; access to health data for research, innovation, policy-making, official statistics, patient safety and regulatory activities will be provided.

Source: Authors' own elaboration

the Legislative and Legal Service (2023), the Bill is vague and indefinite about processing, the purposes of processing and storage of personal data, the scope of data to be collected, the entire data flow of processing and collection of data, further processing and storage of data. This raises doubts as to its compliance with Article 38 of the Constitution of the Republic of Slovenia (Right to protection of personal data) and Article 34 of the Constitution of the Republic of Slovenia (Right to personal dignity) (Constitution of the Republic of Slovenia, 1991). In addition, the Bill does not specify who is responsible for managing the Central Health Information System (only who should implement it) and does not define the relationship between database controllers.

According to the Information Commissioner (2023), the stakeholders' tasks, responsibilities, and competencies (National Institute of Public Health and Health Insurance Institute of Slovenia, Ministry of Health) are insufficiently defined.

A significant dilemma arises in particular about establishing the Central Health Information System operator, a legal entity governed by public law and a limited liability company. It is, therefore, a new legal form of organization. In the opinion of the Legislative and Legal Service (2023), this chosen legal form is poorly explained. Aspects such as controlling the company's activities, its purpose and activities, and its relationship with the Ministry are also insufficiently specified. In the part where the tasks to be performed by the operator are described, it is clear that they partly overlap with the functions already performed by the National Institute of Public Health. The Information Commissioner (2023) also points out that a large amount of personal data will be managed by a company that could operate as a private entity, which would pose a significant risk to the rights of individuals, as private entities are subject to different conditions and requirements regarding the protection of personal data. All this makes it necessary to reconsider the provisions relating to the Central Health Information System operator.

The Healthcare Digitalisation Bill is still under consideration in the National Assembly and is awaiting approval. In any event, it will have to be reviewed and amended by MPs in light of the concerns expressed by the Legislative and Legal Service and the Information Commissioner.

Conclusion

The COVID-19 pandemic has revealed that the EU's mechanisms for dealing with health threats are generally inadequate, and these issues will likely worsen in the future if the EU does not take action. Cooperation is essential to effectively address emerging challenges in the future. Consequently, the EU has initiated the establishment of a robust European Health Union, which aims to unite Member States in preparing for and responding to health crises and collaborating to enhance prevention, treatment, and follow-up.

In response to the first research question, our research demonstrates that creating the European Health Union will strengthen the EU's role in public health policy. While health systems will continue to vary among Member States, this reform will grant the EU a more prominent position as a supranational authority. It will achieve this by expanding the authorities of key agencies (EMA, ECDC, HERA), implementing health and global strategies, and establishing a more comprehensive European health data infrastructure. By comparing the main features of the four fundamental acts adopted to establish the European Health Union, we have illustrated that they represent a significant enhancement and improvement in public health policy when contrasted with the situation before the creation of the European Health Union.

One of the key issues was the creation of a common health data space, which will be one of the main building blocks of the European Health Union. In particular, common rules must be established on the information base and the data format to be collected. Only mutually comparable data can provide a reasonable basis for making the right decisions about individual health and a reasonable basis for making the right decisions in the field of public health policy.

The second research question focused on whether Slovenia meets the European Health Data Space requirements. The survey found that with the latest legislative proposals in the field of public health policy, Slovenia is also following the EU's lead and working to improve the digitalization of healthcare, establish a network of reference laboratories as proposed by the EU, and increase preparedness for possible future health crises. The digitalization of healthcare, which has been increasingly emphasized in recent months, will significantly impact the quantity and quality of health data. Policymakers have also realized that only good, consistent data can provide a reasonable basis for sound policy decisions. While the Bill is still under review and will need to be adapted in the light of the opinion of the Legislative and Legal Service and the Information Commissioner, we remain optimistic that decision-makers will be able to amend it appropriately. As we have shown, there are many benefits to be gained from digitalizing healthcare, both in terms of public health policy and at the level of individuals and their health.

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Zdravstvena unija EU: pravni vidiki in digitalno zdravje

Izvleček

Ponavljajoče se zdravstvene krize in izbruhi nalezljivih bolezni mednarodnih razsežnosti so privedli do oblikovanja posebne politike EU, politike javnega zdravja. Njeno vlogo je še dodatno okrepila pandemija COVID 19, ki je sprožila naslednjo stopnjo v integracijskem procesu držav članic: Evropsko zdravstveno unijo. Raziskavo smo izvedli z metodo literarnega pregleda (pregled literature in dokumentov na področju politike javnega zdravja in Evropske zdravstvene unije) ter s primerjalno-pravno metodo, s katero bomo medsebojno primerjali pravne akte EU, na katerih temelji zdravstvena unija (endogena primerjava) ter pravne akte EU in RS (eksogena primerjava). Ugotovitve smo proučili z metodo kvalitativne analize vsebine, ki omogoča smiselno združevanje in uporabo proučevanih podatkov za pridobivanje odgovorov na raziskovalna vprašanja ter jih z metodo sinteze strnili v odgovor na raziskovalni vprašanji. Evropska zdravstvena unija vsebinsko nadgrajuje in razširja obstoječa področja javnega zdravja ter od držav članic zahteva večjo stopnjo integracije. Eden njenih pomembnejših stebrov je enoten informacijski sistem z enotno bazo podatkov, ki bo omogočal izboljšanje zdravja posameznikov, odpornost na čezmejne zdravstvene krize, mobilnost pacientov ter skupne raziskave najtežjih bolezni. Zavezam EU na področju javnega zdravja morajo slediti države članice, vključno s Slovenijo. Kot izhaja iz analize slovenskega zakonodajnega predloga s področja digitalizacije zdravstva, bo pri tej zahtevni nalogi morala spoštovati tudi institute (varovala) drugih pravnih področij.

Ključne besede: Evropska zdravstvena unija, javno zdravje, evropski podatkovni prostor, zdravstveni informacijski sistem, zakonodajni okvir