

UDK: 614 : 004 (497.5)
342.721 : 614 (497.5)
Review paper

Ana-Marija Kraljik, PhD student
Faculty of Law, University of Osijek, Croatia
E-mail: ana-marija.kraljik@obz.hr
ORCID ID: 0009-0009-4730-0549

EUROPEAN HEALTH DATA SPACE - A NEW APPROACH TO THE DIGITAL TRANSFORMATION OF THE EUROPEAN UNION

ABSTRACT

Digital transformation is the most important factor in the further economic, technological, security and international strengthening of the European Union. The first common European data space of the European Union relates to health and the protection of health data. This paper examines the current state of health data protection of citizens of the Republic of Croatia in the context of other EU member states. The paper analyzes the impact of technological innovations on the security of health data processing, ie their interoperability. The risks and challenges related to the security of health data processing in the context of technological innovations are assessed. In conclusion, the potential contribution of the European health data space is determined and recommendations are made for improving the security of health data with new digital solutions.

Keywords: Regulation (EU) 2025/327, public health, European Union.

1. INTRODUCTION

The European Health Data Space (EHDS) is a key initiative of the European Union (EU) aimed at the digital transformation of the healthcare sector. The aim of the EHDS is to establish an integrated system that enables secure access, exchange and reuse of health data across the EU, thereby stimulating innovation, research and improving healthcare.¹ Digital transformation has become an indispensable part of modern society, permeating all aspects of life, including the healthcare

¹ The European Health Data Space (EHDS) is an important pillar of a strong European Health Union and is the first common EU data space for a specific area to emerge from the European Data Strategy, https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space_hr, 17.01.2025.

sector.² The EU has recognised the need to integrate digital technologies into healthcare systems in order to improve the quality of care, increase efficiency and enable personalised medicine. In this context, the EHDS represents a fundamental initiative for achieving these goals.³ The paper presents the legal framework of the EHDS at the EU level and provides a comparative overview with the Republic of Croatia (RC). The topic of the implementation of the new Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Area and amending Directive 2011/24/EU and Regulation (EU) 2024/2847 (hereinafter: the EHDS Regulation) is addressed, which enables better access for patients and healthcare professionals to comprehensive and up-to-date health data regardless of geographical borders.⁴ Finally, the paper presents initiatives and provides guidelines for further action and harmonisation of the Croatian healthcare sector in promoting further digitalisation, interoperability, and primary and secondary processing of patient health data within the EHDS. The problem-based research paper presents individual open provisions important for the primary and secondary use of health data regulated by the EHDS Regulation.

2. EUROPEAN HEALTH DATA SPACE – LEGAL FRAMEWORK

The EHDS legal framework should be clearly demarcated into horizontal-vertical legal legislation that forms the backbone of the legal framework within which primary and secondary processing of health data in the EU operates.⁵ Within the

² European Declaration on Digital Rights and Principles for the Digital Decade COM (2022) 28 final "Digital transformation is also a challenge for our democratic societies, our economies and for individuals. As the digital transformation is accelerating, it is time for the EU to make clear how its values and fundamental rights that apply offline should apply in the digital environment. Digital transformation should not lead to a regression of rights. What is illegal offline is also illegal online."

³ Council Conclusions on Strengthening the European Health Union (14029/21) "Continued and coordinated strategic investments in improving health systems will strengthen their resilience and optimize healthcare in the future. While they play a crucial role in overcoming current and future health challenges, health systems are also crucial for the development of our societies and economies.", 30.11.2021, Brussels.

⁴ Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a Programme of the Union's action in the field of health (EU4Health Programme) for the period 2021–2027 and repealing Regulation (EU) No. 282/2014, OJ L 107, 26 March 2021.

⁵ European Commission, *Assessment of EU Member States' rules on health data in the context of the General Data Protection Regulation*, 2021, <http://ec.europa.eu>, 17 February 2025.

horizontal legal legislation, in addition to the General Data Protection Regulation,⁶ the Directive on Cross-Border Healthcare stands out.⁷ The Directive on Cross-Border Healthcare mentioned the term e-health for the first time in EU legislation,⁸ marking the beginning of a digital reform in the field of digitalisation of healthcare. Given that the provisions of the Directive on Cross-Border Healthcare are applied voluntarily, this explains why the Directive has shown limited effectiveness in terms of processing electronic health data. The evaluation of the Directive's e-health provisions concluded that its effectiveness and efficiency are quite limited due to the voluntary nature of the actions related to the e-health network.⁹ In addition, the use of personal electronic health data for primary purposes in the context of cross-border healthcare is progressing slowly. The MyHealth@EU platform¹⁰ has been introduced in only 10 Member States and currently supports only two services (electronic prescription and patient medical summary). The weak and slow implementation is partly linked to the fact that the Cross-Border Healthcare Directive, while establishing the right of individuals to a written record of their treatment, does not require that medical records be in electronic form. Individuals' access to their personal electronic health data remains difficult and individuals have limited control over their health data and the use of that health data for medical diagnosis and treatment. The eHealth Network recommended that Member States implement standards and specifications for the exchange of electronic health records in their procurement procedures in order to achieve interoperability. However, their actual implementation of this format has been limited, leading to a fragmented environment and unequal access to and portability of electronic health data. On the other hand, the EHDS, as part of the overall EU data policy strategy, is designed to complement other EU legislation, including the General Data Protection Regulation.¹¹ The EHDS also aims to develop vertical legal regulation, which is *a conditio sine qua non* for an efficient,

⁶ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), OJ L 119, 4 May 2016,

⁷ Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare, OJ L 88, 4 April 2011.

⁸ Article 14 of the Directive on cross-border health care: "The Union supports and facilitates cooperation and exchange of information between Member States operating within a voluntary network connecting state bodies responsible for e-health, designated by Member States".

⁹ Regulation of the European Parliament and of the Council on the European Health Data Space, No. 2022/0140,

¹⁰ The cross-border infrastructure for the primary use of electronic health data is regulated by Article 13 of the proposal of the General Data Protection Regulation (My Health@EU).

¹¹ Hansen, J. et al., Assessment of the EU Member States' Rules on Health Data in the Light of GDPR, 2021, https://ec.europa.eu/health/system/files/2021-02/ms_rules_health-data_en_0.pdf, 17 February 2025.

cost-effective and effective public health sector. Among the vertical regulations that are important for the functioning of the EHDS, we can single out sectoral regulations, among which the Regulation on serious cross-border threats to health stands out,¹² which is important for establishing an epidemiological framework in the event of new public health crises. Given that a large number of electronic data that will be accessed within the EHDS are personal health data, the EHDS Regulation was designed as the core of the legal framework together with the Regulation on the protection of individuals with regard to the processing of personal data by the institutions, bodies, offices and agencies of the Union.¹³ The importance of harmonizing the horizontal-vertical legal framework related to the primary and secondary processing of individual health data is a factor without which the story of a single European data space within the European Health Union cannot succeed. Time will tell how pretentious the plan of the EU and its institutions is aimed at the right of individuals to access their own personal electronic health data.¹⁴

3. IMPLEMENTATION OF THE REGULATION ON THE EUROPEAN HEALTH DATA SPACE AND OPEN PROVISIONS

The EHDS Regulation represents a key legislative framework for ensuring the interoperability of health data in the EU at a vertical level. In order to implement the provisions of the EHDS¹⁵ Regulation into the legal system of the Republic of

¹² Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No. 1082/2013/EU., "In view of the experience gained during the current COVID-19 pandemic and in order to facilitate adequate preparedness and response at Union level to all cross-border threats to health, it is necessary to extend the legal framework for epidemiological surveillance, monitoring, early warning and combating serious cross-border threats to health."

¹³ Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of individuals with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No. 45/2001 and Decision No. 1247/2002/EC, OJ L 295, 21 November 2018.

¹⁴ The slogan of the EU "*United in diversity*" shows in the best way that in a legally uneven system like the EU, a way should be found to find an interoperable way of exchanging and processing health data within the EHDS.

¹⁵ Law on data and information in healthcare "Narodne novine" No. 14/19., Ordinance on the scope and content of data and on the manner of keeping e-Karton "Narodne novine" No. 74/23., Ordinance on the manner of processing health and other personal data in health national and institutional information systems in healthcare, methods of storing and protecting health data and creating health indicators, standardized forms and registers and records in healthcare "Narodne novine" No. 150/24. and Rulebook on procedural, technical,

Croatia in terms of open provisions, it is necessary to harmonize national legislation, primarily existing laws such as the Health Data and Information Act and implementing secondary legislation. This is evident from the key provisions of the EHDS Regulation related to the individual's right and their *primary use* of personal electronic health data, these are the provisions defined in Articles 3, 8, 10 and 11, which regulate; the individual's right to access their own personal electronic health data (Article 3), the right to restrict access (Article 8), the individual's right to be excluded from primary use (Article 10) and access by healthcare professionals to personal electronic health data (Article 11). In addition to the above, the key provisions of the EHDS Regulation are set out in Articles 53 and 71 of the EHDS Regulation, which relate to the purposes for which electronic health data may be processed for secondary use (Article 53) and the right to object to the processing of personal electronic health data for secondary use (Article 71). Relying on the provisions of the General Data Protection Regulation, which lay down specific provisions on the rights of individuals with regard to the processing of their personal data, in particular the right of individuals with regard to the processing of their personal data.¹⁶ The EHDS Regulation builds on these rights and supplements some of them. Thus, the EHDS Regulation defines personal and non-personal electronic health data.¹⁷ Furthermore, Article 3 of the EHDS Regulation establishes that individuals have the right to access personal electronic health data belonging to priority categories and which are processed for the purpose of providing healthcare through electronic health data access services, free of charge. In accordance with Article 23 of the General Data Protection Regulation, Member States may limit the scope of the right, in particular where restrictions are necessary for reasons of patient safety and ethical requirements. Here, *the de lege lata* link between horizontal and vertical legal regulations is clearly visible. In practice, the right to access health data is still provided in many places in paper form or in the form of scanned documents. On the other hand, the EHDS Regulation promotes electronic access to health data and implies an immediate response or fulfillment of requests for access.¹⁸ However, in practice, it is necessary to allow for the postponement of the provision of access to electronic health data if they would be harmful to the safety of individuals or unethical.¹⁹ One of the provisions of the EHDS Regulation is regulated by Article

organizational and semantic data processing standards for professional and business areas in healthcare "Narodne novine" No. 117/24.

¹⁶ Article 2 of the EDPS Regulation: "1. For the purposes of this Regulation, the following definitions shall apply: (a) the definitions of "personal data", "processing", "pseudonymisation", "controller", "processor", "third party", "consent", "genetic data", "data concerning health", "international organisation" set out in points 1, 2, 5, 7, 8, 10, 11, 13, 15 and 26 of Article 4 of Regulation (EU) 2016/679."

¹⁷ Article 2, points a) to c) of the General Data Protection Regulation.

¹⁸ Recital 9 of the EDHS Regulation.

¹⁹ Recital 10 of the EDHS Regulation, *ibid.* Article 3, paragraph 3.

10, which speaks of the right of an individual to be exempted from primary use. However, selective sharing of personal electronic health data should be supported and implemented only in cases where individuals are aware of the risks to which they are exposed or which are related to the safety of the patient. On the other hand, the unavailability of limited personal electronic health data for healthcare professionals may affect the provision of healthcare services to the individual. Therefore, if restrictions on access to personal electronic health data could have life-threatening consequences, healthcare professionals should be allowed access to such data.²⁰ It is recommended that Member States enact provisions in their national law on mechanisms that restrict individuals' access to parts of their electronic health data. In the Republic of Croatia, it is first necessary to enact the Act on the Implementation of Regulation (EU) 2025/327 of 11 February 2025 on the European Health Data Area and amending Directive 2011/24/EU and Regulation (EU) 2024/2847, and to enact a subordinate legislation related to supplementing the so-called open provisions of the EHDS Regulation. In particular, the rights of healthcare professionals with regard to exemptions from primary use in the case of cross-border data exchange. Namely, such exemptions as well as the right of an individual to restrict access to healthcare professionals and healthcare providers to all of their electronic health data pose a risk to both the individual and the public health. In that case, Member States must establish rules and specific safeguards for such restriction mechanisms.²¹ As stated in the Republic of Croatia, it is necessary to enact a subordinate legislation establishing rules and safeguards. As already indicated, three subordinate legislations are in force regulating e-health, namely: the Ordinance on the method of processing health and other personal data in national and institutional health information systems in healthcare, the method of storing and protecting health data and creating health indicators, standardized forms and registers and records in healthcare, the Ordinance on process, technical, organizational and semantic standards of data processing for professional and business areas in healthcare, and the Ordinance on the scope and content of data and the method of maintaining e-Cards. Given that they changed during 2023 and 2024, they need to be amended again, as does the Act on Data and Information in Healthcare from 2019. Given that the EDHS Regulation enters into force on 25.03.2025. and that it applies from 26.03.2027., Croatian and European experts and legislators have enough time to adapt the same legal regulations. Contributions are also possible through EU

²⁰ Article 9(2)(c) of the General Data Protection Regulation.

²¹ In Article 71(1) of the EHR Regulation, an individual has the right to object at any time and without giving reasons to the processing of personal electronic health data relating to them for secondary use. However, in paragraph 4 of the same Article, an exception to the right to object is established, whereby a Member State may provide in its national law for a mechanism for making available data in respect of which the right to object has been exercised for specified reasons.

projects implemented by the Croatian Institute of Public Health and the Croatian Institute of Health Insurance. In order to further improve the implementation of the open provisions of the EHDS Regulation, it is necessary to determine the body and its role in the implementation of the EHDS Regulation through national law in the Republic of Croatia.²²

Furthermore, as far as positive legal regulations are concerned, we should first of all single out the Health Care Act and the Patient Rights Protection Act,²³ which regulate that healthcare activities are performed at the primary, secondary and tertiary levels and at the institution level.²⁴ It is important to point out that the healthcare system in the Republic of Croatia is based on the principles of social insurance, i.e. the compulsory social health insurance model based on contributions from wages.²⁵ Precisely because it is based on compulsory health insurance, it has the characteristics of the Bismarck model.²⁶ In addition to the above, the cost-effectiveness assessment system in Croatia is not fully developed, which leads to the fact that cost-effectiveness criteria are not taken into account when making decisions, which reduces the likelihood of providing quality care. In addition to the financial part, the legal and institutional framework needs to be adjusted in a timely manner and more agile and up-to-date activity in numerous EU projects related to the EHDS needs to be encouraged.²⁷ However, there is

²² Each member state appoints one or more digital health authorities responsible for the implementation and enforcement of the primary use of health data, Article 19 of the EHDS Regulation.

²³ Health Care Act, Official Gazette, No. 100/2018, 125/2019, 133/2020, 147/2020, 136/2021, 119/2022, 156/2022, 33/2023, 145/2023, 36/2024; and Act on the Protection of Patient Rights, Official Gazette, No. 169/2004, 37/2008.

²⁴ Article 28 of the Health Care Act reads: "Healthcare activity is an activity of interest to the Republic of Croatia that is performed as a public service and that is performed by healthcare workers in accordance with professional medical doctrine and with the use of medical technology when providing healthcare, under the conditions and in the manner prescribed by this Act.", <https://www.iusinfo.hr/zakonodavstvo/zakon-o-zdravstvenoj-zastiti/clanak-28>, 24.02.2025.

²⁵ Malešević, A., *Digital Health in Croatia: Expectations, Challenges and Implementation*, Doctoral Thesis, Sociology: Values, Identity and Social Changes in Croatian Society, Zagreb, June 2024.

²⁶ Health systems are often described by their predominant source of financing (e.g. "Bismarckian" social health insurance systems, general "Beveridge" tax-financed systems), <https://repo.ozs.unist.hr/islandora/object/ozs:1579/datastream/PDF/view>, 24.02.2025.

²⁷ One of the current European projects is CHDC, the Croatian Health Data Centre, about which you can read more or less on the website of the Croatian Institute of Public Health. In November 2023, the Croatian Institute of Public Health launched the establishment of the Croatian Health Data Centre (HZCP). The planned duration of the project is 4 years, financed through the EU Direct Grant, and three institutional partners are participating in the implementation: the Croatian Institute of Public Health as the project leader and the Croatian Institute of Public Health (HZZO) and the Ministry of Health (MiZ) as associated partners. The CHDC will connect to the HealthData@EU infrastructure to enable cross-border workflows for the secondary use of electronic health data at the European Union

scientific research by relevant experts in the field of personal data protection; e-card, e-health, the application of artificial intelligence in healthcare and data and information management in healthcare, which significantly helps to better understand and implement European law.²⁸ However, the data on measuring the satisfaction of health service users is worrying, which is also reflected in the establishment of an interoperable public health framework within the EHDS. Among others, it is important to highlight the Health Care Quality Act.²⁹ It is important to highlight that the Compulsory Health Insurance Act transposes the provisions of Directive 2011/24/EU of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare.³⁰ The Health Care Act also states the transposition of Directive 2011/24/EU into Croatian legislation.³¹ In this context, the Croatian Institute for Health Insurance (hereinafter referred to as HZZO) acts as a national contact point for providing information on the use of health care in other EU member states.³² In conclusion, the Republic of Croatia, or rather the competent institutions, can only solve the problems of adaptation and interoperability of the Croatian health system through interdisciplinary teamwork and timely involvement in its implementation. *De lege ferenda*, the Republic of Croatia needs an operable, efficient and effective way of acting for the satisfactory implementation of the EHDS Regulation.

(EU) level. Furthermore, CHDC will actively cooperate with already established Health Data Access Authorities (HDABs) and Member States that are in the process of establishing HDABs, relevant networks and other stakeholders to facilitate access to secondary use of health data and participate in the exchange of health data at the EU level, <https://www.hjz.hr/projekti/hrvatski-centar-za-zdravstvene-podatke-eng-croatian-health-data-centre-chdc/>, 24.02.2025.

²⁸ Boban, M., *E-card – challenges of implementation and protection of patients' personal data*, in: 4th "KOKOZ" Congress and 6th Croatian Congress of Medical Law with International Participation, Novi Vinodolski, 2023, pp. 147–177.; Boban, M., *Personal data protection and the new EU data protection regulation*, Bulletin of the Croatian Medical Informatics Society, vol. 24, no. 1, 2018, pp. 26–40.; Boban, M., *Data and information management in health information systems of the Republic of Croatia – security, protection and responsibility*, in: *Medicina, pravo & družba, Proceedings*, Maribor, 2021, pp. 211–233.

²⁹ Law on the Quality of Health Care, Official Gazette No. 118/18 and 40/2025.

³⁰ Compulsory Health Insurance Act, Official Gazette, No. 80/2013, 137/2013, 98/2019, 33/2023.

³¹ Health Care Act "Official Gazette" No. 100/2018, 125/2019, 133/2020, 147/2020, 136/2021, 119/2022, 156/2022, 33/2023, 145/2023, 36/2024, Date of entry into force of the Act: 1. 1. 2019. " This Act transposes the following directives into Croatian legislation: Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare (OJ L 88, 4. 4. 2011).

³² <https://hzzo.hr/pristup-zdravstvenim-podatcima/europski-prostor-za-zdravstvene-podatke>, unfortunately, although it acts as a national contact point until the research date of 20.02.2025., an error or page error occurs on the HZZO website and there is no relevant information about the European health data space.

3.1. Open provisions of the EHDS Regulation

On 25 March 2025, the EHDS Regulation will enter into force with a transitional period of two to four years for its application. Although the transitional periods may seem long, the European Commission has a lot of work to do to facilitate the implementation of the EHDS Regulation. It is important to establish the operation of the EHDS under the EHDS Regulation during the transitional period so that stakeholders, be they Member States, healthcare providers or the European Commission itself, can prepare. The EHDS Regulation therefore includes a deadline for the adoption of key implementing acts, namely 26 March 2027. The key implementing acts referred to above are legally open provisions that leave room for the legislator to supplement the EHDS Regulation through other implementing legal acts. The key implementing acts with the specified deadline are the following provisions of the EHDS Regulation: Article 13(4) on data quality requirements in primary use, Article 15(1) on technical specifications for ERHRxF, Article 23(4) on MyHealth@EU, Article 36(1) on common specifications for harmonised components of the EHR system, Article 70(1) on templates for applications, permissions and requests for access to data, Article 73(5) on requirements for secure processing environments, Article 75(12) on HealthData@EU, Article 77(4) on requirements for dataset descriptions, and Article 78(6) on data quality and usefulness labelling. Those implementing acts will undergo the usual comitology procedures³³ involving the Member States, as well as the necessary public consultations, while delegated acts adopted by the European Commission will be subject to a period during which the European Parliament and the Council may object to the delegated act. With regard to Article 13(4), the European Commission shall, by means of implementing acts, establish data quality requirements, including in relation to semantics, uniformity, consistency, accuracy and completeness, for the registration of personal electronic health data. The European format for the exchange of electronic health records is regulated by the open provision of Article 15(1), which states that the European Commission shall, by 26 March 2027, by means of implementing acts, establish technical specifications for the priority categories of personal electronic health data referred to in Article 14(1), specifying a European format for the exchange of electronic health records. That format must be common and machine-readable and enable the transfer of personal electronic health data between software applications, devices and healthcare providers. Such a format must support the transfer of structured and unstructured health data. Furthermore, in accordance

³³ Comitology applies when implementing powers are conferred on the Commission in the text of a law. The same law also stipulates that the Commission should be assisted by a committee in determining the measures set out in the final implementing act. https://commission.europa.eu/law/law-making-process/adopting-eu-law/implementing-and-delegated-acts/comitology_hr, 25.03.2025.

with Article 23(4), the European Commission shall, by 26 March 2027, adopt implementing acts on the necessary measures for the technical development of the MyHealth@EU infrastructure, detailed rules on the security, confidentiality and protection of personal electronic health data and the conditions for the conformity checks required for connection to the MyHealth@EU infrastructure. In accordance with Article 36(1), the European Commission shall, by 26 March 2027, adopt implementing acts on common specifications for the essential requirements set out in Annex II, including a common template and a deadline for the implementation of those common specifications. Those common specifications shall, where relevant, take into account the specificities of medical devices and high-risk AI systems referred to in Article 27(1) and (2), including state-of-the-art health informatics standards and a European format for the exchange of electronic health records. In Article 70(1), the European Commission shall, by 26 March 2027, establish by means of implementing acts the templates for the request for access to health data, for the data authorisation and for the request for health data referred to in Articles 67, 68 and 69 of the EHDS Regulation. In addition, Article 73(5) regulates the secure processing environment, for which the European Commission shall, by 26 March 2027, establish by means of implementing acts the technical and organisational requirements, requirements in terms of information security, confidentiality and data protection, and requirements in terms of interoperability for secure processing environments, including in terms of the technical features and tools available to the user of health data in the secure processing environment. Then, in Article 75(12), Section 4 of the EHSS Regulation, which regulates the cross-border infrastructure for secondary use, the European Commission will adopt implementing acts, which, among other things, establish the requirements, technical specifications and IT architecture of the HealthData@EU infrastructure, which ensures state-of-the-art data security, confidentiality and protection of electronic data in the HealthData@EU infrastructure. In Article 77(4), which regulates the quality and usefulness of health data for secondary use, the European Commission will establish, by means of implementing acts, the minimum elements that health data owners must specify for data sets and the characteristics of these elements. To conclude the overview of the open provisions of the EHSS Regulation, Article 78(6) regulates the quality and usefulness of data, which establishes the visual characteristics and technical specifications of the quality and usefulness of data. All of the above open provisions, which determine the adoption of implementing acts in the comitology procedure, are important for understanding the complexity of the application of the EHSS Regulation. This is why the implementation deadlines for its application are so long. This is a comprehensive and detailed overview of open provisions that actually opens the door to further research into the European health data space in the narrow sense and the public health system in the field of EU public health. Professional and scientific cooperation of consistent and capable human resources is needed not only at the

EU level but also at the level of each EU Member State separately. So far, the implementation of the Directive on Cross-Border Cooperation has been visible, which did not have the same legal force as the EHDS Regulation. From its implementation, it is evident that by adopting and entering into force, and by applying the EHDS Regulation, an attempt is made to create a coherent legal, technical, and IT entity within the EU. Precisely because of its complexity, the next chapter of the paper will address the entry into force and application of the EHDS Regulation.

4. ENTRY INTO FORCE AND APPLICATION OF THE EHDS REGULATION

As stated in the previous chapter, the EHDS Regulation will enter into force on 25 March 2025 and will apply from 26 March 2027. However, certain provisions will apply in stages, starting from 26 March 2029 or 2031. There are also provisions from Article 75, paragraph 5, which will apply from 2035.³⁴ In order to better understand the basis for the vertical implementation of the EHDS Regulation into the legal system of the Republic of Croatia, it is necessary to present its legal framework in more detail and in a meaningful way. The EHDS Regulation is an important milestone in the EU's efforts to build a secure and efficient digital health system as part of the European digital data strategy.³⁵ The EHDS Regulation itself is important because it encompasses a comprehensive framework for access to and use of electronic health data in all EU Member States. The benefits of the newly established European Health Data Space, implemented through the EHDS Regulation, are the empowerment of citizens and the strengthening of the reuse of health data. When we talk about empowering citizens, we primarily mean better control over their personal health data, which will enable unhindered access to medical records throughout the EU where they need healthcare (primary use).³⁶ The Regulation, in Chapter II, regulates a number of issues related to the primary use of individual health data, from the right to access their own personal electronic health data, the provision of electronic health data access services for individuals

³⁴ EHDS Regulation, Article 105. Entry into force and application.

³⁵ Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847.

³⁶ Ibidem., Chapter II. Primary Use, Section 1. Rights of individuals with regard to the primary use of their personal electronic health data and related provisions, Articles 3-18, Section 2. Governance for primary use, Articles 19-22, Section 3. Cross-border infrastructure for the primary use of personal electronic health data, Articles 23-24.

and their representatives,³⁷ the right of an individual to enter information into their own electronic health record, the right of an individual to correction, to data portability, to restriction of access, the right to obtain information about access to data, the right of an individual to be excluded from primary use, and access by healthcare professionals to personal electronic health data. In addition to the above, the Regulation deals with the registration of personal electronic health data, priority categories of personal electronic health data for *primary use* and the European format for the exchange of electronic health records, identification management. Furthermore, in the same Chapter II, Section 2, the Governance for primary use is discussed, more specifically on the Digital Health Authority, reporting to the Digital Health Authority, the right to lodge a complaint with the Digital Health Authority, and the relationship with the supervisory authority under Regulation (EU) 2016/679.³⁸ Section 3 regulates the cross-border infrastructure for the primary use of personal electronic health data, where the European Commission establishes a central interoperability platform for digital health, *Mojezdravlje@EU*, to facilitate the provision of services that support and facilitate the exchange of personal electronic health data between the national contact points for digital health of the Member States.³⁹ Chapter III of the Regulation regulates electronic health record systems and applications for well-being, where the scope and general provisions on electronic health record systems are elaborated.⁴⁰ Chapter IV elaborates on the secondary use of health data. When it comes to *the secondary use* of health data, the definition of the term is given in Article 2, paragraph 1, point e of the Regulation, where secondary use means the processing

³⁷ Ibidem, Article 4, paragraph 1. Member States shall ensure the establishment of one or more electronic health record access services at national, regional or local level...Such electronic health record services shall be free of charge for individuals and their representatives.

³⁸ Ibidem., Article 22. The supervisory authority or authorities responsible for monitoring and enforcing the application of Regulation (EU) 2016/679 shall also be competent for monitoring and enforcing the application of Article 3 and Articles 5 to 10 of this Regulation. Relevant the provisions of Regulation (EU) 2016/679 apply *mutatis mutandis*. Supervisory bodies are authorized to impose administrative fines up to the amount from Article 83, paragraph 5 of Regulation (EU) 2016/679.

³⁹ Ibidem, Article 23(3). Each national contact point for digital health shall enable the exchange of personal electronic health data referred to in Article 14(1) with national contact points for digital health in other Member States via *MyHealth@EU*. This exchange shall be based on the European format for the exchange of electronic health records.

⁴⁰ Chapter III. Titled Electronic health record systems and welfare applications, Section 1. Scope and general provisions on electronic health record systems Articles 25-29, Section 2. Obligations of economic operators with regard to electronic health record systems, Articles 30-35, Section 3. Conformity of harmonised software components of electronic health record systems, Articles 36-42, Section 4. Market surveillance of electronic health record systems, Articles 43-46, Section 5. Other provisions on interoperability, Articles 47-48, Section 6. Registration of electronic health record systems and welfare applications, Article 49.

of electronic health data for purposes set out in Chapter IV of the Regulation that are not for the original purposes for which they were collected or prepared.⁴¹ When researching the EDHS Regulation, great attention should also be paid to the recitals of the Regulation, which are legally binding, because they contain explanations for numerous truncated definitions that could lead experts, scientists and professionals astray.⁴² In addition to the above, an important feature of this Chapter is the establishment of the EU Dataset Catalogue regulated by Article 79, where it is clearly emphasized that we can define three categories of EU dataset catalogues; the first is the EU dataset catalogue, the second are national dataset catalogues, and the third are catalogues of authorised participants in the HealthData@EU infrastructure.⁴³ Chapter V of the Regulation provides for additional capacity-building measures, training and information programmes for healthcare professionals, digital literacy, additional requirements for public procurement, storage of personal electronic health data for primary use, provisions on the transfer of electronic data to third countries and international access by authorities to non-personal electronic health data.⁴⁴ Chapter VI deals with European governance and coordination, where the European Space Committee is defined,⁴⁵ the Stakeholder Forum is established, and⁴⁶ the MyHealth@EU and

⁴¹ Chapter IV . Regulations Secondary use , Section 1. General conditions for secondary use, Articles 50-54, Section 2. Governance and mechanisms for secondary use, Articles 55-65, Section 3. Access to electronic health data for secondary use, Articles 66-74, Section 4. Cross-border infrastructure for secondary use , Section 5. Quality and usefulness of health data for secondary use, Articles 77-80, Section 6. Complaints, Article 81.

⁴² Recitals 55-63 explain the context of secondary use of health data, user rights, their availability, etc.

⁴³ Article 79 of the Regulation The Commission shall establish an EU dataset catalogue which shall bring together the national dataset catalogues established by the health data access authorities in each Member State, as well as the dataset catalogues of authorised participants in the HealthData@EU infrastructure.

⁴⁴ Regulation, Chapter V. Additional measures, Articles 82-91.

⁴⁵ Regulation, Article 92. "A European Health Data Area Board is hereby established to facilitate cooperation and exchange of information between Member States and with the Commission. The European Health Data Area Board shall be composed of two representatives from each Member State, one representative for primary use and one representative for secondary use, appointed by each Member State. Each Member State shall have one vote. The members of the European Health Data Area Board shall undertake to act in the public interest and independently."

⁴⁶ Regulation, Article 93. " A Stakeholder Forum shall be established to facilitate the exchange of information and promote cooperation between stakeholders in relation to the implementation of this Regulation. 2. The Stakeholder Forum shall be balanced in composition and shall consist of relevant stakeholders, including representatives of patient organisations, healthcare professionals, industry, consumer organisations, scientific researchers and academia, and shall represent their views. Where business interests are represented in the Stakeholder Forum, the representation of such interests shall be based on a balanced combination of large companies, small and medium-sized enterprises and start-ups. The tasks of the Stakeholder Forum shall cover both primary and secondary use."

HealthData@EU Infrastructure⁴⁷ Steering Groups are established. Chapter VII regulates the delegation of powers,⁴⁸ while Chapter VIII elaborates on sanctions.⁴⁹ It is important to note that the aforementioned Chapter VIII, in Article 103, deals with the Amendment of Directive 2011/24/EU,⁵⁰ specifically its Article 14, which for the first time in EU law referred to healthcare and the interoperability of health technologies. We can therefore draw a link and briefly emphasize the importance of recital 8 of the Regulation, which speaks about the meaning of Regulation (EU) 2016/679, which establishes specific provisions on the rights of individuals with regard to the processing of their personal data. The European Health Data Area is based on these rights and supplements some of them as they apply to personal electronic health data. These rights apply regardless of the Member State in which personal electronic health data are processed. At the very end of the EDHS Regulation is Chapter IX. Under the title Deferred application, transitional and final provisions, which clearly states that in principle the Regulation applies from 26 March 2027, and enters into force 20 days after its publication in the Official Journal of the EU, more precisely on 25.03.2025. Therefore, the entry into force of the EHDS Regulation is important because it begins to apply two years later. This means that the difference between the entry into force and the start of application of the EHDS Regulation lies in their legal effect and time frame: entry into force means that the EHDS Regulation enters into force on the date specified in the text of the regulation itself, usually 20 days after its publication in the Official Journal of the European Union (unless otherwise specified). This means that the legislative act becomes part of the EU legal order, but does not necessarily

⁴⁷ Regulation, Article 95. " The management group *MojeZdravlje@EU* (*MyHealth@EU*) and the management group *Zdravstvenipodatci@EU* (*HealthData@EU*) ("management groups") are established for the cross-border infrastructures provided for in Articles 23 and 75. Each management group consists of one representative from each Member State appointed among the relevant national contact points. 2. Management groups make operational decisions on the development and operation of *My Health@EU* and *HealthData@EU* infrastructures. 3. Management groups make decisions by consensus..."

⁴⁸ Article 97 "1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article. 2. The power to adopt delegated acts referred to in Article 14(2), Article 49(4) and Article 78(5) shall be conferred on the Commission for an indeterminate period of time from 25 March 2025. ..."

⁴⁹ Article 99 of the Regulation "Member States shall establish rules on sanctions applicable to violations of this Regulation, in particular violations that are not subject to administrative fines in accordance with Articles 63 and 64, and shall take all necessary measures to ensure their implementation. The provided sanctions must be effective, proportionate and dissuasive. Member States shall notify the Commission of these rules and measures by March 26, 2027, and shall notify it without delay of to all subsequent changes that affect them."

⁵⁰ Directive on the application of patient rights in cross-border health care , Article 14 "E-health 1. The Union supports and facilitates cooperation and exchange of information between member states operating within a voluntary network connecting state bodies responsible for e-health, which have been appointed by member states."

have to be applied yet. On the other hand, the start of application means that the Regulation starts to apply from the date expressly specified in the regulation. This date can be immediately after the entry into force or with a certain deferral period (e.g. six months, a year or more). This period allows Member States, institutions and economic operators to adapt to the new rules.⁵¹ Such a complex deferred application, or transitional and final provisions that are complex, will be difficult to monitor. Therefore, the provisions on education and information of stakeholders through regulation in the Regulation are an essential part of the implementation. Given that the European Health Data Space is the first common data space in the EU, the long period of application is understandable. The paper briefly covers the content of the EDHS Regulation, and it can be concluded that the Regulation has Chapter IX, 105 articles and Annex IV, of which 115 recitals.⁵² For the first time, the research provides an overview of the new EHDS Regulation and its open provisions in order to clarify the legal framework for action in further research. The overview of the EHDS Regulation itself and other relevant legal regulations that directly or indirectly affect the interoperability and establishment of health data in the EU is truly, despite the difficulties in the EU, a pioneering undertaking. Even a small step forward is a step towards the goal. In conclusion, it is up to scientists and experts to make an effort at all levels to solve the upcoming

⁵¹ The Regulation shall enter into force on 26.03.2025, and shall apply from 26.03.2027, with the exceptions that Articles 3 to 15, Article 23, paragraphs 2 to 6, Articles 25, 26, 27, 47, 48 and 49 shall apply as follows: (a) from 26 March 2029 for the priority categories of personal electronic health data referred to in Article 14, paragraph 1, points (a), (b) and (c) and for electronic health record systems intended by the manufacturer for processing such categories of data; (b) from 26 March 2031 for the priority categories of personal electronic health data referred to in Article 14, paragraph 1, points (d), (e) and (f) and for electronic health record systems intended by the manufacturer for processing such categories of data; (c) from one year from the date specified in the delegated act to be adopted pursuant to Article 14(2) for any change to the main characteristics of personal electronic health data set out in Annex I, provided that that date is later than the date of application referred to in points (a) and (b) of this subparagraph for the categories of personal electronic health data concerned. Chapter III shall apply to the electronic health record systems referred to in Article 26(2) from 26 March 2031, Chapter IV It shall apply from 26 March 2029. However, Article 55(6), Article 70, Article 73(5), Article 75(1) and (12), Article 77(4) and Article 78(6) shall apply from 26 March 2027, points (b), (f), (g), (m) and (p) of Article 51(1) shall apply from 26 March 2031 and Article 75(5) shall apply from 26 March 2035. The implementing acts referred to in Article 13(4), Article 15(1), Article 23(4) and Article 36(1) shall apply from the dates referred to in the third paragraph of this Article depending on the categories of personal electronic health data referred to in Article 14(1)(a), (b) and (c) or points (d), (e) and (f) of Article 14(1). The implementing acts referred to in Article 70, Article 73(5), Article 75(12), Article 77(4) and Article 78(6) shall apply from 26 March 2029.

⁵² Recital 115 of the Regulation provides an explanation for the long period of application: "Given the need for technical preparation, this Regulation should apply from 26 March 2027. In order to support the successful implementation of the European health data area and to create effective conditions for European cooperation in the field of health data, implementation should be gradual."

challenges that the European Health Data Space brings us during the implementation period. The European Health Data Space, and after the entry into force of the EHDS Regulation, will not solve the problems like a magic wand, but will only achieve the goal for which the EHDS Regulation was adopted through the efforts and commitment of the professional and scientific community.⁵³

5. KEY EU INITIATIVES IN THE FIELD OF E-HEALTH AND GUIDELINES FOR THE REPUBLIC OF CROATIA

Generally speaking, the digitalization of the EU has been discussed for more than two decades, and the COVID-19 pandemic has led to a strengthening of the EU policy framework for the digitalization of healthcare. Back in 2002, the eEurope 2005 Action Plan was adopted, where EU-27 countries were to ensure that citizens would be provided with online health services (e.g. Electronic Health Records) by 2005.⁵⁴ In 2020, the Digital Compass was adopted, where 100% of European citizens should have online access to their electronic health records by 2030.⁵⁵ As can be seen from the previously mentioned sources, in 2023, the Republic of Croatia ranked 20th in the EU-27 group in terms of the development of online health services. However, in terms of access of European citizens to their electronic health records, the Republic of Croatia ranked 12th in⁵⁶ the EU-27

⁵³ Recital 1 of the Regulation: "The objective of this Regulation is to establish a European health data area in order to improve individuals' access to and control over their personal electronic health data in the context of healthcare, as well as to better achieve other purposes involving the use of electronic health data in the health or care sector that would benefit society, such as research, innovation, policy-making, preparedness and response to health threats including prevention and response to future pandemics, patient safety, personalised medicine, official statistics or regulatory activities. Furthermore, this Regulation aims to improve the functioning of the internal market by establishing a single legal and technical framework, in particular for the development, marketing and use of electronic health record systems in line with the values of the Union. The European health data area will be a key component in creating a strong and resilient European Health Union."

⁵⁴ eEurope Action Plan 2005, The eEurope Action Plan 2005 succeeds the 2002 Action Plan which focused mainly on Internet connectivity in Europe. The new Action Plan, endorsed by the Seville European Council in June 2002, aims to translate this connectivity into increased economic productivity and improved quality and availability of services for all European citizens, based on a secure broadband infrastructure accessible to the largest possible number of people, COM(2002) 263 final.

<https://eur-lex.europa.eu/legal-content/HR/TXT/?uri=celex%3A52002DC0263>
25.02.2025.

⁵⁵ Decision (EU) 2022/2481 establishing a policy programme for the Digital Decade up to 2030, op.cit., note 49.

⁵⁶ European Commission, "Digital Decade 2024" Annex Short country report Croatia, file:///C:/Users/aputric/Downloads/7_Annex_3_Croatia_Executive_Summary_TUGznDxJ9YCrD6ANcpnuMxxI70_106832%20(3).pdf, 25.02.2025.

group. The current state of the digital e-health services infrastructure is best measured through the My Health@EU infrastructure, which enables Member States to exchange e-prescription documents and patient medical data summaries. The long-term goal is to expand the use of the digital infrastructure to the specified priority categories for processing health data as regulated by the Regulation on the European Health Data Area.⁵⁷ The proposals for improving the implementation of the EHDS Regulation in the Croatian healthcare system are as follows: 1. Strengthening interoperability and system standardization: Establishing a single national platform for digital health services that is aligned with European e-health standards and Implementing standardized protocols for data exchange between different healthcare institutions and stakeholders. Connecting the Croatian health information system with the EU initiative *My Health@EU* to facilitate the exchange of e-prescriptions and medical data. 2. Improving cybersecurity and patient data protection: Introducing advanced security protocols to protect electronic health records, increasing capacity to monitor and respond to cyber threats within the healthcare sector, and strengthening the implementation of the General Data Protection Regulation (GDPR) through regular audits and education of healthcare professionals. 3. Digitalization and modernization of healthcare services: in improving electronic health records so that patients have better insight into their own health data, integrating artificial intelligence to analyze health data and improve diagnostics, further developing telemedicine services to enable quality care in remote and less developed areas. 4. Ensuring financing and transparency in the implementation of digital solutions: establishing a system for monitoring the costs of digitalization and transparent reporting to EU institutions, leveraging EU funds and other available financial mechanisms to accelerate the implementation of digital reforms and involving the private sector and start-ups in the development of innovative e-health solutions. 5. Education and awareness-raising among healthcare professionals and citizens: organization of continuous education programs for medical staff in the field of digital skills, awareness campaigns of citizens about the benefits of e-health and data security and development of user-friendly digital interfaces so that all citizens can easily use e-health services. By implementing these measures, Croatia can significantly improve its position in European e-health and ensure higher quality and more accessible healthcare for all citizens. Historically, the Republic of Croatia has only been part of the EU for a little over 10 years and must take great steps towards the digitalization of the system, as legislative initiatives in the EU began back in 1999. Therefore, it is necessary to view the digitalization process as a whole framed by a new legal framework that is only facing challenging times of implementation. (Annex I.). In addition to key EU initiatives to achieve operational digitalization of the health systems of the EU-27 group of countries, the security of individual

⁵⁷ Regulation on the European Health Data Area, op.cit., note 13.

health data has come to the fore in recent years, which is also a key issue in the context of protecting privacy and citizens' trust. Misuse of health data can cause serious consequences, including discrimination, loss of trust or damage to mental or physical health. In accordance with the General Data Protection Regulation, which horizontally regulates data processing within the EU, ensuring adequate protection of individual health data is not only a legal obligation but also an ethical imperative. Therefore, the Republic of Croatia faces a new challenging time of major digital reform of the healthcare system, which, hand in hand with cybersecurity and artificial intelligence, leads to new areas of digital transformation of the European Health Union.

6. CONCLUSION

The evolution of the digitalization of the EU healthcare system through the establishment of the European Health Data Space (EHDS) represents one of the most important initiatives within the European health policy. The digital transformation of healthcare is becoming a key priority, given the increasing need for efficient, secure and interoperable systems that can respond to the challenges of the modern healthcare sector. In this context, the EHDS brings revolutionary changes in the way health data of EU citizens are collected, exchanged and used. As a prerequisite for the successful implementation of the EHDS, it is necessary to establish a modern and secure digital infrastructure that will enable the smooth exchange of data between different Member States through implementing acts of the European Commission. In addition to the above, it is important to adopt national regulations in the Republic of Croatia to resolve the issue of open provisions as presented in the paper. The key challenge lies in ensuring the interoperability of systems, data standardization and harmonization of the legislative framework at the EU level, which would enable primary and secondary processing of health data. On the one hand, primary processing implies direct benefits for patients through improved healthcare, while secondary processing enables the use of data for scientific research, innovation and health policy development, where the protection of privacy and security of personal data are of paramount importance. This paper provides a detailed overview of key e-health initiatives within the EU, starting from the first steps in the digitalization of the healthcare system since 1999, up to modern strategies and regulations that define the future development of EHDS. Special attention is paid to the analysis of the legal framework, including the EHDS Regulation and the Cross-Border Healthcare Directive, which represent the basis for the legal regulation and implementation of digital healthcare solutions in the EU. The paper also deals with a detailed comparative analysis of the legal legislation of e-health in the Republic of Croatia, with the aim of identifying key challenges and opportunities for

improving national legislation and adapting to the EHDS. Within the European healthcare system, the Republic of Croatia occupies a specific position, since its healthcare model primarily rests on the Bismarckian system, which is based on mandatory health insurance and solidarity. In this context, it is important to consider the role of key institutions such as the Croatian Health Insurance Institute (HZZO), which serves as the national contact point for the implementation of the EHDS. The implementation of the EHDS brings numerous benefits, both for healthcare institutions and professionals, and for citizens themselves, enabling them to have better access to health data, improving cross-border healthcare and improving the quality and continuity of treatment. However, in order to ensure a successful transition to the EHDS, it is necessary to establish a clear strategy in the preparatory period, ensure political will and encourage mutual cooperation between all stakeholders - from decision-makers and regulatory authorities, to healthcare institutions, scientific organizations and the IT sector. It is crucial to create an enabling environment for the implementation of digital solutions, while ensuring appropriate education and training of healthcare professionals to work in the new digital system. It is also important to emphasize the need to raise awareness among citizens about the advantages of digitalization of healthcare, while ensuring high standards of privacy protection and data confidentiality. This work represents the basis for further research and development of strategies that will enable a successful digital transformation of the healthcare system in the EU and the Republic of Croatia. The digitalisation of healthcare is not only a technological challenge, but also an opportunity to improve the quality of healthcare, increase the efficiency of the system and strengthen citizens' trust in digital healthcare services. The implementation of the EHDS brings a new era in healthcare, in which data will play a key role in providing personalised and timely healthcare, but also in developing innovative therapeutic methods and health policies. Therefore, the EU and its Member States have a responsibility to harness the potential of digitalisation in a way that will ensure the long-term sustainability of healthcare systems and the well-being of all citizens. A new era of the digital healthcare revolution has begun, and the success of this process depends on the cooperation, innovation and strategic commitment of all stakeholders involved. The EHDS is not just a digitalisation project – it is a vision of a future in which healthcare becomes more accessible, efficient and tailored to the needs of each individual.

REFERENCES

BOOKS AND ARTICLES

1. Boban, M., *Data and information management in healthcare information systems of the Republic of Croatia - security, protection and responsibility*, in: *Medicine, Law & Society, Proceedings*, Maribor, 2021, pp. 211–233.
2. Boban, M., *E-card – challenges of implementation and protection of patients' personal data*, in: *4th „KOKOZ“ Congress and 6th Croatian Congress of Medical Law with International Participation*, Novi Vinodolski, 2023, pp. 147–177.
3. Boban, M., *Personal data protection and the new EU data protection regulation*, *Bulletin of the Croatian Medical Informatics Society*, vol. 24, no. 1, 2018, pp. 26–40.
4. Croatian Academy of Sciences and Arts, Scientific Council for Public Administration, Judiciary and the Rule of Law, *European Health Union*, roundtable held on 17 February 2022, edited by Jakša Barbić, Zagreb, 2023.
5. Hansen, J.; Wilson, P.; Verhoeven, E.; Kroneman, M.; Kirwan, M.; Verheij, R.; van Veen, E. B., *Assessment of the EU Member States' Rules on Health Data in the Light of GDPR*, European Union, 2021.
6. Malešević, A., *Digital Health in Croatia: Expectations, Challenges and Implementation*, Doctoral Thesis, Sociology: Values, Identity and Social Changes in Croatian Society, Croatian Catholic University, Zagreb, June 2024.
7. Ostojić, R., *E-health – improving the health system through the use of information and communication technology*, *Social Research: Journal of General Social Issues*, vol. 21, no. 4 (118), 2012, pp. 843–862.
8. Sokol, T., *Health care and the European Pillar of Social Rights*, *Proceedings of the Faculty of Law, University of Rijeka*, vol. 44, no. 3, 2023, pp. 701–722.
9. Stevanović, R. et al., *Establishment and development of the Croatian integral health information system*, *Medicus*, vol. 13, no. 2, 2004, pp. 131–137.

LEGAL ACTS

1. Act on the implementation of Regulation (EU) No. 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use and repealing Directive 2001/20/EC, *Official Gazette*, No. 14/2019.
2. Compulsory Health Insurance Act, *Official Gazette*, No. 80/2013, 137/2013, 98/2019, 33/2023.

3. Health Care Act, Official Gazette, No. 100/2018, 125/2019, 133/2020, 147/2020, 136/2021, 119/2022, 156/2022, 33/2023, 145/2023, 36/2024.
4. Law on Data and Information in Healthcare, Official Gazette, No. 14/2019.
5. Law on the Protection of Patients' Rights, Official Gazette, No. 169/2004, 37/2008.
6. Law on the Quality of Health Care, Official Gazette, No. 118/2018.
7. Law on the implementation of Regulation (EU) 2017/745 on medical products and Regulation (EU) 2017/746 on in vitro diagnostic medical products, in force since 22 November 2018.
8. Ordinance on the method of processing health and other personal data in national and institutional health information systems in healthcare, the method of storing and protecting health data and creating health indicators, standardized forms and registers and records in healthcare, Official Gazette, No. 150/2024.
9. Regulation of the European Parliament and of the Council on the European Health Data Space, No. 2022/0140, 3 May 2022.
10. Council Conclusions on Strengthening the European Health Union, 14029/21, Council of the EU, 30 November 2021.
11. Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare, OJ L 88, 4 April 2011, p. 45.
12. Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC, OJ L 119, 4 May 2016, pp. 1–88.
13. Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of individuals with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No. 45/2001 and Decision No. 1247/2002/EC.
14. Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a Programme of the Union's action in the field of health (EU4Health Programme) for the period 2021–2027 and repealing Regulation (EU) No. 282/2014, OJ L 107, 26 March 2021, p. 1.
15. Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU.
16. Regulation (EU) 2022/868 of the European Parliament and of the Council of 30 May 2022 on European data governance and amending Regulation (EU) 2018/1724.

17. Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No. 1082/2013/EU.
18. Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847.

NETWORK RESOURCES

1. https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space_hr, 17.01.2025.
2. https://ec.europa.eu/health/system/files/2021-02/ms_rules_health-data_en_0.pdf, 17 February 2025.
3. <https://interoperable-europe.ec.europa.eu/>
4. https://commission.europa.eu/law/law-making-process/adopting-eu-law/implementing-and-delegated-acts/comitology_hr , 25.03.2025.
5. <https://www.hzjz.hr/projekti/hrvatski-centar-za-zdravstvene-podatke-eng-croatian-health-data-centre-chdc/> , 24.02.2025
6. <https://eur-lex.europa.eu/legal-content/HR/TXT/?uri=celex%3A52002DC0263> _25.02.2025.
7. <https://op.europa.eu>
8. <https://www.eca.europa.eu/>
9. <https://hzzo.hr/pristup-zdravstvenim-podatcima/europski-prostor-za-zdravstvene-podatke>
10. <https://repo.ozs.unist.hr/islandora/object/ozs:1579/datastream/PDF/view>
11. <https://www.iusinfo.hr/zakonodavstvo/zakon-o-zdravstvenoj-zastiti-clanak-28>

Annex I. The most important EU initiatives promoting eHealth

1999.	Communication "eEurope: information society for all"
2000	Communication "eEurope 2002: Action Plan"
2002.	Communication "eEurope 2005: Action Plan"
2004.	Communication "Action plan for a European eHealth Area"
2007.	"Action Plan in the area of eHealth: ICT solutions for patients, medical services and payment institutions (contribution to the communication entitled "Lead Market Initiative for Europe")"
2008.	Communication "Telemedicine for the benefit of patients, health systems and society"
2010.	Communication "Digital Agenda for Europe"
2011.	Directive on the Application of Patients' Rights in Cross-Border Healthcare (Directive on Cross-Border Healthcare)
2012	Communication "eHealth Action Plan 2012-2020: Innovative healthcare for the 21st century"
2015	Communication "A Digital Single Market Strategy for Europe"
2018.	Communication "Enabling digital transformation on a single digital market in the field of health and care"
2019.	Recommendation on a European format for the exchange of electronic health records
2021.	Digital Compass 2030: a European approach for the digital decade ('Digital Compass Communication')
2022.	Communication "European Health Data Space: unlocking the potential of health data for citizens, patients and innovation"
2022.	Proposal for a Regulation of the European Parliament and of the Council on a European Health Data Area (Regulation on the European Health Data Area)
2022.	Decision establishing a policy programme for the Digital Decade by 2030.
2023.	"European Declaration of Digital Rights and Principles for the Digital Decade"
2025.	Regulation (EU) 2025/327 on the European Health Data Area