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PROPOSED LAW FOR THE EUROPEAN HEALTH DATA SPACE IN CONTEXT

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Abstract Analysing electronic health records could improve medicine, but personal data protection impedes this research. The European Health Data Space shall unleash these data. The focus now shifts on how best to balance this effort while at the same time protecting patients' privacy and autonomy. Still, we need to address the reality. Research on images, laboratory results and prescriptions will be easy, as they are electronic. However, the written core of health records is not structured, and establishing summaries for all patients is challenging. Regulations instead of directives are a laudable solution to help simplify the situation. Nonetheless, new challenges emerge with the co-existence of supranational and national frameworks if the former is to have far-reaching ambitions.

Keywords
healthcare, privacy, health records, EU integration, COVID-19

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1 Intrudaction

"European Health Data Space" (EHDS) will improve cross-border healthcare and support the analysis of health data. The proposal for a regulation (EHDSR) has sparked intense debate since its unveiling in May 2022. Let us consider the critical aspects of this envisaged uniform standard, expanding on the research of transformations of directives into regulations resulting in such uniformity (Křepelka, 2021).

The conceptualisation of the text reflects this task. We will first consider medical confidentiality and health[1] records (chapter 2) and the role of the European Union (hereinafter EU) in medicine and healthcare (chapter 3), before examining the proposal itself (chapter 4) and its various aspects (chapter 5).

Better understanding the origins of medical confidentiality and health records (subchapter 2.1), their purpose and substance (2.2), their forms (2.3), standards (2.4), their internationalisation (1.5), and the linguistic dimension (1.6) helps to inform us regarding the substance of the proposal, as the current literature from experts about their interconnection ignores these important facets.

The EU integrates healthcare, financed and organised and medicine regulated by the Member States as an economic activity subject to internal market rules (3.1), while the C-19 pandemic cause considerable stress to this arrangement (3.2). Harmonisation and subsequent unification of personal data protection are crucial to understanding the EU's involvement (3.3). Still, the EU has also focused its efforts on health data beyond this protection (3.4). We cannot ignore its multilingualism (3.5).

The proposal (4.1) sparked considerable debate (4.2). One may expect lengthy deliberations as the expectations differ among stakeholders (4.3). Still, as lawyers, we need to discuss competence (4.4) and consider the choice of a regulation (4.5), entanglement of such regulation with related regulations (4.6), and national laws to implement it (4.7), while properly evaluating its multilingual expression (4.8).

[1] This paper uses the terminology of EHDSR. Still, English texts mention "medical records" or "patient records".

The final chapter addresses particular aspects of the proposed framework. It questions remnant paper records (5.1), shows an understanding of the self-certification of health record systems (5.2), and discusses the position of national authorities (5.3). Second, distinguishing primary use in healthcare (5.4) and secondary use in research (5.5) is crucial, while fees for the latter shall contribute to the financing (5.6). Third, the scope of data deserves our interest, including sensitive ones (5.7). Still, patient summaries as structured datasets differ from traditional entries in health records (5.8), whose translation deserves our attention (5.9).

The article traces the origins of medical confidentiality and standards for health records. It summarises the roles played by the EU in healthcare and medicine. Nevertheless, the interpretation (*Rechtsdogmatik* in German legal science) of the proposed provisions identified as crucial forms its core, while it offers suggestions for their clarifications (*Rechtspolitik*). The article does not rely on empirical legal studies on the issue but instead refers to findings of other disciplines.

2 Confidentiality and Health Records

2.1 Historic Introduction

Privacy of one's personal health information was not the primary concern in the past. Most people simply strived for basic livelihood, while many lacked basic freedoms. Foremost, medicine was exceptional care, the privilege of the rich and mercy for the poor. Methods and techniques were primitive for millennia. Despite this, confidentiality has been valued since antiquity, as the Hippocratic Oath indicates (Hanák et al., 2019).

Few understand Old Greek Ἃ δ' ἂν ἐν θεραπείῃ ἢ ἴδω, ἢ ἀκούσω, ἢ καὶ ἄνευ θεραπηίης κατὰ βίον ἀνθρώπων, ἃ μὴ χρὴ ποτε ἐκλαλέεσθαι ἔξω, σιγήσομαι, ἄῤῥητα ἡγεύμενος εἶναι τὰ τοιαῦτα, but mentioning the original honours its legendary author. Its translation to Latin *Quae vero inter curandum, aut etiam Medicinam minime faciens, in communi hominum vita, vel videro, vel audivero, quae minime in vulgus efferri oporteat, ea arcana esse ratus, silebo* as the language used for centuries and influencing expert parlance follows. Citing English *Whatever, in connection with my professional practice, or not in connection with it, I see or hear, in the life of men, which ought not to be spoken of abroad, I will not divulge, as reckoning that all such should be kept secret*, the global experts' language in

which also this text appears, helps international readers. The author's Czech *Cokoli, co při léčbě i mimo svou praxi ve styku s lidmi uvidím a uslyším, co se nesmí sdělit, to zamlčím a uchovám v tajnosti* represents national languages used in the communications between patients and their physicians and nurses.[2]

The Oath does not mention health records. The milieu of Hippocrates of Kos[3] was ancient Greek civilisation in its heyday. The script was its part. Despite this, written documents were rare both then and in the next two millennia. Among the general public, reading was not a general skill, and writing was expensive. Still, the breach of confidentiality can consist of misuse of these records, their leaks, release or incursion. It is not a reach to interpret the Oath as expecting to keep records confidential. Privacy concerns are paramount to rendering health data electronic and their interconnection, including EHDS.

Historiography does not inform us of any notorious records. Maybe these records concerned elite patients, while physicians kept them secret and destroyed them when they became useless or feared their disclosure. While the first evidence for the existence of health records in the West dates to the 16th century, they were not maintained in a systematic way before the 19th century (Gillum, 2013). We may ask about other traditions of health records, perhaps Arabic or Chinese ones.

2.2 Purpose, Content and Evolution of Health Records

Health records primarily serve the interests of providing good treatment and refreshing physicians' familiarity with cases, as it is impossible for medical providers to remember all the information concerning hundreds of patients. These records assist the teamwork in hospitals. The institutions financing treatment and authorities controlling its quality also have an interest in the records. They provide evidence in deciding on complaints and actions.

Health records summarise anamnesis, diagnosis, treatment, prognosis, communication with patients or relatives, and decisions by physicians and patients. Before the 20th century, descriptions with numbers indicating measures or counts

[2] For the Old Greek, Latin and English versions of the Oath see Oath of Hippocrates - Wikisource, the free online library, for Czech version "Hippokratova přísaha" in Czech wikipedia. Please note that various translations of the Old-Greek original exist.
[3] Hippocrates (c. 450-380 B.C.E.) in *Internet Encyclopedia of Philosophy*, iep.utm.edu/hippocra.

prevailed. Drawings were sporadic, as they were time-consuming, and most physicians were not talented artists. The situation changed in the 20th century, when records started to include laboratory results and imagery. Despite this, verbalisation remained indispensable. One infrequent word, *epicrisis*, conclusions on the disease and treatment, more commonly known today as a medical case summary or history, deserves mention.

2.3 Paper and Databases

Handwritten records were exclusive until the 19th century. Shorthand, developed for recording parliamentary discussions, did not enter medicine, as few mastered it. Typewriters prevailed in the 20th century. Physicians wrote or dictated to nurses and secretaries. Files in furniture contained these records, while hospitals had entire rooms for this purpose.

The telegraph, telephone, radio, and television could also assist in emergency services and the delivery of pharmaceuticals. More recently, voice recordings and their rewriting by administrative staff have helped to alleviate burdens on physicians in some hospitals.

Data processing and storage have improved with the advances in information technologies in the last decades. Decreasing costs allowed computers and their interconnection with the Internet in science, industry, business, education, military, government and leisure. Medicine also enjoyed this modernisation (Cesnik & Kidd, 2010; Haux, 2010). Computers accompanied research and enabled advanced techniques, which *computer tomography* represents by its name.

However, regarding health records, the industry was often laggard. Computers replaced typewriters, but the interconnection often stopped at institutional walls. Many countries have rendered electronic health records interoperable. However, others have failed until recently, including the author's Czechia. The situation may not reflect a country's economic and technical development but rather its diverging attitudes, concerns, policies, and management. Czechia, for example, introduced electronic communication but has failed until recently to make it attractive for people (Kučera & Kyncl, 2010). Nonetheless, Czechia has addressed issues

pertaining to electronic health records with a specific law[4] which, among other things, aims recently to improve their interconnection (Těšitelová, 2021).

2.4 Standards for Health Records

Keeping health records became a deontological and legal requirement in the 19th and 20th centuries. Czechia has detailed statutory provisions and an entire ministerial decree regulating this field.[5] Such detailed laws need not be representative, as Czechoslovakia nationalised its healthcare (Křepelka, 2017). Recent attention reflects increased litigation in which health records provide evidence. Instead, guidelines of medical associations and chambers representing and controlling the profession may specify them. Hospitals also may specify them because teamwork requires a seamless exchange of information. Institutions financing healthcare could be another source of standards. In the end, the differences between the substance of the standards may be insignificant. Still, styles may differ among countries and their respective languages.

Physicians protected their paper health records with locks. Incursions leading to the disclosure of medical information were sporadic, but we know little about secret misuses. Patients are often reluctant to ask for access to the records concerning them. Even requests by a patient‘s relatives for medical information were met with unwillingness. Health authorities and institutions financing medical treatment enjoy access necessary for control. Unsurprisingly, the interest of police officers to access medical records to aid in investigating crimes has been controversial. Nonetheless, a patient’s entitlement to analyse one's own records seemed manifest. Granting access to other researchers was premised on the notion of collegiality.

Swift and remote access to electronic records is advantageous, but disclosure and misuse may be instant and orchestrated from a distance. Unsurprisingly, electronisation reshaped the deontological and regulatory landscape. Similar challenges to privacy also emerged outside medicine. General *personal data protection* has thus become an issue.

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[4] Zákon č. 325/2021 Sb., o elektronizaci zdravotnictví [Law on Electronisation of Healthcare].

[5] Zákon č. 372/2011 Sb., o zdravotních službách a podmínkách jejich poskytování [Law on Medical Services and the Conditions of their Delivery], §§ 53-69c Zdravotnická dokumentace [Health records] and Vyhláška Ministerstva zdravotnictví 98/2012 Sb., o zdravotnické dokumentaci [Decree of the Ministry of Healthcare on Health records]

2.5 Internationalisation of the Standards

International pacts and conventions on human rights and international codes of biomedical ethics stipulate dignity and privacy.[6] One may extrapolate from these documents that they ought to protect health records, but they do not explicitly say so.

The World Health Organisation (WHO), in performing its briefs, relies on information provided by its Member States. These countries, in turn, rely on data collected and analysed by their ministries, public health authorities and other administrations. WHO contributes significantly to assessing methods and techniques in medicine. Nevertheless, it does not play any significant role in standardising health records. Similarly, the World Medical Association (WMO), which promotes the interests of physicians' associations and chambers, does not specify any standards in this area. Maintaining and protecting electronic health records and systems for them has attracted the attention of the International Standardization Organization (ISO), which has addressed healthcare as a service with its norm 13808:2011 and its updates (Munoz et al., 2011; Austin et al., 2013).

2.6 Role of Languages

Citing the confidentiality requirement in the Hippocratic Oath reminds us that communicating rules is language-based. In general, communication in the medical sphere is between patients and physicians (and other healthcare practitioners) and entries in health records are that, and so are – directly or indirectly – leaks.

Repeating the Hippocratic medical confidentiality requirement in four languages reminds us about the potential pitfalls associated with international communication, complicated here by the evolution of languages. As the Oath served for centuries as a traditional code of medical ethics, vivid discussions about its provisions exist, encompassing its translations (Smith, 2012).

Keeping health records by overburdened physicians resulted in abbreviations, acronyms, incomplete sentences, often illegible writing, and peculiar formulations.

[6] Article 10 Private life and right to information: (1) Everyone has the right to respect for private life in relation to information about his or her health, Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, ETS No. 164, 4. 4. 1997, Council of Europe.

Resorting to Latin with an admixture of Greek indicated the role of these classical languages in education, culture and science (Wulff, 2004). Physicians switched to national languages but have retained Latin and Greek words (Jóskowska & Grabarczyk, 2013). Unsurprisingly, some laypeople may suspect physicians that continue to employ these do so in order to keep their *ars* arcane. We do not dare to estimate how much this Latinisiation eased communication between physicians in infrequent cases of internationally mobile patients.

3 Health data and the EU Integration

3.1 Economic Integration as Context

The Member States of the EU organise, finance, and control their healthcare. These policies reflect their socioeconomic development and political choices. One less manifest aspect of this competence is the law addressing the relationship between the patient and his relatives with providers and their physicians and nurses, respectively. Many countries consider the relationship contractual. Confidentiality and health records are related issues.

Nonetheless, healthcare as an industry is subject to integration with the free movement of goods, persons, capital, and services. The European communities and the EU have increasingly addressed these issues with secondary law. In parallel, the Court of Justice has contributed by interpreting basic economic freedoms, sometimes far-reaching. One may thus consider EU health law (Hervey & McHalle, 2015).

We may only mention legislation on medicinal products (pharmaceuticals) and medical devices, on the qualifications of healthcare practitioners or the extension of coordination of social security to public health insurance, including the necessary treatment of tourists. All these standards have an informatic dimension. Seeking treatment abroad and paying for it was always an option. Harmonising national laws by the Patients' Rights in Cross-border Healthcare Directive (CBHCD) specifying this reimbursement deserves our attention for its interest in health informatics.

3.2 The COVID-19 Pandemic

The COVID-19 pandemic hit all humankind in 2020-2022. Countries adopted unprecedented requirements and restrictions: contact tracing, mandatory testing, quarantines, isolations, suppressed contacts, prohibited activities, closed businesses and schools and curtailed domestic and international travel.

The pandemic also had a profound impact on the EU. People realised that public health belongs in the realm of national competence. Tackling this epidemic became a political issue par excellence. National policies differed during the three seasons. The EU Member States curtailed mobility and controlled the trade in essential medicinal products. Realising its auxiliary role, the EU acknowledged these restrictions.

The EU exercised its competence, among other things, in the accelerated authorisation of vaccines (Donati, 2022) and surveillance of repurposed pharmaceuticals. It entered new fields by coordinating their purchase. It introduced the EU Covid certificate for restoring cross-border mobility.[7]

Integration enthusiasts swiftly called for the EU‘s increased engagement.[8] The European Commission harnessed these calls with the European Health Union,[9] encompassing improved epidemic cooperation,[10] stabilising "medical countermeasures",[11] and enhancing health informatics. Nonetheless, we can conclude three years later that no revolution concerning healthcare emerged. Europeanisation is impossible if healthcare expenditures exceed money redistributed by this supranational polity.

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[7] Regulation 2021/953 of the European Parliament and of the Council (…) on a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates.

[8] Manifesto for a European Health Union, http://europeanhealthunion.eu/#manifes, launched 24. 11. 2020, with 1353 signatures in 29. 12. 2022.

[9] Communication from the Commission to the European Parliament, the Council (EPaC) and (…). Building a European Health Union: Reinforcings the EU's resilience for cross-border health threats, 11. 11. 2020, COM/2020)724 final. Proposal for a Regulation (EPaC) on serious cross-border threats to health and repealing Decision 1082/2013/EU COM/2020/727 final, Proposal for a Regulation (EPaC) amending Regulation 851/2004 establishing a European centre for disease prevention and control COM/2020/726 final, Proposal for Regulation on a reinforced role for the European Medicines Agency in crisis preparedness.

[10] Regulation (EU) 2022/2371 of the European Parliament and of the Council (…) on serious cross-border threats to health and repealing Decision No 1082/2013/EU, OJ L 314, 6.12.2022, pp. 26–63.

[11] Council Regulation (EU) 2022/2372 (…) on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level.

Still, one may add improving health informatics to this post-pandemic resilience package. The COVID-19 pandemic boosted electronic communication. It encompassed education, the home office of white collars and live culture, providing a further impulse for digital administration and telemedicine. Unsurprisingly, the EU COVID certificate was primarily electronic.

3.3 Harmonising and Unifying Data Protection

European countries recognised that personal data deserve protection with a convention agreed upon under the auspices of the Council of Europe.[12] Still, the Council does not play a significant role due to intensive law-making by the European Communities and the EU.

The first framework was the Personal Data Protection Directive (PDPD). The European Community justified harmonising the national laws on personal data to enable their cross-border movement. Enterprises and institutions collecting, maintaining, and using them should keep them accurate and protect against espionage and sabotage. The PDPD classified data related to health as sensitive but accepted its traditional treatment under Article 8(3).[13]

The Member States choose how they transpose directives. Among others, they can do it with several laws. As personal data protection overlaps with the standards for health records, it was possible to transpose PDPD by adjusting them. Unfortunately, PDPD was among the directives whose transposition was perfunctory years after its implementation deadline (Korff, 2008).

The General Data Protection Regulation (GDPR) is the most notorious uniform standard which replaced harmonisation. The impulse was a new, specific competence provision to protect personal data. However, because it led to increased bureaucratisation, and given its complexity and ambiguity, the GDPR has been frequently perceived as a regulatory monster (Voss, 2021). In response, big

[12] Convention for the protection of individuals with regard to automatic processing of personal data (ETS No. 108, 28.01.1981).

[13] Article 8(3) PDPD: "Paragraph 1 (prohibiting processing special categories of data) shall not apply where processing of the data is required for the purposess of preventive medicine, medical diagnosis, the provision of care or treatment ort he management of health-care services, and where those data are processed by a health professional subject under national law or rules established by national competent bodies to the obligation of professional secrecy or by another person also subject to an equivalent obligation of secrecy".

businesses has had to engage data supervisors, while small ones have had to hire advisors or fear sanctions due to non-compliance. Paperwork has proliferated. Extensive interpretations questioned various practices.

Concerning healthcare, small providers enjoyed the guidance of their associations and representations. The legal authority for collecting personal data would stem from both the performance of the contract and the legal duty to keep health records (Article 6(1)(b)(c)). Therefore, explicit patient consent is unnecessary. Moreover, it would be undesirable, as we would hardly perceive it as voluntary if patients need treatment and ask for it. Patients are vulnerable, and their data sensitive. The GDPR considers data regarding health- and social care, including protecting public health and health at the workplace, as specific, and their use is subject to restrictions (Article 9(2)(h)). The GDPR has a chilling effect on analysing existing health records, just when this data mining has become attractive thanks to information technologies (Hansen et al., 2022).

3.4 Interest in Medical Data

The EU's interest in health data has gone beyond personal data protection. The cited Cross-border Healthcare Directive encourages cooperation concerning cross-border care. *MyHealth@EU*[14] and *HealthData@EU*, two electronic platforms of the *eHealth Digital Service Infrastructure* (eHDSI), have been developed for this cross-border interconnection. There are initiatives for its improvement, TEHDAS being the most prominent.[15]

Despite these efforts, this interconnection is not omnipresent if we need to learn about pairs of Member States where cross-border e-prescriptions, e-dispensations and patient summaries are available.[16] Nonetheless, as an idea and project, EHDS predates the proposal analysed here (Iacob & Simonelli, 2020).

[14] See information My health@EU. Electronic cross/border health services in the EU, available at http://health.ec.europa.eu/system/files/2020-09/myhealth_qa_en_0.pdf.
[15] "Towards European Health Data Space", http://tehdas.eu, co-funded by the Health Programme of the EU and Sitra (Finnish Innovation Fund), involving partners from 21 EU Member States and four other European countries.
[16] For recent situation, consult Electronic cross-border health services (europa.eu).

Several adopted and proposed regulations are the legal expressions of a new approach of the EU, pursuing its Digital Strategy and construing a Digital Single Market.[17] The EHDS shall be among its dozen sectoral data spaces.[18]

3.5 European Multilingualism

Linguistically defined nations have established European countries. The EU has grown significantly beyond international organisations. Nonetheless, it is incapable of federalising. Several observers and laypeople would consider the absence of *démos*, i.e., a political nation, as an obstacle. Europeans lack one language for political deliberations. Under these conditions, EU law claiming direct effect and primacy over inconsistent national law – the essence of its supranationality - must exist in all the Member States' national languages.

Multilingualism has repercussions for economic integration. Undoubtedly, goods, including medicinal products (pharmaceuticals) and medical devices, are subject to extensive international trade. Nonetheless, manufacturers and distributors must accompany them with information translated into national languages. Physicians, nurses and other healthcare practitioners enjoy welcoming attitudes thanks to their frequent shortage. However, medicine requires excellent knowledge of the local language for effective communication with patients. We shall also consider language barriers on cross-border migration for treatment and necessary treatment of tourists.

4 Proposed Standard for Interconnection

4.1 The Proposal

The European Commission unveiled the proposal for a regulation establishing the European Health Data Space (EHDSR) in May 2022. Nonetheless, it was no surprise as the European Commission presented it as its priority,[19] in harmony with rotating presidencies.

[17] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: A Digital Single Market Strategy for Europe. COM/2015/0192 final.
[18] Commission staff working document on Common European Data Spaces, 23.2.2022 SWD(2022) 45 final.
[19] Combined evaluation roadmap / Inception Impact Assessment Ref. Ares (2020)7907993, 23. 12. 2020.

The proposal is a lengthy legal text addressing the issue in detail. An explanatory memorandum introduces this act, which includes in-built substantiation with numerous recitals. The annexes set technical specifications and items in patient summaries.[20] Estimates of expenditures follow. The proposal refers to several studies. It reveals that the Regulatory Scrutiny Board, an internal body of the Commission for better regulation, negatively assessed its first version in 2021.[21]

4.2 Appraisals and Criticism

The leaked proposal of EHDSR already sparked criticism, allegedly meeting the business interests.[22] Its presentation in May 2022 sparked a wave of reactions.

Unsurprisingly, *digitalEurope*, the lobby of "data majors", cherished the proposal.[23] Numerous institutions, associations and consortia representing patients, providers, the pharmaceutical industry, and universities voiced support. Among others, the statement by dozens of European associations deserves mentioning.[24] The perception of GDPR as an obstacle to data mining in health records could contribute to it.

Nonetheless, the European Data Protection Supervisor and the European Data Protection Board, the EU authorities charged with personal data protection, voiced concerns in their joint report,[25] namely, compromising patients' autonomy concerning their data.

The attitudes changed in the autumn of 2022. We hypothesise that the critical observers needed time to summarise their objections and debate them internally. Among others, one cannot ignore the criticism of the European Consumer

[20] Annex I – Main characteristic of electronic health data categories, namely 1. Patient summary and annex II – Essential requirements for EHR systems and products claiming interoperability with EHR systems.
[21] See Explanatory memorandum to EHDSR, impact assessment.
[22] See 'Santé numérique: les inquiétants projects d'Emamanuel Macron et de l'UE', 29. 4. 2022, available at https://multinationales.org/Sante-numerique-les-inquietants-projets-d-Emmanuel-Macron-et-de-l-UE.
[23] Welcoming press release on 3. 5. 2022, but already in 29. 7. 2022, the digitalEurope published an extensive opinion: https://www.digitaleurope.org/resources/initial-reactions-to-the-european-health-data-space-proposal/.
[24] European Patients Forum. 'EHDS Consensus Statement: Ensuring the full potential of EHDS: Stakeholder's recommendations on how to make the digital transformation a success across Europe', available at https://www.eu-patient.eu/news/latest-epf-news/2022/ehds-consensus-statement/.
[25] EDPB-EDPS (further EDPB-EDPS) 'Joint opinion on the proposal for a Regulation on the European Health Data Space', 22-07-12_edpb_edps_joint-opinion_europeanhealthdataspace_en_.pdf (europa.eu)

Association (BEUC, 2022). The Standing Committee of European Doctors also voiced concerns (CPME, 2022).

4.3 Legislative Procedure

EUR-Lex – Procedure enables us to observe law-making progress in the EU. The proposal is subject to ordinary legislative procedure. Concerning the political dimensions – interests, positions and contexts- we follow media coverage of EU politics.

The Economic and Social Council has already delivered its opinion, welcoming the project and mentioning its risks.[26] The Committee of Regions has proposed changes underlining local and regional dimensions.[27] However, the European Parliament has not completed even the first reading until September 2023. The proposal is pending in its committees. One may only speculate recently about inputs of the directly elected body. Anyway, deliberations in the Council will be crucial, as the Member States will implement EHDS in their healthcare systems. EUR-Lex indicates modest progress during the Czech presidency (7-12/2022), while it stalled for months during the Swedish presidency (1-6/2003). *Euractiv* informs about partial achievements in this law-making body. The Council / COREPER agreed to delete the telemedicine provision (Article 33) and reformulate the secondary use provisions (Holmgaard Mersh, 2022; Fortuna, 2023).

4.4 Competence Issues

EHDS belongs to the EU legislative initiatives that the integration enthusiasts welcome as magnificent, while sceptics consider it redundant, if not dangerous. One may discuss its contribution to patient mobility and biomedical research. Assessing efforts and expenditures would be helpful. The author joins those concluding that proportionality and subsidiarity are beyond the legal scrutiny. The EU law-making institutions should decide whether this interconnection is desirable.

[26] EESC 2022/02531, 22. 9. 2022, published in OJ C 486, 21.12, 2022, p. 123-128.
[27] Interinstitutional File 2023/0140(COD), 6403/23, 14. 2. 2023

Competence is a different issue. The Commission proposes EHDSR on the general competence to regulate the internal market in Article 114 Treaty on the Functioning of the European Union (TFEU) and the specific one stipulating personal data protection in its Article 16. Nevertheless, concerning healthcare, the EU balances the Member States' mentioned roles and tasks while carving out exceptions in Article 168(5) TFEU. Article 168 prohibits harmonisation, so one may argue *a fortiori* that unification is also illicit.

EHDSR would primarily interconnect existing electronic health information systems. Despite this, this legislative act would also have harmonising and unifying effects. Therefore, it is understandable to question the competence to legislate on this issue.[28] Once enacted, EHDSR will surely provide an example of competence creep (Prechal, 2010). Therefore, in order to avoid future disputes, unanimity in the Council will be desirable under these conditions.

4.5 The Choice of Instrument

Explanatory memoranda accompanying the regulations and directives recently proposed by the Commission contain a "choice of the instrument" section. Concerning EHDSR, the direct effect will establish individual rights, while uniformity should reduce fragmenting. Contrary to the memoranda accompanying other proposals, it also states that a directive would be unfeasible as its different transposition undermines personal data flow across borders.[29]

[28] Among stakeholders' opinions, 'Positionspapier der ABDA – Bundesvereinigung Deutscher Apothekerverbände e. V.', Oktober 2022, available at http://abda.de/fileadmin/user_upload/assets/Bilder/Newsroom/ABDA-RS_2297_221021_Positionspapier_EHDS-Verordnung_10-2022_Anlage.pdf.

[29] "The proposal takes the form of a new Regulation. This is considered the most suitable instrument, given the need for a regulatory framework that directly addresses the rights of natural persons and reduces fragmentation in the digital single market. To prevent the fragmentation that resulted from inconsistent use of the relevant clauses in the GDPR (e.g. Article 9(4)), the EHDS uses the options for an EU law offered by the GDPR Regulation concerning the use of health data, for various purposes. In the preparing the proposal, different national legal contexts that built upon the GDPR by providing national legislation were carefully analysed. In order to prevent major disruption, but also inconsistent future developments, the EHDS aims to put forward an initiative that takes into account the main common elements of different frameworks. A Directive was not selected, as it would allow a divergent implementation and a fragmented market that could affect the protection and free movement of personal data in the health sector. The proposal will strengthen the EU's health data economy by increasing legal certainty and guaranteeing a fully uniform and consistent sectoral legal framework. The proposed Regulation also calls for stakeholder involvement to ensure that requirements meet the needs of health professionals, natural persons, academia, industry and other relevant stakeholders."

Once enacted, EHDSR will repeal Article14 CBHCD, which encourages the interconnection of health information systems (e-health), with the limited achievements mentioned above. We may consider this provision as a recommendation in the directive. Nonetheless, this provision expected the standards for this interoperability of national electronic information systems by derived acts, so it is desirable to consider them.

The Commission enacted an implementing decision for this purpose,[30] while technology advances resulted in its recast.[31] When the COVID-19 pandemic required tracing contacts, it amended this recast decision, enabling the cross-border interconnection of these applications.[32] As these apps were voluntary, their contribution to tackling the pandemic was limited.

Still, we need to consider the entire supranational privacy standard. Article 14 refers to the PDPD and the E-privacy Directive.[33] Meanwhile, the GDPR resulting from a transformation of the directive deserves consideration as it applies to health records. On the contrary, the cited directive applies further, as the intent to replace it with e-privacy regulation has stalled.[34]

Despite its focus on interconnection, EHDSR stipulates (Article 1(2) and Article 3) the rights of patients. It is possible to interpret providers' corresponding duties and responsibilities. Still, explicitly prescribing them would be better.

[30] Commission Implementing Decision 2011/890/EU (…) providing the rules for the establishment, the management and the functioning of the network of national responsible authorities on eHealth.
[31] Commission Implementing Decision 2019/1765 (…) providing the rules for the establishment, the management and the functioning of the network of national authorities responsible for eHealth (…).
[32] Commission Implementing Decision (EU) 2020/1023 (…) amending Implementing Decision (EU) 2019/1765 as regards the cross-border Exchange of data between national contact tracing and warning mobile applications with regard to combatting the COVID-19 pandemic.
[33] Directive 2002/58/EC of the European Parliament and of the Council (…)concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications), OJ L 201, 31. 7. 2002, 37—47.
[34] Proposal for a Regulation of the European Parliament and of the Council concerning the respect for private life and the protection of personal data in electronic communications and repealing Directive 2002/58/EC (Regulation on Privacy and Electronic Communications), COM (2017), an ensuing endless negotiations in the Council and its auxilliary bodies.

4.6 Overlapping Regulations

Laws may apply in parallel, while multiple requirements are possible until inconsistencies and conflicts emerge. At that moment, it would be necessary to resolve the conflicts, with principles *lex posterior derogat legi priori* and, more importantly, *lex specialis derogat legi generali*, respectively.

Nonetheless, GDPR has encouraged the perception that it has acquired a quasi-constitutional position as the specification of TFEU and the CFREU provisions on personal data. Other regulations "mimic" it (Papakonstantinou & Hert, 2021). EHDSR indicates another preference for unleashing data for research. Unsurprisingly, many stakeholders presenting their views have called for clarification of the relationship between GDPR and EHDSR.

Another issue will be its coherence with regulations - branded as "acts" in their short titles - forming the Single Digital Market. The European Parliament and the Council have already adopted several,[35] while others are pending.[36] The legal environment will thus develop, and we should consider new "acts" when adopted. Several provisions of these regulations may change the regulatory landscape in health informatics interconnected with EHDSR.

4.7 Implications for National Laws

In theory, the primacy of the EU law applies, and regulations enjoy a direct effect. EHDSR will establish rights, duties and restrictions for individuals and other private subjects, putting aside possible incompliant provisions of the Member States.[37]

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[35] Regulation 2019/881 of the European Parliament and the Council (…) on ENISA (the European Union Agency for Cybersecurity) and on information and communications technology cybersecurity certification (…) (Cybersecurity Act), and Regulation 2022/868 (…) on European data governance (Data Governance Act).

[36] Proposal for a Regulation of the European Parliament and the Council on a Single Market for Digital Services (Digital Services Act) (…), 15/12/2020 COM (2020) 825 final 2020/0361(COD), proposal for a Regulation EPaC on contestable and fair markets in the digital sector (Digital Markets Act), 15/12/2020, COM (2020) 842 final 2020/0374 (COD), proposal for a Regulation EPaC laying down harmonised rules on artificial intelligence (Artificial Intelligence Act), 21/4/2021, COM (2021) 206 final 2021/0106(COD), proposal for a Regulation EPaC on harmonised rules on fair access to and use of data (Data Act). COM (2022) 68 final, 23/2/2022, 2022/0047(COD).

[37] Judgments 34-73 Fratelli Variola S.p.A. v. Amministrazione italiana delle Finanze, ECLI:EU:C:1974:101 (10. 10. 1973) and 47–71 Politi S.A.S. v. Ministero delle Finanze, ECR 1971, 01039 (10. 12. 1971).

The Member States enforce most EU laws. Despite the outlined direct effect, accompanying national legislation is necessary. Namely, the Member States establish or empower institutions, stipulate sanctions and specify procedures. Once enacted, EHDSR will be among them, expressing these expectations (Article 69).

Nonetheless, we do well to consider its actual repercussions. EHDSR would enable the cross-border movement of patient data. However, it does not harmonise national laws addressing health records. Therefore, the Member States' laws addressing them will not become redundant. On the other hand, one cannot say that EHDSR would spare them as it expects their particular arrangement for their interconnection.

New regulations addressing in detail the issues addressed previously by directives also increasingly contain directive-like provisions. To mention one, EHDSR empowers (Article 33(5)) the Member States to require the patient's consent to the research on specified data.

4.8 Language(s) of the Regulation

English has become the first global lingua franca of elite and expert communication worldwide. This article is written in this language to achieve international readership. The EU forms no exception, despite Brexit. English has become one of its two or three working languages, dominating most settings (except French at the Court of Justice). Recent translation statistics (European Commission, 2021, p. 7)[38] suggest drafting in English. Therefore, our focus on it in international discussions is understandable.

Nonetheless, the proposal for EHDSR has been available in all twenty-four official languages, and the outcome will be authentic in them. National authorities of the Member States will consider primarily their versions. This analysis does not discuss its terminology in other languages due to capacity constraints, but it would be helpful to consider possible dissonances. The doctrine encourages comparing language versions.

[38] 7. 2,541,294 of 2,767,078 pages were translated from English to other languages in 2021, thus exceeding 90 percent of all the source documents. If we consider documents originating in other language countries, the documents resulting from the all-EU negotiations are likely in English.

5 Particular Issues

5.1 Paper Records

Our analysis of EHDSR should start by asking whether electronic records will be mandatory. EHDSR solely mentions environmental benefits.[39]

In Czechia, harnessing e-health is the principal issue. Old-age physicians using paper seem to be already an anecdote. Most providers operate electronic health record systems. However, the legislative framework requires that electronic records have a robust backup system. Therefore, even the advanced providers print and store entries as official records.[40]

Costly cyberattacks on hospitals[41] justify these fears. Moreover, critics consider interconnection as enabling surveillance by authorities, alluding to "Big Brother". As mentioned, the state authorities are incapable of promoting feasible e-solutions. It took an entire decade just to introduce e-prescriptions in Czechia (Bruthans, 2019).

Expecting that all health records are electronic would be optimistic even if Czechia were the exceptional laggard. As previously mentioned, slow voluntary interconnection indicates that the situation could be similar in other European countries.

There are arguments for both interpretations. On the one hand, establishing the patients' rights in their mobility and "unleashing" health data research necessitates them to be in electronic form. On the other hand, such far-reaching requirements should be unequivocal.

5.2 Certification of Systems

EHDSR (Articles 14–30) envisages self-certifications of electronic health records systems regarding their interoperability and security. Several cited stakeholders voiced dissatisfaction with this approach (BEUC, 2022, pp. 9–10; CPME, 2022, pt.

[39] See explanatory memorandum to EHDSR, impact assessment.
[40] As stated by in-house counsels of one leading university hospital and of one regional emergency service.
[41] For detailed expert information in English see Brno University Hospital ransomware attack (2020) - International cyber law: interactive toolkit (ccdcoe.org).

7). We suggest accepting this approach as reducing the burden on operators (in general, Erixon & Lamprecht, 2018).

Nonetheless, even these requirements deserve clarification. Countries have already stipulated standards for these systems. The question is whether EHDSR will pre-empt the existing national licencing and surveillance or whether both standards will apply in parallel. Although retaining national requirements would pose an undue double burden, their pre-emption amounts to an unlawful unification.

Moreover, the Member States establish and operate providers, including principal hospitals. Supporting them concerning informatics is unsurprising. The Member States with advanced health informatics may also support private providers. Outsourcing to software firms and resorting to internal expertise may be used in tandem. There is no provision for "homemade" systems. Therefore, self-certification applies to them. We should remember this engagement during the legislative procedure, as several stakeholders require certification.

5.3 National Authorities

EHDSR requires (Article 10) the Member States to designate their "digital health authority". One may expect they will consider as qualified their authorities already regulating and managing healthcare. Therefore, the question is whether these institutions could also become national regulators overseeing the implementation of EHDSR.

Calls for independent authority by stakeholders may reflect recurrent tendencies emphasising the independence of administration (OECD, 2017) and judiciary. However, they primarily indicate a reading of EHDSR that the Member States could include this agenda in the existing ones and consider it problematic. If this interpretation is correct, we should ask whether reorganisation with in-built boards or particular officials would suffice.

As mentioned, observers and commentators call for clarification of the interrelationship of EHDSR with GDPR. EHDSR promises synergy. Under these circumstances, national data protection authorities will continue their control of providers operating health record systems.

5.4 Treatment as the Primary Use

Different requirements will apply in primary (treatment, healthcare) and secondary uses of patient data (research, data mining) in interconnected health records. Therefore, distinguishing between them is crucial. There are, however, borderline activities that do not fall neatly into either category.[42]

Concerning treatment, EHDSR raises the question regarding access to health records. Consenting to specific treatment need not amount to granting access to information available thanks to their interconnection. Some patients may perceive particular health data, namely those concerning psyche or sexuality, as extraordinarily sensitive and do not want to disclose them even to their general practitioners or other specialists.

EHDSR (Article 2(2)a) underlines patients' rights to decide on the use of their data. Therefore, it is surprising that it will open access to health data. It would be desirable to emphasise that accessing the health records of untreated patients is prohibited. Empowering patients to approve access to their data may resolve this dilemma. Indeed, it is infeasible in urgent situations. Patients could benefit from the possibility of deciding in advance about access. Notification of every access to the patient health records could serve to help control possible misuse.

At the same time, physicians do not need such far-reaching access. They may even consider an ensuing expectation to examine the entire health data of their patients as overly burdensome. When considering treatments, physicians ask for concrete information with straightforward questions. Filtering this data from interconnected records for particular warnings may be optimal.

Moreover, experts promoting safety in medicine suggest intense communication with patients. For example, practitioners repeatedly question their patients before surgery to avoid mistaken identity or confusion about the planned intervention. Patients incapable of communicating benefit from increased attention. One could not recommend refraining from asking these questions even if these health records were complete and actual.

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[42] See also CPME p. 1, ft. 2 underlines that "A precision should be made in relation to research that uses electronic health data from biobanks and dedicated databases. Biobanks are created for research purposes – this is their primary purpose, and thus do not fit well within the secondary use system concept."

5.5 Research as the Secondary Use

GDPR has provided fertile soil for the idea that personal data forms individual identity. Even their pseudonymisation or anonymisation does not remove its potential for being compromised by illegitimate use (Donnelly & McDonagh, 2019; Demotes-Mainard, Cornu & Guerin, 2019). Unsurprisingly, the "unleashing" of health data promised with EHDSR sparks outrage, as it is a paradigm change.

As mentioned, there is a widespread perception that GDPR has chilled the analyses of health records as an activity requiring patients' explicit consent and empowering them to demand clarification. GDPR expects national laws to specify the rules for data research. However, it seems that the Member States have so far hesitated to do so.

Still, patient data pseudonymisation and anonymisation have become subjects of intense debate. Several commentators see these measures as sufficient, but others insist that perfect decoupling data from patients is difficult, if not impossible, mentioning genetics as one example (Mitchell et al., 2020; BEUC, 2022, p. 12, 4.3).

Meanwhile, advanced informatics would allow individuals to decide whether to include or exclude their data, as this would be possible with several clicks on the screen in platforms interconnecting electronic records. Opt-out and opt-in regimes or their combinations are possible. Surprisingly, EHDSR will not empower patients to do so when it becomes technically feasible.

EHDSR will prohibit (Article 37) research aimed at specified illicit purposes: insurance, advertisement, and development of harmful products. One may ask about the rationale of this provision if pseudo- and anonymisation promise to disconnect patients from their health data. It will deliver an argument for the opponents if it indicates mistrust towards these methods. And it is mere virtue signalling by the EU lawmakers towards the European general public if these methods work.

5.6 Data Quality and Fees

EHDSR will entitle (Article 56) researchers to examine prospective health data before purchasing access. Undoubtedly, this approach is sensible, and we could generalise it. The data in health records form no gold mine. If they were, managers

would overcome obstacles resulting from personal data protection. These health data have become a valuable commodity recently because of advanced informatics, as automated data mining has become cheap.

The proposal stipulates (Article 42) that researchers' fees for data access should be reasonable. One may defend this as an adequate arrangement addressing the issue. Still, it expresses public interest in health data research.

Israel exchanged the patients' data it collected systematically and structured feasibly for preferential delivery of the then-scarce COVID-19 vaccines (Birnhack, 2021). Two decades ago, the deCODE launched national genetic scrutiny in Iceland for promising investment in the national economy and growth impulse (Merz & McGee, 2004). In both cases, the decision-making on behalf of entire nations was political. Parliaments or executives responsible to parliaments decided on the bargain. Despite this, vivid discussions emerged. General standards for this commercialisation expected by EHDSR may underestimate variable political, societal, economic and psychological aspects of particular research projects.

Ethics committees approving the projects (CPME, 2022, point 8)[43] may mitigate the problem if EHDSR expects general data openness. Still, these projects have already become subject to their scrutiny, as scientific journals often require their approvals.

5.7 Selected Special Data

EHDS will grow incrementally. Still, it prioritises several data: electronic prescriptions by physicians addressed to patients and pharmacies, laboratory results related to particular patients, and medical imagery (Article 5). Other categories shall follow. Let us discuss the selected ones.

One sensitive category is data related to the financing of healthcare.[44] Coupling these data with interventions and treatments would be interesting for economists. Their analyses could expose various phenomena in healthcare financing and thus contribute to transparency but may also serve competitors. EHDSR lacks detail on this topic. Therefore, we need to discuss what data it will expect. Among others,

[43] And the accompayning flyer 'Role of Ethics Committees in the European Health Data Space', 25. 5. 2022, cpme.eu/api/documents/adopted/2022/04/AR_CPDP_Flyer_220427.pdf.
[44] Article 33(1)(j) EHDSR.

there are calculations to insurance funds or similar authorities for financing healthcare and prices charged to patients. Significant differences exist among the national systems, which combine public and private elements. Should this provision also encompass economic data related to privately-paid medicine?

Another such category is data from biomedical research. This research is subject to bioethics, business standards, and international and national laws. Regarding clinical trials of medicinal products (pharmaceuticals), the EU has just made its uniform standard applicable.[45] Case report forms are clinical trial records concerning research subjects, i.e. volunteers or patients. As the second and third phases of clinical trials also form treatment, information about administering investigational medicinal products enters standard patient health records. Access to these data has economic, societal, psychological, political, and legal repercussions. Unsurprisingly, the business has voiced concerns about publicising research data (Levy & Johns, 2016). EHDSR recognizes (Article 33(4)) this concern rhetorically, mentioning protecting competition and intellectual property rights.

5.8 Patient Summaries

German *Krankengeschichte* for traditional paper records indicates an understanding of its nature. Particular entries summarise the patient's situation identified by the physician, anamnesis, diagnoses and interventions, which their communication accompanied. This patient's history consists of entries arranged chronologically. Multiple providers keep these records, as patients often received care from multiple specialised providers and often change providers.

[45] Regulation (EU) No 536/2014 EPaC (…) on clinical trials on medicinal products for human use, and repealing Directive 2001/20/, Article 98(2), Article 98(1) CTR, concerning clinical trials approved before the entry into force (31 Jan 2022) in accordance with Commission decision (EU) 2021/1240 (…) on the compliance of the EU portal and the EU database for clinical trials of medicinal products for human use with the requirements referred to in Article 82(2) of Regulation (EU) No 536/2014 (…).

On the contrary, a *patient summary* should deliver (Annex 1-1 EHDSR) relevant information.[46] Concerning its content, EHDSR builds on its gradual development with the EU (Maarseveen & Thorp, 2014)[47] and international standards.[48]

Nonetheless, such datasets usually do not exist. Completing them would be demanding. Foremost, older paper records are unavailable as laws enable their shredding. We may hope they are not essential, as newer health records reflect everything relevant. It would be necessary to concentrate existing health records – including the electronic ones - on one designated provider or another institution. Otherwise, entries by multiple providers would need coordination. EHDSR does not stipulate guidelines on this issue, so we question whether the Member States could specify it.

The proposal for EHDSR acknowledges that existing health records are incompatible (rec. 18), justifying lengthy transitional periods.[49] The proposal is silent on the proportion of completed patient summaries or similar datasets and the effort necessary for completing them. Therefore, we can only speculate on the length of time it would take to complete one patient's summary. Let readers imagine their case. Middle-aged or elderly individuals often have a complex history of illnesses, injuries and findings. Their treatment could consist of repeated visits or recurrent hospitalisations over a period of years, sometimes even decades. These records could consist of hundreds of pages. Patient summaries cease to be summaries in their cases, so additional substantive entries would be better. Moreover, patient summaries need actualisations, as they can become obsolete within short periods of time due to new diseases, or injury and ensuing treatment.

[46] Patient summary: 1. Personal details, 2. Contact information, 3. Information on insurance, 4. Allergies, 5. Medical alerts, 6. Vaccination/prophylaxis, possibly in the formo f a vaccination card, 7. Current, resolved, closed or inactive problems, 8. Textual information related to medical history, 9. Medical devices and implants, 10. Procedures, 11. Functional status, 12. Current and relevant past medicines, 13. Social history observations related to health, 14. Pregnancy history, 15. Patient-provided data, 16. Observation results pertaining to the health condition, 17. Plan of care, 19. Information on a rare disease such as details about the impact or characteristics of the disease.

[47] See also 'Guidelines on Minimum/non-exhaustive patient summary dataset for electronic Exchange in accordance with the Cross-border Directive 2011/24/EU', adopted by the e Health Network, version 1.0, 19. 11. 2013, available at http://health.ec.europa.eu/systém/files/2019-02/guidelines_patient_summary_en_0.pdf.

[48] International Patient Summary and European standard aligned by Comité Européen de Normalisation CEN and International Standard Organization ISO EN ISO 27269:2022 as equivalent to ISO 27269:20221.

[49] Article 72 EHDSR expects one year of *vacatio legis* and encompassing the most prioritised data in one additional year and other data within three years.

Physicians are undoubtedly the most qualified for this task but are busy professionals who routinely, and rightly, complain about bureaucracy. They have hundreds of patients. Expecting them to spend dozens of hours on the issue is naive. Training others for this task may be the solution, but it would spark outrage about other persons' access to patient data.

In any case, completing and updating patient summaries necessarily comes at substantial cost. Let us thus consider resorting to rapidly advancing artificial intelligence. Its deployment in healthcare has become a reality (Briganti & Moine, 2020), and this is a realistic option for generating patient summaries (Pivovarov & Elhahad, 2015). Nevertheless, it has also become a concern, and the EU has already proposed an "act" for its surveillance.[50] Even this solution, however, would require scanning existing records en masse. Surprisingly, the proposal and accompanying studies do not expect it, perhaps due to outlined underestimates of the effort that would be involved.

Patient summaries would constitute an excellent source for research. From this viewpoint, their completion is desirable. Their merits for particular treatments are less apparent. Deploring duplicities has become commonplace, but we know little about their incidence and consequences. Moreover, repeated checks are not entirely undesirable, as they increase safety. Reliance on the information available through EHDS need not compromise professional cautiousness even if all data were perfect.

5.9 Translations of Verbal Entries

EHDSR pays little attention to the language of health records and their interconnection. Its entire text mentions language(s) solely when admitting that existing health data are not structured, so their machine translation is infeasible (rec. 18).

Several explanations for this laxity are possible. Imagery, laboratory results and data generated by medical devices are non-linguistic, while international trade in computers and software results in the global convergence of file formats and

[50] Proposal for a Regulation of the European Parliament and the Council laying down harmonised rules on artificial intelligence (Artificial Intelligence Act), 21. 4. 2021, COM (2021) 206 final 2021/0106(COD).

software. Moreover, experts' international communication in English may result in underestimating the linguistic dimension.

Nevertheless, verbalised information forms an indispensable part of health records. Therefore, one should consider the machine translation, its quality, and the perspectives of its enhancement. In some cases, encouraging reading of the original and its translation with the patient's assistance may be suitable.

6 Conclusions

All four chapters of this article finish with sub-chapters mentioning relevant language aspects. This symbolism emphasises the roles of language(s) in every communication and the challenges for international trade, mobility, and European integration.

Predicting whether a particular legislative proposal will succeed is tricky, especially in supranational settings. The recent promise (Pištorová & Plevák, 2022; Fortuna, 2023) to complete law-making in 2024 and render the EHDS applicable in 2025 is ambitious in September 2023.

The supranational lawmakers should resolve the tension between data protection, considered an identitarian issue, and the interest of scientists in the research of these data. Fortunately, various compromises are possible.

Besides, it is necessary to ascertain whether the existing health data are interoperable and how to render them such if they are not. Political analysis identifying unpreparedness even in Germany (Wrosch, 2022) provides a cautionary warning. Commitment to EHDS may primarily serve as an impulse for completing the interconnection of health records in domestic settings.

Characterising the "acts" adopted and proposed for the Single Digital Market as "regulatory brutality", i.e. introducing new standards without much willingness to consider existing national frameworks (Papakonstantinou & Hert, 2022), also fits EHDSR. Once enacted, it will expand on the issues addressed by the national lawmakers, including their recently adopted laws promoting health informatics. It is time to discuss the aspects in which it supersedes them and these it will complement.

For these reasons, its provisions deserve intense discussion. One should not underestimate the psychological, political, and technical challenges of construing EHDS. Generally, frequent enchantment in the scholarly debates about EU law (Leino-Sandberg, 2022) is counterproductive in developing our supranational polity. This ambitious project could quickly fail without such care for details.

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Legal acts, standards and proposals of them

CBHCD – Cross-Border Health Care Directive - Directive 2011/24/EU of the European Parliament and the Council (…) on the application of patients' rights in cross-border healthcare, *OJ L 88, 4 .4. 2011, p. 45–65.*

EHDSR: Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space (Text with EEA relevance), 3.5.2022 COM(2022) 197 final 2022/0140(COD), {SEC(2022) 196 final} - {SWD(2022) 130 final} - {SWD(2022) 131 final} - {SWD(2022) 132 final}.

GDPR - Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons 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) (Text with EEA relevance), OJ. L 119, 4.5.2016, pp. 1–88.

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Povzetek v slovenskem jeziku

Analiza elektronskih zdravstvenih zapisov bi lahko izboljšala medicino, vendar možnosti za to omejuje varovanje osebnih podatkov. Evropski zdravstveni podatkovni prostor naj bi te podatke sprostil. Poudarek se zdaj preusmerja na najboljše načine za uravnoteženje tega prizadevanja hkrati z varovanjem zasebnosti in avtonomije pacientov. Kljub temu se moramo spoprijeti z realnostjo.

Raziskave o slikah, laboratorijskih rezultatih in receptih bodo preproste, saj so elektronske. Vendar pa pisna jedro zdravstvenih zapisov ni strukturirano, vzpostavljanje povzetkov za vse paciente pa je zahtevno. Namesto direktiv so uredbe hvalevredna rešitev za poenostavitev položaja. Kljub temu pa se pojavljajo novi izzivi povezani s sobivanjem nacionalnih pravnih okvirov in nadnacionalnega pravnega okvira, če naj bi prvi imel daleč segajoče ambicije.

Ključne besede: