European health data space

OVERVIEW

The COVID-19 pandemic has shone a light on the growing importance of digital health technologies, both to enable remote medical care and to facilitate the health response by international, national and local authorities. At the same time, personal health data have been key for containment measures such as the EU digital COVID-19 certificate.

The European Commission's proposal for a regulation on a European health data space aims to improve individuals' access to and control of their electronic personal data (primary use), while facilitating data re-use for societal good across the EU (secondary use). Grounded in the EU data strategy, which mentions health as one of the nine European common data spaces, it cuts across several other EU policy priorities, such as the health union and the digital single market.

The proposal establishes a set of rules, infrastructure and governance mechanisms to promote both primary and secondary uses of electronic health data, while ensuring data protection and strengthening cybersecurity.

The Commission expects the initiative to have a broad socio-economic impact, ranging from improving people's health, to facilitating the uptake of evidence-based policy-making. Its success is thought to depend not only on the capacity to implement the legal basis effectively, but also on broader conditions such as EU-wide connectivity, social trust and digital skills.

The legislative procedure is in its early stages. A European Parliament rapporteur has not yet been appointed.

Proposal for a regulation of the European Parliament and of the Council establishing the Union Health Data Space		
Committee responsible:	Civil Liberties, Justice and Home Affairs (LIBE)	COM(2022) 197 3.5.2022
Rapporteur:		2022/0140(COD)
Shadow rapporteurs:		
Next steps expected:	Publication of draft report	Ordinary legislative procedure (COD) (Parliament and Council on equal footing – formerly 'co-decision')

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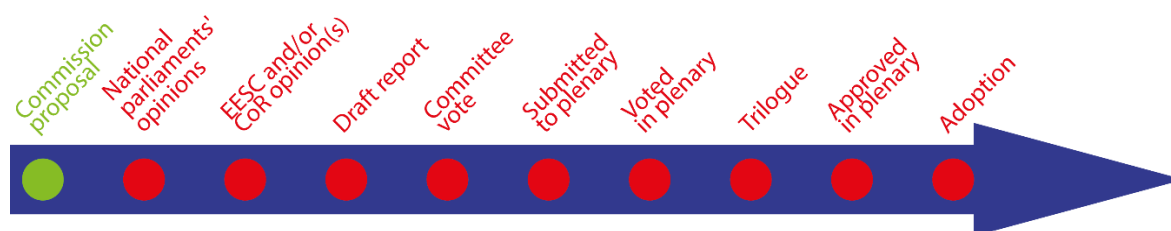
Introduction

Digital health refers to the use of digital technologies and information and communications technology (ICT) by individuals and healthcare systems for health purposes. It covers a wide range of goods, including medical devices, and services, such as remote care delivery tools, health data and information management solutions, and patient management, including tele-monitoring and diagnosis.

The rollout of digital technologies is rapidly changing the way in which health and care services are provided. In particular, the diffusion of online and portable devices extends the scope of health data processing from electronic health record systems [1] to new technologies enabling individuals to access, generate, process and transmit more granular health data.

Among the outcomes of the Conference on the Future of Europe, the conference plenary included the establishment of a European health data space (EHDS) as one of the 49 proposals. [2] The EHDS is also conducive to the implementation of the European health union, which aims to strengthen preparedness and response during health crises and deliver resilient health systems.

According to the Commission proposal of 3 May 2022, the EHDS will allow qualified actors to link health data sets and make them accessible within and across Member States. It is also expected to strengthen natural persons' (i.e. individuals') control over their data, while facilitating re-use of data for scientific, innovative and public policy purposes.

Context

The digitalisation of health is shaped by both technological progress and regulation. Several EU legislative initiatives – General Data Protection Regulation (GDPR), EU Data Protection Regulation, EU Data Governance Act, data act, Network and Information Systems (NIS) Directive – aim to harness the digital transition. They have established a framework enabling individuals to secure, access and control data, not least relating to health. According to a 2022 paper by the Organisation for Economic Co-operation and Development (OECD), health data sharing improved significantly within the public sector. Beyond the primary use of health data, the paper also highlights the relevance of data re-use (secondary use): up-to-date health data are considered key to taking well-informed public-health decisions.

The principles of health data use have been defined in the GDPR and the EU Data Protection Regulation. Both aim to protect individuals' fundamental rights and freedoms, including their right to the protection of personal health data. Personal data concerning health is defined broadly as 'all data pertaining to the health status of a data subject which reveal information relating to the past, current or future physical or mental health status of the data subject' (Recital 35 GDPR). Such personal health data qualifies as a special category of personal data, the processing of which is subject to strict conditions (Article 9 GDPR). Interestingly, the GDPR also contains legal grounds allowing for re-use of health data, for instance in response to serious cross-border threats to health, and for scientific research purposes (Article 9(2)(h-j) GDPR). Lastly, the right to data portability (Article 20 GDPR) entitles data subjects (natural persons) to access and control their data.

The primary use of health data across the EU has also led to regulatory initiatives designed to ensure the flow of health data across the EU. The current EU legal framework in force on the cross-border exchange of health data is laid down in Directive 2011/24/EU on the application of patients' rights in cross-border healthcare (Cross-border Healthcare Directive). Its scope entails only individual patients benefiting from healthcare in a Member State other than their Member State of affiliation. To facilitate cooperation and the exchange of information among Member States, a voluntary network connecting national authorities responsible for e-health in the Member States is established (the 'eHealth network'). Among other tasks, the network aims to deliver interoperable applications, with a view to achieving a high level of trust and security, enhancing continuity of care, and ensuring access to safe and high-quality healthcare.

The EU Data Governance Act, adopted in 2022 by the co-legislators, establishes a horizontal framework across sectors with common governance mechanisms and rules to enhance access to data for re-use. In particular, the newly established European Data Innovation Board, which will comprise a subgroup on health, will advise and assist the Commission on developing re-use of protected data held by public-sector bodies. The set of provisions to encourage and regulate 'data altruism' (Chapter IV, Articles 16-25 Data Governance Act on data altruism) is expected to facilitate the uptake of secondary use of health data.

Moreover, EU legislative initiatives on cybersecurity are key to ensuring the continuity of healthcare services, as well as increasing societal trust in the digitalisation and flow of health data. The provisional agreement between the co-legislators on the proposal for a directive on a high common level of cybersecurity in the EU includes health among the critical sectors to be protected through appropriate cybersecurity risk management measures and reporting obligations. Between April 2020 and June 2021, the EU cybersecurity agency, ENISA, was notified of 150 incidents in the healthcare sector. However, the 2021 ENISA report on Computer Security Incident Response Teams (CSIRT) capabilities the health sector concludes that only three Member States (France, Luxembourg, the Netherlands) have established a health sectoral CSIRT, with a further four (Bulgaria, Denmark, Croatia, Austria) planning to do so.

Public-health initiatives have also referred to the establishment of the EHDS as an enabler of their respective objectives. This is notably the case of the health union package, in which the cross-border interoperability of health data will be key to allowing the European Medicine Agency and the European Centre for Disease Prevention and Control to comply with their extended mandates. This is also true for the European pillar of social rights action plan, which features the EHDS among its actions, ensuring a crucial contribution to the European health union.

Existing situation

According to the impact assessment accompanying the EHDS proposal,[3] the global digital health market has seen a steady increase in terms of size from €16 billion in 2015 to €31 billion in 2020. Digital health encompasses electronic health (e-health) systems based on the use of ICT to improve existing processes, such as electronic health records. It also comprises mobile health (m-health) systems based on the increasing computing power and prevalence of mobile devices, to empower individuals or allow for remote monitoring.

Electronic health records are so far the biggest market sector. According to an analysis, the size of the global market in 2020 was estimated at €25.11 billion, and expected to grow to €32.67 billion by 2028. According to the EHDS impact assessment, the EU market represents a significant part of the expected global growth. In the EU, the cost of setting up national electronic health record systems ranges between a few hundred million euros to €1.4 billion for mid-sized and large Member States, depending on the service coverage. At the EU level, this would correspond to a market of up to €16 billion, out of which €3-9 billion need to be set up or further developed.

The COVID-19 pandemic spurred the uptake of m-health solutions, in particular in the EU. According to another analysis, European spending in health and fitness mobile applications increased by 70 % annually in 2020 to an estimated €0.508 billion. Downloads of health and fitness applications saw a significant surge in Europe during 2020, rising by approximately 46 % year-over-year in 2020 to 830 million. The amount of sales in health and fitness applications in Europe accounted for 30 % of global spending in the category, up from a 27 % share in 2019.

Primary use. The Commission communication on an EHDS stresses that natural persons cannot yet fully exercise their right to access and control their health data. Additionally, the design and deployment of new digital health products and services is hindered by the fragmentation of standards and specifications, within and across Member States. Interoperability of health information systems comprises complementary components: legal (same rules), organisational (similar policy and care processes), semantic (similar way of coding the data to be processed) and

technical interoperability (for applications and information technology infrastructure). The scope includes not only electronic health records, but also interoperability among digital devices and digital health applications.

On the basis the 2011 Cross-border Healthcare Directive, the eHealth network, a voluntary network connecting national authorities responsible for e-health, was set up, together with the e-health digital service infrastructure (eHDSI).[4] With the adoption of the 2019 Commission recommendation on the European electronic health record exchange format (EHRxF), Member States are set to provide citizens and healthcare professionals with online access to their electronic health records, also across Member States, using secure electronic identification means, while ensuring high standards for the protection of health data.

Two cross-border services are being introduced progressively in 25 Member States[5] by end 2025:

- e-prescription and e-dispensation allow EU citizens to access their medication in another EU country thanks to the online transfer of their electronic prescription from their country of affiliation to the country of travel (e-prescription). The country of residence is informed of the cure obtained in the country of travel (e-dispensation);
- the digital patient summary provides information on important aspects of a person's health status, such as allergies, current medication, previous illness and surgeries. It is part of a larger collection of health data (the European health record), which will be implemented throughout the EU. The digital patient summary provides health practitioners with essential information in their own language, even when the patient comes from another EU country.

The eHealth network approved recommendations on the interoperability ecosystem and funding criteria. The main information domains being standardised (coded, made interoperable for data exchange, etc.) include patient summaries, e-prescriptions/e-dispensations, laboratory reports, medical images and reports, and hospital discharge reports. These information domains are not the only documents included in an electronic health record. The network has also issued, for instance, technical specifications for EU digital COVID-19 certificates. So far, according to the Commission communication on the EHDS, ten Member States exchange health data through this infrastructure.

Interoperability is still facing challenges. In a 2021 preparatory study for the EHDS, a survey conducted among Member State representatives from the eHealth network points to different hurdles: from a legal point of view, 39 % of respondents deem that legislation and national rules do not prescribe technical operability. From a policy perspective, 39 % of respondents declare that their country has not yet issued any practical implementation guidelines, nor a framework to share good practice among stakeholders.

Beyond the legal background and the issue of health information systems interoperability, citizens' capacity to access and control their health data also depends on them having internet access, digital skills and trust, as mentioned in a 2021 assessment of Member States' rules on health data.

Secondary use. As mentioned above, the GDPR describes the secondary use of health data for research, innovation (including on pharma, medical devices, AI), and policy-making purposes. EU investment in research and innovation (R&I), not least in research infrastructure, facilitates re-use of health data generated through scientific activities. For instance, European Open Science Cloud initiative, EOSC-life, pools 13 life science research infrastructures to create an open, digital and collaborative space for biological and medical research, with different deliverables such as a repository for COVID-19 clinical trial data. Beyond this direct support to the establishment of such infrastructure, the EU's R&I policy priority of open science also facilitates re-use of data in general.

According to the Commission impact assessment on EHDS, the eHealth network is not effective in dealing with secondary use of health data, despite several Member States having established dedicated entities (such as Findata, the Finnish social and health data permit authority). Divergent rules and frameworks prevent data holders[6] from facilitating re-use of health data. The wide variety

of GDPR interpretations across Member States has made cross-country studies very difficult, as data re-users must comply with different requirements in each jurisdiction. A 2021 report by the Open Data Institute on secondary use of health data in Europe concludes that most Member States and the Commission qualify as leaders in re-use, based on the policy framework and the advancement of its implementation.

Comparative elements

The United Nations (UN), in the framework of the UN 2030 Agenda, are promoting digitalisation as a determinant of health. The COVID-19 pandemic has highlighted long-standing data governance topics such as intellectual property rights and data sharing. Globally, persistent data gaps and fragmented approaches to governing health data in different contexts are deemed major roadblocks to promoting data as a public good. The World Health Organization (WHO) global strategy on digital health 2020-2025 considers that 'digital health should be an integral part of health priorities and benefit people in a way that is ethical safe, secure, reliable, equitable and sustainable. It should be developed with principles of transparency, accessibility, scalability, replicability, interoperability, security and confidentiality'. In June and September 2021, the WHO organised a health data governance summit. This led to the publication of a call for health data governance, which emphasised international cooperation to harness health data as a global public good, both for primary and secondary uses. It states that 'high quality health data is crucial to accelerating progress towards the 2030 Sustainable Development Goals'.

In 2016, the OECD Council adopted a recommendation on health data governance, which calls for the implementation of health governance frameworks to unlock data potential, the development of cross-border cooperation in processing health data for public interest, and the engagement with a wide range of stakeholders to ensure interoperability. The 2016-2021 implementation report identifies two EU Member States (Denmark and Finland), together with South Korea, as the strongest countries in national health data availability and health dataset governance policies and practices.

Parliament's starting position

The Parliament has provided guidance on health data, before the tabling of the EHDS. In February 2019, it adopted a resolution on the implementation of the Cross-border Healthcare Directive, where it emphasises that eHealth interoperability should be made a priority, in order to improve global patient records and continuity of care, while guaranteeing patient privacy. With its December 2019 resolution on enabling the digital transformation of health in the digital single market, it stresses that citizens have the right to access and share their personal health data in accordance with the GDPR in order to obtain better healthcare. It also calls on the Commission to involve actively citizens and all other actors in the healthcare chain, and to develop specific applications for high-security cross-border health data exchange for research and health policy. This would improve the prevention, diagnosis and treatment of diseases, also enhancing health systems preparedness.

With its November 2021 resolution on a pharmaceutical strategy for Europe, the Parliament welcomes the establishment of an EHDS as an interoperable digital infrastructure. It considers that this initiative should promote both primary and secondary health data uses, in full compliance with the GDPR. The Parliament outlines several requirements to ensure this alignment: the Commission should work with Member States to ensure harmonised application of the GDPR, and the principles of data protection enshrined in Regulation (EU) 2018/1725 (EUPDR). The Parliament also specifies the need to develop European federated networks to contribute to R&I (including artificial intelligence – AI) and healthcare. In particular, it calls for the interoperability of high performance computing infrastructure with the EHDS sets, to tackle rare diseases and paediatric conditions, as well.

Parliament's February 2022 resolution on strengthening Europe in the fight against cancer suggests that the Commission could lay the foundation for the EHDS in association with the Digital Health

Europe project. Specifically, this would entail collecting, analysing and exchanging anonymised medical data (from cancer registries, hospitals, academic clinical trials and cohorts) and biological data (from blood and tumour samples) in a European cancer cloud.

The Parliament also contributed to precise the legal framework on data re-use in other legislative initiatives. For instance, in its April 2022 resolution on the proposal for a regulation on a European governance act, it specified that re-use should be designed in a manner promoting scientific research. It strengthened further the rights of data holder by specifying that public sector bodies should not allow re-use of information stored in e-health applications by insurance undertakings or any other service provider for the purpose of discriminating in the setting of prices. It also restricted the flow of non-personal data with third countries whenever the transfer to third countries of non-personal data held by public sector bodies may put at risk EU public policy objectives, such as public health.

Council and European Council starting position

The European Council supports the creation of an EHDS. With its conclusions of 1 and 2 October 2020, it welcomes the creation of common European data spaces, and invites the Commission to give priority to the one on health. In its conclusions of 21 and 22 October 2021, it stresses the importance of making rapid progress on other existing and future initiatives, to unlock the value of data in Europe, notably through a comprehensive regulatory framework that facilitates data portability and fair access to data, and ensures interoperability.

The Council of the EU has translated the European Council's political guidance in conclusions, but also in its legislative activities. With its conclusions of 16 June 2021 on access to medicines and medical devices for a stronger and resilient EU, it welcomes the preparation of the proposal for an EHDS to promote digital health and leverage data quality. It considers that this would establish strong infrastructure and interoperability, while promoting data privacy within and across Member States, and require the development of a system of data governance and rules for data access and exchange with emphasis on data privacy. In its negotiating mandate of 1 October 2021, the Council encourages the design and implementation of data altruism policies in Member States. These policies might consider supporting data subjects in making personal data related to them held by public sector bodies available voluntarily for data altruism. They might also set out the necessary information to be provided to data subjects on re-use of their data in the general interest.

Preparation of the proposal

With its 2020 communication on the European Strategy for Data, the Commission identified the low availability of data for re-use and fragmentation among Member States' legislative initiatives as significant risks to the further development of an EU single market for data. In addition to the preparation of a cross-sectoral legislative framework on data access and re-use (the Data Governance Act and data act mentioned above), the communication highlights the Commission commitment to invest in establishing European data spaces and federated cloud infrastructures. Among the nine sectoral data spaces to be established, the EHDS shall facilitate health data uptake in general, and the dissemination of digital technologies. The collection, access, storage, use and re-use of data in healthcare present specific challenges that need addressing, in particular to ensure compliance with European values, fundamental rights and rules. This requires a regulatory framework that protects individuals' interests and rights, in particular as regards the processing of sensitive personal health data.

The preparation of the proposal was informed by an online public consultation between 3 May and 26 July 2021, which focused on two main issues: (i) access to and use of health data for healthcare provision, R&I, and policy-making; and (ii) support for a genuine single market for digital health services and products, including innovative ones.

The vast majority of the 382 valid responses submitted support both the primary and secondary uses of health data. For instance, 88 % of respondents consider the EHDS should promote citizens' control over their own health data, including access to them, and transmission of their health data in electronic format; and 83 % deem that the EHDS should facilitate the delivery of healthcare to citizens across borders. As regards support for the secondary use of research, 89 % of respondents would like the EHDS to support and accelerate research in health.

The impact assessment also highlights several studies and opinions that fed into the proposal's preparation. Among them, the 2020 preliminary opinion by the European Data Protection Supervisor on the EHDS strongly supports promoting health data flows, and stresses that the success of EHDS will depend on the establishment of a strong data governance scheme. This scheme should comply with lawful, responsible, ethical management anchored in EU values. The opinion also considers that the EHDS should aim to mitigate the 'current fragmentation of rules applicable to the processing of health data and to scientific research'.

The changes the proposal would bring

The proposal has three complementary specific objectives: (i) ensuring individuals' control over their electronic health data; (ii) setting the rules for the solutions offered on the market for health record systems and wellness applications; and (iii) allowing researchers, innovators and policy-makers to harness the health data available. It sets out the rules, infrastructure and governance for developing both the primary (including cross-border) and secondary use of health data.

Primary use of health data. The proposal provides for individuals' right to access their personal health data free of charge (article 3). This access may also apply to data not registered electronically before the regulation's entry into force, subject to Member States' requirements. Individuals' right to free access includes their right to receive an electronic copy of their data, the authorisation to insert such data into their electronic health records (EHRs), and the capacity to transmit their data free of charge to recipients of their choice from the health or social security sector. Whenever electronic registration of personal health data takes place in a Member State different from that of affiliation, interoperability will be ensured by using the affiliation country's personal identification data. Together with individuals' right to free access, the proposal also establishes a specific right of access for health professionals, who should have access to the relevant data of the individuals under their treatment, regardless of their Member State of affiliation and the Member State in which the treatment is given. However, the latter access may be restricted by individuals who have the right to restrict access to all or part of their electronic health data to health professionals (article 3(9)).

The scope of electronic health data encompasses six priority categories (article 5): patient summaries, e-prescriptions, e-dispensations, medical images/image reports, laboratory results, and discharge reports. The nature and granularity of both the data and the associated metadata that correspond to those six categories are set in annex I to the proposal.

The proposal also details a specific governance mechanism allowing primary use of health data. Each Member State should identify a digital health authority responsible for implementing the access rights granted to individuals and health professionals (article 10). Member States should also appoint a national contact point that would ensure the connection with all other national contact points and with MyHealth@EU (article 12), the central platform for supporting and facilitating exchange of electronic health data between the national contact points for digital health in the Member States.

Chapter II of the proposal specifies several requirements to ensure effectiveness of the infrastructure underpinning primary use of health data. The first requirement aims to lay down the technical specifications for the exchange format. It includes datasets containing health data and their defining structure, the coding systems to be used, and the technical specifications for the exchange of data (article 6). The relevant Member State authorities should establish electronic health data services in their jurisdiction (article 3), and use only technical solutions that are in line with these specifications

(article 10). To ensure cross-border flow of health data, the proposal establishes MyHealth@EU as the central platform. Another requirement concerns identification management of individuals and health professionals, which should be compliant with any means of electronic identification recognised under Regulation (EU) 910/2014 (article 9).

Secondary use of health data. The proposal defines the minimal set of health data to be made available for secondary use by the data holders, with the only exception being micro enterprises. It entails 15 types of data, ranging from pathogen genomic data, to health-related administrative data, such as reimbursement data (article 33). This must cover data processed for the provision of public health, and R&I in the health or care sectors (article 33(3)).

Lawfulness of the secondary use of health data is aligned with the relevant GDPR provisions, in particular Articles 6 and 9(2) GDPR. Eight fields of lawful purposes are derived: in addition to education, scientific research, and public interest, innovation purposes are also recognised, comprising inter alia the training, testing and evaluation of algorithms and the development of AI systems (article 34). The proposal also contains also a clause enumerating six categories of prohibited health data re-use. These include, in particular, any processing for the purpose of taking a decision to exclude one or several individuals from the benefit of an insurance contract (article 35).

Health data re-use is subject to both an authorisation and a compensation scheme. Secondary use of health data requires the potential data 're-user' to lodge an application for access, the modalities of which also depend of the format of the data sought (articles 45 and 47). These requests would then need to be assessed by the competent health data access body in charge of delivering the permission to access the data (article 46). By design, secondary use of health data implies that the data holder or the data access body charge fees. The amount of these fees must be set out in transparent conditions, and must not restrict competition (article 42).

Chapter IV of the proposal provides for a specific governance mechanism relating to secondary health data use. Member States are required to set up health data access bodies for secondary use of electronic health data, and ensure that data holders make data available to data users (article 36). These bodies' tasks include decisions on data access applications; ensuring the traceability of the requests lodged and permits granted; cross-border cooperation; and the uptake of data altruism (article 37).

Several provisions underpin the infrastructure needed to access data across the EU. All health data access bodies are required to provide access to health data through a secure processing environment only (article 50). A cross-border platform for secondary use is to be established as HealthData@EU. It should connect the participants, composed of the national contact points to be appointed by Member States, EU institutions and bodies, and health-related infrastructure based on EU law (article 52).

Third countries or international organisations may become authorised participants in HealthData@EU, where they comply with the rules of chapter IV of the proposal on secondary use. They are, in particular, required to provide access to data users located in the EU on equivalent terms and conditions (article 52). Moreover, if there is a risk of re identification of non-personal data made available by health data access bodies, the data transfer to a third country must comply with the requirements set by the data governance act on highly sensitive information (articles 61 and 62). As regards personal electronic health data, Member States may further limit international access and transfers (article 63).

EHR systems and wellness applications. The proposal introduces a mandatory self-certification scheme for EHR systems, the primary use of which falls into the scope of the six priority categories defined under article 5 and listed above (article 14). Following entry into force or placement on the market or into operation, EHR systems should be subject to compliance with the requirements underpinning self-certification (article 15).

EHR systems must comply with the common specifications to be adopted by the Commission by means of implementing acts, on the grounds of the essential requirements defined in annex II to the proposal. These requirements address essential interoperability and cybersecurity standards (article 23). High-risk AI systems, to be defined in the forthcoming EU artificial intelligence act, would be subject to those common specifications (article 14).

All commercial EHR system operators would need to comply with the common specifications: manufacturers (article 17), importers (article 19) and distributors (article 20). They must also meet a set of obligations regarding technical documentation (article 24) and the EU declaration of conformity (article 26). The market surveillance authorities responsible for EHR systems are entrusted with monitoring the common specifications (article 28). Their remit includes both risk-based monitoring (article 29) and powers to dissuade the relevant operators from noncompliance (article 30).

Moreover, the proposal establishes voluntary labelling of wellness applications, interoperable with EHR systems, and sets up an EU database in which certified EHR systems and labelled wellness applications will be registered (article 30).

Horizontal governance. The proposal suggests establishing an EHDS board chaired by the Commission and composed of the representatives of the Member States' digital health authorities and health data access bodies (article 64). The board would assist Member States in coordinating digital health authorities' practices, also through written opinions (article 65).

Advisory committees

The European Economic and Social Committee is preparing an opinion, expected to be adopted during its September 2022 plenary session (rapporteur Gonçalo Lobo Xavier, Employers – Group I / Portugal).

National parliaments

The proposal was transmitted to national parliaments for scrutiny on 4 May 2022. The deadline for submitting reasoned opinions on the grounds of subsidiarity is 2 September 2022. No national parliament has so far issued a reasoned opinion. In its resolution adopted in the context of the political dialogue, the Czech Chamber of Deputies stresses several concerns about the proposal, including the cost of the transition towards digitalisation of patient health records, notably for health professionals.

Stakeholder views[7]

The proposal was discussed extensively during its preparation phase. In addition to the EDPS's preliminary opinion mentioned above, the European Data Protection Board (EDPB) has provided guidance to specific situations where primary and secondary uses of health data have been at stake. With its statement of 16 June 2020 on the data protection impact of the interoperability of contact tracing apps, the EDPB highlights several transparency requirements for the uptake of health applications for primary use. It stresses, for instance, that interoperability should not lead to the lowering of data accuracy and quality, hinting at both e-health applications' settings and interoperability infrastructure and processes. Moreover, with its document of 2 February 2021 on consistent application of the GDPR and health research, the EDPB recalls that the principle of data minimisation (see Article 89 GDPR) applies to the processing of any data for scientific purposes, and constitutes a condition for any further processing. Overall, there is support for the initiative from stakeholders active in public health, research, and industry. For instance, the summary of the discussions during an event organised in May 2022 by a consortium of EU public health institutions from 21 Member States, funded by the EU health programme (TEHDAS), highlights the participants' interest in the initiative, and their concerns regarding implementation.

Primary use. There is broad agreement that the uptake of health data will require both connectivity and individuals' trust and skills. For instance, in a May 2022 news release, the European Patients Forum stresses the need for citizens and patients to be included in the design of the technical requirements and standards. The forum also thinks that citizens and patient organisations should be involved in the initiative's governance. On the industry side, following the adoption of the proposal, the European Federation of Pharmaceutical Industries and Associations issued a supporting statement on the proposal, mentioning its intention to get involved in its governance. Digital Europe reiterated its positive opinion, deeming the EHDS an ambitious step forward, while emphasising the need to act faster, not least to invest in infrastructure and digital health skills.

Secondary use. In May 2022, the Guild of European Research-intensive Universities issued a statement indicating its views on how to facilitate re-use of health data for scientific purposes. While identifying fragmented GDPR interpretation as a disincentive to health research, the guild considers that the governance established in the proposal should strive to harmonise GDPR interpretations. The guild also welcomes the proposal's provisions on data altruism. However, it calls for exploring the inclusion of a scheme of 'dynamic consent' by patients to re-use of health data for health research, in order to maximise data availability. This recommendation echoes the above-mentioned opinion by Digital Europe, which notes that inclusiveness is a condition for the EHDS to success in promoting trust in health data re-use. The guild and other stakeholders such as the European Public Health Alliance hint at the importance of investment in technological development for confidentiality, for instance in blockchain and cryptography (through investment under Horizon Europe, the EU's R&I programme).

EHRs. In its May 2022 statement, COCIR (the European Trade Association for medical imaging, radiotherapy, health ICT and electromedical industries) welcomes the proposal. It notes that the conformity assessment of EHR systems and products claiming interoperability with EHR systems should factor in the added value for healthcare systems of such products and services.

Legislative process

The file has been assigned to Parliament's Committee on Civil Liberties, Justice and Home Affairs (LIBE). On 14 June 2022, the Council held a first exchange of views on the proposal.

EUROPEAN PARLIAMENT SUPPORTING ANALYSIS

Amand-Eeckout L., Building up resilience to cross-border health threats: moving towards a European health union, EPRS, European Parliament, December 2021.

EU Health data centre and a common data strategy for public health, Scientific Foresight Unit (STOA), EPRS, European Parliament, September 2021.

Mildebrath H., Data governance act, EPRS, European Parliament, March 2022.

OTHER SOURCES

European Health Data Space, Legislative Observatory (OEIL), European Parliament.

Health governance for the digital age: Implementing the OECD recommendation on health data governance, OECD, 2022.

Secondary use of health data in Europe, Open Data Institute (commissioned by Roche), 2021.

Use of digital health tools in Europe: Before, during and after COVID-19, European Observatory on Health Systems and Policies, 2021.

Van Kessel R. et al., 'Is Europe prepared to go digital? Making the case for developing digital capacity: An exploratory analysis of Eurostat survey data', PLOS digital health, February 2022.

Wong, Brian Li Han et al. (on behalf of the European Public Health Association, EUPHA), 'The dawn of digital public health in Europe: Implications for public health policy and practice', *The Lancet Regional Health-Europe*, Vol. 14, March 2022.

ENDNOTES

1   The February 2019 Commission recommendation on a European health record exchange format defines these records as collections of longitudinal medical records or similar documentation of an individual, in digital format.

2   See 8. Proposal – Reinforce the healthcare system: 'The creation of a European health data space, which would facilitate exchange of health data; individual medical records could be made available – on a voluntary basis – through an EU individual electronic health passport, in compliance with data protection rules', Conference of the Future of Europe, report on the final outcome, 2022.

3   For an initial appraisal of the Commission impact assessment, see S. Vettorazzi, Establishing the European health data space, EPRS, European Parliament (forthcoming).

4   The eHDSI connects eHealth national contact points, enabling them to exchange patient summaries and e-prescriptions. The first exchanges took place between Estonia and Finland in January 2019.

5   Denmark and Romania are not yet included.

6   Article 2 of the proposal defines data holder as 'any natural or legal person, which is an entity or a body in the health or care sector, or performing research in relation to these sectors, as well as Union institutions, bodies, offices and agencies who has the right or obligation, in accordance with this Regulation, applicable Union law or national legislation implementing Union law, or in the case of non-personal data, through control of the technical design of a product and related services, the ability to make available, including to register, provide, restrict access or exchange certain data'.

7   This section aims to provide a flavour of the debate and is not intended to be an exhaustive account of all different views on the proposal. Additional information can be found in related publications listed under 'European Parliament supporting analysis'.

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