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EUROPEAN POLICY ANALYSIS

The European Health Data Space: Challenges and Opportunities

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Summary

In her 2020 State of the Union address, the European Commission President Ursula von der Leyen announced a new legislative proposal to create a European Health Data Space. Its aim is to make electronic health data accessible in order to support healthcare delivery, health research, innovation, effective policymaking and regulation, and personalised medicine. This European Policy Analysis examines the Commission's proposal and its implications for patients, healthcare providers, market actors and national administrations.

The analysis shows that the Commission's Proposal has significant potential benefits for a wide range of stakeholders. However, concerns still remain regarding aspects such as the empowerment of individuals in relation to their data, adjustments that will need to be made by the healthcare sector, incentives for innovation, and trust in EU governance. At the time of writing, the European Parliament and the Council have adopted their negotiating positions. However, a number of changes are likely to be introduced before the Commission's Proposal is agreed and can be implemented in the Member States.

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1. Unleashing the Potential of Health Data (and Managing the Implications)

In May 2022, the European Commission put forward a proposal for a European Health Data Space ('the Proposal') that aims to strengthen patients' rights in relation to their electronic health data and make diverse categories of such data accessible in order to support healthcare delivery, health research, innovation, policy-making, regulation and personalised medicine.[1] The Proposal includes a set of rules, common standards and practices, as well as infrastructure and a governance framework, for the use of electronic health data across the EU. The Proposal is anchored in the European strategy for data, a roadmap put forward by the Commission in 2020 for the building of a single market for data based on common European rules and values.[2] The Proposal is now in the process of being negotiated, and has also drawn significant interest from a range of stakeholders and the public, given its far-reaching implications.

The Proposal was crafted in the aftermath of the COVID-19 pandemic, with an awareness of the difficulties posed by the fragmented regulatory landscape for health data across the EU. Currently, access to health data is generally governed by national laws, even though the EU General Data Protection Regulation ('GDPR') defines rules for the free movement of data.[3] Moreover, health data tends to take different forms in different jurisdictions, and to be located in various – not necessarily interoperable – systems. The Proposal, therefore, aims to define a common approach to access to health data under the GDPR, in order to unleash the potential of electronic health data. More concretely, the Proposal enhances access to electronic health data via two routes, in healthcare – regulated as the primary use – for the benefit of patients, including when travelling in the EU, and in the general interests of society – regulated as the secondary use – to meet diverse health needs, such as health research, innovation and policy-making. A key to achieving this is the introduction of interoperable electronic health record ("EHR') systems for healthcare and common administrative infrastructure and procedures for actors who wish to apply for access to electronic health data for secondary uses.

> 'If established and operationalised successfully, the European Health Data Space is likely to transform the governance of electronic health data across Europe.'

If established and operationalised successfully, the European Health Data Space ('EHDS') is likely to transform the governance of electronic health data across Europe. However, it is difficult to foresee the actual shape of the EHDS in its final form, as the Proposal currently leaves various central aspects to the European Commission for further specification through delegated and implementing acts.[4] Furthermore, quite a number of changes can be expected during the legislative procedure in areas in which important policy and constitutional questions are at stake for the EU and its Member States.

This policy analysis aims to provide deeper insights into the Proposal and to examine the expected implications for key stakeholders. The analysis begins by setting out the background and context to the Proposal and introducing the central pillars of the EHDS. It then moves on to explore the implications for three selected groups of stakeholders (patients and healthcare providers, market actors, and public administrations at the EU and national levels), and, where relevant, to highlight policy choices. Finally, it offers reflections regarding what are expected to be the central battles to be fought before the Proposal is passed.

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1 Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space COM/2022/197 final.

2 Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, A European strategy for data COM(2020) 66 final (the 'European strategy for data').

3 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.

4 Delegated and implementing acts are legally binding acts that are adopted not with a so-called legislative procedure but by the Commission or, in some cases, directly by the Council.

2. Central Pillars of the European Health Data Space

2.1 Legal basis and the legislative process

With the Proposal, the EU is taking a step towards strengthening its role in public health and healthcare, despite its limited legal competencies in the field. Regarding healthcare, it is expressly stated in the Treaty on the Functioning of the European Union ('TFEU') that any EU action in the field of health 'must respect the responsibilities of the Member States for the definition of their health policies and the organisation and delivery of health services and medical care'.[5] As a consequence, however, the EU has often used other legal bases where it has greater competence to legislate – such as that relating to the internal market – in areas pertaining to health. This is also the case with the Proposal. Even though it targets public health and healthcare, the Commission has set it on the legal bases of data protection and the internal market, Articles 16 and 114 of the TFEU. This, however, stands in contrast with the approach taken for legislating on patients' rights in cross-border healthcare, for which the EU invoked the public health objectives of Article 168 alongside the legal basis of the internal market.[6] During the negotiations on the Proposal, the addition of Article 168 as an additional legal basis has been discussed, since the proposal has clear implications for the organisation and delivery of health services and medical care.[7]

Since this is the first sectoral data space that has been proposed under the European strategy for data, it is still unclear what outcomes are to be expected. Furthermore, the Proposal is still at an early stage in the legislative process. Following the presentation by the European Commission, the Economic and Social Committee[8] and the European Committee of the Regions[9] have expressed their opinions. The Council and the European Parliament have both now adopted their positions and are about to start negotiating.[10] The overall ambition to create preconditions to unleash the potential of electronic health data has generally been welcomed.[11] However, the provisions for achieving this have also received criticism from stakeholders and scholars.[12] Different views on how to improve the Proposal may be expected in the legislative process – as examples, the option for a patient to opt out from making his or her health data available for secondary use, as well as better alignment with the GDPR, have been discussed in the European Parliament.[13]

2.2 The EHDS proposal in a nutshell

2.2.1 Regulating electronic health data

The Proposal builds on the notion of electronic health data, which captures personal electronic health data such as information in digital form about a patient's health status, as well as non-personal electronic health data, such as the same information presented in anonymous form.[14] It distinguishes between two uses of such data – primary use and secondary use – and this distinction forms the two central pillars of the

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5 Consolidated version of the Treaty on the Functioning of the European Union, 13 December 2007, 2008/C 115/01, Article 168(7) TFEU.
6 Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare OJ L 88/45.
7 European Parliament, Legislative Train Schedule.
8 Opinion of the European Economic and Social Committee on the Communication from the Commission to the European Parliament and the Council – A European Health Data Space: Harnessing the power of health data for people, patients and innovation COM(2022) 196 final, OJ C 486/123.
9 Opinion of the European Committee of the Regions on the European Health Data Space COR 2022/03754, OJ C 157/64.
10 Procedure 2022/0140/COD COM (2022) 197: Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space.
11 For example, EFPIA et al., 'Ensuring the Full Potential of EHDS: Stakeholders' Recommendations on How to Make the Digital Transformation a Success across Europe' (2022).
12 See, for example, MedTech Europe, 'Regulation for a European Health Data Space – The View from MedTech Europe 28 July 2022'. See also European Patients Forum, 'EPF's Response to the European Commission's Call for Feedback on the European Health Data Space'.
13 European Parliament, Legislative Train Schedule (n 7).
14 Proposal, Article 2(2)(c).

proposed framework. The provisions on primary use focus on the processing of electronic health data for patients themselves, for use in the provision of healthcare.[15] Those on secondary use focus on the processing of electronic health data by businesses, researchers and governments for defined purposes of general interest, such as education or teaching activities related to the health or care sectors, scientific research, development, and innovation.[16] To ensure the functioning of these two pillars, rules, common standards and practices, infrastructure, and a governance framework are prescribed.[17]

'As current formats of data presentation and processing, as well as practices of digitalisation, vary greatly across the Member States, this approach implies a dramatic shift in the digitalisation of health data.'

First of all, the Proposal sets out specific requirements for how personal health data for primary use are to be processed electronically. In particular, it subjects patient summaries, electronic prescriptions, electronic dispensations, medical images and image reports, laboratory results and discharge reports to certain access and exchange requirements when these data are processed electronically.[18] Member States must ensure that these data are issued in a new European exchange format and that healthcare providers accept and read data in the prescribed format.[19] As current formats of data presentation and processing, as well as practices of digitalisation, vary greatly across the Member States, this approach implies a dramatic shift in the digitalisation of health data.

For secondary uses – the processing of electronic health data for specified societal interests – the Proposal establishes mechanisms and procedures for ensuring access to various categories of electronic health data (for example, electronic health records, data that have an impact on health, health-related administrative data and human genomic data).[20] The Proposal defines several purposes for which electronic health data may be processed for secondary use; amongst others, these purposes are public and occupational health interests, education and research, training of AI, public health surveillance and official statistics.[21] There are five purposes that are explicitly prohibited, and these include the purpose of making certain decisions detrimental to individuals, and advertising or marketing activities towards health professionals.[22] By prescribing the categories and uses of data, the Proposal seeks to set up an EU-wide uniform electronic health data sharing mechanism. For this to function, the Proposal also creates a duty on anyone classified as a 'data holder'[23] to make electronic health data available for secondary use. This obligation will not, however, apply to micro-enterprises.[24]

2.2.2 Technical and administrative mechanisms

For the primary and secondary use mechanisms to function in accordance with the Proposal, both technical and administrative mechanisms are essential. Regarding the *technical* aspects, the health industry is expected to ensure that EHR systems for healthcare needs, which must be designed and functioning in compliance with the Proposal, are available in the market. The Commission is tasked with establishing a central platform for digital health – MyHealth@EU – to provide the services necessary to support and facilitate the exchange of electronic health data between national contact points of the Member States.[25] In reality, this platform was first launched in 2015 and was subject to voluntary

[15] Proposal, Article 2(2)(d).
[16] Proposal, Article 2(2)(e).
[17] Proposal, Article 1.
[18] See the Proposal, Article 5(1).
[19] Proposal, Article 6(3).
[20] See the Proposal, Article 33(1). This list is subject to expansion.
[21] Proposal, Article 34(1).
[22] Proposal, Article 35.
[23] Proposal, Article 2(2)(y).
[24] Proposal, Article 33(2), unless exceptions apply.
[25] Proposal, Article 12(1).

participation, but it experienced limited success in facilitating cross-border exchanges across the EU.[26] Additionally, the Member States are obliged to ensure that all healthcare providers are connected to the national contact points[27] and that each national contact point enables the exchange of personal electronic health data with all other national contact points.[28]

Regarding secondary use, the data will be made available to the 'data user' in a secure processing environment, under the principle of 'bring questions to data instead of moving data', whenever possible.[29] The Commission will be responsible for setting up a cross-border structure for the secondary use of electronic health data, HealthData@EU, for the secure cross-border sharing of electronic health data.[30]

The *administrative* aspects capture a range of measures and mechanisms to enable the EHDS to function. For example, when it comes to primary use (that is, healthcare needs), a key tool to ensure that healthcare providers and patients can access electronic health data across borders is the European EHR exchange format. For secondary use (that is, different general interest needs), the Proposal introduces administrative tools and a common administrative procedure for those seeking access to electronic health data or information about these data.

The Proposal foresees the assignment of new tasks and the establishment of new administrative bodies at both the European and the national levels. For healthcare, each Member State will have to designate a national contact point for digital health to ensure connection with other national contact points,[31] and a digital health authority responsible for the functioning of the primary use pillar.[32] For secondary use (general interest purposes), Member States are to appoint health data access bodies, tasked with assessing applications for access to electronic health data.[33] Furthermore, at the EU level, the European Health Data Space Board ('EHDS Board') is to be established, whose main task will be to facilitate cooperation and the exchange of information among the Member States.[34]

3. Implications for Patients, Other Individuals and Healthcare Providers

If adopted, the Proposal will introduce various opportunities and have various implications for patients and other individuals, such as, in particular, participants in medical research and healthcare providers, healthcare institutions and medical practitioners. Its implementation will require resources, which could pose constraints on already resource-drained healthcare systems and institutions and could, in the worst case, affect both the cost of care and the accessibility of medical services. The following section will address both healthcare (primary use) and general interest (secondary use) implications for individuals and healthcare providers.

3.1 Primary use

3.1.1 Patients

The central novelty for patients when it comes to the primary use of electronic health data is the set of new rights put forward in the Proposal. In proposing these, the Proposal partially builds and expands on the rights and obligations set out in the GDPR.

To begin with, the GDPR introduced a right to access to personal data, which enables individuals to receive information about the processing of their data and to obtain a copy of the data undergoing the processing. However, this right has certain

[26] Commission Staff Working Document, Impact Assessment Report accompanying the document Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space SWD/2022/131 final. For insights into its functionality, see https://health.ec.europa.eu/ehealth-digital-health-and-care/electronic-cross-border-health-services_en
[27] Proposal, Article 12(5).
[28] Proposal, Article 12(3).
[29] Proposal, Article 50, Recital 54–55.
[30] Proposal, Article 52.
[31] Proposal, Article 12(2).
[32] Proposal, Article 10.
[33] Proposal, Article 37.
[34] Proposal, Article 64–65.

limitations. It can take some time to access health data, and, moreover, the data may be provided in paper form, which is less convenient for further use. Additionally, as this right regulates the receipt of 'a copy of the personal data undergoing processing' and does not expressly cover access to medical documents, some Member States, such as Sweden, collect a fee if medical records are requested.[35] The Proposal aspires to put an end to these challenges. It introduces an unambiguous right of individuals to access their own personal electronic health data, processed in the context of primary use, immediately, free of charge, and in a user-friendly form.[36] Moreover, it enables patients to receive an electronic copy of their electronic health data. This right extends, as a minimum, to the priority categories of personal data mentioned in section 2 of this analysis.[37]

The right to access electronic health data will not, however, be an absolute prerogative. If access to data puts patient safety at risk or is incompatible with ethics, a Member State may choose to allow access to the electronic health data to be temporarily withheld.[38] This could, for example, occur when the disclosure of information could cause immediate and serious harm to a patient. The operationalisation of this possibility, however, may not necessarily be a straightforward task, given the diversity of the EHR systems that could be in use and the different levels of centralisation of electronic health records in different Member States.

Generally, medical records have been a domain of the medical profession, with a limited role for patients. For example, under the GDPR, patients have a right to rectify incorrect data and a right to have incomplete data completed. These rights, however, do not extend to an entitlement for a patient to freely add information to their data. The Proposal intends to change this. It aspires to enable patients to insert electronic health data into their electronic health records,[39] thereby making medical records a platform that is shared between healthcare professionals and patients.

> 'The Proposal [...] aspires to enable patients to insert electronic health data into their electronic health records, thereby making medical records a platform that is shared between healthcare professionals and patients.'

This is potentially one of the most significant areas of empowerment for patients, and could have a positive influence on self-care and prevention. However, there is simultaneously a risk that it could pose challenges. As an example, no mechanisms are proposed to ensure that the information that is added actually relates to health. Furthermore, the Proposal requires the electronic health data inserted by the patient to be specifically marked, but it does not prescribe any quality requirements. Consequently, whether this information can be used for patient care is uncertain. If actions are taken based on information that lacks quality and accuracy, this could negatively affect the quality of healthcare, and patient safety, and raise complex liability questions that are considered below. Furthermore, high-quality data is essential for secondary use, including training algorithms for AI systems and medical research.[40] Particular efforts will be needed to manage data inserted by patients in order for such data to support, rather than hamper, secondary use.

Another novelty set out in the Proposal is a power for patients to restrict health professionals' access to their health data – either in whole or in part.[41] This means that patients will have control regarding whether and to what extent healthcare professionals

[35] This practice is also difficult to align with the GDPR. See C-307/22 – FT (Copies du dossier médical), ECLI:EU:C:2023:811.
[36] Proposal, Article 3(1).
[37] Proposal, Article 3(2).
[38] Proposal, Article 3(3).
[39] Proposal, Article 3(6).
[40] See Anastasiya Kiseleva and Paul de Hert, 'Creating a European Health Data Space: Obstacles in Four Key Legal Areas' (2021) 5 European Pharmaceutical Law Review (EPLR) 21.
[41] Proposal, Article 3(9).

are able to access their electronic health data. It is intended that these patient-imposed restrictions will apply unless vital interests are at stake.[42] In line with the so-called 'data minimisation principle', it has been acknowledged that not all patient health data should be indiscriminately revealed to health professionals. Instead, only information which is necessary for the professional to perform the specific task should be accessible.[43] However, the right has the potential to go well beyond the data minimisation principle, and to allow the individual to choose what information is withheld from healthcare professionals.[44]

'Importantly, the Proposal does not require healthcare professionals to be informed that they do not have access to complete information. This creates a tension between a patient's right to self-determination and the quality of the patient's care [...].'

Importantly, the Proposal does not require healthcare professionals to be informed that they do not have access to complete information. This creates a tension between a patient's right to self-determination and the quality of the patient's care, and raises difficult liability questions that are considered below. The Member States will need to find solutions that give full effect to this new right, including safeguards to mitigate the risks associated with the withholding of information. These could include notification to healthcare providers (as noted above) and information to patients regarding the risks and implications of excluding access to certain parts of their medical records. Although it is clear that safeguards are jurisdiction-dependent, further guidance in the recitals of the proposed Regulation could produce a more uniform practice. As things stand now, each Member State is left to reinvent the wheel regarding such safeguards.

Rights that ensure transparency of data processing have long been seen as a way to empower individuals, and are also regulated under the GDPR. However, the exercise of these rights in practice is not necessarily straightforward. The Proposal seeks to introduce new, enhanced possibilities to facilitate the control of any unlawful access to the patient's own data. In particular, it enables a patient to obtain – immediately and free of charge – information on the healthcare providers and professionals who have accessed their electronic health data.[45] Depending on the current shape of the EHR system, the realisation of this right could require adequate adjustments of the EHR system.

The Proposal also equips patients with rights that directly further the functioning of the healthcare market – within a Member State and across the EU – in that it prevents lock-in with healthcare providers. This is done by assigning patients the right to give access to, or request a data holder to transmit their electronic health data to, a data recipient of their choice from the health or social security sector, immediately, free of charge, and without hindrance. To support this, a duty to accept and read these data by the respective recipients is also envisaged.[46] This is a major change for countries in which medical records are decentralised, and medical record transfer and exchange is hampered by the existing technical solutions, such as in Sweden. Furthermore, when healthcare is accessed in a different Member State, patients may benefit, in that their electronic health records will be enriched with details about the healthcare they have received abroad. Currently, there are no uniform mechanisms to add information to a patient's medical records when care is provided in another EU Member State. This may have positive implications for continuity of care and the completeness of medical records.

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[42] Proposal, Article 4(4).
[43] European Data Protection Board (EDPB) and European Data Protection Supervisor (EDPS), 'EDPB-EDPS Joint Opinion 03/2022 on the Proposal for a Regulation on the European Health Data Space', p. 17.
[44] The principle of data minimisation under the GDPR requires that data controllers limit the collection of personal information to what is directly relevant and necessary for the specific purpose of processing. See Article 5(1)(c) GDPR.
[45] Proposal, Article 3(10).
[46] Proposal, Article 3(8).

Patients may themselves manage their new rights in the context of primary use or they may appoint a person of their choice to access their electronic health data on their behalf.[47] The Proposal is, however, silent on how this will apply to groups that generally require particular consideration, such as minors and persons lacking decision-making capacity.[48] Particular guidance in the legislative process is necessary in this regard. Moreover, the Commission's proposal relies heavily on the digital literacy of patients and their access to digital tools. Among groups where digital literacy or access is limited, particular solutions, including support, might be necessary.

3.1.2 Healthcare providers: professionals and institutions

The effective functioning of the primary use of electronic health data will depend strongly on the healthcare providers. Relevant technical and administrative solutions will need to be in place at healthcare institutions in order that they can fulfil their new duties. This may include practical adjustments as well as various learning and training initiatives. Moreover, it may turn out to be expensive. While the Proposal prescribes the new duties, the implementation will mainly be carried out by the Member States. The costs will have to be borne within already constrained national healthcare budgets, and may, in the worst case, affect healthcare accessibility and affordability.

Depending on how a Member State chooses to implement the primary use provisions in the Proposal, parallel systems such as traditional paper-form health records may continue to exist. This could add to the administrative burden for healthcare providers. Moreover, the realisation of the primary use pillar rests heavily on the digital literacy of healthcare providers.

As discussed above, the Proposal sets out various powers for patients that may have implications for the provision of their care, including the possibility that they may limit access to their personal health data. Complex questions regarding the liability of healthcare workers may emerge, as actions based on restricted information can result in unintended consequences for a patient's treatment. The question is further complicated by the fact that liability mechanisms differ between the EU Member States.

Moreover, to ensure the realisation of the rights of individuals regarding the primary use of their electronic health data, the Proposal foresees sanctions. In particular, non-compliance with the rights of individuals set out in the Proposal risks the imposition of an administrative fine under the GDPR.[49] This is an extension of the strict sanctions set out in the GDPR and will co-exist with the national liability mechanisms regarding violations in healthcare. In countries where there are sanctions for non-compliance with patient rights, this will create a parallel sanction system for patient rights. If the sanctions for other violations are lower than those prescribed in the GDPR, this will lead to discussion regarding the price tags for data privacy and other rights, such as personal integrity, and whether these stand in adequate proportion.

3.2 Secondary use

3.2.1 Individuals

The secondary use of electronic health data for general interest purposes applies to both personal and non-personal electronic health data. Regarding personal data, the Proposal enables the use of electronic health data only in pseudonymised form.[50] The rights of individuals under the GDPR are only protected when personal data are concerned. However, it is well known that the line between pseudonymised data regarded as personal data and data regarded as anonymous data can be rather difficult to draw.[51] Interestingly, the Commission has paid close attention to this problem in relation to data transfers to third countries, noting that there could be 'a risk of re-identification through means going beyond those likely reasonably to be used'.[52] However, the same concern does not exist – according to

[47] Proposal, Article 3(5)(a).
[48] This is also a concern highlighted by the stakeholders. See, for example, The Standing Committee of European Doctors (CPME), 'Position on the European Health Data Space'.
[49] Proposal, Article 3(10).
[50] Proposal, Article 44.
[51] See Case C-582/14 Breyer para 44 and T-557/20 SRB v EDPS paras 104 and 105.
[52] Proposal, Article 61(1).

the Commission – internally within the EU. This means that special conditions for the transfer of data to third countries can be prescribed by the Commission as a delegated act pursuant to the Data Governance Act,[53] but because of the presumption of the effective functioning of the GDPR across the EU, transmission of data within the EU will not be subjected to such rules.

As mentioned above, several different types of electronic health data are subject to secondary use. The Proposal is, in this way, intended to give a legal basis for lifting the prohibition on the processing of health and genetic data that is set out in Article 9(1) GDPR. Importantly, however, the Proposal does not envisage a particular role for the individual's consent, although it does accommodate the fact that some Member States may wish to retain the requirement for consent in relation to some processing.[54] The implications of this are somewhat unclear. Two completely different interpretations are possible: either health data that are subject to consent at the national level cannot be shared unless such consent is given, or, regardless of whether consent is given, electronic health data must be shared within the EHDS. In the former case, hindrances to data sharing will be inevitable, whereas in the latter case, the effect is that the EU objectives for data sharing will trump national privacy protections.

The actual role assigned to consent has implications for individuals, as well as for how the EHDS will function. Although the absence of a requirement for consent potentially expands the datasets that are available for secondary use, it could also easily disrupt trust in the system. Therefore, stakeholders have called for a credible information and participation mechanism to be included instead.[55] As things now stand, the lack of a clear role for consent and the absence of the possibility to opt out from particular uses risk creating forced participation in secondary use activities, such as research. This does not sit well with existing ethical standards. As actors involved in the legislative process have signalled in their draft positions, it is expected that these questions will be subject to particular discussions in the negotiations.[56]

> '[...] the lack of a clear role for consent and the absence of the possibility to opt out from particular uses risk creating forced participation in secondary use activities, such as research.'

Moreover, as will be discussed below, individuals will lack a say regarding *how* their data are used for secondary general interest purposes. The Proposal does, however, set out some general prohibitions that were noted previously in section 2.2.1, including a prohibition on the use of data for making decisions that would be detrimental to the particular individual.[57] Although these could be regarded as safeguards for individuals, some stakeholders have argued that they are too restrictive and could limit innovation in healthcare.[58]

Another issue that has been identified is that of transparency. The obligations of a health data access body towards natural persons are limited to providing general information concerning the relevant legal basis for processing, technical and organisational safeguards, and the applicable rights in relation to secondary use. These bodies are thus intended to be exempted from providing

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[53] Regulation (EU) 2022/868 of the European Parliament and of the Council of 30 May 2022 on European data governance and amending Regulation (EU) 2018/1724 (Data Governance Act) (Text with EEA relevance) PE/85/2021/REV/1 OJ L 152/1.
[54] Proposal, Article 33(5).
[55] BBMRI-ERIC, 'Statement by BBMRI-ERIC on "A European Health Data Space"'.
[56] See the draft report on the proposal for a regulation of the European Parliament and of the Council on the European Health Data Space (COM(2022)0197 – C9-0167/2022 – 2022/0140(COD)) 2022/0140(COD).
[57] Proposal, Article 35.
[58] See Digital Europe, 'Digital Europe's Position Paper on the European Health Data Space proposal 19 January 2023' p. 12 and MedTech Europe, 'MedTech Europe's Position on the Proposed European Health Data Space Regulation 22 February 2023' p. 11.

more detailed information pursuant to Article 14 GDPR.[59] This has caught the attention of the EDPB and EDPS because it creates a problem under the very same GDPR norm on which it is built.[60] This approach will mean that transparency can be expected to deteriorate,[61] and it will also be difficult to exercise bottom-up oversight regarding the use of personal data.[62]

'As the Proposal seeks to overcome the fragmentation attributable to the GDPR, it should equally strive to reduce any new fragmentation.'

In addition, over the last few years, the question of the return of findings that may have an impact on the health of an individual has been at the frontier of research ethics and practice. There is a growing consensus that findings of high clinical importance and actionability should be offered to the individual. However, the return of such results is surrounded by ethical and legal complexities, and requires not only adequate training for the person returning the result but also a procedure that respects individuals' autonomy, including any wish to receive only certain information and any choice not to be informed about some or any findings.[63] The Proposal requires data users to inform the health data access body of 'clinically significant findings that may influence the health status of the natural persons'.[64] However, when it comes to the obligations of the health data access body, the Proposal indicates that the 'body may inform the natural person and his or her treating health professional'. This could present significant challenges.[65] First, the Proposal does not elaborate on what these actionable findings are. Although in the ethical literature there is an emerging consensus that relevant information should be reported to the individual, what this information is could differ in different contexts and for different groups.[66] As the Proposal is framed, the health data access body has a discretion on whether to report results and on what results to report. No further guidance regarding the reporting is prescribed. The Proposal also lacks an explicit delegation to allow the situation to be further regulated at a national level. If the EU does not prescribe further rules, national legislatures would be expected to act. This, however, inevitably risks there being different practices across the EU, which is something that could cause further regulatory fragmentation for research. As the Proposal seeks to overcome the fragmentation attributable to the GDPR, it should equally strive to reduce any new fragmentation. However, this is not an easy task as ethical considerations are different in different societies, and competencies in ethics are something that remains with national legislators.

3.2.2 Healthcare providers: professionals and institutions

Generally, healthcare institutions are expected to be considered data holders under the Proposal and consequently subject to the rules pertaining to the secondary use of electronic health data.[67] This will apply to all data they collect for which they will be considered data holders. In that regard, they can expect a greater administrative capacity to collaborate with the health data access bodies in order to fulfill their duties regarding data sharing.

Healthcare institutions and professionals will be able to benefit from the secondary use framework and access data from other data holders, as long as

[59] Proposal, Article 38(1)-(2).
[60] See EDPB and EDPS (n 43) pp. 22-23.
[61] See Luca Marelli et al., 'The European Health Data Space: Too Big to Succeed?' (2023) 135 Health Policy 104861.
[62] Santa Slokenberga, 'Scientific Research Regime 2.0? Transformations of the GDPR Research Regime that the Proposed EHDS Regulation Promises to Bring Along' (2022) Technology and Regulation 145.
[63] Ciara Staunton, Mahsa Shabani, Deborah Mascalzoni, Signe Mežinska, and Santa Slokenberga, 'Ethical and Social Reflections on the Proposed European Health Data Space', forthcoming in the European Journal of Human Genetics.
[64] Proposal, Article 46(12).
[65] See further Staunton et al. (n 63).
[66] See further Staunton et al. (n 63).
[67] See Proposal, Article 2(2)(y).

the intended purpose falls within one of the general interest categories specified in the Proposal.[68] This can be of particular relevance to those providers engaging in research, education, or teaching, as well as providing personalized healthcare.

The framework, by enhancing access to electronic health data for secondary use, simultaneously transforms the rules on medical secrecy. The disclosures, even with safeguards, are mandatory, which has an indirect bearing on the doctor-patient relationship. Healthcare professionals must make sure patient data sets, such as electronic health records, include only necessary information, in line with the data minimization principle set out in the GDPR and as further regulated nationally under the relevant rules on patient data or medical records, and that they do not exceed what is necessary for the purpose.

4. Implications for Market Actors

The Proposal will have implications for a wide variety of market actors within the health industry, including EHR systems and wellness app manufacturers, pharmaceutical companies and pharmacies. Furthermore, it will have significant implications for competition in the development of AI in the health industry. The following section will address the implications for market actors of both the primary and the secondary use provisions of the Proposal.

4.1 Electronic health record systems

As defined in the Proposal, EHR systems are appliances or software that have been developed for purposes such as the storing, exporting and viewing of electronic health records.[69] EHR systems play a pivotal role in the Proposal because they will facilitate the secure and free movement of electronic health data across the EU. However, the current systems use different standards and have limited interoperability, which creates obstacles for cross-border and cross-regional healthcare in the EU. Additionally, because of the sensitive nature of the health data processed by EHR systems, security and privacy are serious concerns.

The Proposal aims to resolve these issues by adopting mandatory self-certification for EHR systems involving interoperability and security aspects, as well as a CE to mark compliance.[70] Although this is a positive step towards ensuring the Proposal meets its goals, this aspect of the Proposal has received criticism from stakeholders.

Regarding the security and privacy concerns, the Proposal elaborates on interoperability and security requirements but makes no mention of the important principles of so-called data minimisation and data protection by design.[71] With regards to the technical standards, concerns have been raised regarding the common specifications provided for interoperability and security. The common specifications may not be in line with internationally recognised standards, which will result in additional technical burdens for manufacturers of EHR systems operating within and outside the EU.[72] The costs of these additional technical burdens may ultimately be transferred to healthcare professionals and patients, which would run counter to the objectives of the Proposal.[73]

4.2 Wellness apps

Wellness apps such as MyFitnessPal and Fitbit are having a growing influence on healthcare and have

[68] See the Proposal, Article 34.
[69] Proposal, Article 2(2)(n). Subparagraph (m) provides a definition of electronic health records.
[70] See the Proposal, Article 17 and Annex II.
[71] EDPB and EDPS (n 43) p. 20. See n 44 of this report for an explanation of data minimisation. Data protection by design means that a data controller implements technical and organisational measures to ensure privacy and data protection when it designs new systems, services and products. See Article 25 GDPR.
[72] See, for example, MedTech Europe (n 58) p. 8, 9. See also Digital Europe (n 58) p. 17. The adoption of internationally recognised standards has been recommended instead, to avoid additional costs and barriers for EHR systems.
[73] Part 1 of the Explanatory Memorandum of the proposed EHDS Regulation states that the Proposal, among other objectives, 'aims to contribute to a genuine single market for digital health products and services, by harmonising rules, and so boost healthcare system efficiencies'. Higher costs for healthcare providers will not contribute to efficiencies.

the potential to facilitate the shift from treatment to preventive healthcare.[74] By allowing healthcare professionals and patients to monitor health data from wellness apps, the Proposal will make it more possible to identify and treat potential illnesses before they have actually developed. The Proposal facilitates this transition by encouraging the sharing of wellness app data between patients and healthcare professionals.

In order to promote the interoperability of wellness apps with EHR systems, a voluntary labelling scheme is proposed under which manufacturers of wellness apps will obtain a label that demonstrates compliance with the interoperability and security requirements.[75] The voluntary labelling scheme will ensure transparency for users regarding compliance, and will also allow them to make more informed choices about the most suitable app for their needs.[76]

There are still issues, however, concerning the regulation of wellness apps in the Proposal. First, whether wellness apps will be considered to be data holders is not entirely clear. The definition of a data holder is broad, and includes entities in 'the health or care sector, or performing research in relation to these sectors'.[77] The Proposal also lacks a definition of the health sector but its definition of healthcare specifically refers to health services provided by health professionals, which would not cover wellness applications.[78] It is most likely that wellness apps are intended by the Commission to be included as data holders because of their important role in the Proposal and the health data they hold, but more clarity is recommended.

Various stakeholders have questioned the value of the health data generated by wellness apps. In particular, the quality of the health data they generate is considered to be low. Sharing all types of data from these apps could result in enormous amounts of low-quality data being uploaded into the health data space, making it difficult for data users to derive any valuable insights.[79] Suggested solutions to this problem vary significantly: some stakeholders recommend removing the health data generated from wellness apps from the Proposal altogether, while others recommend only requiring the sharing of validated and actionable output data that will actually provide insights for data users.[80] As a result of the ability of wellness app health data to facilitate preventive healthcare, allowing firms and researchers to study these data could be valuable, so requiring the sharing of validated and actionable output data would be the most beneficial option. This would, admittedly, have implications for privacy but improvements to the Proposal addressing aspects such as the robustness of the consent mechanism would help to counteract this concern.

4.3 Pharmaceutical companies

The value of European pharmaceutical industry exports has increased dramatically from 90.9 billion euros in 2000 to 670 billion euros in 2022.[81] In Sweden, for example, pharmaceuticals is one of the largest export groups, with total exports reaching 139 billion Swedish krona (equivalent to more than 12.3 billion euros) in 2022.[82] The Proposal will have significant implications for the industry, and ultimately could even have an impact on European production and exports.

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[74] PGEU, 'PGEU Position Paper on the European Health Data Space' (2022) p. 3. Pharmacists, for example, are increasingly often being asked by patients to interpret their health data.
[75] Proposal, Article 31.
[76] Proposal, Recital 35.
[77] Proposal, Article 2(2)(y).
[78] See Article 2(1)(b) of the Proposal, which refers to Article 3 Directive 2011/24/EU. This Directive defines 'healthcare' as 'health services provided by health professionals to patients to assess, maintain or restore their state of health, including the prescription, dispensation and provision of medicinal products and medical devices'.
[79] The EDPB and EDPS seem to consider that wellness apps should be considered as data holders: EDPB and EDPS (n 43) p. 11. See also MedTech Europe (n 58) p. 9 and Digital Europe (n 58) p. 19. See also section 3.1 above on the implications of low quality health data on healthcare quality and patient safety.
[80] Digital Europe (n 58) p. 12; MedTech Europe (n 58) p. 10.
[81] European Federation of Pharmaceutical Industries and Associations, 'The Pharmaceutical Industry in Figures: Key Data 2023 p,. 3.' https://www.efpia.eu/media/rm4kzdlx/the-pharmaceutical-industry-in-figures-2023.pdf
[82] Lifescience Sweden, 'Sveriges export av läkemedel slår nya rekord' [Sweden's pharmaceutical exports break new record] This number amounts to 7% of total exports from Sweden and a 100% increase over the past decade.

Whether pharmaceutical companies[83] will be considered as data holders is still not entirely clear in the Proposal. The broad definition of data holders, however, suggests that this will be the case. Furthermore, pharmaceutical companies are likely to be considered as entities performing research in relation to the health or care sectors.[84] It is relevant to note that it has been suggested that, in the case of clinical trials, the clinical trial sponsor should be considered to be the data holder for the clinical trial data.[85]

Regarding the categories of health data that pharmaceutical companies will have to provide for secondary use, there will be a wide variety, including EHRs, clinical trials and research cohorts, questionnaires and surveys related to health.[86] Concerns have been raised that these data, which it may have taken vast amounts of time and resources to obtain, will be shared with competitors.[87] Additionally, because of the commercial value of these data, the industry has asked for more clarity regarding whether only raw source data from clinical trials can be provided or whether processed data insights, which are often protected by IP and are trade secrets, must also be shared.[88]

Since IP and trade secrets are essential assets for a wide variety of firms operating in the healthcare industry, including medical device companies and pharmaceutical companies, there is a serious concern that the Proposal obliges the sharing of health data which may be protected by these rights.[89] With regards to this, the preamble states that the purpose of making these types of protected health data available is to avoid scenarios such as restrictions on access to health data by public authorities and regulators in pandemics that prevent them from carrying out their legal mandates.[90] There is no mention, however, of allowing private actors to access these types of protected data, and therefore more clarity should be provided as this uncertainty may have significant consequences.

'Since IP and trade secrets are essential assets for a wide variety of firms operating in the healthcare industry [...] there is a serious concern that the Proposal obliges the sharing of health data which may be protected by these rights.'

It is essential to emphasise that IP rights and trade secrets are protected under EU law as fundamental rights.[91] Such a far-reaching provision should require a proportionality assessment, but this has not been provided in the Proposal.[92] Furthermore, the Proposal provides little information on how it intends to avoid IP rights and trade secrets being revealed. Additionally, no legal mechanisms have been proposed to allow firms to defend themselves against interference with their fundamental rights.

In order to address these concerns, it has been recommended that, as regards data that may reveal IP rights and trade secrets, more control should be granted to the right holder in order to determine the conditions of the data access request; this could be done, for example, by allowing for non-disclosure and confidentiality agreements.[93] A dispute mechanism has also been proposed that would allow data holders to contest requests

[83] Pharmaceutical companies in this section is used to refer to companies active in the research, development and manufacture of medicinal products in Europe for human use.
[84] Proposal, Article 2(2)(y). The European Federation of Pharmaceutical Industries and Associations ('EFPIA') also considers that it is unclear whether pharmaceutical companies will qualify as data holders but presumes that they will. EFPIA, 'EFPIA Response to the Consultation on a Legislative Proposal for a European Health Data Space', p. 4.
[85] Digital Europe (n 58) p. 8.
[86] See Proposal, Articles 33(1)(a), (j) and (l). See also EFPIA (n 81) p. 8 for more information.
[87] EFPIA (n 81) p. 5.
[88] ibid.
[89] Proposal, Article 33(4).
[90] Proposal, Recital 4.
[91] Charter of Fundamental Rights of the European Union 2000/C 364/01, Article 17.
[92] MedTech Europe (n 58) p. 12.
[93] See also MedTech Europe (n 58) p. 12 and Digital Europe (n 58) p. 22.

for confidential information.[94] Both of these suggestions are reasonable and would incentivise the sharing of valuable health data, but dispute mechanisms that create further obligations for health data access bodies should be introduced with caution. The mechanisms could potentially be outsourced to an external body that deals specifically with these types of disputes.

4.4 Pharmacies

Pharmacies are expected to play a crucial role in the EHDS, as more and more patients are asking their pharmacists for advice on interpreting health data. Furthermore, pharmacies are pivotal for the exchange of and access to different types of electronic health data such as electronic prescriptions.[95] The rapid growth of online pharmacies in Europe is also playing an important role in the transition towards electronic healthcare. Sweden is now one of Europe's most developed online pharmacy markets, with total revenues reaching 980 million Swedish krona per month in January 2023.[96]

Under the Proposal, pharmacies are likely to fall under the definition of a data holder, since a pharmacy will be considered to be an entity within healthcare according to Directive 2011/24/EU.[97] With regards to the categories of data pharmacies must provide, there will be a wide variety of these, such as dispensing data and data on adverse reactions to medicines.[98]

In order to provide the vast amounts of health data they collect, pharmacies will require technical and financial resources to facilitate data organisation and transfer. Resources will also be required in order to deal with data requests by patients wishing to obtain or transfer their health data, which may include data from electronic prescriptions and dispensations.[99] These obligations could prove costly, and therefore it is essential that both technical and financial support is provided at the European and national levels to aid compliance.[100]

One final concern that could indirectly raise costs for pharmacies is that if additional burdensome interoperability requirements are imposed on third-country EHR manufacturers operating in the EU, this could result in higher prices for mandatory software licences, which could have negative implications for pharmacies.[101]

4.5 Health data, AI and competition

Although this is not a goal of the Proposal, the Proposal may have the effect of creating a more level playing field and more competition in markets for health-related products and services. Because of the importance of health data for drug discovery, and also to feed AI-based technologies, Big Tech and Big Pharma have for years been using strategies to obtain large quantities of valuable health data in order to gain a competitive advantage.[102] The risk that arises is that the firms that can control the largest quantity of high-quality data will be able to develop the most advanced AI-driven medicines and technologies, resulting in the potential monopolisation of healthcare markets. Once these firms have monopolised their respective markets, they will then be able to collect more data from the services they offer, to feed their AI, which will further entrench their

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[94] Digital Europe (n 58) p. 24.
[95] PGEU (n 71) p. 3.
[96] It is estimated that the EU market will grow at a compound annual growth rate of over 15% between 2019 and 2025. Shop Apotheke, 'Annual Report 2021' [2016] p. 5 and Sveriges Apoteksförening, 'Branschrapport 2023', p. 11.
[97] As noted above, Article 2(1)(a) of the Proposal refers to Directive 2011/24/EU for definitions of terms such as healthcare.
[98] PGEU (n 71) p. 12.
[99] See the Proposal, Articles 3 and 5.
[100] Resources for the implementation of the EHDS have been presented as a key consideration by many stakeholders. See EFPIA et al. (n 11) p. 2.
[101] PGEU (n 71) p. 13.
[102] See Aileen Berghold, Constanze Hübner, Björn Schmitz-Luhn and Christiane Woopen, 'Tech Giants in Healthcare', Bertelsmann Stiftung (2022), for a thorough analysis of how big tech is entering the healthcare industry. See also https://www.reuters.com/article/us-pharmaceuticals-data-idUSKCN1GD4MM for examples of how Big Pharma is targeting health data.

monopolies.[103] The Proposal therefore presents a potential solution to this problem by obliging firms to share their health data with each other. As a result, it may become harder for dominant tech and pharmaceutical firms to hoard all the valuable health data in the industry in order to gain a competitive advantage. Furthermore, the Proposal may be a more effective tool than competition law to address these concerns, because competition law requires a complex *ex post* legal analysis of the facts which may take too long: by the time enforcement occurs, healthcare markets may already have been monopolised.

> '[...] firms such as Google and Amazon hold extremely valuable non-health data gathered from their other services, and they may combine these data with health data obtained from the EHDS.'

Although the Proposal may address these concerns, its implementation poses new problems. For example, Big Tech has for many years been trying to enter the healthcare industry by gaining access to valuable health data through partnerships with healthcare providers.[104] Once the health data from hospitals and pharmacies is made available for all, Big Tech will no longer have to invest time and resources in obtaining the data. More importantly, however, firms such as Google and Amazon hold extremely valuable non-health data gathered from their other services, and they may combine these data with health data obtained from the EHDS.[105] This competitive advantage may result in incumbent firms and innovative start-ups operating in healthcare markets in Europe being unable to compete.

Addressing this competitive advantage under competition law is challenging because of the difficulties in demonstrating harm to competition. Furthermore, creating data-sharing obligations for certain types of non-health data gained by Big Tech may be too intrusive. However, the Proposal could at least provide some form of guarantee that profits, services and IP rights generated by Big Tech from health data from the EHDS will benefit EU citizens.[106] Furthermore, higher fines for non-compliance with the purposes of processing health data under the Proposal may help to address this concern.[107] Deterrence through high fines may be the optimal solution, considering the difficulties in monitoring the enormous amounts of electronic health data that will be shared, especially if they may be shared by single data holders.

Another concern with the Proposal is that imposing obligations on dominant firms in healthcare markets to share their valuable health data may in fact reduce their economic incentive to invest in collecting health data and thus to compete and innovate. Having to share the data that is considered by many firms to be an asset that provides them with a significant competitive advantage may result in firms putting less time and resources into collecting health data, and thus the quality of the data in the market will decrease. This will, in turn, result in less innovation, as low-quality data will result in lower quality AI for healthcare. Although this is a complex problem, providing clear guidelines and granting adequate control over the sharing of health data protected by IP rights and trade secrets may be the most appropriate solution moving forward. This may need to be complemented by adequate legal mechanisms to allow firms to contest data requests that could reveal commercially sensitive data.

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[103] See Sheen S Levine and Dinkar Jain, 'How Network Effects Make AI Smarter', Harvard Business Review, 2023.
[104] Berghold et al. (n 99).
[105] For example, Google may use the data it has on young males in a certain city (such as location, purchasing, search and email data) and combine it with health data concerning young males in that city to develop new healthcare technologies and services. See Marelli et al. (n 61), p. 3.
[106] ibid. These authors have, for example, proposed that specific provisions should be incorporated in order to ensure that the public value of use of health data for secondary purposes is assessed and audited.
[107] The Committee of the Regions has, for example, proposed a fine of up to 10% of the data user's annual turnover for the previous financial year, which brings the Proposal into line with the GDPR. See amendment 26 of the Opinion of the European Committee of the Regions (n 9).

5. Implications for Public Administration

A third area that can be expected to be greatly affected by the Proposal is public administration, at both a European and a national level. New EU bodies are to be established, which will cooperate closely with other EU bodies as well as with national authorities. The health data access bodies established at the national level will assess applications for access to electronic health data according to a standardised procedure, and will cooperate with each other in multi-country applications.

5.1 Building a trusted governance system for electronic health data

The EU has in recent decades put quite a strong emphasis on the construction of efficient mechanisms for the implementation and enforcement of Union policies, involving both EU and national authorities in an integrated or composite administration.[108] While the responsibility to implement EU law has traditionally been a matter for the Member States,[109] the EU legislators have begun to introduce collaborative mechanisms and common tools in secondary law to enhance compliance. The GDPR provides an illustrative example: data protection authorities at the national level cooperate closely with the European Data Protection Board, which is equipped with effective investigatory powers and a mandate to enact substantial administrative sanctions.[110] This administrative governance system has been an important factor in the development of the GDPR into a flagship EU regulatory policy.[111] With the Proposal, the Commission continues to develop EU administrative governance systems in the same direction.

5.2 Primary use bodies: tasks and competences

The new digital health authorities to be established at the national level will have a central coordinating role in the implementation of the rules on primary use.[112] Their main focus will be organisational and technical oversight, information, and capacity-building, both nationally and in collaboration at the European level. The list of neighbouring authorities with which the digital health authorities are to cooperate mirrors the complexity of the Proposal: the national authorities for market surveillance, cybersecurity, and electronic identification, the European Artificial Intelligence Board, the Medical Device Coordination Group, and the European Data Innovation Board. Further, it is proposed that data protection authorities will play an important role because of the significant amount of data processing that will take place under the Proposal.[113]

The putting in place of an inter-operational EHR system will be a challenging task, from an economic, technical and organisational point of view. A significant amount of technical and administrative capacity will therefore be needed. According to the Proposal, the costs for public authorities at the national and EU level for setting up the infrastructure for primary use could amount to 0.1 billion euros.[114] It is proposed that the Commission will have a central function in this endeavour, to support the sharing of best practice and expertise, and to draw up benchmarking guidelines.[115] The EHDS Board, which is the new EU body to be established under the Proposal, will also be tasked with supporting the capacity-building of the digital health authorities, the exchange of information and collaboration.[116]

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[108] Herwig CH Hofmann and Alexander Türk, 'The Development of Integrated Administration in the EU and Its Consequences' (2007) 13 European Law Journal 253.
[109] This is known as the doctrine of national institutional and procedural autonomy.
[110] Hielke Hijmans, 'The DPAs and Their Cooperation: How Far Are We in Making Enforcement of Data Protection Law More European?' (2016) 2 European Data Protection Law Review 362, 367, 369 et seq.
[111] Anu Bradford, *The Brussels Effect: How the European Union Rules the World* (Oxford University Press 2020) 7, 132 et seq.
[112] Proposal, Article 10.
[113] See EDPB and EDPS (n 43) p. 24.
[114] Proposal, para 4.
[115] Proposal, Article 59.
[116] Proposal, Article 65.

5.3 Secondary use bodies: tasks and competences

A central part of the Proposal's rules on the secondary use of electronic health data is the administrative procedures set out for applications and access. The health data access bodies will be responsible for granting access, as well as providing a secure processing environment and hosting the national gateway to HealthData@EU.[117] In order to access electronic health data, data users may apply for a data permit,[118] with the data being made available through a secure processing environment in either anonymised or pseudonymised form.[119] An application must include elements such as a detailed explanation of the intended use of the electronic health data, the type of data requested, and whether the data is requested in anonymised or pseudonymised form.[120] A description of the safeguards planned to prevent any other use of the electronic health data and protect the rights and interests of the data holder and the individuals concerned should also be included.[121] If a data user seeks access to electronic health data from more than one Member State, it is enough to apply to one of the concerned health data access bodies concerned, which will in turn share the application with the others. However, each body remains responsible for deciding on a data permit for data held within its Member State.

When a data user receives a permit, the data holder must put the electronic health data at the disposal of the health data access body within two months, although this period may be extended.[122] The health data access body will function as a joint controller together with the data user, for the duration of the permitted processing.[123]

The Proposal allows for derogations to the application procedure in two cases. First, any application for electronic health data from a single data holder in a single Member State may be submitted directly to the data holder, without a health data access body being involved. The same assessment criteria apply and the single data holder is responsible for providing a secure processing environment in which the data user can access the data.[124] This presupposes that data holders have the necessary resources, capacities and knowledge as regards both the legal and the technical prerequisites. Secondly, national public sector bodies and EU institutions and bodies that seek electronic health data for the purpose of 'carrying out the tasks enshrined in their mandate, based on national or Union law' are exempted from the requirement of a data permit.[125] Instead, the less detailed procedure laid down in the Data Government Act is to be applied.[126] There is also a simplified route for accessing data, via a data request, which only gives access to data in an anonymised statistical format and does not provide access to the electronic health data used.[127]

The Proposal includes several forms of sanctions, directed to both data holders and data users. If data holders do not respect timelines, they can be fined for each day of delay.[128] In the case of repeated breaches, a data holder may be banned from participation in the EHDS for a period of up to five years.[129] Data users who do not comply with the Regulation and with the data permit may have their permit revoked, and may also be banned from any access to electronic health data for a period of up to five years.[130] Data users who try to re-identify pseudonymised data or who do not respect measures taken to ensure pseudonymisation

[117] Proposal, Articles 36(1), 45, 46, 50 and 52.
[118] Proposal, Article 45.
[119] Proposal, Article 41(3).
[120] Proposal, Article 45(2)(a)-(d).
[121] Proposal, Article 45(2)(c)-(f).
[122] Proposal, Article 41(4).
[123] Proposal, Article 51.
[124] Proposal, Article 49 (1)-(2).
[125] Proposal, Article 37(1)(b) or (c) and 48.
[126] Proposal, Article 48, referring to Article 9 Data Governance Act.
[127] Proposal, Article 47.
[128] Proposal, Article 41 and 43(5).
[129] ibid.
[130] Proposal, Article 43(4).

are to be subject to appropriate penalties under national law.[131] It should be mentioned that the Proposal puts pressure on health data access bodies to act swiftly, since should a health data access body fail to provide a decision within the established time limit, a 'failure to act' procedure means that the permit will be issued.[132] Considering the complexity of the assessment, this does not seem a convincing provision.

'One aspect is surprisingly absent, namely a data holder's right to participation in the administrative procedure as well as effective remedies.'

One aspect is surprisingly absent, namely a data holder's right to participation in the administrative procedure as well as effective remedies. As discussed in section 4 regarding health data protected by IP rights and trade secrets, the Proposal does not provide any mechanisms (for example a right to be heard before a decision is taken, or a right to appeal a decision) for a data holder to object to a data request being issued. This could be relevant in a case where the data holder finds it to be contrary to its legal obligations to transfer the data, due, for example, to rights relating to confidentiality or data protection.[133] Only in respect of a decision on penalties does the Proposal guarantee a right to an effective judicial remedy.[134] This suggests that a data holder has to wait until it is subjected to a penalty before it can initiate a review. These administrative and judicial safeguards could, however, be provided via national law.

Lastly, the costs of this infrastructure for secondary use will be far higher for public administrations than the equivalent costs for primary use. It is estimated that the public authorities at the Member State and EU level will bear costs of approximately 0.4-0.7 billion euros for establishing health data access bodies as well as the necessary digital infrastructure in order to facilitate cooperation and promote interoperability and data quality.[135] Both health data access boards and single data holders may charge fees for making electronic health data available for secondary use, which, for actors other than the health data access bodies and public sector bodies, may include compensation for some of the costs of collecting the electronic health data.[136] It should be added that ensuring that health data access bodies have the necessary resources is fundamental for the success of the EHDS. However, it may be expected that part of the costs will also be passed on to the data users. For researchers and research funders, this could be a challenge.

5.4 Trusted EU governance?

As is evident in this analysis, the EHDS is part of the EU's bigger plan for the data driven economy that is set out in the European strategy for data. One of the central aims of this strategy is to ensure that the rules for the access to and use of data are fair, practical and clear. Furthermore, there must be clear and trustworthy data governance mechanisms in place.[137] For the electronic health data sector, the Commission has underlined the importance of using health data responsibly and with full respect for fundamental rights, in order to realise its benefits.[138] In addition, the Commission holds that 'fragmented and divergent legal and administrative rules, frameworks, processes, standards and infrastructure for reusing health data' constitute an obstacle.[139]

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[131] Proposal, Article 44(3) and Article 69.
[132] Proposal Article 46(3).
[133] Compare Article 9(2) Digital Governance Act, which provides that 'any natural or legal person directly affected by a decision as referred to in paragraph 1 shall have an effective right of redress in the Member State where the relevant body is located'. The review could be performed by an authority.
[134] Proposal, Article 43(9).
[135] Proposal, para 4. However, the Commission considers that many of these costs will be offset through fees charged by health data access bodies. Furthermore, national policy makers and regulators will benefit from the existence of health data access bodies because they will have lower costs for accessing data. EU funds will also provide further support to aid Member States with digitalisation. See p. 2 of EU Commission, 'Executive Summary of the Impact Assessment Report on EHDS'.
[136] Proposal, Article 42(1).
[137] The European strategy for data (n 2) 5.
[138] Opinion of the European Economic and Social Committee (n 8) p. 1.
[139] ibid p. 6.

Will these ambitions be achieved with the Proposal? On the one hand, the Proposal sets out strong general data protection safeguards, particularly as regards data minimisation, by only allowing access to anonymised or pseudonymised data, by purpose limitations and by requiring secure processing environments. By only permitting electronic health data to be processed locally, health data access bodies or single data holders need only apply national rules when assessing data access applications. On the other hand, the assessment that is to be conducted by a health data access body may still be challenging. This assessment could include any of the 15 categories of electronic health data, for any one or more of the eight categories of permissible purposes.[140] The legal requirements for processing health data vary between Member States because of the decentralised structure of the GDPR, but they have at least one point in common in that the processing is often closely regulated.[141] This makes for a diverse and complex regulatory landscape, even within one national legal order. In Finland, where a similar centralised health data access regime has been introduced, there are reports of the procedure being lengthy and expensive.[142] In relation to multi-country applications, the assessment process can be expected to be especially complex and demanding. The Proposal does not provide any tools to overcome these challenges, but foresees that the Commission can enact implementing acts to define templates for different steps in the procedure, as well as providing capacity-building support to the Member States.[143] These soft governance tools will not, however, provide the legal security and foreseeability needed in such a sensitive sector as that of electronic health data.

Another weakness of the proposed procedures is the lack of clarity relating to the natural and legal persons who are concerned by the processing. The Proposal sets out efficient procedures for applying for access to electronic health data, but provides no formal role for data holders before a data permit is granted. This adds to the complexity of the assessment procedures, since the way in which national administrative procedures could complement the Proposal remains unclear. This piecemeal approach is unfortunately quite typical of the ever-developing administrative cooperation between the EU and its Member States, with EU secondary law often laying down minimum rules for administrative and judicial procedures for functions that are carried out in common, with other functions being left to the Member States to deal with individually.[144]

6. Conclusion

The Proposal for a European Health Data Space is a commendable attempt by the European Commission to lay out a legal framework that can help transform healthcare and catalyse health-related innovation and research in Europe, thus making the EU a leading actor in the global health sector. However, negotiations are still ongoing between the co-legislators and there are still major questions that call for further scrutiny and reconsideration.

When it comes to primary use, the extended possibilities for patients to access and control their electronic health data in their own healthcare, can be seen as an empowerment. The consequence of realising certain particular rights for patients however, such as the right to modify information in their own patient records, may at the same time jeopardize the quality of healthcare and raise questions regarding the liability of health professionals.

Quite on the contrary, another key tension to be expected in the negotiations is the weak role of the individual when it comes to secondary use. The

[140] Proposal, Article 33(1) and 34(1).
[141] See, in regards to biobanking, Olga Tzortzatou et al., 'Biobanking Across Europe Post-GDPR: A Deliberately Fragmented Landscape', in Santa Slokenberga, Olga Tzortzatou and Jane Reichel (eds), *GDPR and Biobanking: Individual Rights, Public Interest and Research Regulation across Europe* (Springer International Publishing 2021).
[142] Aleksi Reito et al., 'Toisiolaki – lääketieteellisen tutkimuksen mahdollistaja vai tukahduttaja?' [Enabler or Suppressor? – Survey on the Effects of the Act on the Secondary Use of Health and Social Data on Medical Research], Suom Lääkäril 2022; 77: e30589.
[143] Proposal, Articles 45(6), 51, 52(5), (13), 59.
[144] Jane Reichel, 'The European Data Strategy and Trust in EU Administrative Governance. The Case of Access to Publicly Held Data' (2023) 4 CERIDAP 129

Proposal lays down an elaborate administrative application procedure for businesses, researchers and governments to access electronic health data, but, as of now, the Proposal does not include an independent mechanism for individuals to have their say in the process. In national law, the autonomy of the individual concerned is usually protected via requirements for informed consent or an opt-out procedure, or by administrative safeguards in the form of a requirement for ethical approval. The role of these safeguards in the administrative application procedure is not quite clear from the Proposal. Although the approach envisaged by the Commission might enhance the data pools available for secondary use, there is a risk that the limited role given to the individuals concerned will decrease the legitimacy of the EHDS.

> '[...] there is a risk that the limited role given to the individuals concerned will decrease the legitimacy of the EHDS.'

As discussed above, the Proposal will also have important effects on market actors. In order to incentivise firms to provide high-quality health data and thus contribute to the Proposal's goal of innovation in healthcare, appropriate legal mechanisms must be in place. In particular, providing greater clarity regarding access to health data protected by IP rights and trade secrets, but also offering guarantees of confidentiality and non-disclosure, is crucial. Furthermore, private actors will only be willing to participate if there are dispute mechanisms in place to allow them to fairly contest certain data requests before a competent authority.

Regarding competition and the future of AI and healthcare, the EHDS can be expected to have a positive impact on competition since health data will be accessible to all kinds of applicants; this will limit data hoarding by dominant firms in the tech and pharma sectors. However, the result could also be that dominant companies' access to valuable health data is even easier through the EHDS, leading to new risks of monopolisation in healthcare markets. This is particularly problematic when one considers that health data from the EHDS may risk being used for corporate interests that do not directly benefit European citizens. Therefore, it is vital that strong sanctions are in place to deter non-compliance with the rules, especially considering the difficulties in monitoring the enormous number of data permits that will be issued.

Significant implications for national and EU public administrations can also be foreseen. The introduction of interoperable EHR systems for primary use and a common application procedure for secondary use will challenge both national healthcare budgets and administrative routines and traditions. The importance of resources to build necessary capacity and ensure effective implementation of the EHDS cannot be understated, especially in times when national budgets are under strain.

Furthermore, there is also an underlying tension in the Proposal between the EU's and the Member States' competencies to regulate the administrative procedural aspects. The procedures could be complemented by national law, which could lead to uncertainties for the individuals and market actors involved, not least in cross-border situations. Although this is in line with the subsidiarity principle, it may lead to problems for the effective implementation and enforcement of the Proposal.

Moreover, there is also a risk that the procedures for access will become overly complex and expensive. It may therefore be necessary to take the foundation for administrative cooperation more seriously, especially in light of the EU again preparing to welcome new Member States into the Union. Overall, both the technical and the administrative features of the Proposal will most definitely affect a wide range of areas in the Member States: the organisation of healthcare services, the practical delivery of healthcare, competition, and research and innovation in AI and medicine.

However, negotiations in Brussels between the Parliament and the Council will introduce changes to the Proposal, which may address many of these issues. Throughout the process, engaging with stakeholders, civil society and academics across Europe will be necessary for a more rigorous legal framework and appropriate implementation. Importantly, the success of the EHDS is heavily dependent on a broad group of stakeholders; without their full trust and cooperation, it may ultimately fail.