The European Health Data Space: The Next Step in Data Regulation

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Abstract

The European Health Data Space (Regulation (EU) 2025/327, EHDS) is an ambitious regulatory project concerning the accessibility of health data. The rules established through this initiative can play a crucial role in addressing the currently fragmented state of digitalisation in healthcare across Member States. Major changes occur in the area of primary use of health data. By granting individuals more autonomy over their electronic health records, the EHDS ensures that patients can access, add, rectify and manage their health records more easily. This also provides healthcare professionals with a greater understanding of a patient's medical history, thus improving treatment quality, especially in cross-border scenarios. Furthermore, the EHDS creates a novel framework for the secondary use of health data, mainly for research, innovation and policymaking. It does so by stipulating specific cases of secondary use for which different categories of data can be accessed. If all criteria are fulfilled, a data permit will be issued. The EHDS establishes a set of rules and guidelines for such application processes. However, the implementation of the EHDS raises complex questions, particularly regarding its relationship with the General Data Protection Regulation and the resulting legal conflicts. Additionally, the risk of national fragmentation in interpretation and application of the EHDS could hinder its effectiveness. Despite these challenges, the EHDS could represent an important step towards harnessing the vast potential of health data within the European Union. With its focus on empowerment of individuals, improved healthcare, and research facilitation, the EHDS might transform European healthcare systems and drive innovation in the sector. If successful, the initiative could possibly shape future data-sharing practices and influencing the development of other European data spaces

1. Introduction

The COVID-19 pandemic has thrown an alarming spotlight on the problems facing modern European healthcare systems: often insufficiently digitalised health authorities, a lack of reliable data, and inadequate international cooperation (European Commission, Directorate-General for Health and Food Safety, 2022). Moreover, Europe has long since ceased to lead the way in the development of innovative pharmaceuticals (Horgan et al, 2022, p. 3). At the same time, vast amounts of health data are collected every day through various methods, but often remain unused. Indeed, just think of the information that doctors routinely collect about their patients or the amount of data that fitness applications collect from smartwatches. Here, existing potential within the EU is not being sufficiently utilised. This imbalance has also been recognised by European legislators, who wish to remedy the situation with by establishing a European Health Data Space (Regulation (EU) 2025/327, EHDS). On the one hand, this will establish a new framework for the primary use of health data so as to provide patients with increased autonomy over their own data and healthcare professionals with better information for their treatment (especially in the context of cross-border treatments). On the other, the EHDS will establish an access right to health data for secondary uses – in particular, research.

After a brief description of the legislative history, this chapter seeks to show the new law's structure. To this end, the regulatory regime of the new primary and secondary use are outlined. Subsequently, existing uncertainties and difficulties in the Regulation's implementation are highlighted through pertinent examples. At its close, the chapter ventures an outlook and examines the extent to which the EHDS is suitable as a model for other sectoral data spaces.

2. Legislative history

As with the Data Act and the Data Governance Act,[1] the origins of the EHDS can be traced back to the Data Strategy published by the European Commission in 2020 (European Commission, 2020a). The strategy intro-

1 For more information on the Data Act, see Chapter 13 'Internet of Things Data within the Context of the Data Act: Between Opportunities and Obstacles' by Prisca von Hagen. For more information on the Data Governance Act, see Chapter 11 'The Data Governance Act – Is "Trust" the key for Incentivising Data Sharing?' by Lucie Antoine.

duces the implementation of nine sector-specific data spaces with the aim to make larger pools of data available (European Commission, 2020a, p. 21). Sectors in which data spaces are envisioned include for example mobility, finance, and agriculture.

It may well have been the impact of the COVID-19 pandemic that prompted the establishment of a European health data space as a primary legislative initiative – a goal which also aligns with the declared aim of establishing a European Health Union (European Commission, 2020b). To this end, the European Commission presented a proposal for a European Health Data Space in May 2022 (European Commission, 2022). Existing health data spaces in Member States, particularly in Finland (*Laki sosiaali- ja terveystietojen toissijaisesta käytöstä*, see also: Männikkö et al, 2024), may have served as an inspiration. At the end of 2023, both the European Parliament and Council agreed on a negotiating mandate. This signalled the start of the trialogue negotiations, in which an agreement was reached in March 2024. The EHDS was then voted on by the European Parliament in April 2024, with formal approval from the Council granted in January 2025. I The EHDS was published in the Official Journal of the European Union on 5 March 2025 as Regulation (EU) 2025/327, and enters into force on 26 March 2025. The key parts of the EHDS will enter into application in March 2029.

3. Primary use

The first major innovation introduced by the EHDS concerns the primary use of electronic health data. Primary use refers to "the processing of electronic health data for the provision of healthcare, in order to assess, maintain or restore the state of health of the natural person to whom those data relate, including the prescription, dispensation and provision of medicinal products and medical devices, as well as for relevant social, administrative or reimbursement services" (Art. 2(2)(d) EHDS). Electronic health data within the meaning of this definition include both personal and non-personal data (cf. Art. 2(2)(c) EHDS).

The declared aim in the area of primary use is "to empower individuals to take control of their own health data and to allow its use for better healthcare delivery" (European Commission, 2022b, p. 2). The mechanisms by which this is to be achieved are outlined below.

3.1 More control over the individual's electronic health data

When it comes to achieving the ambitious goal of unlocking the potential of electronic health data, the first step envisioned is to create more data sovereignty for patients. At present, this varies greatly within the EU. While the Nordic and Baltic states already have extensive options for accessing one's own health data, this status quo is far from being established across the EU (European Commission, Directorate-General for Communications Networks, Content and Technology et al, 2023).

This is where the EHDS comes into play. Art. 3 EHDS is key in establishing the right of natural persons to access their electronic health data. Art. 3(1) EHDS stipulates that "natural persons shall have the right to access at least personal electronic health data relating to them that belong to the priority categories referred to in Article 14 and are processed for the provision of healthcare". Moreover, Art. 7 EHDS grants a right to data portability. A natural person can request healthcare providers to transmit the data to another healthcare provider (Art. 7(1) EHDS) or a to a clearly identified recipient in the social security or reimbursement services sector (Art. 7(3) EHDS).

Furthermore, the EHDS ensures that natural persons have the opportunity to influence the data that is stored about them. Specifically, this means that they can rectify incorrect data and insert missing data, Arts. 5 and 6, Recitals 12 and 13 EHDS. If data has been added in such a way, it will be clearly distinguishable to take account of the fact that the information may be less reliable than that of healthcare professionals (Art. 5 EHDS).

It is also possible for patients to make the reversible decision to block certain, often sensitive, information from third parties. Especially in the areas of sexual or mental health, this is often of great importance to those affected. In such cases, however they should be informed of the possible risks associated with such decisions and the incomplete datasets that result from them. However, an exception applies to "protect vital interests in emergency situations", (Art. 8, Recital 17 EHDS). In addition, the Member States are free to enact such a right even without an emergency override (Recital 18 EHDS). In order to have effective control over their own health data, Art. 9 EHDS standardises a natural person's right to information about the healthcare providers who have been granted access to their data.

Many of these rights have already been laid out in principle in the General Data Protection Regulation (GDPR). For example, Arts. 15–22 of

the GDPR grant the right to access by the data subject (Art. 15 GDPR), the right to rectification (Art. 16 GDPR), and the right to data portability (Art. 20 GDPR). The rights introduced by the EHDS are therefore ultimately more of a concretisation (Petri, 2022, p. 418) or an add-on (EDPB-EDPS, 2022, para. 47). As a result, the exact relationship between the EHDS and GDPR must also be further explored (EDPB-EDPS, 2022, para. 47; see also Section 5).[2]

3.2 Better treatment through better data

The improved data accessibility in the area of primary use is intended to ultimately lead to more needs-based medical treatment (Recital 19 EHDS). Practitioners in Member States with low levels of digitalisation in the medical sector are currently often faced with incomplete documentation of patients' health histories. Obtaining relevant information frequently involves a considerable amount of administrative work and time. Therefore, in Art. 11, the EHDS establishes a possibility for healthcare professionals to access the electronic health data of their patients. However, the above-mentioned restrictions that natural persons can impose regarding access to their health data still apply.

Special attention is also paid to the cross-border flow of data. This is intended to ensure the possibility of continuous treatment when travelling or moving to another Member State, cf. Art. 11(2) and Recital 33 EHDS. For example, if a Dutch tourist suffers a broken leg while on a skiing holiday in Austria and receives surgery there, the doctor providing follow-up treatment in the Netherlands can access the crucial findings and X-ray images. Currently, a direct and safe health data transfer from one country to another fails due to a lack of interoperability and a missing legal framework.

3.3 Data access made easy?

According to Art. 3(1) EHDS, patients must be able to access their health data immediately, free of charge, and in an easily readable, commonly used format, which is also necessary for access for treatment purposes. Due to the high sensitivity of the data, a secure infrastructure must be created for

2 For more information on the GDPR, see Chapter 14 'EU Data Protection Law in Action: Introducing the GDPR' by Julia Krämer.

this purpose. Art. 4 EHDS obliges Member States to create health data access services. In Chapter III, the EHDS also establishes rules and standards against which those EHR systems will be measured in future. This includes, for example, requirements for both the security and interoperability of the systems, with the aim of fostering a genuine internal market for such systems (Recitals 1, 36, 41, and 110 EHDS).

It should also be noted that, as seen above, inconsistent systems in the various Member States could lead to access to health data failing due to technical hurdles, particularly in the case of cross-border treatment. Accordingly (and pursuant to Art. 23 EHDS), the MyHealth@EU service is to be further expanded, and national contact points created. This will enable access to prescriptions abroad, as well as to patient summaries.

4. Secondary use

The regulatory regime of the EHDS promises to foster innovation in the area of secondary use. According to Art. 2(2)(e) EHDS, secondary use is understood as "the processing of electronic health data for the purposes set out in Chapter IV of this Regulation, other than the initial purposes for which they were collected or produced". As such, this is a use of data that does not serve the original healthcare provision, but rather subsequent, additional purposes.

Access to health data is currently difficult, predominantly due to a fragmented legal landscape, both at Member State and EU-wide levels (European Commission, Directorate-General for Health and Food Safety et al, 2022, Kühling and Schildbach, 2024). The EHDS now creates a standardised legal framework for the secondary use of electronic health data.

4.1 Application process

The EHDS introduces a new system for organising access to health data. Unlike the Data Act (DA; see Art. 4(13), (14), Art. 6(1), Art 8(1) DA), the EHDS does not rely on contractual solutions. Instead, so-called data permits are to be issued. To obtain such a permit, in accordance with Art. 67 EHDS, an application for data access can be submitted to a national health data access body – according to Art. 67(1) EHDS, any natural or legal person is eligible to apply. The article also specifies a range of information

that the applicant must provide. The national data access body then checks the requirements in accordance with Art. 68 EHDS, particularly in terms of whether one of the purposes specified in Art. 53 EHDS (see Section 4.2) applies and whether the requested data is necessary for this purpose. If so, a data permit will be issued. Access to the data is granted by the health data access bodies in a secure processing environment (Art. 73 EHDS). The Commission's original proposal also consisted of a simplified application process from a single data holder (Art. 49 EHDS-P). The amendments made during the trilogue negotiations will, however, likely result in limited applicability of the provision (Art. 72 EHDS).

The cost regulations established in the EHDS are also interesting to consider, especially compared to the DA, which, like the EHDS, is part of the European Commission's Data Strategy. Costs within the EHDS amount to administrative fees (described in detail in Art. 62 EHDS), meaning that it is not the data themselves for which the applicant must pay, but rather the work that must be conducted to make it accessible. This becomes all the clearer when one considers that the DA refers to "compensation" (Art. 9 DA), which may be subject to FRAND (Fair, Reasonable, and Non-Discriminatory) conditions. The terminology of the EHDS, on the other hand, is based around "fees" (Art. 62 EHDS), which may include compensation for the data holder: "compensation for part of the costs for collecting the electronic health data specifically under this Regulation in addition to the fees that may be charged" (Art. 62(2) EHDS). However, the inclusion of a margin is, in contrast to Art. 9(1) DA, not intended in the EHDS. Consequently, the EHDS does not create a market for electronic health data. This concept is not entirely new as the Open-Data-Directive (ODD)[3] has similar provisions in Art. 6. However, the ODD only applies to public sector information, whereas the EHDS does not distinguish between public and private data (see also Richter, 2018).

3 For more information on the ODD, see Chapter 12 'The Open Data Directive: Potential and Pitfalls for the Social Sciences' by Nik Roeingh and David Wagner.

4.2 Purposes

Art. 53 EHDS lists the purposes for which the access to electronic health data for secondary use can be granted:

(a) public interest in the area of public and occupational health, such as activities for protection against serious cross-border threats to health and public health surveillance or activities ensuring high levels of quality and safety of healthcare, including patient safety, and of medicinal products or medical devices;
(b) policy-making and regulatory activities to support public sector bodies or Union institutions, bodies, offices or agencies, including regulatory authorities, in the health or care sector to carry out their tasks defined in their mandate;
(c) statistics as defined in Article 3, point (1), of Regulation (EU) No 223/2009, such as national, multi-national and Union-level official statistics, related to health or care sectors;
(d) education or teaching activities in health or care sectors at vocational or higher education level;
(e) scientific research related to health or care sectors that contributes to public health or health technology assessments, or ensures high levels of quality and safety of healthcare, of medicinal products or of medical devices, with the aim of benefiting end-users, such as patients, health professionals and health administrators, including:
    (i) development and innovation activities for products or services;
    (ii) training, testing and evaluation of algorithms, including in medical devices, in vitro diagnostic medical devices, AI systems and digital health applications;
(f) improvement of the delivery of care, of the optimisation of treatment and of the provision of healthcare, based on the electronic health data of other natural persons

The list is exhaustive. There is consequently no possibility of gaining access to data for any other purpose, which, due to the sensitive nature of health data, is to be welcomed. Nevertheless, there is already a highly broad range of purposes covered. It is interesting to note that commercial research also constitutes a purpose for which data can be processed for secondary use, as Art. 53(1)(e) EHDS contains no restriction to public research. On the contrary, Recital 61 EHDS explicitly lists privately funded research as well. In the debate surrounding the legislation, the fear was often expressed that

both Big Pharma and Big Tech would have unrestricted access to data (European Digital Rights, 2023, Schipper and Ollivier de Leth, 2024). The extent to which certain actors have gained access to health data under the EHDS will therefore be quite interesting to study once the regulation has come into effect.

4.3 Scope of data that can be accessed

To assess the scope of the rules on secondary use, it is necessary to examine the data for which permits may be issued.

4.3.1 Categories

In accordance with Art. 51 EHDS, a wide range of data can be accessed. The following is an incomplete selection of the collected data to be made available for secondary use by data holders:

(a) electronic health data from EHRs;
(b) data on factors impacting on health, including socio-economic, environmental and behavioural determinants of health;
(f) human genetic, epigenomic and genomic data;
(g) other human molecular data such as proteomic transcriptomic, metabolomic, lipidomic and other omic data;
(h) personal electronic health data automatically generated through medical devices;
(i) data from wellness applications;
(j) data on professional status, and on the specialisation and institution of health professionals involved in the treatment of a natural person;
(o) data from registries for medicinal products and medical devices;
(q) health data from biobanks and associated databases.

According to Art. 50(1) EHDS, there are two groups of health data holders that are exempted from the obligation to make the data outlined in this chapter available. The first group consists of individual researchers and natural persons; the second are legal persons that qualify as micro-enterprises, as defined in Art. 2 of the Annex to Commission Recommendation 2003/361/EC. Here, a micro-enterprise is defined as one which employs fewer than 10 persons and whose annual turnover and/or annual balance sheet total does not exceed 2 million EUR.

The far reaches of the data categories are remarkable. Human genetic, epigenomic, genomic, and other molecular data in particular (Art. 51(1)(f) and (g) EHDS), but also data on socio-economic, environmental, and behavioural determinants of health (Art. 51(1)(b) EHDS) can contain a particularly large amount of information about the natural person from whom they originate. In addition, Art. 51(2) EHDS provides that Member States can add further data categories to this list on a national level. In this context, it is interesting to note that the mandates of the Parliament and the Council have led to several changes that appear minor at first glance but are nevertheless capable of significantly influencing data availability. For example, "social" became "socio-economic determinants of health" (cf. Art. 33(1)(b) EHDS-P, Art. 51(1)(b) EHDS). Compared with the current Art. 53(1)(f) and (g) EHDS, the original Commission draft only included human genetic, genomic, and proteomic data (Art. 33(1)(e) EHDS-P).

Furthermore, the EC's proposal had faced criticisms over privacy concerns, in that data from wellness applications were also covered under Art. 33(1)(f) EHDS-P (EDPB-EDPS, 2022, para. 79–81). However, this criticism was not adopted in the trilogue procedure, meaning that wellness applications are still covered by the law (Art. 51(1)(i).

4.3.2 Patient protection through anonymisation and pseudonymisation

Electronic health data should generally be made available to applicants in anonymised forms (Art. 66(2) EHDS) or, if this is not possible, in pseudonymised forms (Art. 66(3) EHDS). This distinction has consequences, particularly in terms of the scope of the GDPR's application. Anonymised data is not personal, and thus outside the GDPR's scope. In contrast, pseudonymised data, in accordance with Art. 4(4), Recital 26 GDPR, is still considered personal, meaning that the Regulation's regime applies.

Anonymisation or pseudonymisation should occur as early as possible during the process, but must be done at the latest by the health data access body before the data is shared with applicants (Recital 72 EHDS). It should be noted that the enormous increase in computing capacity means that re-identification is now possible with increasingly less effort (Rocher et al, 2019). Since the range of data collected is potentially extremely large (see above), and the nature of health data, it is necessary that anonymisation or pseudonymisation processes function securely and reliably for efficient patient protection to be guaranteed. It is therefore a key point for the

success of the proposed legislation. In order to ensure this, Art. 61(3) EHDS explicitly bans re-identification. After initial criticism that the penalty rules in case of an infringement of this ban stated in the commission proposal were insufficiently clear (EDPB-EDPS, 2022, para. 127), the agreement text now offers more detailed rules: the re-identification of natural persons can lead to a fine of up to 20 million EUR or of up to 4% of the total worldwide annual turnover of the preceding financial year (Art. 64(5)(c) EHDS). It remains to be seen whether this instrument can suitably prevent re-identification, and thus sufficiently guarantee data protection.

4.4 Prohibited secondary uses

Art. 54 EHDS explicitly states purposes that are not permitted in the context of secondary use. The decisive factor here is the protection of natural persons:

(a) taking decisions detrimental to a natural person or a group of natural persons based on their electronic health data; […]
(b) taking decisions in relation to a natural person or groups of natural persons in relation to job offers, offering less favourable terms in the provision of goods or services, including exclusion of such persons or groups from the benefit of an insurance or credit contract, the modification of their contributions and insurance premiums or conditions of loans, or taking any other decisions in relation to a natural person or a group of natural persons which result in discriminating against them on the basis of the health data obtained;
(c) carrying out advertising or marketing activities;
(d) developing products or services that may harm individuals, public health or societies at large […];
(e) carrying out activities in conflict with ethical provisions pursuant to national law.

The categories listed are hardly surprising. For example, the risks of using AI to select job applications are well known (Dinika and Sloane, 2023). In this context, it is conceivable that an applicant could be screened out based on their medical history due to an algorithm predicting long periods of illness-related absences. European legislators also seem to be aware of the risks of medical data being used to adjust insurance premiums to the detriment of consumers. Suppose, for example, that a health insurance

company can access data from a fitness app and concludes that the person in question leads an unhealthy lifestyle. This could result in high costs for the insurance in the long term and, subsequently, entice it to significantly increase this person's insurance premiums. Art. 54(b) EHDS attempts to prevent such developments.

Another danger is the misuse of data relating to reproductive health. This has been discussed in the course of the overturning of *Roe v. Wade* in the USA (Malki et al, 2024). For example, there are a number of apps that enable women to track their periods. This data can also provide information on abortions, possibly endangering women in states with strict anti-abortion laws. Although this problem is currently less imminent in the EU, it should be used as an example of how far-reaching the consequences of malicious use of health data can be for natural persons. Art. 54(a) EHDS provides a general provision for such, or previously unforeseeable, risks. However, it should be noted that the rather vague wording of this Article could also lead to legal uncertainty.

As shown previously, the EHDS constitutes a basis by which various players could access vast amounts of health data. The prohibitions stated in Art. 54 EHDS, together with the option to penalise their infringement pursuant to Art. 64(5)(a) EHDS, could be a central part of ensuring that natural persons are sufficiently protected. Whether this is enough to prevent a misuse of health data remains an open question.

5. To consent or not to consent

Perhaps the most passionately debated issue in the legislative process was the extent to which patient consent is required for the processing of health data for primary and secondary uses. There are three options here. The first and strictest is the opt-in solution, which means that explicit consent must be given. However, this could also be done in a somewhat weakened form by way of broad consent (on the concept of broad consent Cepik, 2021). A second option is to create an opt-out solution, which in turn means that consent is initially assumed, but one can object. Finally, there is also the option of simply not requiring any form of a patient's consent. The model choice likely has an impact on the chances of the EHDS's success. For example, the consent rates of studies using an opt-in procedure for processing for secondary uses are lower than in opt-out scenarios (de Man et al, 2023). It is also remarkable that the consenting study participants are less repre-

sentative of the overall population than in those with an opt-out procedure (de Man et al, 2023). Consequently, the decision to require natural persons to opt-in might result in a less complete dataset with limited applicability. The Commission certainly had these trends in mind when drawing up its legislative proposal. It therefore decided to completely abstain from the need for consent for secondary uses. This led to criticism, particularly from those with data protection in mind (Datenschutzkonferenz, 2023).

After a long struggle (for an overview of the differentiating mandates, (see Salokannel, 2024; Sokol, 2024), it was ultimately agreed that there should be no general opt-out option for primary use, but that Member States should have the possibility of introducing a modified option at a national level (Art. 10 EHDS). While Member States cannot provide a basis for data subjects to opt-out of the creation of an EHR, they can provide rules that allow the data subject to block access for primary use altogether (Sokol, 2024). For example, Germany has followed a similar approach and established such options with the introduction of the *Gesetz zur Beschleunigung der Digitalisierung des Gesundheitswesens* in the existing *Sozialgesetzbuch* (§§ 342, 353 SGB V, Kühling and Schildbach, 2024).

In the context of secondary use, Art. 71 EHDS introduced an opt-out option. According to this, patients should be able to object to the use of their data for secondary purposes at any time and without giving reasons. This represents a compromise between protecting patients' rights and achieving the goal of containing an as-complete-as-possible dataset.

6. Remaining questions

Even after the adjustments to the European Commission's proposal in the trilogue negotiations, there are still unanswered questions about the implementation of the EHDS that could significantly hinder its success. Some of them are presented here as examples.

6.1 Relation to the GDPR

The EHDS is just one building block in an abstract web of European data regulations. In particular, its relationship to the GDPR still raises a number of questions.

Few forms of data are as sensitive as health data. Accordingly, Art. 4(1) GDPR constitutes health data as personal data. This is especially true for

the primary use scenarios described earlier. Whenever health data are not anonymised (see Section 4.3), the processing of pseudonymised data also falls under the scope of the GDPR (see Art. 2(1)). As the relationship between the two legal acts is controversial in many places, only a few open questions will be addressed here.

The processing of personal data always requires a legal basis, according to Art. 6(1) GDPR. Health data is also a special category of personal data pursuant to Art. 9(1) GDPR and is therefore subject to stricter rules. The EHDS bases the processing of health data for secondary purposes on Art. 9(2) (g)–(j) GDPR (cf. Recital 52 EHDS). However, it is doubtful whether this can really be sufficient in view of the sensitivity of this data (Slokenberga, 2022).

The GDPR also stipulates that the principle of data minimisation must be met when processing personal data, which requires such data to be "adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed" (Art. 5(1)(c) GDPR). However, this is not the case when the data is specifically passed on to the health data access bodies and is only taken into account in the context of subsequent anonymisation (Petri, 2022, p. 418).

Another aspect that raises questions is the fact that the EHDS could deviate from Art. 14 GDPR. Indeed, Art. 38(2) EHDS-P stipulates that:

> Health data access bodies shall not be obliged to provide the specific information under Article 14 of Regulation (EU) 2016/679 to each natural person concerning the use of their data for projects subject to a data permit and shall provide general public information on all the data permits issued pursuant to Article 46.

Although this is possible in principle in accordance with Art. 14(5)(b)–(c) GDPR, a potential restriction of the rights of natural persons has been criticised (EDPB-EDPS, 2022, para. 25f.). For this reason, that wording can no longer be found in the corresponding Art. 58 of the final text. However, no obligation corresponding to Art. 14 GDPR has been introduced. Whether this is sufficient from a data protection standpoint is questionable.

6.2 Differences between the Member States

It is also unclear to what extent any national fragmentation in the handling of the law may affect its success. This starts with the primary use of health data, as some countries will make use of the option to block access to the EHR, such as Germany (see Section 5). In addition, the health data

access bodies are under the control of the Member States. This means that the establishment of these access bodies progresses at different speeds, and the processing times for applications could also vary greatly. This in turn might open up the possibility of forum shopping if certain Member States process applications more quickly or interpret the requirements to issue a data permit less strictly. In this context, it is also unclear to what extent the fee system will be harmonised. While fees are broken down transparently on the Finnish access body's website (Findata, 2024), it remains to be seen how other Member States will handle this in future. It has also already been pointed out that the issuing practice can differ between Member States (Staunton et al, 2024). The Joint Action Towards the European Health Data Space (TEHDAS), which consists of 30 European states, has set itself the task of eliminating remaining uncertainties resulting from the different handling of the EHDS at national levels (TEHDAS, 2022). The project has now reached the second phase (TEHDAS 2), yet to what extent harmonisation will ultimately be possible remains unclear. Additionally, a uniform level of cybersecurity must be guaranteed by all Member States, especially considering the data's sensitivity.

6.3 Garbage in/garbage out?

The quality of the research that can be conducted with the data that is now made accessible is only as good as the data itself (Kilkenny and Robinson, 2018). Accordingly, it is important to bear in mind that data do not constitute a panacea ("Dataism": van Dijck, 2014; Haggart and Tusikov, 2023, p. 117). In order for the EHDS's objectives to be achieved, especially in the area of secondary use, clear formats and designations are needed to facilitate data exchanges (TEHDAS, 2022, 6.10). It is also necessary to ensure high data quality (TEHDAS, 2022, 6.11). Only then can truly meaningful research be conducted with the data. The introduction of a label for data quality that is also interlinked with the diligence obligations for data governance in Art. 10 AI Act is envisaged in Art. 78 EHDS and could contribute to more high-quality data.

7. Outlook

The EHDS is the first of its kind. Although the list of data spaces envisaged in the future is long, these are not necessarily accompanied by a legally

enshrined right of access to the respective data, but are often limited to the de facto establishment of a sharing infrastructure (an overview can be found at European Commission, 2024). It should be noted that there is also an initial proposal for a Financial Data Access Regulation (FIDA) in the financial sector (European Commission, 2023). However, there are significant differences in the regulatory structure: for example, data is transferred from holder to user following a request from a costumer (see Art. 4 FIDA). In practice, this is done through data access permission dashboards (Art. 5(3)(d), Recital 21 FIDA). The FIDA mechanism differs considerably from that of the EHDS, where data is collected across the board and made available by health data access bodies. Whether the EHDS concept can and should also be transferred to other data spaces will be a point of discussion in the future. However, it must be taken into account that the interests are not necessarily the same as those of the healthcare sector. Ultimately, much will depend on whether the EHDS proves successful or fails to achieve its ambitious goals.

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