Processing Electronic Health Data in the European Health Data Space

Julian Sellner*
University of Heidelberg, Heidelberg, Germany
julian.sellner@bioquant.uni-heidelberg.de

Giovani Francois Nantcha**
University of Heidelberg, Heidelberg, Germany
giovani.nantcha@uni-heidelberg.de

Fruzsina Molnár-Gábor***
University of Heidelberg, Heidelberg, Germany
fruzsina.molnar-gabor@uni-heidelberg.de

* BSc, research assistant at the Chair of Prof. Dr. Molnár-Gábor and a fully qualified lawyer.
** LL.M (College of Europe), research assistant in the research group of Prof. Dr. Molnár-Gábor.
*** Professor Dr., she holds the Chair for International Medical and Health Law as well as Data Protection Law at the University of Heidelberg.

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Abstract

The widespread use and exchange of health data is central to modern digital medical care and research as well as the development of a European market for healthcare services and products. With the Regulation on the European Health Data Space (2025/327, hereinafter 'EHDS'), the European Union is pursuing a landmark data infrastructure project that aims at improving the use of health data for healthcare, health research, health innovation, and health policy-making throughout the European Union (EU). This paper examines the EHDS' functioning, structure, and relation to the General Data Protection Regulation (GDPR), also including its legislative development, and assesses it from the perspective of legislative competence in the areas of the internal market, data protection, public health, and the principle of proportionality.

Keywords

European Health Data Space – healthcare – secondary data processing – administrative infrastructure – legal competences

I. Introduction

The widespread availability of health data and genetic data[1] provides the basis for the development of future digital healthcare and biomedical research. Person-centric medicine is transitioning to also become a data-driven healthcare system that brings together a large amount of sensitive data and

[1] On Terminology: The GDPR defines the two terms separately (Art. 4 Nos. 13, 15 GDPR, Art. 9(1)(4) GDPR). In the EHDS, however, both categories of data fall under the generic term of *personal electronic health data*, if processed in electronic form (Art. 2(1)(a), (2)(a) EHDS). For further a wider discussion on *health data* as a term in the EHDS context see Franziska Sprecher, 'Regulierung von Gesundheitsdaten und Gesundheitsdatenräumen', MedR 40 (2022), 829-838 (830-832).

increasingly stratifies treatments. This requires the digitalisation of healthcare systems, for example, in the form of the collection and storage of patient data within an e-health system that allows health data to be accessed in a secure and rapid way. The electronic patient file plays a central role in this shift, already used in several EU countries and recently introduced in Germany.[2]

The rapid and widespread availability of health data enables the improvement of existing care concepts, the development of new ones, and the testing and introduction of innovations, such as Artificial Intelligence (AI)-driven diagnostics. At the same time, this data is particularly sensitive and confidential and needs the highest possible level of protection.

As part of the European Data Strategy to create a single European market for data,[3] the Commission proposed the European Health Data Space in May 2022.[4] Following extensive negotiations and discussions,[5] it entered into force on 26 March 2025, will apply from 26 March 2027, with key provisions effective from 26 March 2029.[6] It aims to enable the use of electronic health data for healthcare and for the promotion of research, innovation and policy-making, in compliance with the GDPR.[7]

Currently, health data is fragmented across various types of data systems in all Member States.[8] There are divergent administrative models for data

2 German Federal Ministry of Health, Die ePA für alle, <https://www.bundesgesundheitsministerium.de/themen/digitalisierung/elektronische-patientenakte/epa-fuer-alle.html>, last access 19 November 2025.

3 European Commission, *A European Strategy for Data*, Communication of 19 February 2020, COM/2020/66 final, 5; see also Behrang Raji, 'Datenräume in der Europäischen Datenstrategie', Zeitschrift für Datenschutz 2023, 3-8 (5 f.).

4 European Commission, 'Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space', Communication of 3 May 2022, COM/2022 hereafter: 'draft EHDS Regulation'.

5 Among others by EDPB-EDPS, *Joint Opinion 3/2022 on the Proposal for a Regulation on the European Health Data Space of 12 July 2022*, <https://edpb.europa.eu/our-work-tools/our-documents/edpbedps-joint-opinion/edpb-edps-joint-opinion-032022-proposal_en>, last access 19 November 2025.

6 Regulation 2025/327/EU of 11 February 2025 on the European Health Data Space and amending Directive 2011/24/EU and Regulation 2024/2847/EU, OJ L 2025/327.

7 Regulation 2016/679/EU 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.

8 European Commission, *A European Strategy for Data* (n. 3), 34; DG SANTÉ, 'Combined Evaluation Roadmap/Impact Assessment European Health Data Space', Ares(2020) 7907993, 2, available at <https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12663-Digital-health-data-and-services-the-European-health-data-space>, last access 19 Nobember 2025; European Commission, 'Study Supporting the Impact Assessment of Policy Options for an EU Initiative on a European Health Data Space', April 2022, 7, <https://health.ec.europa.eu/publications/study-supporting-impact-assessment-policy-options-eu-initiative-european-health-data-space_en>, last access 19 November 2025.

access[9] as well as national rules governing the processing of health data. The latter were also not harmonised by the GDPR, due to its broad opening clauses, particularly for the processing of health data (in particular Articles 9 (2)(h)(i)(j) and 9(4) GDPR).[10]

During its legislative process, the draft EHDS Regulation has been the subject of controversial debate, especially concerning its relationship to the provisions of the GDPR and the question of GDPR conformity.[11] Our aim is to present the EHDS in detail, giving due consideration to the final structure and its relation to the GDPR (II.), and to add an additional aspect to the discussion, namely an assessment from the perspective of legislative competences (III. 2.-4.). To this end, the competences relevant to the processing of health data (public health, internal market, and data protection) will be examined in greater detail (III. 1.), concluding with an outlook (IV.).

II. The European Health Data Space (EHDS)

1. Objective and Subject Matter of the EHDS Regulation

The EHDS Regulation establishes a European Health Data Space providing for common rules, standards and infrastructures and a governance framework, for both the primary and secondary use of electronic health data[12] (Article 1(1) EHDS). As it fosters EU-wide electronic health data access for better provision of healthcare (*primary use*), and research, innovation, and policy-making (*secondary use*) on the one hand,[13] natural persons are to be

9 European Commission, *A European Strategy for Data* (n. 3), 34; Nadina Iacob and Felice Simonelli, 'Towards a European Health Data Ecosystem', European Journal of Risk Regulation 11 2020, 884-893.

10 See Jürgen Kühling, 'Datenschutz im Gesundheitswesen', MedR 37 (2019), 611-622 (613); Christina Kühnl, Kerstin Rohrer and Nick Kai Schneider, 'Ein europäischer Gesundheitsdatenschutz', DuD 42 (2018), 735-740; see also Raji (n. 3), 6; Thomas Petri, ‚Die primäre und sekundäre Nutzung elektronischer Gesundheitsdaten', DuD 46 (2022), 413-418 (414).

11 See EDPB-EDPS, *Joint Opinion 3/2022* (n. 5), Michael Denga, 'Die Nutzungsgovernance im European Health Data Space als Problem eines Immaterialgütermarkts', EuZW 34 (2023), 25-32 (29); Luca Marelli et al., 'The European Health Data Space: Too Big To Succeed?', Health Policy 135 (2023), 104861; Robin van Kessel et al., 'The European Health Data Space Fails to Bridge Digital Divides', British Medical Journal 378 (2022), 378.

12 Art. 2(2)(a), 1(2)(b), (f) EHDS.

13 See <https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space_en>, last access 19 November 2025. Although the EHDS may still be insufficient for research cases described in: Regina Becker, Davit Chokoshvili and Edward S. Dove, 'Legal Bases for Effective Secondary Use of Health and Genetic Data in the EU: Time for New Legislative Solutions to Better Harmonize Data for Cross-Border Sharing?', International Data Privacy Law 14 (2024), 223-246.

given better control over their health data,[14] on the other. To this end, the EHDS Regulation establishes two new cross-border infrastructures: *MyHealth@EU* for primary use and *HealthData@EU* for secondary use.[15] In addition, the Regulation creates a harmonised legal framework for the development, marketing, and use of *electronic health record systems*.[16]

2. Legal Basis and Structure of the EHDS Regulation

The Commission bases the EHDS Regulation on Articles 114 and 16 TFEU. It is embedded within a comprehensive system of other data-related legal acts of the Union, including the GDPR, the Data Governance Act, the Data Act, and the AI Act, to which it refers in several places. According to Article 1(3)-(7) EHDS, these legal acts are not affected by the EHDS Regulation.[17]

The Regulation is divided into nine chapters, of which Chapters I, II, IV and VI are the focus of this paper. Chapter I presents the subject matter and scope of the Regulation, while Chapters II and IV set out rules on primary and secondary use of electronic health data. Chapter VI establishes a governance structure, including an EHDS Board and Steering groups for MyHealth@EU and HealthData@EU.

3. The Primary Use of Electronic Health Data in the EHDS

Chapter II EHDS regulates the primary use of electronic health data, which refers to data processed for the purpose of providing healthcare to the individual, including associated services.[18] The EHDS Regulation also aims to 'improve natural persons' access to and control over their personal electronic health data in the context of healthcare'[19] and explicitly provides data protection rights in Articles 3-10 EHDS (see II. 3. b).

a) Systematic Storage of Health Data in EHR Systems at the National Level for the Purpose of Healthcare Provision

To improve the availability of electronic health data across the EU, Member States ensure that health professionals register 'priority categories of

14 Primarily through Chapter II EHDS, in addition to GDPR rights (Art. 1(2)(a) EHDS).

15 See Art. 1(2)(d), (e) EHDS, Art. 23 EHDS, Art. 75 EHDS.

16 Art. 2(2)(k), 1(2)(b), Chapter III EHDS.

17 However, the AI Act (Regulation 2024/1689/EU) and also the Medical Device Regulation 2017/745/EU only to a limited extent, Art. 1(5) EHDS. Still, this does not mean that the relationship between the EU's legislative acts concerning data does not raise any questions.

18 Art. 2(2)(d) EHDS.

19 See Recital 1 EHDS.

personal electronic health data' into an Electronic Health Record System (EHR system),[20] as per Article 13(1) EHDS.[21] The specific categories include patient summaries, electronic prescriptions and dispensations, medical images, test results, and discharge reports.[22]

Once registered, healthcare professionals shall have access to these categories of health data of persons under their treatment and update them with regard to healthcare services provided.[23] This access is to be provided securely via 'health professional access services',[24] who may be provided and maintained either by public or private entities, depending on the decision of each Member State.[25]

These EHDS provisions raise questions related to data protection law, especially with regard to the applicable legal basis under the GDPR, some of which, however, are left to be answered by Member State laws. As for the registration of health data in EHR systems, the EHDS Regulation as such does not require consent within the meaning of Article 6(1)(a) GDPR.[26] Instead, national legislation, as required by Article 13(1) EHDS, will presumably introduce a legal obligation for healthcare professionals to register health data in EHR systems, thereby constituting a legal basis in accordance with Article 6(1)(c), (3) GDPR. Recital 11 EHDS suggests, that Member States may introduce further conditions such as a consent requirement under national legislation based on Article 9(4) GDPR.

With regard to health professional access services, Recital 19 EHDS clarifies that their provision is a task in the public interest, establishing a legal basis under Article 6(1)(e), (3) GDPR for its providers. It also states that the EHDS Regulation provides for 'conditions and safeguards' necessary to process under Article 9(2)(h) GDPR, which is to be ensured in particular through the technical requirements for EHR systems.[27]

From a data protection perspective, it is also crucial to define the scope of healthcare providers' access to health data. However, this task falls to the Member States,[28] who must ensure compliance with Article 5 GDPR and

20 Defined in Art. 2(2)(j) EHDS.

21 Art. 13(1) EHDS reads like a regulatory mandate to the Member States to adopt corresponding legislation.

22 Art. 14(1) EHDS. The Commission is empowered to further define data quality requirements via implementing acts, Art. 13(4) EHDS.

23 Art. 12, 13(2) EHDS.

24 Service supported by an EHR system that enables healthcare professionals to access the data of natural persons under their care (Art. 2(2)(i) EHDS).

25 Art. 12, Recital 19 EHDS.

26 Denga (n. 11), 2).

27 See Chapter III EHDS, Annex II EHDS.

28 Art. 11(3) EHDS.

data minimisation, without unduly restricting access to data essential for healthcare provision.

b) Rights of Natural Persons with Regard to Electronic Health Data

Against the backdrop of the fundamental right to the protection of personal data under Article 8 Charter of Fundamental Rights of the European Union, making electronic health data available must be matched by a corresponding control of natural persons over their data. To this end, Articles 3-10 EHDS provide for rights that are partly based on the rights of data subjects under GDPR and are specifically tailored to personal electronic health data.

Building on Article 15 GDPR, Article 3(1) EHDS grants natural persons the right to access their own personal electronic health data *immediately,*[29] free of charge and in an easily readable, consolidated and accessible form, via an 'electronic health data access service'[30] set up by Member States.[31] Beyond access, individuals may enter information into their EHR (e. g. through wellness applications)[32] and have the right to rectification in line with Article 16 GDPR.[33] This is supplemented by a right to obtain information on data access, including who accessed data, when, and for what purpose, under Article 9 EHDS. Article 7 EHDS further introduces a right to give access to, and transmit their data to another healthcare provider (right to data portability), this includes derived data and applies irrespective of the legal basis, therefore going beyond Article 20 GDPR.[34]

Article 8 EHDS allows individuals to partially or fully restrict access of health professionals and healthcare providers to their electronic health data. In addition, Article 10 EHDS allows Member States to introduce an absolute right for individuals to opt out from access to their personal electronic health data by anyone other than the healthcare provider that initially entered the

29 Thus, going beyond Art. 15 GDPR, Recital 9 EHDS.

30 Defined in Art. 2(2)(h) EHDS as 'online service, such as a portal or an application for mobile devices, that enables natural persons not acting in a professional capacity to access their own electronic health data or the electronic health data of those natural persons whose electronic health data they are legally authorised to access'.

31 Art. 4(1) EHDS.

32 Art. 5 EHDS.

33 Art. 6 EHDS.

34 Art. 20 GDPR 'is limited to data which the data subject has provided', Alexander Dix, 'Art. 20' in: Indra Spiecker gen. Döhmann, Vagelis Papakonstantinou, Gerrit Hornung and Paul De Hert (eds), *General Data Protection Regulation* (C. H. Beck 2023), para. 6; European Commission, *Frequently Asked Questions on the European Health Data Space*, v1.0 of 05 March 2025, 12, <https://health.ec.europa.eu/document/download/4dd47ec2-71dd-49fc-b036-ad7c14f6ed68_en?filename=ehealth_ehds_qa_en.pdf>, last access 19 November 2025.

data. This includes individual's access to their own data via electronic health data access services and thus goes beyond Article 8 EHDS.[35] However, the registration and availability of health data in local systems are not affected.[36] The introduction of Article 10 EHDS during the legislative process marks a clear improvement in terms of data control.[37] While leaving its implementation optional for Member States may lead to unequal protection across the EU and may appear to stand in contrast to the Regulation's aims of improving individuals' control over their health data alongside data availability,[38] this regulatory approach may better reflect the respective competences of the EU and the Member States competences in the context of healthcare provision. As we will show in Section III. 3., the EHDS will have a significant impact on Member States' healthcare systems whose responsibilities for the organisation and management of those systems, as well as for the provision of healthcare must be respected (Article 168(7) Treaty on the Functioning of the European Union [TFEU]). Introducing a uniform right to opt-out of data access services that Member States have yet to create or have already established, could interfere with their competences.

Given the potential overlap with GDPR subject rights, the European Data Protection Board (EDPB) and European Data Protection Supervisor (EDPS) had criticised the unclear relationship between EHDS and GDPR in earlier EHDS drafts for the creation of legal uncertainty.[39] As Recital 9 EHDS now emphasises, the EHDS rights are to complement the GDPR subject rights and improve their effectiveness (e. g. with shorter delays and full digitalisation), with the latter continuing to apply. If implemented in an easily accessible and comprehensible way, it could improve individuals' effective control and transparency over their data. If not, individuals run the risk of further confusing their EHDS and GDPR rights.

35 See Recital 18 EHDS; The opt-out may also apply to specific data categories like genetic data.

36 European Commission, *EHDS FAQ* (n. 34), 14.

37 The Commission's original EHDS proposal (2022) did not include an opt-out mechanism. Which was rightly criticised Ulrich M. Gassner, 'Forschung und Innovation im europäischen Gesundheitsdatenraum', DuD 46 (2022), 739-746 (744 f.) and Centrum für Europäische Politik (cep), 'EU-Gesundheitsdatenraum' (EU Health Data Space), 18 f., <https://www.cep.eu/fileadmin/user_upload/cep.eu/Analysen/COM_2022_197_EU-Gesundheitsdatenraum/cepAnalyse_Langfassung_EU-Gesundheitsdatenraum_COM_2022__197.pdf>, last access 19 November 2025.

38 Recital 1 EHDS.

39 EDPB-EDPS, *Joint Opinion 3/2022* (n. 5), para. 47. In addition, Art. 3 of the draft EHDS Regulation allowed for the assertion of some rights via access services for electronic health data, potentially threatening a de facto exclusion of persons with only limited access to digital services, van Kessel et al. (n. 11), 378.

c) Implementation of a National Digital Health Authority

On the national level, Member States designate, fund, and staff one or more digital health authorities responsible for implementing and enforcing the EHDS provisions on primary use at the national level.[40] Responsibilities of these digital health authorities include implementing rights and obligations under Chapters II and III EHDS, supervising the national contact point for digital health,[41] and other technical and coordinative tasks to support the MyHealth@EU infrastructure.[42] It must also ensure compliance with interoperability and security standards, cooperate with data protection and cybersecurity authorities, and contribute to Union-level specification work.[43] Natural persons can lodge a complaint with this authority.[44]

EDPB and EDPS had criticised the unclear relationship between the national digital health authorities and the data protection supervisory authorities in earlier EHDS drafts.[45] The EHDS now includes a more structured relationship. While national digital health authorities remain competent to enforce the EHDS provision for primary use,[46] data protection authorities retain exclusive competence to monitor and enforce Articles 3 and 5-10 EHDS, and may exert their powers under Articles 58 and 83 GDPR, including imposing administrative fines.[47] To this end, national digital health authorities can only receive complaints under Articles 3 and 5-10 EHDS and transmit them to the data protection authorities.

d) MyHealth@EU Cross-Border Infrastructure

'MyHealth@EU' is the central interoperability[48] platform for digital health and a further development of the existing infrastructure of the same name.[49] Unlike the latter, connecting to MyHealth@EU will become mandatory for the Member States, which must each designate a national contact point for digital health.[50] Internationally, these national contact points are

40 Art. 19(1), (3) EHDS.
41 See II. 3. d).
42 Art. 19(2) EHDS.
43 Art. 19(2) EHDS.
44 Art. 21 EHDS.
45 EDPB-EDPS, *Joint Opinion 3/2022* (n. 5), para. 67.
46 Art. 19(1) EHDS.
47 Arts 21 and 22 EHDS.
48 Definition: Art. 2(2)(f) EHDS.
49 Art. 23(1) EHDS; European Commission, *EHDS FAQ* (n. 34), 15.
50 See Art. 23(2) EHDS.

connected to all other national contact points of the Member States to facilitate the cross-border exchange of priority health data for primary use through MyHealth@EU.[51] Nationally, the contact points are connected to healthcare providers and professionals, pharmacies[52] so that they can exchange data.[53] While MyHealth@EU does not include a central repository for health data,[54] it shall provide services to support and facilitate the cross-border exchange of personal electronic health data.[55] It is set up by the Commission, which is empowered to set the technical requirements and standards, including detailed rules concerning the security, confidentiality, and protection of health data, to join the platform.[56] The EHDS thus leaves it largely to the Commission's implementing acts to ensure GDPR-compliance in terms of data security for cross-border data exchange. However, it assumes to provide a sufficient legal basis for data exchange via MyHealth@EU in the sense of Article 6(1)(e), (3), 9(2)(h) GDPR, including adequate safeguards.[57]

With regard to data governance, Article 23(7) EHDS specifies that national contact points act as joint controllers for the processing operations in which they are involved, while the Commission merely acts as a processor. As a result, they may be subject to measures taken not only by the digital health authority but also by data protection supervisory authorities and may be liable for GDPR infringements.

At Union level, a MyHealth@EU Steering group composed of all national contact points decides on the development and operation and is supported by the EHDS Board.[58] The governance structure mirrors that of HealthData@EU also addressed in Section II. 4. f). Member States may introduce supplementary services through MyHealth@EU such as telemedicine, mobile health, vaccination cards, or connections to Client-Patient Management Systems.[59]

Third countries and international organisations may be connected to MyHealth@EU, provided that the requirements of Article 23 EHDS as well as those of Chapter V GDPR are met.[60] However, as Member States may

51 Art. 23(2), (3) EHDS.
52 Enabling EU-wide dispensation of prescriptions.
53 Art. 23(5), (6) EHDS.
54 European Commission, *EHDS FAQ* (n. 34), 15.
55 As in Art. 14(1) EHDS.
56 Art. 23(1), (4) EHDS.
57 See Recital 34 EHDS. Member States may still exert influence on these implementing acts according to Art. 98(2) EHDS, Art. 5 Regulation 182/2011/EU.
58 See Art. 95(1), Art. 94 EHDS, e. g. exchange of best practices and information.
59 Art. 24 EHDS.
60 Art. 24(3) EHDS.

introduce further conditions under Article 9(4) GDPR on international access to and transfer of personal electronic health data,[61] cross-border data sharing to third countries for primary use will likely continue to vary between EU countries, leading to a regulatory fragmentation in the context of third country data transfers.

4. The Secondary Use of Electronic Health Data in the EHDS

Chapter IV EHDS regulates the secondary use of electronic health data, such as for scientific research, innovation, policy-making, and public health (Article 53(1) EHDS), whereby it assumes compliance with the GDPR and intends to reinforce individual data control.[62] Essentially, Chapter IV creates a sector-specific data access mechanism whereby access to health data held by various health data holders is granted and intermediated by public authorities at the request of health data users via secure processing environments (SPEs)[63], while the health data remains stored in a decentralised manner with the health data holders. Through a single application, users can request access to data from multiple holders and its linked provision within an SPE. For these reasons, the EHDS has the potential to significantly improve the availability of health data for secondary processing and to meet important data needs.

a) Obligation of Health Data Holders to Provide Electronic Health Data

Articles 60(1) and 51(1) EHDS obliges health data holders to make a broad variety of electronic health data, such as patient records, administrative data, genetic and genomic data, and data from biobanks or medical devices, available for the purposes listed in Article 53(1) EHDS. This includes data processed for primary use[64], among other categories of health data, even if protected by intellectual property or trade secrets.[65] The term *health data*

61 Art. 90 EHDS.

62 Art. 1(3), (2)(a), (c) EHDS; see also Christian Dierks, 'European Health Data Space – Anforderungen und Chancen für die pharmazeutische Industrie', PharmR 45 (2023), 369-374 (370 f.).

63 See Art. 2(1)(c) EHDS refers to the definition laid down in Regulation 2022/868/EU (Data Governance Act).

64 Art. 51(1)(a) EHDS and Art. 60(1) EHDS.

65 However, HDABs take measures to protect business secrets and intellectual property (Art. 52(1), (3) EHDS).

holder covers a wide range of public and private actors in the health sector, such as health insurance companies, pharmacy data centres, public authorities, research data infrastructures, or private companies developing products or services intended for the health, healthcare or care sector.[66]

'(M)aking available' within Article 51(1) EHDS means making the electronic health data available to a *health data access body* (HDAB) at its request[67], which in turn grants access to the data users via a SPE[68] it operates.[69] Further duties of health data holders are listed in Article 60 EHDS.[70] National law may provide that the duties of certain categories of health data holders are to be fulfilled by health data intermediation entities.[71]

In line with the Regulation's objective to improve individuals' control,[72] an opt-out mechanism was introduced in the legislative process under Article 71 EHDS, marking a significant shift from the Commission's proposal. Compared to primary use, this opt-out is mandatory,[73] its design, however, is largely left to Member State law. In Germany, such an opt-out mechanism has yet to be created.

b) Health Data Access Bodies (HDABs) as Intermediaries of Electronic Health Data for Secondary Use

Under Article 55(1) EHDS, Member States designate one or more national HDABs. HDABs receive, assess, and decide on applications, process, collect and compile the electronic health data, and make that data available via a SPE.[74] In Germany, a central data access and coordination body for health data was established at the Federal Institute for Drugs and Medical Devices

66 See Art. 2(2)(t) EHDS; natural persons and microenterprises are exempted (Art. 50(1) EHDS). Although *data holder* is now clearer defined than in earlier drafts, the definition of the EHDS *data holder* partly diverges from the wider DGA *data holder* definition (Art. 2(8) DGA), which could lead to confusion among the actors concerned.

67 Art. 60(4) EHDS.

68 It is subject to technical and organisational measures within the meaning of Art. 32 GDPR (Art. 73(1) EHDS), which the Commission determines via implementing act, (Art. 73 (5) EHDS). HDABs stay in control of the data at all times (Recital 77 EHDS).

69 See Art. 68(7) EHDS and Art. 73(1), (2) EHDS.

70 For example, providing a general description of the datasets available to them, creating open access to non-personal data via open databases, providing an updated dataset after a dataset has been augmented following the receipt of a data permit.

71 Art. 50(3) EHDS.

72 Recitals 1 and 54 EHDS.

73 See 'shall' (Art. 71(1) EHDS) versus 'may' (Art. 10(1) EHDS).

74 Art. 57(1)(a), (b) EHDS, Art. 68 EHDS and Art. 73 EHDS.

(BfArM)[75] which is likely to become the coordinating HDAB within the meaning of EHDS.[76]

In their supervisory function, HDABs also supervise compliance by data users and holders, and impose penalties in case of infringement.[77] For transparency towards the public, HDABs publish biannual activity reports.[78] As for informing natural persons, Article 58 EHDS introduces a public information approach, departing from Article 14 GDPR's individual notice requirement.[79] The restriction of the information obligations of the HDABs vis-à-vis natural persons under Article 14 GDPR in the draft version of the Regulation has been heavily criticised, as it was seen as undermining the effective control of data subjects over their data,[80] and has been amended by Article 58 EHDS. Further HDAB tasks are listed in Article 57 EHDS.

c) Health Data Access Application Process

Potential data users[81] may submit health data access applications. HDABs assess those applications, essentially taking into consideration whether the data requested serves (a) a permitted purpose of processing, (b) is necessary, adequate, and proportionate for the requested purposes, the requestor (c) has a legal basis under Article 6(1) GDPR, (d) has the required expertise (e) and sufficient measures against misuse, and (f) has an ethical assessment, if mandated by national law (Article 68(1) EHDS).

The permitted purposes in Article 53(1) EHDS reflect a broad understanding of secondary use,[82] and include scientific research related to the health or care sector, training and testing of algorithms, including in medical devices, AI systems and health applications, as well as support for public authorities or Union bodies to perform their statutory tasks. Conversely, Article 54 EHDS lists prohibited purposes (e. g. discriminatory processing and advertising) and prohibits reidentification by data users.

In the standard procedure, HDABs assess the legality, necessity, and risk of the application and issue data permits that are valid for up to ten years.[83] They

75 Section 3 of the Health Data Utilisation Act (GDNG).

76 See German Federal Institute for Drugs and Medical Devices, <https://www.bfarm.de/DE/Das-BfArM/Aufgaben/Datenzugangs-und-Koordinierungsstelle/Aktuelles/News/01_Newsletter-01-25.html>, last access 19 November 2025.

77 Art. 63 EHDS.

78 Art. 59 EHDS.

79 Also, Recital 66 EHDS.

80 EDPB-EDPS, *Joint Opinion 3/2022* (n. 5), para. 23; see also Marelli et al. (n. 11).

81 Natural and legal persons and Union entities Art. 67(1), 2(2)(u) EHDS.

82 EDPB-EDPS, *Joint Opinion 3/2022* (n. 5), para. 33.

83 Art. 68(1), (2), (12) EHDS.

may charge fees for the provision of health data, which may include compensation for the costs incurred by the health data holder in compiling and preparing the data. This portion of the fees shall ultimately be paid to the health data holders by the HDAB.[84] HDABs are held to limit the data permit's scope to what is necessary for the processing's purpose.[85] Also, HDABs are held to only grant anonymised data access, unless data users can prove that pseudonymised access is necessary. Once issued, HDABs request the data from the relevant data holders.[86] Health data users can then access the health data via the HDABs SPE,[87] while HDABs ensure that users are only able to download non-personal electronic health data from the SPEs.[88] However, since this includes anonymised data,[89] HDABs may soon face the well-known question of when personal data can be considered truly anonymised.

By contrast, Article 72 EHDS allows a simplified procedure in which *trusted health data holders*, designated by Member States, provide their data directly via their own secure environment, without the HDAB as intermediary.[90] While the HDAB still issues the data permit, trusted holders may assess applications and propose a decision, provided the applications meet the EHDS requirements.[91] Member States must provide an accelerated procedure for national public sector bodies and Union institutions with a public health legal mandate.[92] In addition, data users also have the possibility to submit a data request with the aim of obtaining a response in an anonymised statistical format (Article 69 EHDS).

d) Legal Bases and Data Protection Roles for the Secondary Use of Electronic Health Data

Given that health data is sensitive data under Article 9 GDPR, each separate processing must be based on Articles 6 and 9 GDPR.[93] According to

84 Art. 62(1), (2) EHDS.
85 Art. 66(1) EHDS.
86 Art. 68(7) EHDS.
87 Art. 57(1)(a)(i) EHDS.
88 Including health data in an anonymised statistical format, see Art. 73(2) EHDS.
89 See Art. 2(2)(b) EHDS.
90 Art. 68(7) EHDS and Art. 72(2) EHDS.
91 Art. 72(2)-(5) EHDS
92 Art. 68(6) EHDS.
93 The ECJ has ruled that processing based on Art. 9(2) GDPR must also fulfil Art. 6 (1) GDPR. For instance ECJ, *ZQ v. Medizinischer Dienst der Krankenversicherung Nordrhein, Körperschaft des öffentlichen Rechts*, judgment of 21 December 2023, case no. C-667/21, ECLI:EU:C:2023:1022, para. 79, on Art. 9(2)(h) and Art. 6(1) GDPR; See András Jóri, 'Art. 9' in: Indra Spiecker gen. Döhmann, Vagelis Papakonstantinou, Gerrit Hornung, and Paul De Hert (eds), *General Data Protection Regulation* (C. H. Beck 2023), paras 12-17.

Recital 52 EHDS, the EHDS builds upon the GDPR's option to create a Union-law legal basis, including the safeguards necessary under Article 9(2)(g)-(j) GDPR, for the secondary use of personal electronic health data. As adequate safeguards in the sense of Article 9(2) GDPR, the legislator views the EHDS provisions on access governance through HDABs, processing of pseudonymised data in SPEs[94] and on the further arrangements for data processing, set out individually in the data permits for data users.

Articles 6 and 9 GDPR apply without modification through EHDS provisions to the initial processing of data processed by *data holders*. For *data holders* making data available, Article 51 EHDS constitutes a legal obligation within the meaning of Article 6(1)(c) and Article 9(2)(i), (j) GDPR. *HDABs* are, according to Recital 52, performing a public interest task and can thus process data under Articles 6(1)(e) and Article 9(2)(g)-(j) GDPR. *Data users* have to provide an independent legal basis. Recital 52 clarifies that for data users choosing Article 6(1)(e)(f) GDPR as legal basis, the EHDS provides the necessary Article 9(2) GDPR safeguards.

Member States may not maintain or introduce under Article 9(4) GDPR further conditions, such as consent, for secondary use under the EHDS, except for specific categories of data as listed in Article 51(4) EHDS, such as genomic data.[95]

The EHDS thus not only harmonises access and processing rules for secondary use but also establishes uniform safeguards regardless of the data user's processing purpose (Article 9(2)(g)-(j) GDPR). However, HDABs retain a degree of discretion in assessing the legal basis of individual data users.[96] Consequently, their future decision-making will be crucial in determining whether the EHDS achieves equal access to health data and a consistent level of data protection across the EU.

As for data protection roles, in the regular procedure, data holders are controllers for the making available of personal data while HDABs are controllers when fulfilling their tasks; when providing through a secure processing environment, HDABs are processors on behalf of data users, who are deemed controllers.[97] Conversely, in the simplified procedure, trusted data holders act as controllers for their own processing, and as processors for

94 Technical and safety requirements for SPEs will be determined by the Commission via implementing acts, Art. 73(5) EHDS.

95 Recital 52 EHDS. EDPB-EDPS, *Joint Opinion 3/2022* (n. 5), para. 89, criticised the previous drafts for omitting to clarify the extent of national discretion under Art. 9(4) GDPR.

96 E. g. if a requested processing is necessary for a substantial public interest or for legitimate interests that outweigh those of data subject (see Art. 6(1)(e), (f) GDPR and Art. 9(2)(g) GDPR).

97 Art. 74(1) EHDS.

the data they provide through the secure processing environment on behalf of data users (Article 74(2) EHDS).

e) Relationship Between HDABs and Data Protection Supervisory Authorities

In their supervisory functions, HDABs closely cooperate with data protection supervisory authorities and inform them of 'any penalties imposed' where personal data is affected. Data protection supervisory authorities remain exclusively competent to enforce the GDPR. Therefore, HDABs may impose fines for EHDS-specific infringements (e. g. Articles 63 and 64 EHDS), while only data protection supervisory authorities can enforce GDPR-specific measures and are also exclusively competent for supervising the right to opt-out (Articles 65 and 71 EHDS). Given this approach, the health data access bodies and the data protection supervisory authorities complement each other in their supervisory functions.

f) HealthData@EU Cross-Border Infrastructure

To enable cross-border access to health data for secondary use, Article 75 EHDS establishes HealthData@EU as a cross-border infrastructure comprising a central platform run by the Commission, national contact points for secondary use[98] designated by each Member State, the Union health data access service,[99] and other authorised participants, including research infrastructures and, under certain conditions, third countries or international organisations.[100] Member State participation is mandatory. An EU dataset catalogue connecting the national dataset catalogues set up by HDABs, allows users to find and access data sets for secondary use across all Member States.[101]

98 The national contact point for secondary use may be the coordinator health data access body referred to in Article 55(1). It is not necessarily the entity as national contact points for primary use.

99 Art. 56 EHDS.

100 See Art. 74(5) EHDS: third countries or international organisations must comply with the rules of Chapter IV EHDS and provide access to health data users located in the Union, on equivalent terms and conditions, to the electronic health data available to their health data access bodies, subject to compliance with Chapter V of Regulation 2016/679/EU. The prior compliance check, executed by the Commission, is a prerequisite for connecting these actors to HealthData@EU, Art. 75(5), (13).

101 Art. 79 EHDS.

Cross-border access via HealthData@EU follows the single-application principle: a data user may submit one application to any HDAB under Article 67(3) EHDS. The application is then automatically forwarded to all relevant HDABs, which decide on access within their competence pursuant to Article 68 EHDS and request the necessary data from data holders.[102] Access may be granted either through each HDAB's SPE[103] or, at the request of at least two national contact points, via a central SPE hosted by the Commission, in which HDABs put their data.[104] Depending on the processing purpose, use of the central SPE may be advantageous for the data user, as analyses involving pseudonymised data are likely limited to within a single SPE and not across multiple SPEs.[105]

In parallel to MyHealth@EU, national contact points for secondary use act as joint controllers for processing within HealthData@EU, while the Commission acts as processor.[106] Operational decisions on the HealthData@EU infrastructure itself are taken by the HealthData@EU Steering Group, while the EHDS Board has a coordination and advisory role.[107]

III. Assessment of Legal Competences

As outlined in Section II, the EHDS significantly impacts national health systems – not only regarding data registration, availability, and flows, but also through the creation of new administrative bodies such as digital health authorities and HDABs. This raises concerns about the limits of EU legislative competence, particularly in light of the relationship between Articles 114 and 16 TFEU and Article 168(7) TFEU, which reserves health policy and the organisation of healthcare to the Member States. Although the EU is authorised to adopt legislation based on Article 114 TFEU that significantly affect national health systems, we argue that some EHDS provisions are at least doubtful to be covered by EU competence and that the EU should better justify its future legislative acts in the health sector with a view to Article 168(7) TFEU.

102 A data permit already issued may benefit from mutual recognition by other data access bodies (Art. 68(5) EHDS).

103 In the absence of other provisions in the EHDS, the same procedure likely applies as for a purely national data access application.

104 Art. 68(8) EHDS and Art. 75(9) EHDS.

105 Only non-personal electronic health data can be downloaded from SPEs, see Art. 73(2) EHDS.

106 Art. 75(9), (10) EHDS; the Commission may specify these roles by implementing acts, Art. 75(12)(d)(e) EHDS.

107 Art. 95(2), 94(2) EHDS.

1. Constitutional EU Law Context (Articles 16, 114, 168 TFEU and the Principle of Subsidiarity)

Article 114 TFEU (internal market)

Through Article 114 TFEU, the EU can harmonise Member State law by eliminating obstacles to the internal market, one of the Union's central objectives (see Article 3(3) Treaty on European Union [TEU]).[108] The regulatory scope of this provision is not limited to specific subject matters[109] and also includes the harmonisation of laws to create an internal market for data as economic goods.[110] Article 114 TFEU requires internal market finality,[111] which may arise from a concrete[112] obstacle to cross-border trade addressed by harmonisation.[113] The European Court of Justice (ECJ) assesses internal market finality based on legislative intent and the measure's objective effectiveness in removing market barriers.[114] In addition, in the Court's view, the establishment of the internal market must be the main objective[115] or focus.[116] However, the measure may also pursue other objectives, in particular, the protection of health referred to in Article 114(3) TFEU, even if these objectives are of crucial importance.[117] Nevertheless, all the requirements under Article

108 Meinhard Schröder, 'Art. 114 TFEU' in: Rudolf Streinz (ed.), *TEU/TFEU* (3rd edn, C. H. Beck 2018), paras 6 f.; See also Christian Tietje, 'Art. 114 TFEU' in: Eberhard Grabitz, Meinhard Hilf and Martin Nettesheim (eds), *Das Recht der Europäischen Union* (85th edn, C. H. Beck 2025), para. 5.

109 See Tietje (n. 108), para. 32.

110 See Jürgen Kühling, 'Art. 16 TFEU' in: Matthias Pechstein, Carsten Nowak and Ulrich Häde (eds), *TEU/GRC/TFEU* (2nd edn, Mohr Siebeck 2023), paras 36 et seq.

111 Schröder, 'Art. 114' (n. 108), para. 28.

112 ECJ, *Germany v. European Parliament and Council of the European Union*, judgment of 5 October 2000, case no. C-376/98, ECLI:EU:C:2000:544.

113 Schröder, 'Art. 114' (n. 108), para. 28.

114 Schröder, 'Art. 114' (n. 108), paras 33 et seq.

115 See ECJ, *Kingdom of the Netherlands v. European Parliament and Council of the European Union*, judgment of 9 October 2001, case no. C-377/98, ECLI:EU:C:2001:523, paras 27 f.; Tietje (n. 108), para. 129.

116 See in this respect, ECJ, *European Parliament v. Council of the European Union*, judgment of 23 February 1999, case no. C-42/97, ECLI:EU:C:1999:81, paras 39 f.; ECJ, *Kingdom of Spain v. Council of the European Union*, judgment of 30 January 2001, case no. C-36/98, ECLI:EU:C:2001:64, para. 59 ('one [objective] as the essential or paramount one'); see also Schröder, 'Art. 114' (n. 108), para. 30.

117 ECJ, *The Queen v. Secretary of State for Health ex parte: British American Tobacco (Investments) Ltd and Imperial Tobacco Ltd,* judgment of 10 December 2002, case no. C-491/01, ECLI:EU:C:2002:741, para. 62; ECJ, *Arnold André GmbH & Co. KG v. Chief Executive of the District of Herford,* judgment of 14 December 2004, case no. C-434/02, ECLI:EU:C:2004:800, para. 32.

114 TFEU must be met,[118] especially that establishing the internal market must not be a 'merely incidental or complementary objective' of the measure.[119]

Article 16(2) TFEU (data protection and free flow of data)

Article 16(2) TFEU allows EU legislation on the free movement of data on one side and on data protection[120] in application of EU law for both Union entities and Member States acting within the scope of Union law on the other.[121] While the latter requirement is not conclusively defined,[122] the prevailing view supports a broad interpretation including purely domestic processing without crossing borders.[123] The ECJ takes this view with regards to the GDPR's scope of application (Article 2(2)(a) GDPR), which, in accordance with Article 16(2) TFEU, ends where an activity does not fall within the scope of application of Union law.[124] According to some authors in the legal literature, the competence to regulate the *free movement of data* is a *lex specialis* in relation to the internal market competence under Article 114 TFEU,[125] and is therefore definitive for the internal market.[126] Other voices argue that Article 16(2) TFEU is not limited to regulating data flows that aim at establishing an internal market, but go beyond that.[127] In regulatory

118 ECJ, *British American Tobacco* (n. 117), para. 62, See also Schröder, 'Art. 114' (n. 108), para. 135.

119 See ECJ, *Kingdom of the Netherlands* (n. 115), paras 27 f.; Tietje (n. 108), para. 129.

120 Christoph Sobotta, 'Art. 16 TFEU' in: Eberhard Grabitz, Meinhard Hilf and Martin Nettesheim (eds), *Das Recht der Europäischen Union* (85th edn, C. H. Beck 2025), para. 27.

121 Meinhard Schröder, 'Art. 16 TFEU' in: Rudolf Streinz (ed.), *TEU/TFEU* (3rd edn, C. H. Beck 2018), para. 9.

122 See in this regard Amadeus Wolff and Antje von Ungern-Sternberg, 'Grundlagen und bereichsspezifischer Datenschutz' in: Heinrich Amadeus Wolff, Stefan Brink and Antje von Ungern-Sternberg (eds), *BeckOK Datenschutzrecht* (53rd edn, C. H. Beck August 2025), Syst. A. para. 12.1.

123 Kühling, Art. 16 (n. 110), para. 33.

124 ECJ, *VQ v. State of Hesse*, judgment of 9 July 2020, case no. C-272/19, ECLI:EU:C:2020:535, para. 66; See on the Data Protection Directive: ECJ, *Court of Audit v. Austrian Broadcasting and Others and Christa Neukomm and Joseph Lauermann v. Austrian Broadcasting*, judgment of 20 May 2003, case no. C-465/00, C-138/01 and C-139/01, ECLI:EU:C:2003:294.

125 Thorsten Kingreen, 'Art. 16 TFEU' in: Christian Calliess and Matthias Ruffert (eds), *TEU/TFEU* (6th edn, C. H. Beck 2022), para. 8; Schröder, 'Art. 16' (n. 121), para. 10; 'In Opinion 1/15, the CJEU […] state[d] that an EU legal instrument containing detailed rules concerning the use of personal data should be based on Article 16(2) TFEU', Hielke Hijmans, Author Notes, 'Article 1' in: Christopher Kuner, Lee A. Bygrave, Christopher Docksey and Laura Drechsler (eds), *The EU General Data Protection Regulation (GDPR): A Commentary* (Oxford University Press 2020), B.4.

126 Schröder, 'Art. 16' (n. 121), para. 10.

127 Kühling, Art. 16 (n. 110), para. 37.

practice, however, the Union legislator also draws on Article 114 TFEU for legal acts that promote the free movement of data (such as the Data Act).[128] However, as Article 1(3) GDPR shows, the GDPR, which is based on Article 16(2) TFEU, as the fundamental data-related legal act of the Union, contains provisions on both *data protection* and the *free movement of data*. As a shared competence,[129] the exercise of Article 16 is also subject to subsidiarity (Article 5(3) TEU).

Article 168 TFEU (public health)

Within health care, Article 168 TFEU provides EU competence for *public* health only,[130] which is population-based and preventive in nature.[131] For individual sub-areas[132] listed in Article 168(4) TFEU, the EU has shared competence.[133] Beyond these areas, the Union's role is limited to supplementing, coordinating and supporting the Member States' policies in accordance with Articles 2(5) and 6 TFEU.[134] While the EU may adopt binding acts based on Article 168(5) TFEU, it may not harmonise Member State law.[135] However, the prohibition on harmonisation does not prevent the EU from influencing national systems under other legal bases, notably Article 114 TFEU, provided the requirements on subsidiarity are met.[136]

128 Kühling, Art. 16 (n. 110), para. 33.

129 Schröder, 'Art. 16' (n. 121), para. 8.

130 Brigitta Lurger, 'Art. 168 TFEU' in: Rudolf Streinz (ed.), *TEU/TFEU* (3rd edn, C.H. Beck 2018), para. 17.

131 Birgit Schmidt am Busch, 'Art. 168 TFEU' in: Eberhard Grabitz, Meinhard Hilf and Martin Nettesheim (eds), *Das Recht der Europäischen Union* (85th edn, C.H. Beck 2025), para. 9; Lurger (n. 130), para. 17.

132 With regard to the regulation of quality standards for medical devices and medicinal products, with regard to measures to establish high quality and safety standards for organs and substances of human origin as well as for blood and blood derivatives, and with regard to measures in the areas of measures in the veterinary and phytosanitary fields with the direct aim of protecting public health.

133 See Art. 2(2) TFEU and Art. 4(2)(k) TFEU; regarding shared competences, see for example Martin Nettesheim, 'Art. 2 TFEU' in: Eberhard Grabitz, Meinhard Hilf and Martin Nettesheim (eds), *Das Recht der Europäischen Union* (85th edn, C. H. Beck 2025), paras 23 et seq.

134 Schmidt am Busch (n. 131) para. 41; Lurger (n. 130), para. 53.

135 See Art. 168 (5) TFEU and generally for complementary, coordinating and supporting competences Art. 2 (5) subpara. 2 TFEU; examples of binding legal acts: EU4Health or ECDC; see also Schmidt am Busch (n. 131), para. 70.

136 According to the ECJ, Art. 114 TFEU can always be used as a legal basis despite Art. 168(5) TFEU if its internal market-specific conditions are met, see ECJ, *Federal Republic of Germany v. European Parliament and Council of the European Union*, judgement of 5 October 2000, case no. C-376/98, ECLI:EU:C:2000:544, paras 76 et seq.; ECJ, *British American Tobacco* (n. 117) para. 62; see also Schmidt am Busch (n. 131), para. 112 with further references on the case law of the ECJ.

Article 168(7) TFEU reserves the responsibility for defining health care policy, organising the healthcare system and medical care to the Member States. According to the ECJ, although Union measures relating to these areas are not inadmissible *per se*, they must not interfere with the national sovereignty of the Member States in the areas referred to in Article 168(7) TFEU.[137] According to some authors, such interference is deemed to be present when Member States are forced by a Union measure to reorganise their healthcare system.[138] It is disputed whether Article 168(7) TFEU only applies to Union measures based on Article 168 TFEU, or also limits the exercise of other titles of competence, in particular Article 114 TFEU.[139] The ECJ has yet to give an explicit ruling on this issue. However, elements of case law seem to indicate that Article 168(7) TFEU also applies to other titles of competence.[140]

If a legal act based on Article 114 TFEU relates to the health sector, not only the question of the applicability of Article 168(7) TFEU arises, but also the question of the relationship between Article 114 TFEU and the prohibition of harmonisation set out in Article 168(5) TFEU. According to the ECJ, Article 168(5) TFEU may not be circumvented through the use of other legal foundations.[141] Nevertheless, a measure can be based on Article 114 TFEU, even if health protection is of crucial importance.[142] Article 168(1) TFEU also acts as a horizontal clause requiring health protection across all Union policies, which is reflected in Article 114(3) TFEU.

On subsidiarity & proportionality

Given that Articles 16, 114, and 168 TFEU concern shared EU competences, their exercise is subject to the principles of subsidiarity and propor-

137 See ECJ, *The Queen, on the Application of: Yvonne Watts v. Bedford Primary Care Trust, Secretary of State for Health,* judgment of 16 May 2006, case no. C-372/04, ECLI:EU:C:2006:325, para. 147; ECJ, *European Commission v. Grand Duchy of Luxembourg,* judgment of 27 January 2011, case no. C-490/09, ECLI:EU:C:2011:34, para. 45.

138 Schmidt am Busch (n. 131), para. 82.

139 For validity within the framework of Art. 168 TFEU only, Schmidt am Busch (n. 131), para. 83; for validity also outside the scope of Art. 168 TFEU, see Kingreen (n. 125), para. 26. Frank Niggemeier, 'Art. 168 TFEU', in: Hans von der Groeben, Armin Hatje and Jürgen Schwarze (eds), *European Union Law* (7th edn, C. H. Beck 2015), para. 73.

140 ECJ, *Novartis Farma SpA v. Agenzia Italiana del Farmaco (AIFA) and Others*, judgment of 21 November 2018, case no. C-29/17, ECLI:EU:C:2018:931, paras 47 et seq. Here, the ECJ had pointed out in relation to a directive based on Art. 100a EEC (now Art. 114 TFEU) that the directive in question also does not affect the competence of the Member States in the areas referred to in Art. 168(7) TFEU, only to then state that they must nevertheless comply with Union law when exercising their competence.

141 See ECJ, *Germany* (n. 112), para. 79.

142 ECJ, *British American Tobacco* (n. 117), para. 62. See also Schröder, 'Art. 114' (n. 108), para. 135.

tionality (Article 5(3), (4) TEU). Under subsidiarity, EU action is only justified if the objectives of the measure cannot be sufficiently achieved by the Member States, but can be better achieved at Union level due to their scale or effects (Article 5(3) TEU). Under proportionality, Union action must not exceed what is necessary in scope or form to achieve the objectives of the Treaties (Article 5(4) TEU).

2. Articles 114 and 16 TFEU as the Basis of Competence for the EHDS Regulation

The EHDS Regulation is based on Article 16 and 114 TFEU. The choice of a dual basis of competence is possible, insofar as no clear attribution can be made after analysing the legislative proposal in accordance with its focus,[143] and Article 16 TFEU and Article 114 TFEU both follow the same legislative procedure. Article 168 TFEU could also be considered a relevant competence standard given the implications for health policy in the EHDS Regulation, in particular with regard to the rules on the primary use of electronic health data. However, this might not underpin the EHDS Regulation due to the prohibition of harmonisation in Article 168(5) TFEU. Nevertheless, as explained, the pursuit of health policy objectives alongside the objective of realising the internal market is not excluded under Article 114 TFEU.

Competence under Article 114 and 16 TFEU

A prerequisite of Article 114 TFEU is the internal market finality of the measure (see III. 1.), i. e. pursuing the objective of establishing the internal market. The provisions of Chapter III EHDS, which are not dealt with here, provide for the harmonisation of Member State regulations regarding requirements for EHR systems, the obligations of manufacturers and importers of EHR systems, and the introduction of market surveillance. There is also a specific barrier to free movement with regard to the exchange of health data.

143 Eckhard Pache, 'Art. 5 TEU' in: Matthias Pechstein, Carsten Nowak and Ulrich Häde (eds), *TEU/GRC/TFEU* (2nd edn, Mohr Siebeck 2023), para. 49, with reference to ECJ, *Commission of the European Communities v. Council of the European Communities*, judgment of 11 June 1991, case no. C-300/89, ECLI:EU:C:1991:244, para. 17; ECJ, *Commission of the European Communities v. Council of the European Union*, judgment of 11 September 2003, case no. C-211/01, ECLI:EU:C:2003:452, para. 40; ECJ, *Commission of the European Communities v. European Parliament and Council of the European Union*, judgment of 8 September 2009, case no. C-411/06, ECLI:EU:C:2009:518, para. 47.

The Commission has analysed existing national regulations on, among other things, certification schemes for EHR systems and requirements for the processing of health data, and has identified these as contributing to a low level of interoperability of EHRs, as well as the availability and exchange of health data across the EU.[144] In this respect, internal market finality exists both subjectively (e. g. Article 1(2)(b), Recital 1 EHDS) and objectively, since the proposed provisions appear to be suitable for removing these existing barriers. This also applies to the secondary use of electronic health data, which also aims to promote innovation in health data-based products and services,[145] as well as to the primary use in that the EHDS aims at fostering a genuine internal market for digital health services and products (Recital 110 EHDS).

The Commission invokes Article 16 TFEU particularly with regard to the provisions on natural persons' rights that build upon the GDPR rights.[146] Some of the rights provided for in Articles 3-10 EHDS (in particular the right to cross-border data transfer) are designed to promote fundamental freedoms, especially the free movement of persons, and are therefore also instrumental to the internal market. While it could be argued, that the EHDS primarily concerns the free movement of data and data protection, warranting a basis in Article 16 TFEU, the choice of a dual basis with Article 114 TFEU seems justifiable, especially with regard to the provisions of Chapter III EHDS.

Given the dual basis of competence, it is questionable to what extent the limitation in Article 16(2) to the 'scope of EU law' restricts data protection regulation concerning Member States. Some EHDS provisions likely apply to purely national cases, such as access requests within the same Member State. However, the ECJ's broad interpretation of the 'scope of EU law' means this is unlikely to be problematic in practice. Moreover, the EHDS closely links national and cross-border issues, as cross-border access relies on rules also governing national matters.[147] Also, the EHDS complements rather than replaces existing national data access systems by establishing a Union-

144 See p. 7 of the draft EHDS Regulation; Johan Hansen et al., Assessment of the EU Member States' Rules on Health Data in the Light of GDPR, Specific Contract No. SC 2019 70 02 in the context of the Single Framework Contract Chafea/2018/Health/03, 2021, 134; European Commission, Communication of 25 April 2018, COM/2018/233 final, on enabling the digital transformation of health and care in the Digital Single Market, empowering citizens and building a healthier society, 1.

145 See Recital 61 EHDS; EHDS draft Regulation, 8.

146 See draft EHDS Regulation, COM/2022/197 final, under 2. Legal basis, subsidiarity and proportionality.

147 As an example, cross-border data access for secondary use also requires HDABs to request data from national health data holders upon a prior data permit, Art. 68(7) EHDS.

wide framework alongside them thereby ensuring consistency with the scope of Union law.[148]

Limits of Competence: Article 168(7) TFEU, Subsidiarity and Proportionality

The EHDS Regulation does little to justify the competences of the Union with regard to safeguarding the responsibility of the Member States for their healthcare systems in accordance with Article 168(7) TFEU.[149] Although its applicability under other competence titles has not been conclusively established, the legislator seems to assume that it is applicable, or at least wishes to ensure conformity with Article 168(7) TFEU in the form of a consideration *in any case*. However, as we will show in section III. 3. and III. 4., a more detailed justification would certainly have been desirable.

The principle of subsidiarity (Article 5(3) TEU), which applies in relation to shared competences, presupposes that the objectives of the measures under consideration cannot be sufficiently achieved by the Member States at central, regional or local level, but can be better achieved at Union level because of their scale or effects.[150] The Commission has analysed the current status of data governance mechanisms and the possibilities of access to electronic health data for primary and secondary use in a comprehensive study and identified the existence of significant barriers and deficits – not least with regard to the fragmentation of Member State rules governing access, exchange and use of electronic health data.[151]

The EHDS objective of enabling cross-border data exchange and access appears to be more achievable through Union action than through Member State action alone.[152] The requirements of the principle of subsidiarity are

148 See Recital 52 EHDS; an example from Germany is the data access procedure under Section 303 e of the German Social Code, Book V.

149 This is only addressed in Recital 28 EHDS, albeit without any in-depth reason being given. Comparing Recital 21 of the draft EHDS Regulation to the final Recital 28 EHDS indicates a stricter application of Art. 168(7) TFEU. Art. 168 was also addressed in the justification for the choice of legal basis and subsidiarity, p. 6 and 7 of the draft EHDS Regulation.

150 Art. 5(3) TEU.

151 Recital 7 EHDS. Comprehensive and detailed in Hansen et al. (n. 144); see DG SANTÉ (n. 8), 3 f.

152 It should be noted that Member States had coordinated approaches in parallel to the EHDS legislative process, for example as part of the joint action 'Towards a European Health Data Space' (TEHDAS), see <https://tehdas.eu/app/uploads/2022/03/tehdas-leaflet-2022.pdf>, last access 19 November 2025, and continue to coordinate in TEHDAS2 by developing 'common guidelines and technical specifications […] to ensure a harmonised implementation', see <https://tehdas.eu/wp-content/uploads/2024/09/tehdas2-brief-leaflet-7.pdf>, last access 19 November 2025.

therefore generally met. Compliance with the principle of proportionality within the meaning of Article 5(4) TEU, according to which measures of the Union do not go beyond what is necessary to achieve the objectives of the Treaties in terms of content and form, can only be assessed with regard to the specific provisions of the Regulation.

3. Obligations of Member States Regarding the Primary Use of Electronic Health Data in the EHDS

With regard to the provisions on primary use, the question of compatibility with Article 168(7) TFEU arises insofar as its applicability to Articles 114 and 16 TFEU is assumed.

According to Article 168(7) TFEU, the activities of the Union must respect the Member States' responsibility for the definition of their own health policies, the organisation and management of their health systems and the provision of health services and medical care. However, the ECJ holds that this does not preclude Member States from being obliged to make adjustments to their healthcare systems under other Treaty provisions or Union policies based on them, without this being seen as an encroachment upon their sovereign competence.[153] This applies in particular when the realisation of fundamental freedoms is at issue.[154] Conversely, it follows that interference in the competence of the Member States is not permitted. In German doctrine, interference is deemed to exist if the Union policy forces Member States to reorganise their healthcare systems.[155] In any case, all decisions relating to the system are reserved for the Member States.[156]

Articles 13(1), 12, 7(2), and 11(1) EHDS directly affect the provision of healthcare services by requiring healthcare providers to systematically store prioritised health data in EHR systems[157] and to have access to relevant patient data via professional access services – regardless of any cross-border context. Where providers are based in different Member States, the receiving

153 See ECJ, *Watts* (n. 137), para. 147 (with regard to the social security system); see also Schmidt am Busch (n. 131), para. 82.

154 ECJ, *European Commission v. Grand Duchy Luxembourg* (n. 137), para. 45; ECJ, *V. G. Müller-Fauré and Onderlinge Waarborgmaatschappij OZ Zorgverzekeringen UA,* and between *E. E. M. van Riet and Onderlinge Waarborgmaatschappij OZ Zorgverzekeringen,* judgment of 13 May 2003, case no. C-385/99, ECLI:EU:C:2003:270.

155 Schmidt am Busch (n. 131), para. 82.

156 Niggemeier (n. 139), para. 75.

157 Although Art. 13(1) EHDS is directly addressed to the member states and not to healthcare providers, the EHDS stipulates that health data must be stored in an EHR system.

provider must accept data transmitted through MyHealth@EU at the patient's request. These rules shape the rights and obligations of healthcare providers and may be seen as an interference of Member States' competence. However, previous ECJ case law, according to which the realisation of fundamental freedoms may oblige Member States to make adjustments in the areas of Article 168(7) TFEU, would seem to argue against interference. Facilitating the free movement of natural persons through the cross-border availability of their electronic health data is almost inextricably linked to the availability of this data at a purely national level. The EHDS provisions serve this objective by enabling individuals to access, transfer, or request the transfer of their health data, thereby facilitating cross-border healthcare. Notably, Articles 13(1), 12, and 11(5) EHDS also allow Member States to adopt specific national rules in these areas.

The EHDS further requires Member States to designate a digital health authority, establish a national contact point for MyHealth@EU, and ensure connectivity with all national healthcare providers. It also assigns them extensive tasks, particularly regarding the implementation of Chapter II.[158] This effectively compels Member States to digitise and interconnect their healthcare systems. While such measures may appear to infringe on national responsibility for health system organisation, ECJ case law suggests otherwise for the reasons stated above. Nevertheless, a more explicit clarification of Article 168(7) TFEU by the EU legislator would have been desirable.

Commission Powers in Primary Use

In the wake of the Council's and the European Parliament's positions,[159] the Commission's far-reaching authorisations to adopt secondary legislation included in earlier EHDS drafts have been significantly constrained. For example, the Commission is no longer authorised to transfer further tasks to digital health authorities (Article 10(3) draft EHDS Regulation). This reflects better the principle of proportionality under Article 5(4) TEU, i. e. that Member State sovereignty must be protected as far as possible when measures become necessary, given that the EHDS already stipulates Member States to

158 Art. 19(1)(3) EHDS and Art. 23(2), (5) EHDS.

159 E. g. Council of the European Union, Proposal for a Regulation on the European Health Data Space – Mandate for Negotiations with the European Parliament, 7 December 2023, 16048/1/23, 77, <https://data.consilium.europa.eu/doc/document/ST-16048-2023-REV-1/en/pdf>, last access 19 November 2025) and European Parliament, Amendments Adopted by the European Parliament on 13 December 2023 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)), Amendment 162.

adopt administrative structures in the health sector and assigns an extensive catalogue of tasks to digital health authorities under Article 19 EHDS.

4. Obligations of Member States Regarding the Secondary Use of Electronic Health Data in the EHDS

Given the growing integration of research and care in translational medicine, the provisions of Chapter IV EHDS also touch upon health policy and the organisation of healthcare (Article 168(7) TFEU). For example, under Articles 58(3) and 61(5) EHDS, health data users must report significant findings to the HDAB, which informs the data holder, who in turn notifies the data subject or treating healthcare professionals in accordance with national law. While this obligation affects healthcare provision by involving the communication of findings to healthcare professionals, the EHDS respects Member State competences by linking the duty to inform to national legal conditions.

The decision adopted in the EHDS Regulation to make electronic health data widely available for secondary use does not directly affect organisational issues of national healthcare systems in all areas. Nevertheless, some healthcare providers (e. g. public or private hospitals)[160] as data holders are affected by the provisions of the EHDS Regulation governing secondary use. They must establish organisational systems and processes, partly in cooperation with the HDAB, in order to make electronic health data available to them. While health data intermediation entities may perform these tasks if allowed by national law, their implementation may still be resource-intensive. However, this does not infringe Member State competences under Article 168(7) TFEU, as it concerns data availability for secondary use rather than healthcare provision.

Given the extensive range of tasks assigned to national HDABs and contact points, the EHDS is likely to significantly affect the administrative structures of the Member States.[161] In our view, however, it complies with the principle of proportionality under Article 5(4) TEU, as these tasks are necessary to enable the secondary use of electronic health data within the EHDS framework.

160 I. e. all healthcare providers that do not fall under the exception of SMEs, Art. 50(1) EHDS.

161 However, the establishment of the EHDS is also likely to mean an additional administrative burden for the data protection supervisory authorities (see Section II. 4. e.).

Commission's Powers and Safeguarding Member States Sovereignty

The Commission's authorisations to adopt secondary legislation with possibly far-reaching impacts on the administrative structure of the Member States were significantly limited during the legislative process. In light of the principle of proportionality and Article 168(7) TFEU, such a development must be welcomed.

As a first example, Article 37(1) draft EHDS Regulation would have empowered the Commission to amend the list of tasks of HDABs, creating an additional possibility for the Commission to influence the administrative structures of the Member States. Beyond doubts about the necessity of this authorisation, given the already extensive cooperation structures established in the EHDS Regulation,[162] the Council's and the Parliament's opposition[163] reflected broader concerns about the extensive potential for unforeseen Commission-driven changes to national administrative structures.[164]

Second, Article 52(13)(c), (d) draft EHDS Regulation authorised the Commission to define the responsibilities of joint controllers and the Commission as processor for processing operations within the framework of Health@EU through delegated acts. This would have empowered the Commission to exert significant influence on the specific responsibilities and, thus, for example, on issues of liability in the internal relationship between the controllers. In the final EHDS, these authorisations were narrowed. Article 75(12) now limits the Commission's implementing powers to defining its processor obligations toward joint controllers, reflecting a more proportionate balance.

Comparing the draft EHDS Regulation with the adopted EHDS Regulation in terms of Commission's authorisations, it shows that these were limited during the legislative procedure in two ways. First, by deleting several authorisations entirely, secondly by limiting the material scope of the authorisation. For example, where the Commission was formerly empowered to amend the categories of healthcare providers, categories of health data and data quality standards (Article 7(3) draft EHDS Regulation), it is now mainly only empowered to define the latter (Article 13(4) EHDS).[165] This shift in legislative design is not only politically significant, but also doctrinally important in terms of how the balance of competences is maintained under the

162 EHDS Board and the later introduced Steering Groups.

163 European Parliament, *Amendments adopted by the European Parliament on 13 December 2023* (n. 159), Amendment 361; Council of the European Union, *Proposal for a Regulation on the European Health Data Space* (n. 159).

164 See in the context of Chapter 4 of the draft EHDS Regulation on the Establishment of the EHDS for Secondary Processing only Arts 33(7), 37(4), 39(3), 41(7), 42(6), 43(8), 45(6), 46 (8), 50(4), 51(2), 52(5),(7),(13), 53(3), 55(2), 56(4), 58 of the draft EHDS Regulation.

165 And amend Annex I EHDS (Art. 14(2) EHDS).

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treaties. With these changes the final EHDS Regulation was brought closer in line with the prevalent understanding of Articles 16 and 114 TFEU and the limits established by Article 168(7) TFEU.

In contrast, the authorisation of the Commission in Article 62(6) EHDS to lay down principles and rules for fee policy and fee structures through implementing acts seems reasonable. A standardised definition of these rules should benefit the purpose of the EHDS Regulation, which is, to promote cross-border secondary processing.

5. Infringement of the Procedural Autonomy of the Member States, Article 291(1) TFEU?

Given the significant impact on Member State administrative structures, in particular the planned establishment of the digital health authority and the HDABs, it is worth considering whether the EHDS Regulation aligns with the principle of procedural autonomy of the Member States enshrined in Article 291 TFEU.[166] This states that the implementation of Union law is primarily the task of the Member States' administration,[167] and also covers how Union law is organised and enforced.[168] This results in a rule-exception relationship between indirect enforcement by national administrations and direct enforcement by Union institutions, bodies, offices, or agencies.[169] However, the extent and scope to which Article 291(1) TFEU has the effect of limiting competences has not been conclusively established.[170] It cannot be assumed that traditional administrative organisational structures are *per se* resistant to changes from European Law,[171] meaning that the creation of

166 Wolfgang Kahl, 'Art. 4 TEU' in: Christian Callies and Matthias Ruffert (eds), *TEU/TFEU* (6th edn, C. H. Beck 2022), para. 127.

167 Matthias Ruffert, 'Art. 291 TFEU' in: Christian Callies and Matthias Ruffert (eds), *TEU/TFEU* (6th edn, C. H. Beck 2022), para. 5; See Martin Nettesheim, 'Art. 291 TFEU' in: Eberhard Grabitz, Meinhard Hilf and Martin Nettesheim (eds), *Das Recht der Europäischen Union* (85th edn, C. H. Beck 2025), para. 5; See also German Federal Constitutional Court, BVerfGE 151, 202 (2019), para. 243.

168 Stefan Drechsler, '§ 8 Vollzug des Unionsrechts' in: Manfred Dauses and Markus Ludwigs (eds), *Handbuch des EU-Wirtschaftsrechts* (64 edn, C. H. Beck, August 2025), para. 140; Kahl (n. 166), para. 127; Raji (n. 3), 6.

169 Ruffert, 'Art. 291 TFEU' (n. 167), para. 5; BVerfGE 151, 202 (2019), (n. 167), para. 243; Contra: Claus Dieter Classen, 'Art. 197 TFEU' in: Eberhard Grabitz, Meinhard Hilf and Martin Nettesheim (eds), *Das Recht der Europäischen Union* (85th edn, C. H. Beck 2025), para. 11.

170 See Drechsler (n. 168), para. 140.

171 Markus Ludwigs, 'Die Verfahrensautonomie der Mitgliedsstaaten', NVwZ 37 (2018), 1417-1422 (1420).

national authorities with specific tasks for indirect enforcement can also be prescribed by Union law. Compared to the general limits imposed on the exercise of competences by Article 5 TEU (in particular the principles of subsidiarity and proportionality), Article 291 TFEU does not appear to place any further restrictions on competences in indirect implementation.[172] The principle of procedural autonomy of the Member States is therefore not violated by the requirements of the EHDS Regulation to set up digital health authorities and HDABs.

IV. Summary and Outlook

The EU is pursuing a large-scale project in the form of the EHDS with the aim of improving access to and the use of electronic health data across borders, both for healthcare and for research, innovation and policy-making. To that end the EHDS provides for harmonised rules on data access and sharing for primary and secondary use as well as unanimous safeguards and establishes two cross-border infrastructures. The final EHDS Regulation has clarified its relation to the GDPR in several aspects compared to the draft EHDS Regulation, e. g. its relation to Article 9(4) GDPR and national data protection law and the cooperation of EHDS public bodies to data protection supervisory authorities. Notably, the EHDS leaves important technical, organisational, information security, and data protection requirements to the Commission's implementing acts, such as those for joining and remaining connected to the cross-border infrastructures and those applicable to SPEs.

We analysed the EHDS from the perspective of EU legislative competence. While the ECJ has not yet explicitly ruled whether Member States' responsibilities for health policy, the organisation of health systems, and medical care under Article 168(7) TFEU also limit the exercise of other competence titles than Article 168 TFEU, such as Article 114 TFEU, its case law suggests that they do. The rules on both primary and secondary use of the EHDS Regulation foresee extensive influences on the administrative structures of the Member States.

The provisions on primary use in particular, will have a significant impact on national healthcare systems and the provision of healthcare. Although the EHDS provisions partially shape the rights and obligations of healthcare providers and effectively compel Member States to digitise and interconnect their healthcare systems (which they have done to varying degrees), previous ECJ case law would seem to argue against a violation of Article 168(7) TFEU.

172 Drechsler (n. 168), para. 140.

The EHDS provisions on secondary use may partly affect actors in the health system, esp. as health data holders, but do not constitute an infringement of Article 168(7) TFEU.

As the final EHDS Regulation significantly curtailed the Commission's powers to adopt secondary legislation – thereby limiting its influence over national public bodies within the EHDS framework – it is now more consistent with the principle of proportionality.

A major challenge is the technical implementation of the EHDS. In this respect, the regulatory content of the EHDS Regulation remains somewhat abstract,[173] even though the Union, the Member States and healthcare providers are faced with significant tasks in this area. The implementation of an EU-wide European exchange format for hundreds of millions of potential users, the building of capacity to handle numerous data access applications and make health data available or the enormous effort involved in defining the 'implementation of technical solutions at national level' (Article 19(2)(c) EHDS) by the digital health authorities could pose major challenges.[174] Not only Member States but also healthcare providers might face considerable costs -for healthcare providers, for instance, if new EHR systems need to be introduced.[175] To that end, Recital 91 EHDS only states that a 'fair sharing of that burden between Union and national funds will need to be found'. Many details of the implementation are left to the Commission and the Member States. It will therefore be interesting to see the effective implementation of the EHDS.

173 Nikolaus Forgó, 'Der European Health Data Space im Kontext der MMR', MMR 26 (2023), 3-5 (4 f.).

174 Forgó (n. 173), 4 f.

175 See for example Parliament of the Czech Republic, 20 October 2022, Proposal for a Regulation on the European Health Data Space – Opinion on the Application of the Principles of Subsidiarity and Proportionality, accessible at <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CONSIL:ST_13814_2022_INIT&from=EN>, last access 19 November 2025.