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**NOTE**

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|---|---|
| From: | General Secretariat of the Council |
| To: | Delegations |
| Subject: | Proposal for a Regulation on the European Health Data Space<br>- First Presidency compromise proposal (Chapters I and IV) |

Delegations will find in Annex a draft text as prepared by the Presidency on the above-mentioned subject.

Changes compared to the Commission proposal are marked in **bold/underline** for additions and in ~~strikethrough~~ for deletion.

**ANNEX**

2022/0140 (COD)



# Chapter I

# General provisions

*Article 1*

*Subject matter and scope*

1. This Regulation establishes the European Health Data Space ('EHDS') by providing for **common** rules, ~~common~~ standards ~~and practices~~, infrastructures and a governance framework ~~for~~ **with a view to facilitating access to electronic health data for** the **purposes of** primary and secondary use of ~~electronic health~~ **these** data.

2. This Regulation:

   (a) ~~strengthens~~ **specifies and complements, in Chapter II,** the rights **laid down in the Regulation (EU) 2016/679** of natural persons in relation to **primary use** ~~the availability and control~~ of their **personal** electronic health data;

   (b) lays down, **in Chapter III, common** rules for ~~the placing on the market, making available on the market or putting into service of~~ electronic health records systems ('EHR systems') **and wellness applications that claim interoperability with EHR systems** in the Union **for primary use**;

   (c) lays down**, in Chapter II and IV, common** rules and mechanisms ~~supporting~~ **for primary and** secondary use of electronic health data;

   (d) establishes a ~~mandatory~~ cross-border infrastructure enabling the primary use of **personal** electronic health data across the Union **according to Chapter II**;

   (e) establishes a ~~mandatory~~ cross-border infrastructure for the secondary use of electronic health data **according to Chapter IV**;~~.~~

   **(f) establishes governance and coordination on national and European level for both primary and secondary use of electronic health data.**

~~3. This Regulation applies to:~~

   ~~(a) manufacturers and suppliers of EHR systems and wellness applications placed on the market and put into service in the Union and the users of such products;~~

   ~~(b) controllers and processors established in the Union processing electronic health data of Union citizens and third-country nationals legally residing in the territories of Member States;~~

~~(c) controllers and processors established in a third country that has been connected to or are interoperable with MyHealth@EU, pursuant to Article 12(5);~~

~~(d) data users to whom electronic health data are made available by data holders in the Union.~~

**3A. This Regulation shall be without prejudice to Regulations (EU) 2016/679, (EU) 2018/1725, (EU) No 536/2014 and Directive 2022/58/EC.**

4. This Regulation shall be without prejudice to other Union legal acts regarding access to, sharing of or secondary use of electronic health data, or requirements related to the processing of data in relation to electronic health data, in particular Regulations ~~(EU) 2016/679, (EU) 2018/1725,~~ **(EU) 2022/868**[…] ~~[Data Governance Act COM/2020/767 final],~~ and […] [Data Act COM/2022/68 final].

5. This Regulation shall be without prejudice to Regulations (EU) 2017/745, **(EU) 2017/746** and […] [AI Act COM/2021/206 final], as regards the security of medical devices and AI systems that interact with EHR systems.

6. This Regulation shall not affect the rights and obligations laid down in Union or national law concerning health data processing for the purposes of reporting, complying with information requests or demonstrating or verifying compliance with legal obligations.

**7. This Regulation shall not apply to activitites concerning public security, defence and national security.**

*Article 2*

*Definitions*

*Definitions in Article 2(2)(d),(f)-(n) and (p)-(t) are not included in this compromise*

1. For the purposes of this Regulation, following definitions shall apply:

(a) the definitions **of 'personal data', 'processing', 'pseudonymisation', 'controller', 'processor', 'third party', 'consent', 'genetic data', 'data concerning health', 'supervisory authority', 'international organisation' of the** ~~in~~ Regulation (EU) 2016/679;

(b) the definitions of 'healthcare', 'Member State of affiliation', 'Member State of treatment', 'health professional', 'healthcare provider', 'medicinal product' and 'prescription', pursuant to Article 3 (a), (c), (d), (f), (g), (i) and (k) of Article 3 of the Directive 2011/24/EU;

(c) the definitions of 'data', 'access', 'data altruism', 'public sector body' and 'secure processing environment', pursuant to Article 2 (1), (8), (10), (11) and (14) of **Regulation (EU) 2022/868**~~[Data Governance Act COM/2020/767 final]~~;

(d) the definitions of 'making available on the market', 'placing on the market', 'market surveillance', 'market surveillance authority', 'non-compliance', 'manufacturer', 'importer', 'distributor', 'economic operator', 'corrective action', 'risk', 'recall' and 'withdrawal', pursuant to Article 2 (1), (2), (3), (4), (7), (8), (9), (10), (13), (16), (18), (22) and (23) of the Regulation (EU) 2019/1020;

(e) the definitions of 'medical device', 'intended purpose', 'instructions for use', 'performance', 'health institution' and 'common specifications', pursuant to Article 2 (1), (12), (14), (22), (36) and (71) of the Regulation (EU) 2017/745;

(f) the definitions of 'electronic identification', 'electronic identification means' and 'person identification data' pursuant to Article 3 (1), (2) and (3) of the Regulation (EU) No 910/2014.

2. In addition, for the purposes of this Regulation the following definitions shall apply:

(a) 'personal electronic health data' means **personal** data concerning health and genetic data as defined in Regulation (EU) 2016/679 ~~as well as data referring to determinants of health, or data processed in relation to the provision of healthcare services~~, processed in an electronic form;

~~(b) 'non-personal electronic health data' means data concerning health and genetic data in electronic format that falls outside the definition of personal data provided in Article 4(1) of Regulation (EU) 2016/679;~~

(c) 'electronic health data' means personal **health data** or ~~non-personal electronic health~~ data **concerning health or genetic data that do not constitute personal data, processed in electronic form**;

(e) 'secondary use of electronic health data' means the processing of electronic health data for purposes set out in **Article 34** ~~Chapter IV~~ of this Regulation. ~~The data used may include personal electronic health data initially collected in the context of primary use, but also electronic health data collected for the purpose of the secondary use;~~

(o) 'wellness application' means any appliance or software intended by the manufacturer to be used by a natural person for processing electronic health data for other purposes than healthcare, such as well-being and pursuing healthy life-styles;

~~(u) 'national contact point for secondary use of electronic health data' means an organisational and technical gateway enabling the cross-border secondary use of electronic health data, under the responsibility of the Member States;~~

~~(v) 'central platform for secondary use of electronic health data' means an interoperability platform established by the Commission, providing services to support and facilitate the exchange of information between national contact points for secondary use of electronic health data;~~

~~(x) 'HealthData@EU' means the infrastructure connecting national contact points for secondary use of electronic health data and the central platform;~~

(y) '**health** data holder' means a~~ny~~ natural or legal person, which is an entity or a body in the health or care sector, or performing research in relation to these sectors, as well as Union institutions, bodies, offices and agencies who has ~~the right or obligation, in accordance with this Regulation, applicable Union law or national legislation implementing Union law~~ **either:**

**(a) the right or obligation, in accordance with applicable Union law or national legislation, to process personal electronic health data for the provision of health or care or for public health, research, innovation, policy making, official statistics, patient safety or regulatory purposes, in its capacity as a controller; or**

**(b) the ability to make available, including to register, provide, restrict access or exchange electronic health data that do not constitute personal data in the meaning of Article 4 (1) of Regulation (EU) 2016/679**~~non-personal data~~, through control of the technical design of a product and related services, ~~the ability to make available, including to register, provide, restrict access or exchange certain data~~;

(z) '**health** data user' means a natural or legal person who has lawful access to ~~personal or non-personal~~ electronic health data for secondary use **pursuant to a data permit or a data request pursuant to this Regulation**;

(aa) 'data permit' means an administrative decision issued to a **health** data user by a health data access body or a **single health** data holder to process the electronic health data specified in the data permit for the secondary use purposes specified in the data permit based on conditions laid down in **Chapter IV of** this Regulation;

(ab) 'dataset' means a structured collection of electronic health data;

(ac) 'dataset catalogue' means a collection of datasets descriptions, which is arranged in a systematic manner and consists of a user-oriented public part, where information concerning individual dataset parameters is accessible by electronic means through an online portal;

(ad) 'data quality' means the degree to which characteristics of electronic health data are suitable for secondary use;

(ae) 'data quality and utility label' means a graphic diagram, including a scale, describing the data quality and conditions of use of a dataset.

# CHAPTER IV

# Secondary use of electronic health data

## SECTION 1

## SCOPE AND GENERAL CONDITIONS WITH REGARD TO THE SECONDARY USE OF ELECTRONIC HEALTH DATA

### *Article 32A*

### *Scope*

**This Chapter shall apply where a health data user seeks for access to electronic health data referred to in Article 33 from one or more health data holders for secondary use purposes laid down in Article 34.**

### *Article 33*

### *Minimum categories of electronic data for secondary use*

1. **This Chapter shall apply to** ~~Data holders shall make~~ the following categories of electronic **health** data ~~available for secondary use in accordance with the provisions of this Chapter~~:

   (a) **electronic health data from** EHRs, **including the categories in Article 5 of this Regulation**;

   (b) data **on factors** impacting health, including social, environmental behavioural determinants of health;

   (c) relevant pathogen genomic data, impacting on human health;

   (d) health**care**-related administrative data, including claims and reimbursement data;

   (e) human genetic, genomic and proteomic data;

   (f) person generated electronic health data, including medical devices, wellness applications or other digital health applications;

   (g) identification data related to health professionals involved in the treatment of a natural person;

(h)population wide health data registries (public health registries);

(i) electronic health data from medical registries for specific diseases;

(j) electronic health data from clinical trials;

(k) electronic health data from medical devices and from registries for medicinal products and medical devices;

(l) **data from** research cohorts, questionnaires and surveys related to health;

(m) electronic health data from biobanks and dedicated databases;

(n) electronic data related to insurance status, professional status, education, lifestyle, wellness and behaviour data relevant to health;

(o) electronic health data containing various improvements such as correction, annotation, enrichment received by the data holder following a processing based on a data permit.

~~2. The requirement in the first subparagraph shall not apply to data holders that qualify as micro enterprises as defined in Article 2 of the Annex to Commission Recommendation 2003/361/EC[1].~~ MOVED TO ARTICLE 35B(8)

3. ~~The electronic health data referred to in paragraph 1 shall cover data processed for the provision of health or care or for public health, research, innovation, policy making, official statistics, patient safety or regulatory purposes, collected by entities and bodies in the health or care sectors, including public and private providers of health or care, entities or bodies performing research in relation to these sectors, and Union institutions, bodies, offices and agencies.~~ INTEGRATED IN ARTICLE 2(2)(y)

~~4. Electronic health data entailing protected intellectual property and trade secrets from private enterprises shall be made available for secondary use. Where such data is made available for secondary use, all measures necessary to preserve the confidentiality of IP rights and trade secrets shall be taken.~~ MOVED TO THE NEW ARTICLE 35A

~~5. Where the consent of the natural person is required by national law, health data access bodies shall rely on the obligations laid down in this Chapter to provide access to electronic health data.~~ MOVED TO A NEW PARAGRAPH IN ARTICLE 37(6)

~~6. Where a public sector body obtains data in emergency situations as defined in Article 15, point (a) or (b) of the Regulation […] [Data Act COM/2022/68 final], in accordance with the rules laid down in that Regulation, it may be supported by a health data access body to provide technical support to process the data or combing it with other data for joint analysis.~~ MOVED TO A NEW PARAGRAPH IN ARTICLE 37(3B)

7. ~~The Commission is empowered to adopt delegated acts in accordance with Article 67 to amend the list in paragraph 1 to adapt it to the evolution of available electronic health data.~~

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[1] Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36).

8. **Member States may allow additional categories of electronic health data to be made available for secondary use.** ~~Health data access bodies may provide access to additional categories of electronic health data that they have been entrusted with pursuant to national law or based on voluntary cooperation with the relevant data holders at national level, in particular to electronic health data held by private entities in the health sector.~~

*Article 34*

*Purposes for which electronic health data can be processed for secondary use*

1. Health data access bodies shall only provide access to electronic health data referred to in Article 33 **to a health data user** if ~~where~~ the ~~intended~~ purpose of processing ~~pursued by the applicant~~ complies with:

   (a) activities for reasons of public interest in the area of public and occupational health, such as protection against serious cross-border threats to health, public health surveillance or ensuring high levels of quality and safety of healthcare and of medicinal products or medical devices;

   (b) to support public sector bodies or Union institutions, agencies and bodies including regulatory authorities, in the health or care sector to carry out their tasks defined in their mandates;

   (c) to produce national, multi-national and Union level official statistics related to health or care sectors;

   (d) education or teaching activities in health or care sectors;

   (e) scientific research related to health or care sectors;

   (f) development and innovation activities for products or services contributing to public health or social security, or ensuring high levels of quality and safety of health care, of medicinal products or of medical devices;

   (g) training, testing and evaluating of algorithms, including in medical devices, AI systems and digital health applications, contributing to the public health or social security, or ensuring high levels of quality and safety of health care, of medicinal products or of medical devices;

   (h) providing personalised healthcare consisting in assessing, maintaining or restoring the state of health of natural persons, based on the health data of other natural persons.

2. **The purposes referred** ~~Access to electronic health data referred to in Article 33 where the intended purpose of processing pursued by the applicant fulfils one of the purposes referred~~ to in points (a) to (c) of paragraph 1 **are reserved for** ~~shall only be granted to~~ public sector bodies and Union institutions, bodies, offices and agencies exercising their tasks conferred to them by Union or national law, including where processing of data for

carrying out these tasks is done by a third party on behalf of that public sector body or of Union institutions, agencies and bodies.

~~3. The access to privately held data for the purpose of preventing, responding to or assisting in the recovery from public emergencies shall be ensured in accordance with Article 15 of the Regulation […] [Data Act COM/2022/68 final].~~

~~4. Public sector bodies or Union institutions, agencies and bodies that obtain access to electronic health data entailing IP rights and trade secrets in the exercise of the tasks conferred to them by Union law or national law, shall take all specific measures necessary to preserve the confidentiality of such data.~~ MOVED TO A NEW ARTICLE 35A

*Article 35*

*Prohibited secondary use of electronic health data*

**Health data users shall be prohibited to** ~~S~~**s**eek~~ing~~ access to and processing electronic health data obtained via a data permit **or data request** ~~issued pursuant to Article 46~~ for the following purposes ~~shall be prohibited~~:

(a) taking decisions detrimental to a natural person **or a group of natural persons** based on their electronic health data; in order to qualify as "decisions", they must produce legal effects or similarly significantly affect those natural persons;

(b) taking decisions in relation to a natural person or groups of natural persons to exclude them from the benefit of an insurance contract or to modify their contributions and insurance premiums;

(c) advertising or marketing activities ~~towards health professionals, organisations in health or natural persons~~;

~~(d) providing access to, or otherwise making available, the electronic health data to third parties not mentioned in the data permit;~~ MOVE TO ARTICLE 35C(2)

(e) developing products or services that may harm individuals and societies at large, including, but not limited to illicit drugs, alcoholic beverages, tobacco products, or goods or services which are designed or modified in such a way that they contravene public order or morality.

***Article 35A***

***IP-rights and trade secrets***

**1.** Electronic health data entaining protected intellectual property and trade secrets from ~~private enterprises~~ **health data holders** shall be made available for secondary use. ~~Where such data is made available for secondary use, all measures necessary to preserve the confidentiality of IP rights and trade secrets shall be take.~~ MOVED FROM ARTICLE 33(4)

**2.** **Where the health data access body or other** ~~P~~**p**ublic sector bodies or Unions institutions, agencies and bodies obtain access to electronic health data entaining IP rights and trade secrets in the exercise of the tasks conferred to them by ~~Union law or national law~~ **this Regulation**, they shall take all specific measures necessary to preserve the confidentiality of such data. MOVED FROM ARTICLE 34(4)

*Article ~~41~~**35B***

*Duties of **health** data holders* MOVED FROM ARTICLE 41

1. ~~Where a~~ **A health** data holder is obliged to make **the** electronic health data ~~available~~ under Article 33 **they hold available upon request to the health data access body according to a data permit or data request.** ~~or under other Union law or national legislation implementing Union law, it shall cooperate in good faith with the health data access bodies, where relevant.~~ SOME PARTS MOVED TO ARTICLE 35B(5A)

**1a.** The **health** data holder shall put the electronic health data **referred to in paragraph 1** at the disposal of the health data access body within ~~2~~ **3** months from receiving the request from the health data access body. In exceptional cases, that period may be extended by the health data access body for an additional period of ~~2~~ **3** months. MOVED FROM ARTICLE 35B(4)

**1b. Paragraphs 1 and 1a constitutes a legal obligation in the sense of Article 6 (1)(c) of Regulation (EU) 2016/679 for the health data holder to disclose personal electronic health data to the health data access body, in accordance with Articles 9(2)(i) and (j) of Regulation (EU) 2016/679.**

2. The **health** data holder shall communicate to the health data access body a ~~general~~ description of the dataset it holds in accordance with Article 55.

3 Where a data quality and utility label accompanies the dataset pursuant to Article 56, the **health** data holder shall provide sufficient documentation to the health data access body for that body to confirm the accuracy of the label.

~~4. The data holder shall put the electronic health data at the disposal of the health data access body within 2 months from receiving the request from the health data access body. In exceptional cases, that period may be extended by the health data access body for an additional period of 2 months.~~ MOVED TO ARTICLE 35B(1A)

5. Where a **health** data holder has received enriched datasets following a processing based on a data permit, it shall make available the new dataset, unless it considers it unsuitable and notifies the health data access body in this respect.

**5a.** ~~Where a~~ **A health** data holder ~~is obliged to make electronic health data available under Article 33, or under other Union law or national legislation implementing Union law, it~~ shall cooperate ~~in good faith~~ with the health data access bodies, where relevant. SOME PARTS MOVED FROM ARTICLE 35B(1)

~~6. Data holders of non-personal electronic health data shall ensure access to data through trusted open databases to ensure unrestricted access for all users and data storage and preservation. Trusted open public databases shall have in place a robust, transparent and sustainable governance and a transparent model of user access.~~

7. ~~The Commission is empowered to adopt delegated acts in accordance with Article 67 to amend the duties of the data holders in this Article, to reflect the evolution of activities performed by data holders~~.

**8.** The requirement in ~~the first subparagraph~~ **this Article** shall not apply to **health** data holders that qualify as micro enterprises as defined in Article 2 of the Annex to Commission Recommendation 2003/361/EC[2]. **Member States may however decide to apply this Chapter to these health data holders.** MOVED FROM ARTICLE 33(2)

***Article 35C***

***Duties of health data users***

**1.** Health data users shall **only** ~~have the right to~~ access and process the electronic health data in accordance with a data permit **pursuant to Article 46 or a data request pursuant to Article 47** ~~delivered to them on the basis of this Regulation~~. **This includes a prohibition for health data users to re-identify the natural persons or to processing electronic health data for prohibited purposes pursuant to Article 35 or any other misuse of electronic health data**. MOVED FROM ARTICLE 46(7)

**2.** **Where processing electronic health data within the secure processing environments referred to in Article 50, the health data users are prohibited to provid**~~nge~~ access to~~,~~ or otherwise making ~~available,~~ the electronic health data **available** to third parties not mentioned in the data permit. MOVED FROM ARTICLE 35(d)

**3.** **Health** ~~D~~data users shall make public the results or output of the secondary use of electronic health data, including information relevant for the provision of healthcare, ~~no later than~~ **within** 18 months after the completion of the electronic health data processing in the secure environment or after having received the answer to the data request referred to in Article 47. **This period may in justified cases related to research be extended.** Those

[2] Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36

results or output shall only contain anonymised data. The **health** data user**s** shall inform the health data access bodies from which a data permit was obtained and support them to also make the **results or output provided by the health data users** ~~information~~ public on health data access bodies' websites. Whenever the **health** data users have used electronic health data in accordance with this Chapter, they shall acknowledge the electronic health data sources and the fact that electronic health data has been obtained in the context of the EHDS. MOVED FROM ARTICLE 46(11)

**4. Member State law to which the health data access body who granted the data permit is subject may allow the health** ~~D~~**d**ata users ~~shall~~ **to** inform the health data access body of any clinically significant findings that may influence the health status of the natural persons whose data are included in the dataset. MOVED FROM ARTICLE 46(12)

**5. The health data users shall cooperate with the health data access body when the health data access body is fulfilling its tasks, where relevant.**

## SECTION 2

## GOVERNANCE AND MECHANISMS FOR THE SECONDARY USE OF ELECTRONIC HEALTH DATA

*Article 36*

*Health data access bodies*

1. Member States shall designate one or more health data access bodies responsible for **fulfilling the tasks set out in Articles 37, 38 and 39** ~~granting access to electronic health data for secondary use~~. Member States may either establish one or more new public sector bodies or rely on existing public sector bodies or on internal services of public sector bodies that fulfil the conditions set out in this Article. **The tasks described in Article 37 may be divided between different health data access bodies.** Where a Member State designates several health data access bodies, it shall designate one health data access body to act as coordinator, with responsibility for coordinating requests **to access to electronic health data** with the other health data access bodies.

2. Member States shall ensure that each health data access body is provided with the human, technical and financial resources, premises and infrastructure necessary for the effective performance of its tasks and the exercise of its powers.

3. In the performance of their tasks, ~~health data access bodies shall actively cooperate with stakeholders' representatives, especially with representatives of patients, data holders and data users. Staff of~~ health data access bodies shall avoid any conflicts of interest. ~~Health data access bodies shall not be bound by any instructions, when making their decisions~~.

4. Member States shall **notify** ~~communicate to~~ the Commission the identity of the health data access bodies designated pursuant to paragraph 1 by the date of application of this Regulation. They shall also **notify** ~~communicate to~~ the Commission **of** any subsequent modification of the identity of those bodies. The Commission and the Member States shall make this information publicly available.

*Article 37*

*Tasks of health data access bodies*

1. Health data access bodies shall carry out the following tasks:

   (a) decide on data access applications pursuant to Article 45, authorise and issue data permits pursuant to Article 46 to access electronic health data falling within their national remit for secondary use and decide on data requests **pursuant to Article 47** in accordance with **this Chapter and** Chapter II of Regulation **(EU) 2022/868** ~~[…] [Data Governance Act COM/2020/767 final] and this Chapter~~;

**(ab)** ~~Health data access bodies shall~~ monitor and supervise compliance by **health** data users and **health** data holders with the requirements laid down in this Chapter. MOVED FROM ARTICLE 43(1)

(b) support public sector bodies in carrying out the tasks **related to this Regulation** enshrined in their mandate, based on national or Union law;

(c) support Union institutions, bodies, offices and agencies in carrying out tasks **related to this Regulation** enshrined in the mandate of Union institutions, bodies, offices and agencies, based on ~~national or~~ Union law;

(d) process electronic health data **referred to in Article 33** ~~for the purposes set out in Article 34,~~ including the ~~collecting~~ **gathering**, combination~~, preparation~~ and **compiling of necessary requested data from health data holders, the pseudonymisation or anonymisation of the data~~,~~ and the** disclosure of those data for secondary use **to health data users** on the basis of a data permit **or a data request**;

**(da) provide access to electronic health data to health data users pursuant to a data permit in a secure processing environment in accordance with the requirements laid down in Article 50.**

~~(e) process electronic health data from other relevant data holders based on a data permit or a data request for a purposes laid down in Article 34;~~

(f) take all measures necessary to preserve the confidentiality of IP rights and of trade secrets;

~~(g) gather and compile or provide access to the necessary electronic health data from the various data holders whose electronic health data fall within the scope of this Regulation and put those data at the disposal of data users in a secure processing environment in accordance with the requirements laid down in Article 50;~~ SEE ARTICLE 37(1)(d)-(da)

~~(h) contribute to data altruism activities in accordance with Article 40;~~

(i) support **with expertise** the development of AI systems, the training, testing and validating of AI systems and the development of harmonised standards and guidelines under Regulation […] [AI Act COM/2021/206 final] for the training, testing and validation of AI systems in health;

(j) cooperate with and supervise **health** data holders to ensure the consistent and accurate implementation of the data quality and utility label set out in Article 56;

(k) maintain a management system to record and process data access applications, data requests, **the decisions on these** and the data permits issued and data requests answered, providing at least information on the name of the data applicant, the purpose of access the date of issuance, duration of the data permit and a description of the data application or the data request;

(l) maintain a public information system to comply with the obligations laid down in Article 38;

(m) cooperate at Union and national level to lay down appropriate measures and requirements for accessing electronic health data in a secure processing environment;

(n) cooperate at Union and national level and provide advice to the Commission on techniques and best practices for **secondary use of** electronic health data ~~use~~ and management;

(o) facilitate cross-border access to electronic health data for secondary use hosted in other Member States through HealthData@EU and cooperate closely with each other and with the Commission.

(p) send to the **health** data holder ~~free of charge~~, by the expiry of the data permit, a copy of the corrected, annotated or enriched dataset, as applicable, and a description of the operations performed on the original dataset;

(q) make public, through electronic means:

(i) a national dataset catalogue that shall include details about the source and nature of electronic health data, in accordance with Articles 56 and 58, and the conditions for making electronic health data available. The national dataset catalogue shall also be made available to single information points under Article 8 of Regulation **(EU) 2022/868** ~~[…] [Data Governance Act COM/2020/767 final]~~;

(ii) all data permits, requests and applications on their websites within 30 working days after issuance of the data permit or reply to a data request;

(iii) penalties applied pursuant to Article 43;

(iv) results communicated by **health** data users pursuant to Article **35C(3)**~~46(11)~~;

(r) fulfil obligations towards natural persons pursuant to Article 38;

(s) request from **health** data users and **health** data holders all the relevant information to verify the implementation of this Chapter;

(t) fulfil any other tasks related to making available the secondary use of electronic health data in the context of this Regulation.

2. In the exercise of their tasks, health data access bodies shall:

(a) cooperate with supervisory authorities under Regulation (EU) 2016/679 and Regulation (EU) 2018/1725 in relation to personal electronic health data and the EHDS Board;

(b) inform the relevant supervisory authorities under Regulation (EU) 2016/679 and Regulation (EU) 2018/1725 where a health data access body has imposed penalties or other measures pursuant to Article 43 in relation to processing personal electronic health data and where such processing refers to an attempt to re-identify an individual or unlawful processing of personal electronic health data;

(c) cooperate with stakeholders, including patient organisations, representatives from natural persons, health professionals, researchers, and ethical committees, where applicable in accordance with Union ~~and~~ **or** national law;

(d) cooperate with other national competent bodies, including the national competent bodies supervising data altruism organisations under Regulation **(EU) 2022/868** ~~[…] [Data Governance Act COM/2020/767 final]~~, the competent authorities under Regulation […] [Data Act COM/2022/68 final] and the national competent authorities for Regulations (EU) 2017/745**, (EU) 2017/746** and Regulation […] [AI Act COM/2021/206 final] .

3. The health data access bodies may provide assistance to public sector bodies where those public sector bodies access electronic health data on the basis of Article 14 of Regulation […] [Data Act COM/2022/68 final].

**3a.** Health data access bodies shall support **with expertise** the competent authorities designated in accordance with Article 23 of Regulation **(EU) 2022/868** ~~[…] [Data Governance Act COM/2020/767 final]~~ in the monitoring of **the activities of** **recognised** ~~entities carrying out~~ data altruism ~~activities~~ **organisations under Chapter IV of the same Regulation**.MOVED FROM ARTICLE 40(2)

**3b.** **The health data access body may support** ~~Where~~ a public sector body **where it** obtains data in emergency situations as defined in Article 15, point (a) or (b) of the Regulation […] [Data Act COM/2022/68 final], in accordance with the rules laid down in that Regulation, **by** ~~it may be supported by a health data access body to~~ provide**ing** technical support to process the data or combining it with other data for joint analysis. MOVED FROM ARTICLE 33(6)

~~4. The Commission is empowered to adopt delegated acts in accordance with Article 67 to amend the list of tasks in paragraph 1 of this Article, to reflect the evolution of activities performed by health data access bodies.~~

**5. Point d in paragraph 1 constitutes a task carried out in the public interest in the sense of Article 6(1)(e) of Regulation (EU) 2016/679 for health data access bodies for the processing of personal electronic health data and meets the requirements of Articles 9(2)(i) and (j) of Regulation (EU) 2016/679.**

**6.** ~~Where the consent of the natural person is required by national law~~ **Nothwithstanding national laws requesting the consent pursuant to Article 9(4) of Regulation (EU) 2016/679**, health data access bodies shall rely on the obligations laid down in this Chapter when requesting and processing personal electronic health data from the health data holder and disclose ~~provide access to~~ pseudonymised electronic health data to the health data user.MOVED FROM ARTICLE 33(5)

*Article 38*

*Obligations of health data access bodies towards natural persons*

1. Health data access bodies shall make publicly available and eas~~il~~y **to find for natural persons** ~~searchable~~ the conditions under which electronic health data is made available for secondary use, with information concerning:

   (a) the legal basis **pursuant to Articles 6 and the requirements pursuant to Article 9 of Regulation (EU) 2016/679 or Articles 5(1) and 10(2) Regulation (EU) 2018/1725** under which access is granted **to the health data user**;

   (b) the technical and organisational measures taken to protect the rights of natural persons;

   (c) the applicable rights of natural persons in relation to secondary use of electronic health data;

   (d) the **modalities** ~~arrangements~~ for natural persons to exercise their rights in accordance with Chapter III of Regulation (EU) 2016/679;

   (e) the results or outcomes of the projects for which the electronic health data were used **as referred to in Article 35C(2)**.

2. ~~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.~~

   **For the purpose of Article 14 of Regulation (EU) 2016/679, where the health data access body request and process personal electronic health data from a health data holder, if the provision of information by the body, in its capacity as a controller, to each natural person concerned proves impossible or would involve a disproportionate effort in accordance with to Article 14(5)(b) of the same Regulation, the health data access body shall take apprioriate measures and at the minimum make the information provided in Article 14(1) and (2) of Regulation (EU) 2016/679 publicly available.**

3. **Member State law to which the health data access body is subject may allow** ~~Where~~ a health data access body **to be** ~~is~~ informed by a **health** data user of a finding that may impact on the health of a natural person**.**~~,~~ **In this case** the health data access body may inform the natural person and his or her treating health professional about that finding.

4. Member States shall regularly inform the public at large about the role and benefits of health data access bodies.

*Article 39*

*Reporting by health data access bodies*

1. Each health data access body shall publish a~~n~~ **biennial**~~annual~~ activity report which shall contain at least the following:

   (a) information relating to the data access applications for electronic health data access submitted, such as the types of applicants, number of data permits granted or refused, **categories of** purposes of access and categories of electronic health data accessed, and a summary of the results of the electronic health data uses, where applicable;

   (b) a list of data permits involving access to electronic health data processed by the health data access body based on data altruism and a summary description of the general interests purposes pursued, where applicable, including the outcomes of the data permits granted;

   (c) information on the fulfilment of regulatory and contractual commitments by **health** data users and **health** data holders, as well as penalties imposed;

   (d) information on audits carried out on **health** data users to ensure compliance of the processing **in the secure processing environment pursuant to Article 50(1)(e) of** ~~with~~ this Regulation,

   (e) information on **third party** audits on compliance of secure processing environments with the defined standards, specifications and requirements **pursuant to Article 50(3) of this Regulation***;*

   (f) information on the handling of requests from natural persons on the exercise of their data protection rights;

   (g) a description of its activities carried out in relation to engagement with and consultation of relevant stakeholders, including representatives of natural persons, patient organisations, health professionals, researchers, and ethical committees;

   (h) information on cooperation with other competent bodies in particular in the area of data protection, cybersecurity, data altruism, and artificial intelligence;

   (i) revenues from data permits and data requests;

   ~~(j) satisfaction from applicants requesting access to data;~~

   (k) average number of days between application and access to data;

(l) number of data quality labels issued, disaggregated per quality category;

(m) number of peer-reviewed research publications, policy documents, regulatory procedures using data accessed via the EHDS;

(n) number of digital health products and services, including AI applications, developed using data accessed via EHDS.

2. The report shall be **sent** ~~transmitted~~ to the Commission.

3. ~~The Commission is empowered to adopt delegated acts in accordance with Article 67 to modify the content of the annual activity report~~.

~~*Article 40*~~

~~*Data altruism in health*~~

~~1. When processing personal electronic health data, data altruism organisations shall comply with the rules set out in Chapter IV of Regulation **(EU) 2018/1724** […] [Data Governance Act COM/2020/767 final]. Where data altruism organisations process personal electronic health data using a secure processing environment, such environments shall also comply with the requirements set out in Article 50 of this Regulation.~~ MOVED TO ARTICLE 50(3A)

~~2. Health data access bodies shall support the competent authorities designated in accordance with Article 23 of […] [Data Governance Act COM/2020/767 final] in the monitoring of entities carrying out data altruism activities.~~ MOVED TO ARTICLE 37(3A).

~~*Article 41*~~ *MOVED TO ARTICLE 35B*

~~*Duties of data holders*~~

~~1. Where a data holder is obliged to make electronic health data available under Article 33 or under other Union law or national legislation implementing Union law, it shall cooperate in good faith with the health data access bodies, where relevant.~~

~~2. The data holder shall communicate to the health data access body a general description of the dataset it holds in accordance with Article 55 (1).~~

~~3 Where a data quality and utility label accompanies the dataset pursuant to Article 56, the data holder shall provide sufficient documentation to the health data access body for that body to confirm the accuracy of the label.~~

~~4. The data holder shall put the electronic health data at the disposal of the health data access body within 2 months from receiving the request from the health data access body. In exceptional cases, that period may be extended by the health data access body for an additional period of 2 months.~~

~~5. Where a data holder has received enriched datasets following a processing based on a data permit, it shall make available the new dataset, unless it considers it unsuitable and notifies the health data access body in this respect.~~

~~6. Data holders of non-personal electronic health data shall ensure access to data through trusted open databases to ensure unrestricted access for all users and data storage and preservation. Trusted open public databases shall have in place a robust, transparent and sustainable governance and a transparent model of user access.~~

~~7. The Commission is empowered to adopt delegated acts in accordance with Article 67 to amend the duties of the data holders in this Article, to reflect the evolution of activities performed by data holders.~~

*Article 42*

*Fees*

1. Health data access bodies ~~and~~ **or** single **health** data holders **referred to in Article 49** may charge fees for making electronic health data available for secondary use. Any fees shall include and be derived from the costs related to ~~conducting~~ the procedure for requests, including for assessing a data **access** application or a data request, granting, refusing or amending a data permit pursuant to Articles 45 and 46 or providing an answer to a data request pursuant to Article 47, in accordance with Article 6 of Regulation **(EU) 2022/868** ~~[…] [Data Governance Act COM/2020/767 final]~~.

2. Where the data in question are not held by the **health** data access body ~~or a public sector body~~, the fees may also include 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 pursuant to paragraph 1. The part of the fees linked to the **health** data holder's costs shall be paid to the **health** data holder.

~~3. The electronic health data referred to in Article 33(1), point (o), shall be made available to a new user free of charge or against a fee matching the compensation for the costs of the human and technical resources used to enrich the electronic health data. That fee shall be paid to the entity that enriched the electronic health data.~~

~~4. Any fees charged to data users pursuant to this Article by the health data access bodies or data holders shall be transparent and proportionate to the cost of collecting and making electronic health data available for secondary use, objectively justified and shall not restrict competition. The support received by the data holder from donations, public national or Union funds, to set up, develop or update tat dataset shall be excluded from this calculation. The specific interests and needs of SMEs, public bodies, Union institutions, bodies, offices and agencies involved in research, health policy or analysis, educational institutions and healthcare providers shall be taken into account when setting the fees, by reducing those fees proportionately to their size or budget.~~

5. Where **health** data holders and **health** data users do not agree on the level of the fees within 1 month of the data permit being granted, the health data access body may set the fees in proportion to the cost of making available electronic health data for secondary use.

Where the **health** data holder or the **health** data user disagree with the fee set out by the health data access body, they shall have access to dispute settlement bodies set out in accordance with Article 10 of the Regulation […] [Data Act COM/2022/68 final].

6. The Commission may, by means of implementing acts, lay down principles and rules for the fee policies and fee structures. Those implementing acts shall be adopted in accordance with the ~~advisory~~ **examination** procedure referred to in Article 68(2).

*Article 43*

*Penalties by health data access bodies **in case of non-compliance***

~~1. Health data access bodies shall monitor and supervise compliance by data users and data holders with the requirements laid down in this Chapter.~~ MOVED TO ARTICLE 37(1)(ab)

2. When **health data access bodies perform their monitoring and supervising tasks the bodies have the right to** request~~ing~~ from **health** data users and **health** data holders **all** the **necessary** information ~~that is necessary~~ to verify compliance with this Chapter**.** ~~the health data access bodies shall be proportionate to the performance of the compliance verification task.~~

3. Where health data access bodies find that a **health** data user or **a health** data holder does not comply with the requirements of this Chapter, they shall immediately notify the **health** data user or **health** data holder of those findings and shall give it the opportunity to state its views within 2 months.

4. Health data access bodies shall have the power to revoke the data permit issued pursuant to Article 46 and stop the affected electronic health data processing operation carried out by the **health** data user in order to ensure the cessation of the non-compliance referred to in paragraph 3, immediately or within a reasonable time limit, and shall take appropriate and proportionate measures aimed at ensuring compliant processing by the **health** data users. In this regard, the health data access bodies shall be able, where appropriate, to revoke the data permit and to exclude the **health** data user from any access to electronic health data **within the EHDS** for a period of up to 5 years.

5. Where **health** data holders withhold the electronic health data from health data access bodies with the manifest intention of obstructing the use of electronic health data, or do not respect the deadlines set out in Article **35B(1a)**~~41~~, the health data access body shall have the power to fine the **health** data holder with fines for each day of delay, which shall be transparent and proportionate. The amount of the fines shall be established by the health data access body. In case of repeated breaches by the **health** data holder of the obligation of ~~loyal~~ cooperation with the health data access body, that body can exclude the **health** data holder from participation in the EHDS for a period of up to 5 years. ~~Where a data holder has been excluded from the participation in the EHDS pursuant to this Article, following manifest intention of obstructing the secondary use of electronic health data, it shall not have the right to provide access to health data in accordance with Article 49~~.

6. The health data access body shall communicate the measures imposed pursuant to paragraph 4 and the reasons on which they are based to the **health** data user or holder

concerned, without delay, and shall lay down a reasonable period for the **health** data user or holder to comply with those measures.

7. Any penalties and measures imposed **by the health data access body** pursuant to paragraph 4 shall be **notified** ~~made available~~ to other health data access bodies.

8. The Commission may, by means of implementing act, set out the architecture of an IT tool aimed to support and make transparent to other health data access bodies the activities referred to in this Article, especially penalties and exclusions. Those implementing acts shall be adopted in accordance with the ~~advisory~~ **examination** procedure referred to in Article 68(2).

9. Any natural or legal person affected by a decision of a health data access body shall have the right to an effective judicial remedy against such decision.

10. The Commission may issues guidelines on penalties to be applied by the health data access bodies.

## SECTION 3

## DATA PERMIT FOR THE SECONDARY USE OF ELECTRONIC HEALTH DATA

*Article 44*

*Data minimisation and purpose limitation*

1. The health data access body shall ensure that access is only provided to requested electronic health data relevant for the purpose of processing indicated in the data access application by the **health** data user and in line with the data permit granted.

2. The health data access bodies shall provide the electronic health data in an anonymised format, where the purpose of processing by the **health** data user can be achieved with such data, taking into account the information provided by the **health** data user.

3. Where the purpose of the **health** data user's processing cannot be achieved with anonymised data, taking into account the information provided by the **health** data user, the health data access bodies shall provide access to electronic health data in pseudonymised format. The information necessary to reverse the pseudonymisation shall be available only to the health data access body **or a body that acts as trusted third party**. Data users shall not re-identify the electronic health data provided to them in pseudonymised format. The data user's failure to respect the health data access body's measures ensuring pseudonymisation shall be subject to appropriate penalties.

*Article 45*

*Data access applications*

1. A~~ny~~ natural or legal person may submit a data access application for the purposes referred to in Article 34.

2. The data access application shall include **an utilisation plan with the following information**:

   **(aa) a description of the applicant identity, professional function and operation, including the identity of who will have access to the electronic health data;**

   (a) a detailed explanation of the intended use **and benefit related to the use** of the electronic health data, including for which of the purposes referred to in Article 34(1) access is sought;

   (b) a description of the requested electronic health data, their format and data sources, where possible, including geographical coverage where data is requested from several Member States;

(c) an indication whether electronic health data ~~should~~ **need to** be made available in a~~n~~ **pseudonymised** ~~anonymised~~ format;

(d) where applicable, an explanation of the reasons for seeking access to electronic health data in a pseudonymised format;

(e) a description of the safeguards planned to prevent any ~~other use~~ **misuse** of the electronic health data, **including attempts on re-identification of natural persons in the dataset**;

(f) a description of the safeguards planned to protect the rights and interests of the **health** data holder and of the natural persons concerned;

(g) an estimation of the period during which the electronic health data is needed for processing;

(h) a description of the tools and computing resources needed for a secure environment.

3. **Health** ~~D~~**d**ata users seeking access to electronic health data from more than one Member State shall submit a single application to one of the concerned health data access bodies of their choice which shall be responsible for sharing the request with other health data access bodies and authorised participants in HealthData@EU referred to in Article 52, which have been identified in the data access application. For requests to access electronic health data from more than one Member States, the health data access body shall notify the other relevant health data access bodies of the receipt of an application relevant to them within 15 days from the date of receipt of the data access application.

4. Where the applicant intends to access the personal electronic health data in a pseudonymised format, the following additional information shall be provided together with the data access application:

(a) a description of how the processing would comply with Article**s** 6(1) **and 9(2)** of Regulation (EU) 2016/679 **or Articles 5(1) and 10(2) Regulation (EU) 2018/1725;**

(b) information on the assessment of ethical aspects of the processing, where applicable and in line with national law.

5. For the implementation of the **health data access bodies´** tasks referred to in Article 37(1), points (b) and (c), the public sector bodies and the Union institutions, bodies, offices and agencies shall provide the same information as requested under Article 45(2) **and 45(4)**, except for point (g) **in 45(2)**, where they shall submit information concerning the period for which the data can be accessed, the frequency of that access or the frequency of the data updates.

~~Where the public sector bodies and the Union institutions, bodies, offices and agencies intend to access the electronic health data in pseudonymised format, a description of how the processing would comply with Article 6(1) of Regulation (EU) 2016/679 or Article 5(1) of Regulation (EU) 2018/1725, as applicable, shall also be provided.~~

6. The Commission may, by means of implementing acts, set out the templates for the data access application referred to in this Article, the data permit referred to in Article 46 and the data request referred to in Article 47. Those implementing acts shall be adopted in accordance with the **examination** procedure referred to in Article 68(2).

~~7. The Commission is empowered to adopt delegated acts in accordance with Article 67 to amend the list of information in paragraphs 2, 4, 5 and 6 of this Article, to ensure the adequacy of the list for processing a data access application at national or cross-border level.~~

*Article 46*

*Data permit*

1. **Where the** ~~H~~**h**ealth data access bodies **shall make their decisions to grant or refuse access to electronic health data they** shall assess if the applica**n**~~tion~~ fulfils ~~one of the purposes listed in Article 34(1) of this Regulation, if the requested data is necessary for the purpose listed in the application and if the requirements in this Chapter are fulfilled by the applicant. If that is the case, the health data access body shall issue a data permit~~ **the following criterias:**

   **(a) the purposes described in the data access application matches one or more of the purposes listed in Article 34(1) of this Regulation;**

   **(b) the requested data is necessary for the purpose described in the data access application;**

   **(c) the processing complies with Articles 6(1) and 9(2) of Regulation (EU) 2016/679 or Articles 5(1) and 10(2) of Regulation (EU) 2018/1725, in case of access to pseudonymised electronic health data;**

   **(d) the information provided in the application demonstrates sufficient safeguards planned to protect the rights and interests of the health data holder and of the natural persons concerned as well as planned to prevent misuse;**

   **(e) the information on the assessment of ethical aspects of the processing, where applicable, is in line with national law;**

   **(f) other requirements in this Chapter.**

2. **If the health data access body in its assessment comes to the conclusion that the requirements in paragraph 1 are met, the health data access body shall issue a data permit.** Health data access bodies shall refuse all applications ~~including one or more purposes listed in Article 35 or~~ where **the** requirements in this Chapter are not met.

3. **By way of derogation from that Regulation (EU) 2022/868,** ~~A~~**a** health data access body shall issue or refuse a data permit within ~~2~~**3** months of receiving the data access application. ~~By way of derogation from that Regulation […] [Data Governance Act COM/2020/767 final],~~ **T**~~t~~he health data access body may extend the period for responding to a data access application by ~~2~~ **3** additional months where necessary, taking into account the complexity of the request. In such cases, the health data access body shall notify the applicant as soon as possible that more time is needed for examining the application, together with the reasons for the delay. ~~Where a health data access body fails to provide a decision within the time limit, the data permit shall be issued~~.

**3a.** When handling an access application for cross-border access to electronic health data ~~for secondary use~~ **referred to in Article 45(3)**, health data access bodies and relevant authorised participants **in HealthData@EU referred to in Article 52**, shall remain responsible for taking decisions to grant or refuse to electronic health data within their remit in accordance with the requirements for access laid down in this Chapter. ~~A data permit issued by one concerned health data access body may benefit from mutual recognition by the other concerned health data access bodies.~~ **The concerned health data access bodies and relevant authorisated participants shall inform each other of their decisions and may take the information into consideration when deciding**

**on granting or refusing access to electronic health data.** MOVED FROM ARTICLE 54(1)

4. Following the issuance of the data permit, the health data access body shall immediately request the electronic health data from the **health** data holder. The health data access body shall make available the electronic health data to the **health** data user within 2 months after receiving them from the **health** data holders, unless the health data access body specifies that it will provide the data within a longer specified timeframe.

5. When the health data access body refuses to issue a data permit, it shall provide a justification for the refusal to the applicant.

6. The data permit shall set out the general conditions applicable to the **health** data user, in particular:

   (a) ~~types~~ **categories** and format of electronic health data accessed, covered by the data permit, including their sources;

   (b) **a detailed description of the** purpose for which data are made available;

   **(ba) the identity of authorised persons who will have the right to access the electronic health data in the secure processing environment;**

   (c) duration of the data permit;

   (d) information about the technical characteristics and tools available to the **health** data user within the secure processing environment;

   (e) fees to be paid by the **health** data user;

   (f) any additional specific conditions in the data permit granted.

~~7. Data users shall have the right to access and process the electronic health data in accordance with the data permit delivered to them on the basis of this Regulation.~~ MOVED TO ARTICLE 35C(1)

~~8. The Commission is empowered to adopt delegated acts to amend the list of aspects to be covered by a data permit in paragraph **6** 7 of this Article, in accordance with the procedure set out in Article 67.~~

9. A data permit shall be issued for the duration necessary to fulfil the requested purposes which shall not exceed 5 years. This duration may be extended once, at the request of the **health** data user, based on arguments and documents to justify this extension provided, 1 month before the expiry of the data permit, for a period which cannot exceed 5 years. By way of derogation from Article 42, the health data access body may charge increasing fees to reflect the costs and risks of storing electronic health data for a longer period of time exceeding the initial 5 years. In order to reduce such costs and fees, the health data access body may also propose to the health data user to store the

dataset in storage system with reduced capabilities. The data within the secure processing environment shall be deleted within 6 months following the expiry of the data permit. Upon request of the **health** data user, the formula on the creation of the requested dataset shall be stored by the health data access body.

10. If the data permit needs to be updated, the **health** data user shall submit a request for an amendment of the data permit.

~~11. Data users shall make public the results or output of the secondary use of electronic health data, including information relevant for the provision of healthcare, no later than 18 months after the completion of the electronic health data processing or after having received the answer to the data request referred to in Article 47. Those results or output shall only contain anonymised data. The data user shall inform the health data access bodies from which a data permit was obtained and support them to make the information public on health data access bodies' websites. Whenever the data users have used electronic health data in accordance with this Chapter, they shall acknowledge the electronic health data sources and the fact that electronic health data has been obtained in the context of the EHDS.~~ MOVED TO ARTICLE 35C(3)

~~12. Data users shall inform the health data access body of any clinically significant findings that may influence the health status of the natural persons whose data are included in the dataset.~~ MOVED TO ARTICLE 35C(4)

13. The Commission may, by means of implementing act, develop a logo for acknowledging the contribution of the EHDS. That implementing act shall be adopted in accordance with the **examination** ~~advisory~~ procedure referred to in Article 68(2).

~~14. The liability of health data access bodies as joint controller is limited to the scope of the issued data permit until the completion of the processing activity.~~

*Article 47*

*Data request*

1. A~~ny~~ natural or legal person may submit a data request for the purposes referred to in Article 34. A health data access body shall only provide an answer to a data request in an anonymised statistical format and the **health** data user shall have no access to the electronic health data used to provide this answer.

2. A data request shall include the elements mentioned in paragraphs 2 (a) and (b) of Article 45 and if needed may also include:

   (a) a description of the result expected from the health data access body;

   (b) a description of the statistic's content.

3. Where an applicant has requested a result in an anonymised form, including statistical format, based on a data request, the health data access body shall assess, within ~~2~~ **3** months and, where possible, provide the result to the **health** data user within ~~2~~ **3** months.

~~*Article 48*~~

~~*Making data available for public sector bodies and Union institutions, bodies, offices and agencies without a data permit*~~

~~By derogation from Article 46 of this Regulation, a data permit shall not be required to access the electronic health data under this Article. When carrying out those tasks under Article 37 (1), points (b) and (c), the health data access body shall inform public sector bodies and the Union institutions, offices, agencies and bodies, about the availability of data within 2 months of the data access application, in accordance with Article 9 of Regulation […] [Data Governance Act COM/2020/767 final]. By way of derogation from that Regulation […] [Data Governance Act COM/2020/767 final ], the health data access body may extend the period by 2 additional months where necessary, taking into account the complexity of the request. The health data access body shall make available the electronic health data to the data user within 2 months after receiving them from the data holders, unless it specifies that it will provide the data within a longer specified timeframe.~~

*Article 49*

*Access to electronic health data from a single **health** data holder*

1. **Member States may allow** ~~W~~**w**here an applicant requests access to electronic health data only from a single **health** data holder **in that** ~~in a single~~ Member State, by way of derogation from Article 45(1) **or Article 47(1)**, that applicant ~~may~~ **to** file a data access application or a data request directly to the **health** data holder. The data access application shall comply with the requirements set out in Article 45 and the data request shall comply with requirements in Article 47. Multi-country requests and requests requiring a combination of datasets from several **health** data holders shall be adressed to health data access bodies.

**1A. Where an applicant request access to electronic health data from health data holders which are an Union institution, body, office or agency, by way of derogation from Article 45(1) or Article 47(1), that applicant shall file a data access application or a data request directly to each health data holder. The data access application shall comply with the requirements set out in Article 45 and the data request shall comply with requirements in Article 47.**

2. In ~~such case~~ **situations referred to in paragraphs 1 and 2 in this Article,** the **health** data holder may issue a data permit in accordance with Article 46 or provide an answer to a data request in accordance with Article 47. The **health** data holder shall then provide access to the electronic health data in a secure processing environment in compliance with Article 50 and may charge fees in accordance with Article 42.

~~3. By way of derogation from Article 51, the single data provider and the data user shall be deemed joint controller.~~ SEE ARTICLE 51

4. ~~Within 3 months t~~**T**he **single health** data holder**, referred to in paragraph 1 of this Article,** shall **within 3 months** inform the relevant health data access body by electronic means of all data access applications filed and all the data permits issued and the data requests fulfilled under this Article in order to enable the health data access body to fulfil its obligations under Article 37(1) and Article 39.

*Article 50*

*Secure processing environment*

1. The health data access bodies shall provide access to electronic health data **pursuant to a data permit** only through a secure processing environment, with technical and organisational measures and security and interoperability requirements. In particular, they shall take the following security measures:

   (a) restrict access to the secure processing environment to authorised persons listed in the respective data permit;

   (b) minimise the risk of the unauthorised reading, copying, modification or removal of electronic health data hosted in the secure processing environment through state-of-the-art technological means;

(c) limit the input of electronic health data and the inspection, modification or deletion of electronic health data hosted in the secure processing environment to a limited number of authorised identifiable individuals;

(d) ensure that data users have access only to the electronic health data covered by their data permit, by means of individual and unique user identities and confidential access modes only;

(e) keep identifiable logs of access to the secure processing environment for the period of time necessary to verify and audit all processing operations in that environment;

(f) ensure compliance and monitor the security measures referred to in this Article to mitigate potential security threats.

2. The health data access bodies shall ensure that electronic health data can be uploaded by **health** data holders and can be accessed by the **health** data user in a secure processing environment. The **health** data users shall only be able to download ~~non-personal~~ electronic health data **that do not constitute personal data** from the secure processing environment.

3. The health data access bodies shall ensure regular **third party** audits of the secure processing environments.

**3A.** ~~When processing personal electronic health data, data altruism organisations shall comply with the rules set out in Chapter IV of Regulation **(EU) 2018/1724** […] [Data Governance Act COM/2020/767 final].~~ Where **recognised** data altruism organisations **under Chapter IV of Regulation (EU) 2018/1724** process personal electronic health data using a secure processing environment, such environments shall also comply with the requirements set out in **point (a) to (f) in paragraph 1 in this** Article ~~50 of this Regulation~~. MOVED FROM ARTICLE 40(1)

4. The Commission shall, by means of implementing acts, provide for the technical, information security and interoperability requirements for the secure processing environments. Those implementing acts shall be adopted in accordance with the ~~advisory~~ **examination** procedure referred to in Article 68(2).

*Article 51*

*~~Joint~~ **C**ontrollers**hip***

1. ~~The health data access bodies and the data users, including Union institutions, bodies, offices and agencies, shall be deemed joint controllers of electronic health data processed in accordance with data permit.~~ **The health data holder shall be deemed controller for the disclosure of the requested personal electronic health data to the health data access body pursuant to Article 35B(1) and (1a) of this Regulation. The health data access body shall be deemed controller for the processing of the personal electronic health data when fulfilling its tasks pursuant to Article 37(1)(d) of this Regulation. The health data user shall be deemed controller for the processing of personal electronic health data in pseudonymised form in the secure processing environment pursuant to its data permit. The health data access body shall act as a processor for the health data user´s processing pursuant to a data permit in the secure processing environment.**

**1A. In situations referred to in Article 49, the single health data holder shall be deemed controller for its processing of personal electronic health data related to the providing of electronic health data to the health data user pursuant to a data permit or a data request. The single health data user shall act as a processor for the health data user´s processing pursuant to a data permit when providing a secure processing environment to the health data user.**

2. The Commission shall, by means of implementing acts, establish template **that** ~~for~~ **meet the requirements in Article 28(3) of Regulation (EU) 2016/679** ~~joint controllers' arrangement~~. Those implementing acts shall be adopted in accordance with the ~~advisory~~ **examination** procedure set out in Article 68(2).

## SECTION 4

## CROSS-BORDER ACCESS TO ELECTRONIC HEALTH DATA FOR SECONDARY USE

*Article 52*

*Cross-border infrastructure for secondary use of electronic health data (HealthData@EU)*

1. Each Member State shall designate a national contact point for secondary use of electronic health data**. The national contact point shall be an organisational and technical gateway, enabling and** responsible for making electronic health data available for secondary use in a cross-border context**. Each Member States** ~~and~~ shall **notify** ~~communicate their names and contact details to~~ the Commission **the name and contact details of the national contact point by the date of application of this Regulation**. The national contact point may be the coordinator health data access body pursuant to Article 36. The Commission and the Member States shall make this information publicly available.

2. The national contact points referred to in paragraph 1 shall be authorised participants in the cross-border infrastructure for secondary use of electronic health data (HealthData@EU). The national contact points shall facilitate the cross-border access to electronic health data for secondary use for different authorised participants in the infrastructure**. The national contact points** ~~and~~ shall cooperate closely with each other and with the Commission.

3. Union institutions, bodies, offices and agencies involved in **health-related** research, health policy or analysis, shall be authorised participants of HealthData@EU.

4. Health-related research infrastructures or similar structures whose functioning is based on Union law and which support the use of electronic health data for research, policy making, statistical, patient safety or regulatory purposes shall be authorised participants of HealthData@EU.

5. Third countries or international organisations may become authorised participants where they comply with the rules of Chapter IV of this Regulation, **the transfer stemming from such connection complies with the rules in Chapter V of Regulation (EU) 2016/679** and **they** 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. The Commission may adopt implementing acts establishing that a national contact point of a third country or a system established at an international level is compliant with requirements of HealthData@EU for the purposes of secondary use of health data, is compliant with the Chapter IV of this Regulation **and Chapter V of Regulation (EU) 2016/679** and provides access to **health** data users located in the Union to the electronic health data it has access to on equivalent terms and conditions. The compliance with these legal, organisational, technical and security requirements, including with the standards for secure processing environments pursuant to Article 50 shall be checked under the control of the Commission. These implementing acts shall be adopted in accordance with the ~~advisory~~ **examination** procedure referred to in Article 68 (2). The Commission shall make the list of implementing acts adopted pursuant to this paragraph publicly available.

6. Each authorised participant shall acquire the required technical capability to connect to and participate in HealthData@EU. Each participant shall comply with the requirements and technical specifications needed to operate the cross-border infrastructure and to allow the authorised participants to connect to each other within it.

~~7. The Commission is empowered to adopt delegated acts in accordance with Article 67 in order to amend this Article to add or remove categories of authorised participants in HealthData@EU, taking into account the opinion of the joint controllership group pursuant to Article 66 of this Regulation.~~

8. The Member States and the Commission shall set up HealthData@EU to support and facilitate the cross-border access to electronic health data for secondary use, connecting the national contact points for secondary use of electronic health data of all Member States and authorised participants in that infrastructure **and the central platform**.

9. The Commission shall develop, deploy and operate a ~~core~~ **central and interoperability** platform for HealthData@EU by providing information technology services needed to **support and** facilitate the **exchange of information** ~~connection~~ between health data access bodies as part of the cross-border infrastructure for the secondary use of electronic health data. The Commission shall only process electronic health data on behalf of the ~~joint~~ controllers as a processor.

10. Where requested by two or more health data access bodies, the Commission may provide a secure processing environment for data from more than one Member State compliant with the requirements of Article 50. Where two or more health data access bodies put electronic health data in the secure processing environment managed by the Commission, they shall be ~~joint~~ controller and the Commission shall be processor.

11. The authorised participants shall act as ~~joint~~ controllers of the processing operations in which they are involved carried out in HealthData@EU and the Commission shall act as a processor.

12. Member States and the Commission shall seek to ensure interoperability of HealthData@EU with other relevant common European data spaces as referred to in Regulations **(EU) 2022/868** ~~[…] [Data Governance Act COM/2020/767 final]~~ and […] [Data Act COM/2022/68 final].

13. The Commission may, by means of implementing acts, set out:

    (a) requirements, technical specifications, the IT architecture of HealthData@EU, conditions and compliance checks for authorised participants to join and remain connected to HealthData@EU and conditions for temporary or definitive exclusion from HealthData@EU;

    (b) the minimum criteria that need to be met by the authorised participants in the infrastructure;

    (c) the responsibilities of the ~~joint~~ controllers and processor(s) participating in the cross-border infrastructures;

(d) the responsibilities of the ~~joint~~ controllers and processor(s) for the secure environment managed by the Commission;

(e) common specifications for the interoperability and architecture concerning HealthData@EU with other common European data spaces.

Those implementing acts shall be adopted in accordance with the ~~advisory~~ **examination** procedure referred to in Article 68(2).

14. The approval for individual authorised participant to join HealthData@EU or to disconnect a participant from the infrastructure shall be issued by the **Article 66** ~~Joint Controllership~~ group, based on the results of the compliance checks.

*Article 53*

*Access to cross-border **registries or databases** ~~sources~~ of electronic health data for secondary use*

1. In the case of cross-border registries and databases, the health data access body in which the **health** data holder is registered shall be competent to decide on data access applications to provide access to electronic health data. Where **such** ~~the~~ registr~~y~~**ies or databases** has**ve** joint controllers, the health data access body that shall provide access to electronic health data shall be the body in the Member State where one of the joint controllers is established.

2. Where registries or databases from a number of Member States organise themselves into a single network of registries or databases at Union level, the associated registries may designate one of their members as a coordinator to ensure the provision of data from the registries' network for secondary use. The health data access body of the Member State in which the coordinator of the network is located shall be competent to decide on the data access applications to provide access to electronic health data for the network of registries or databases.

3. The Commission may, by means of implementing acts, adopt the necessary rules for facilitating the handling of data access applications for HealthData@EU, including a common application form, a common data permit template, standard forms for common electronic health data access contractual arrangements, and common procedures for handling cross-border requests, pursuant to Articles 45, 46, 47 and 48. Those implementing acts shall be adopted in accordance with the ~~advisory~~ **examination** procedure referred to in Article 68(2).

~~*Article 54*~~

~~*Mutual recognition*~~

~~1. When handling an access application for cross-border access to electronic health data for secondary use, health data access bodies and relevant authorised participants shall remain responsible for taking decisions to grant or refuse access to electronic health data within their remit in accordance with the requirements for access laid down in this Chapter.~~ MOVED TO ARTICLE 46(3A)

~~2. A data permit issued by one concerned health data access body may benefit from mutual recognition by the other concerned health data access bodies.~~

## SECTION 5

## HEALTH DATA QUALITY AND UTILITY FOR SECONDARY USE

*Article 55*

*Dataset description*

1. The health data access bodies shall inform the **health** data users about the available datasets and their characteristics through a metadata catalogue. Each dataset shall include information concerning the source, the scope, the main characteristics, **the** nature of electronic health data and **the** conditions for making electronic health data available.

2. The Commission shall, by means of implementing acts, set out the minimum information elements **health** data holders are to provide for datasets and their characteristics. Those implementing acts shall be adopted in accordance with the ~~advisory~~ **examination** procedure referred to in Article 68(2).

*Article 56*

*Data quality and utility label*

1. Datasets made available through health data access bodies may have a Union data quality and utility label provided by the **health** data holders.

2. Datasets with electronic health data collected and processed with the support of Union or national public funding shall have a data quality and utility label, in accordance with the ~~principles~~ **elements** set out in paragraph 3.

3. The data quality and utility label shall comply with the following elements:

   (a) for data documentation: meta-data, support documentation, data dictionary, format and standards used, provenance, and when applicable data model;

   (b) for assessment of technical quality: completeness, uniqueness, accuracy, validity, timeliness and consistency of the data;

   (c) for data quality management processes: level of maturity of the data quality management processes, including review and audit processes, biases examination;

   (d) for assement of coverage: time period, population coverage and, when applicable, representativity of population sampled, and average timeframe in which a natural person appears in a dataset;

   (e) for information on access and provision: time between the collection of the electronic health data and their addition to the dataset, time to provide electronic health data following electronic health data access application approval;

(f) for information on data enrichments: merging and adding data to an existing dataset, including links with other datasets;

4. The Commission is empowered to adopt delegated acts in accordance with Article 67 to amend the list of **elements** ~~principles~~ for data quality and utility label. Such delegated acts may also amend the list set out under paragraph 3 by adding, modifying or removing requirements for data quality and utility label.

5. The Commission shall, by means of implementing acts, set out the visual characteristics and technical specifications of the data quality and utility label, based on the elements referred to in paragraph 3. Those implementing acts shall be adopted in accordance with the ~~advisory~~ **examination** procedure referred to in Article 68(2). Those implementing acts shall take into account the requirements in Article 10 of Regulation […] [AI Act COM/2021/206 final] and any adopted common specifications or harmonised standards supporting those requirements.

*Article 57*

*EU Datasets Catalogue*

1. The Commission shall establish an EU Datasets Catalogue connecting the national catalogues of datasets established by the health data access bodies and other authorised participants in HealthData@EU.

2. The EU Datasets Catalogue and the national datasets catalogues shall be made publicly available.

*Article 58*

*Minimum dataset specifications*

The Commission may, by means of implementing acts, determine the minimum specifications for cross-border datasets for secondary use of electronic health data, taking into account existing Union infrastructures, standards, guidelines and recommendations. Those implementing acts shall be adopted in accordance with the ~~advisory~~ **examination** procedure referred to in Article 68(2).