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NOTE

From: General Secretariat of the Council
To: Delegations
Subject: Proposal for a Regulation on the European Health Data Space
- First Presidency compromise text (Chapters II and III)

Delegations will find in Annex a draft text as prepared by the Presidency on the above-mentioned subject to be examined at the meeting of the Working Party on Public Health on 18 October 2022.

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

Chapter II

Primary use of electronic health data

SECTION 1

ACCESS TO AND TRANSMISSION OF PERSONAL ELECTRONIC HEALTH DATA FOR PRIMARY USE

Article 3

Rights of natural persons in relation to the primary use of their personal electronic health data

1. Natural persons shall have the right to access their personal electronic health data processed in the context of primary use of electronic health data **and other information, in accordance with Article 15(1) of Regulation (EU) 2016/679. The access shall be provided immediately in a timely manner**, free of charge and in **a consolidated format** ~~an easily readable, consolidated and accessible form.~~
2. Natural persons shall have the right to receive an electronic copy, in the European electronic health record exchange format referred to in Article 6, of at least their **personal** electronic health data in the priority categories referred to in Article 5.
3. In accordance with Article 23 of Regulation (EU) 2016/679, Member States may restrict the scope of ~~this~~ **the right referred to in paragraph (1)** whenever necessary for the protection of the natural person based on patient safety and ethics by delaying their access to their personal electronic health data for a limited period of time until a health professional can ~~properly communicate and~~ explain to the natural person information that can have a significant impact on his or her health.
4. Where the personal health data have not been registered electronically prior to the application of this Regulation, Member States may require that such data is made available in electronic format pursuant to this Article. This shall not affect the obligation to ~~make~~ **give access to** personal electronic health data registered after the application of this Regulation ~~available in electronic format~~ pursuant to this Article.

5. Member States shall:
- (a) establish one or more electronic health data access services at national, regional or local level enabling the exercise of rights referred to in paragraphs 1 and 2;
 - (b) establish one or more proxy services enabling a natural person to authorise other natural persons of their choice to access their **personal** electronic health data, **or part thereof**, on their behalf.

The proxy services shall provide authorisations free of charge, ~~electronically or on paper~~. They shall enable guardians or other representatives to be authorised, either automatically or upon request, to access **personal** electronic health data of the natural persons whose affairs they administer **in equivalent manner as they access their personal electronic health data**. Member States may provide that authorisations do not apply whenever necessary for reasons related to the protection of the natural person, and in particular based on patient safety and ethics. The proxy services shall be interoperable among Member States.

6. Natural persons may insert **information** ~~their electronic health data~~ in their own EHR or in that of natural persons whose **personal electronic health data** ~~health information~~ they ~~can~~ **are authorised to** access, through electronic health data access services or applications linked to these services. That information shall be ~~marked~~ **clearly distinguishable** as inserted by the natural person or by his or her representative. **Natural persons shall not have the possibility to directly alter the information inserted by healthcare professionals.**
7. Member States shall ensure that, when exercising the right to rectification under Article 16 of Regulation (EU) 2016/679, natural persons can easily request **the appropriate data holder** rectification online through the electronic health data access services referred to in paragraph 5, point (a), of this Article.
8. Natural persons shall have the right to give access to or request a data holder from the health~~care~~ or social security sector to transmit; all **or part of** their electronic health data to a data recipient of their choice from the health or social security sector, ~~immediately~~ **without delay**, free of charge and without hindrance from the data holder or from the manufacturers of the systems used by that holder.

~~Natural persons shall have the right that, w~~Where the data holder and the data recipient are located in different Member States and such electronic health data belongs to the categories referred to in Article 5, the data holder shall transmit the data in the European electronic health record exchange format referred to in Article 6, ~~and t~~The data recipient shall ~~read and~~ accept **such data and shall be able to read it.**

By way of derogation from Article 9 of Regulation [...] [Data Act COM/2022/68 final], the data recipient shall not be required to compensate the data holder for making electronic health data available.

~~Natural persons shall have the right that, w~~Where priority categories of personal electronic health data referred to in Article 5 are transmitted or made available by the natural person according to the European electronic health record exchange format referred to in Article 6, ~~such data shall be read and accepted by other healthcare providers~~ **shall accept such data and shall be able to read it.**

9. ~~Notwithstanding Article 6(1), point (d), of Regulation (EU) 2016/679, n~~Natural persons shall have the right to restrict access ~~of health professionals to all or part of their electronic health data,~~ **unless the conditions specified in Article 9(2), point (c) of Regulation (EU) 2016/679 apply.** Member States shall establish the rules and specific safeguards regarding such restriction mechanisms.
10. Natural persons shall have the right to obtain information on ~~the healthcare providers and health professionals that have accessed~~ **any access to their personal** electronic health data in the context of healthcare. The information shall be provided ~~immediately~~ **automatically** and free of charge through electronic health data access services **and shall identify the person who accessed their personal electronic health data.**
11. The supervisory authority or authorities responsible for monitoring the application of Regulation (EU) 2016/679 shall also be responsible for monitoring the application of this Article, in accordance with the relevant provisions in Chapters VI, VII and VIII of Regulation (EU) 2016/679. They shall be competent to impose administrative fines up to the amount referred to in Article 83(5) of that Regulation. Those supervisory authorities and the digital health authorities referred to in Article 10 of this Regulation shall, where relevant, cooperate in the enforcement of this Regulation, within the remit of their respective competences.
12. The Commission shall, by means of implementing acts, determine the requirements concerning the technical implementation of the rights set out in this Article. Those implementing acts shall be adopted in accordance with the ~~advisory~~ **examination** procedure referred to in Article 68(2).

Article 4

Access by health professionals to personal electronic health data

1. Where they process data in an electronic format, health professionals shall:
 - (a) have access to the electronic health data of natural persons under their treatment, **on a need to know basis**, irrespective of the Member State of affiliation and the Member State of treatment;
 - (b) ensure that the personal electronic health data of the natural persons they treat are updated with information related to the health services provided.
2. In line with the data minimisation principle provided for in Regulation (EU) 2016/679, Member States ~~may~~ **shall** establish rules providing for the categories of personal electronic health data required by different health professions. Such rules shall ~~not be based on the source of electronic health data~~ **take into account the possibility of restrictions imposed according to Article 3(9)**.
3. Member States shall ensure that access to at least the priority categories of electronic health data referred to in Article 5 is made available to health professionals through health professional access services. Health professionals who are in possession of recognised electronic identification means shall have the right to use those health professional access services, free of charge.
4. Where access to electronic health data has been restricted by the natural person, the healthcare provider or health professionals shall not be informed of the content of the electronic health data without prior authorisation by the natural person, including where ~~the~~ **healthcare** provider or **health** professional is informed of the existence and nature of the restricted electronic health data. In cases where processing is necessary in order to protect the vital interests of the data subject or of another natural person, the healthcare provider or health professional may get access to the restricted electronic health data. ~~Following such access, the healthcare provider or health professional shall inform the data holder and the natural person concerned or his/her guardians that access to electronic health data had been granted.~~ Member States' law may add additional safeguards.

Article 5

Priority categories of personal electronic health data for primary use

1. Where data is ~~processed~~ **registered** in electronic format, Member States shall implement access to and exchange of personal electronic health data for primary use fully or partially falling under the following categories:
 - (a) patient summaries;
 - (b) electronic prescriptions;
 - (c) electronic dispensations;
 - (d) medical images and image reports;
 - (e) laboratory results;
 - (f) **hospital** discharge reports.

The main characteristics of the categories of electronic health data in the first subparagraph shall be as set out in Annex I.

Member States may enable a Access to and exchange of electronic health data for primary use ~~may be enabled~~ for other categories of personal electronic health data available in the EHR of natural persons.

2. The Commission is empowered to adopt delegated acts in accordance with Article 67 to amend the list of priority categories of electronic health data in paragraph 1. Such delegated acts may also amend Annex I by adding, modifying or removing the main characteristics of the priority categories of electronic health data and indicating, where relevant, deferred application date. The categories of electronic health data added through such delegated acts shall satisfy the following criteria:
 - (a) the category is relevant for health services provided to natural persons;
 - (b) according to the most recent information, the category is used in ~~a significant number~~ **the majority** of EHR systems used in Member States; **and**
 - (c) international standards exist for the category that have been examined for the possibility of their application in the Union.

Article 6

European electronic health record exchange format

1. The Commission shall, by means of implementing acts, lay down the technical specifications for the priority categories of personal electronic health data referred to in Article 5, setting out the European electronic health record exchange format. The format shall include the following elements:
 - (a) datasets containing electronic health data and defining structures, such as data fields and data groups for the content representation of clinical content and other parts of the electronic health data;
 - (b) coding systems and values to be used in datasets containing electronic health data;
 - (c) technical specifications for the exchange of electronic health data, including its content representation, standards and profiles.
 2. Those implementing acts shall be adopted in accordance with the advisory examination procedure referred to in Article 68(2). Member States shall ensure that where the priority categories of personal electronic health data referred to in Article 5 are provided by a natural person directly or transmitted to a healthcare provider by automatic means in the format referred to in paragraph 1, ~~such data shall be read and accepted by the data recipient~~ **shall accept such data and shall be able to read it**.
 3. Member States shall ensure that the priority categories of personal electronic health data referred to in Article 5 are issued in the format referred to in paragraph 1
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- 1 and that the data recipient accepts such data ~~shall be read and~~ **is able to read it** ~~accepted by the data recipient~~

Article 7

Registration of personal electronic health data

1. Member States shall ensure that, where data is processed in electronic format, health professionals ~~systematically~~ register the relevant health data falling under at least the priority categories referred to in Article 5 concerning the health services provided by them to natural persons, in the electronic format in an EHR system.
2. Where electronic health data of a natural person is registered in a Member State that is not the Member State of affiliation of that person, the Member State of treatment shall ensure that the registration is performed under the person identification data of the natural person in the Member State of affiliation.
3. The Commission shall, by means of implementing acts, determine ~~the~~ data quality requirements for the registration of electronic health data by healthcare providers and natural persons, as relevant. ~~Those implementing acts shall establish the following:~~

- ~~(a) — categories of healthcare providers that are to register health data electronically;~~
- ~~(b) — categories of health data that are to be registered systematically in electronic format by healthcare providers referred to in point (a);~~
- ~~(c) — data quality requirements pertaining to the electronic registration of health data.~~

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

Article 8

Telemedicine in the context of cross-border healthcare

~~Where a Member State accepts the provision of telemedicine services, it shall, under the same conditions, accept the provision of the services of the same type by healthcare providers located in other Member States.~~

Article 9

Identification management

1. Where a natural person uses telemedicine services or personal health data access services referred to in Article 3(5), point (a), that natural person shall have the right to identify electronically using any electronic identification means which is recognised pursuant to Article 6 of Regulation (EU) No 910/2014.
2. The Commission shall, by means of implementing acts, determine the requirements for the interoperable, cross-border identification and authentication mechanism for natural persons and health professionals, in accordance with Regulation (EU) No 910/2014 as amended by [COM(2021) 281 final]. The mechanism shall facilitate the transferability of electronic health data in a cross-border context. Those implementing acts shall be adopted in accordance with the advisory examination procedure referred to in Article 68(2).
3. The Commission shall implement services required by the interoperable, cross-border identification and authentication mechanism referred to in paragraph 2 of this Article at Union level, as part of the cross-border digital health infrastructure referred to in Article 12(3).
4. The digital health authorities and the Commission shall implement the cross-border identification and authentication mechanism at Member States' Union and Union Member States² level, respectively.

Article 10

Digital health authority

1. Each Member State shall designate a digital health authority responsible for the implementation and enforcement of this Chapter at national level. The Member State shall communicate the identity of the digital health authority to the Commission by the date of application of this Regulation. Where a designated digital health authority ~~is an entity~~ ~~consisting~~ of multiple organisations, the Member State shall communicate to the Commission a description of the separation of tasks between the organisations. The Commission shall make this information publicly available.
2. ~~Each~~ Digital health authority shall be entrusted with the following tasks:
 - (a) ensure the implementation of the rights and obligations provided for in Chapters II and III by adopting necessary national, regional or local technical solutions and by establishing relevant rules and mechanisms;
 - (b) ensure that complete and up to date information about the implementation of rights and obligations provided for in in Chapters II and III is made readily available to natural persons, health professionals and healthcare providers;
 - (c) in the implementation of technical solutions referred to in point (a), enforce their compliance with Chapter II, III and Annex II;
 - (d) contribute, at Union level, to the development of technical solutions enabling natural persons and health professionals to exercise their rights and obligations set out in this Chapter;
 - (e) facilitate for persons with disabilities to exercise their rights listed in Article 3 of this Regulation in accordance with Directive (EU) 2019/882 of the European Parliament and of the Council¹.
 - (f) supervise the national contact points for digital health and cooperate with other digital health authorities and the Commission on further development of MyHealth@EU;
 - (g) ensure the implementation, at national level, of the European electronic health record exchange format, in cooperation with national authorities and stakeholders;
 - (h) contribute, at Union level, to the development of the European electronic health record exchange format and to the elaboration of common specifications addressing interoperability, security, safety or fundamental right concerns in accordance with Article 23 and of the specifications of the EU database for EHR systems and wellness applications referred to in Article 32;

¹ Directive (EU) 2019/882 of the European Parliament and of the Council of 17 April 2019 on the accessibility requirements for products and services (Text with EEA relevance) (OJ L 151, 7.6.2019, p. 70)

- (i) where applicable, perform market surveillance activities in accordance with Article 28, while ensuring that any conflict of interest is avoided;
- (j) build national capacity for implementing interoperability and security of the primary use of electronic health data and participate in information exchanges and capacity building activities at Union level;
- (k) **support the** offer, in compliance with national legislation, **of** telemedicine services and ~~ensure~~ **promote** that such services are easy to use, accessible to different groups of natural persons and health professionals, including natural persons with disabilities, do not discriminate and offer the possibility of choosing between in person and digital services;
- (l) cooperate with market surveillance authorities, participate in the activities related to handling of risks posed by EHR systems and of serious incidents and supervise the implementation of corrective actions in accordance with Article 29;
- (m) cooperate with other relevant entities and bodies at national or Union level, to ensure interoperability, data portability and security of electronic health data, as well as with stakeholders representatives, including patients' representatives, healthcare providers, health professionals, industry associations;
- (n) cooperate with supervisory authorities in accordance with Regulation (EU) 910/2014, Regulation (EU) 2016/679 and Directive (EU) 2016/1148 of the European Parliament and of the Council² with other relevant authorities, including those competent for cybersecurity, electronic identification, the European Artificial Intelligence Board, the Medical Device Coordination Group, the European Data Innovation Board and the competent authorities under Regulation [...] [Data Act COM/2022/68 final];
- (o) draw up, in collaboration where relevant with market surveillance authorities, an **bi**annual activity report, which shall contain a comprehensive overview of its activities. The report shall be transmitted to the Commission. The **bi**annual activity report shall follow a structure that is agreed at Union level within EHDS Board, to support benchmarking pursuant to Article 59. The report shall contain at least information concerning:
 - (i) measures taken to implement this Regulation;
 - (ii) percentage of natural persons having access to different data categories of their electronic health records;
 - (iii) information on the handling of requests from natural persons on the exercise of their rights pursuant to this Regulation;

² Directive (EU) 2016/1148 of the European Parliament and of the Council of 6 July 2016 concerning measures for a high common level of security of network and information systems across the Union (OJ L 194, 19.7.2016, p. 1).

- (iv) number of healthcare providers of different types, including pharmacies, hospitals and other points of care, connected to MyHealth@EU calculated a) in absolute terms, b) as share of all healthcare providers of the same type and c) as share of natural persons that can use the services;
 - (v) volumes of electronic health data of different categories shared across borders through MyHealth@EU;
 - ~~(vi) level of natural person satisfaction with MyHealth@EU services;~~
 - (vii) number of certified EHR systems and labelled wellness applications enrolled in the EU database;
 - (viii) number of non-compliance cases with the mandatory requirements;
 - (ix) 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;
 - (x) information on cooperation with other competent bodies in particular in the area of data protection, cybersecurity, and artificial intelligence.
- ~~3. The Commission is empowered to adopt delegated acts in accordance with Article 67 to supplement this Regulation by entrusting the digital health authorities with additional tasks necessary to carry out the missions conferred on them by this Regulation and to modify the content of the annual report.~~
- ~~4. Each Member State shall ensure that each digital health authority is provided with the human, technical and financial resources, premises and infrastructure necessary for the effective performance of its tasks and exercise of its powers.~~
- ~~5. In the performance of its tasks, the digital health authority shall actively cooperate with stakeholders' representatives, including patients' representatives. Members of the digital health authority shall avoid any conflicts of interest.~~

Article 11

Right to lodge a complaint with a digital health authority

1. Without prejudice to any other administrative or judicial remedy, natural and legal persons shall have the right to lodge a complaint, individually or, where relevant, collectively, with the digital health authority, **if their rights laid down in this Regulation are affected.** Where the complaint concerns the rights of natural persons pursuant to Article 3 of this Regulation, the digital health authority shall ~~inform~~ **send a copy of the complaint to** the supervisory authorities under Regulation (EU) 2016/679 **and shall consult and cooperate with them in the handling of such complaints.**
- ~~2. The digital health authority with which the complaint has been lodged shall inform the complainant of the progress of the proceedings and of the decision taken.~~

3. Digital health authorities shall cooperate to handle and resolve complaints, including by exchanging all relevant information by electronic means, without undue delay.

Linked provisions:

Article 68

Committee procedure

1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.
2. Where reference is made to this paragraph, Article ~~4~~ 5 of Regulation (EU) No 182/2011 shall apply.

SECTION 2

CROSS-BORDER INFRASTRUCTURE FOR PRIMARY USE OF ELECTRONIC HEALTH DATA

Article 12

MyHealth@EU

1. The Commission shall establish a central platform for digital health to provide services to support and facilitate the exchange of electronic health data between national contact points for digital health of the Member States.
2. Each Member State shall designate one national contact point for digital health to ensure the connection to all other national contact points for digital health and to the central platform for digital health. Where a designated national contact point is an entity consisting of multiple organisations responsible for implementing different services, the Member State shall communicate to the Commission a description of the separation of tasks between the organisations. The national contact point for digital health shall be considered an authorised participant in the infrastructure. Each Member State shall communicate the identity of its national contact point to the Commission by [*the date of application of this Regulation*]. Such contact point may be established within the digital health authority established by Article 10 of this Regulation. Member States shall communicate to the Commission any subsequent modification of the identity of those contact points. The Commission and the Member States shall make this information publicly available.

3. Each national contact point for digital health shall enable the exchange of the personal electronic health data referred to in Article 5 with all other national contact points. The exchange shall be based on the European electronic health record exchange format.
4. The Commission shall, by means of implementing acts, adopt the necessary measures for the technical development of MyHealth@EU, detailed rules concerning the security, confidentiality and protection of electronic health data and the conditions and compliance checks necessary to join and remain connected to MyHealth@EU and conditions for temporary or definitive exclusion from MyHealth@EU. Those implementing acts shall be adopted in accordance with the ~~advisory~~ **examination** procedure referred to in Article 68(2).
5. Member States shall ensure connection of all healthcare providers to their national contact points for digital health and shall ensure that those connected are enabled to perform two-way exchange of electronic health data with the national contact point for digital health.
6. Member States shall ensure that pharmacies operating on their territories, including online pharmacies, are enabled to dispense electronic prescriptions issued by other Member States, under the conditions laid down in Article 11 of Directive 2011/24/EU. The pharmacies shall access and accept electronic prescriptions transmitted to them from other Member States through MyHealth@EU. Following dispensation of medicinal products based on an electronic prescription from another Member State, pharmacies shall report the dispensation to the Member State that issued the prescription, through MyHealth@EU.

(6a) If the Member State of treatment is different from the Member State of affiliation, the Member State of treatment shall ensure that the discharge report is exchanged with the Member State of affiliation. The Commission shall ensure that MyHealth@EU is enabled to transmit the discharge report to the Member State of affiliation.

7. The national contact points for digital health shall act as ~~joint~~ controllers of the electronic health data communicated through 'MyHealth@EU' for the processing operations in which they are involved. The Commission shall act as processor.
8. **By means of implementing acts,** ~~t~~The Commission shall, ~~by means of implementing acts, allocation of responsibilities among controllers and~~ **shall lay down the processing as regards by the processor referred to in paragraph 7 of this Article and its responsibilities towards the controllers,** in accordance with Chapter IV of Regulation (EU) 2016/679 **and of Regulation (EU) 2018/1725.** Those implementing acts shall be adopted in accordance with the ~~advisory~~ **examination** procedure referred to in Article 68(2).
9. The approval for individual authorised participants to join MyHealth@EU for different services, or to disconnect a participant shall be issued by the ~~Joint Controllership group~~ **EHDS board,** based on the results of the compliance checks **performed by the Commission.**

Article 13

Supplementary cross-border digital health services and infrastructures

1. Member States may provide through MyHealth@EU supplementary services that facilitate telemedicine, mobile health, access by natural persons to their translated health data, exchange or verification of health-related certificates, including vaccination card services supporting public health and public health monitoring or digital health systems, services and interoperable applications, with a view to achieving a high level of trust and security, enhancing continuity of care and ensuring access to safe and high-quality healthcare. The Commission shall, by means of implementing acts, set out the technical aspects of such provision. Those implementing acts shall be adopted in accordance with the ~~advisory~~ **examination** procedure referred to in Article 68(2).
2. The Commission and Member States may facilitate the exchange of electronic health data with other infrastructures, such as the Clinical Patient Management System or other services or infrastructures in the health, care or social security fields which may become authorised participants to MyHealth@EU. The Commission shall, by means of implementing acts, set out the technical aspects of such exchanges. Those implementing acts shall be adopted in accordance with the ~~advisory~~ **examination** procedure referred to in Article 68(2). The connection of another infrastructure to the central platform for digital health shall be subject to a decision of the **EHDS Board**. ~~joint controllership group for MyHealth@EU referred to in Article 66.~~
3. Member States and the Commission shall seek to ensure interoperability of MyHealth@EU with technological systems established at international level for the exchange of electronic health data. ~~The Commission may adopt an implementing act establishing that a national contact point of a third country or a system established at an international level is compliant with requirements of MyHealth@EU for the purposes of the electronic health data exchange. Before adopting such an implementing act,~~ **Based on a proposal of any Member State or of its own initiative the Commission may perform** a compliance check of the national contact point of the third country or of the system established at an international level ~~shall be performed under the control of the Commission.~~ **The compliance check shall verify the equivalence of legal, organizational, operational, semantic, technical and cybersecurity measures to those of the Member States in the operation of MyHealth@EU services. Based on the positive outcome of the compliance check, the Commission may adopt an implementing act establishing that the contact point of a third country or a system established at an international level is compliant with requirements of MyHealth@EU for the purposes of the electronic health data exchange.**

The implementing acts referred to in the first subparagraph of this paragraph shall be adopted in accordance with the **examination** procedure referred to in Article 68. The connection of the national contact point of the third country or of the system established at an international level to the central platform for digital health, as well as the decision to be disconnected shall be subject to a decision of ~~the joint controllership group for MyHealth@EU referred to in Article 66~~ **EHDS Board. Member States national security interests shall be taken into account.**

The Commission shall make the list of **national contact points of a third country or of systems established at an international level connected to the central platform for digital health** ~~implementing acts adopted pursuant to this paragraph~~ **and it shall make it** publicly available.

CHAPTER III

EHR systems and wellness applications

SECTION 1

GENERAL PROVISIONS FOR EHR SYSTEMS

Article 14

Interplay with legislation governing medical devices and AI systems

1. EHR systems intended by their manufacturer for primary use of priority categories of electronic health data referred to in Article 5 shall be subject to the provisions laid down in this Chapter.
2. This Chapter shall not apply to general software used in a healthcare environment.
3. Manufacturers of medical devices as defined in Article 2(1) of Regulation (EU) 2017/745 that claim interoperability of those medical devices with EHR systems shall prove compliance with the essential requirements on interoperability laid down in Section 2 of Annex II of this Regulation. Article 23 of this Chapter shall be applicable to those medical devices.
4. Providers of high-risk AI systems as defined in Article 6 of Regulation [...] [AI act COM/2021/206 final], which does not fall within the scope of Regulation (EU) 2017/745, that claim interoperability of those AI systems with EHR systems will need to prove compliance with the essential requirements on interoperability laid down in Section 2 of Annex II of this Regulation. Article 23 of this Chapter shall be applicable to those high-risk AI systems.
5. Member States may maintain or define specific rules for the procurement, reimbursement or financing of EHR systems in the context of the organisation, delivery or financing of healthcare services.

Article 15

Placing on the market and putting into service

1. EHR systems may be placed on the market or put into service only if they comply with the provisions laid down in this Chapter.
2. EHR systems that are manufactured and used within health institutions established in the Union and EHR systems offered as a service within the meaning of Article 1(1), point (b), of Directive (EU) 2015/1535 of the European Parliament and of the Council³ to a natural or legal person established in the Union shall be considered as having been put into service.

Article 16

Claims

In the information sheet, instructions for use or other information accompanying EHR systems, and in the advertising of EHR systems, it shall be prohibited to use text, names, trademarks, pictures and figurative or other signs that may mislead the user with regard to its intended purpose, interoperability and security by:

- (a) ascribing functions and properties to the EHR system which it does not have;
- (b) failing to inform the user of likely limitations related to interoperability or security features of the EHR system in relation to its intended purpose;
- (c) suggesting uses for the EHR system other than those stated in the technical documentation to form part of the intended purpose.

³ Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (OJ L 241, 17.9.2015, p. 1).

SECTION 2

OBLIGATIONS OF ECONOMIC OPERATORS WITH REGARD TO EHR SYSTEMS

Article 17

Obligations of manufacturers of EHR systems

1. Manufacturers of EHR systems shall:
 - (a) ensure that their EHR systems are in conformity with the essential requirements laid down in Annex II and with the common specifications in accordance with Article 23;
 - (b) draw up the technical documentation of their EHR systems in accordance with Article 24;
 - (c) ensure that their EHR systems are accompanied, free of charge for the user, by the information sheet provided for in Article 25 and clear and complete instructions for use;
 - (d) draw up an EU declaration of conformity as referred to in Article 26;
 - (e) affix the CE marking in accordance with Article 27;
 - (f) comply with the registration obligations in Article 32;
 - (g) take without undue delay any necessary corrective action in respect of their EHR systems which are not in conformity with the essential requirements laid down in Annex II, or recall or withdraw such systems;
 - (h) inform the distributors of their EHR systems and, where applicable, the authorised representative and importers of any corrective action, recall or withdrawal;
 - (i) inform the market surveillance authorities of the Member States in which they made their EHR systems available or put them into service of the non-conformity and of any corrective action taken;
 - (j) upon request of a market surveillance authority, provide it with all the information and documentation necessary to demonstrate the conformity of their EHR system with the essential requirements laid down in Annex II.
 - (k) cooperate with market surveillance authorities, at their request, on any action taken to bring their EHR systems in conformity with the essential requirements laid down in Annex II.

2. Manufacturers of EHR systems shall ensure that procedures are in place to ensure that the design, development and deployment of an EHR system continues to comply with the essential requirements laid down in Annex II and the common specifications referred to in Article 23. Changes in EHR system design or characteristics shall be adequately taken into account and reflected in the technical documentation.
3. Manufacturers of EHR systems shall keep the technical documentation and the EU declaration of conformity for 10 years after the last EHR system covered by the EU declaration of conformity has been placed on the market.

Article 18

Authorised representatives

1. Prior to making an EHR system available on the Union market, a manufacturer of an EHR system established outside of the Union shall, by written mandate, appoint an authorised representative which is established in the Union.
2. An authorised representative shall perform the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to do at least the following:
 - (a) keep the EU declaration of conformity and the technical documentation at the disposal of market surveillance authorities for the period referred to in Article 17(3);
 - (b) further to a reasoned request from a market surveillance authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of an EHR system with essential requirements laid down in Annex II;
 - (c) cooperate with the market surveillance authorities, at their request, on any corrective action taken in relation to the EHR systems covered by their mandate.

Article 19

Obligations of importers

1. Importers shall place on the Union market only EHR systems which are in conformity with the essential requirements laid down in Annex II.
2. Before making an EHR system available on the market, importers shall ensure that:
 - (a) the manufacturer has drawn up the technical documentation and the EU declaration of conformity;
 - (b) the EHR system bears the CE marking of conformity;
 - (c) the EHR system is accompanied by the information sheet referred to in Article 25 and appropriate instructions for use.
3. Importers shall indicate their name, registered trade name or registered trade mark and the address at which they can be contacted in a document accompanying the EHR system.
4. Importers shall ensure that, while an EHR system is under their responsibility, the EHR system is not altered in such a way that its conformity with essential requirements laid down in Annex II is jeopardised.
5. Where an importer considers or has reason to believe that an EHR system is not in conformity with the essential requirements in Annex II, it shall not make that system available on the market until that system has been brought into conformity. The importer shall inform without undue delay the manufacturer of such EHR system and the market surveillance authorities of the Member State in which it made the EHR system available, to that effect.
6. Importers shall keep a copy of the EU declaration of conformity at the disposal of the market surveillance authorities for the period referred to in Article 17(3) and ensure that the technical documentation can be made available to those authorities, upon request.
7. Importers shall, further to a reasoned request from a market surveillance authority, provide it with all the information and documentation necessary to demonstrate the conformity of an EHR system in the official language of the Member State where the market surveillance authority is located. They shall cooperate with that authority, at its request, on any action taken to bring their EHR systems in conformity with the essential requirements laid down in Annex II.

Article 20

Obligations of distributors

1. Before making an EHR system available on the market, distributors shall verify that:
 - (a) the manufacturer has drawn up the EU declaration of conformity;
 - (b) the EHR system bears the CE marking of conformity;
 - (c) the EHR system is accompanied by the information sheet referred to in Article 25 and appropriate instructions for use;
 - (d) where applicable, the importer has complied with the requirements set out in Article 19(3).
2. Distributors shall ensure that, while an EHR system is under their responsibility, the EHR system is not altered in such a way that its conformity with the essential requirements laid down in Annex II is jeopardised.
3. Where a distributor considers or has reason to believe that an EHR system is not in conformity with the essential requirements laid down in Annex II, it shall not make the EHR system available on the market until it has been brought into conformity. Furthermore, the distributor shall inform without undue delay the manufacturer or the importer, as well as the market surveillance authorities of the Member states where the EHR system has been made available on the market, to that effect.
4. Distributors shall, further to a reasoned request from a market surveillance authority, provide it with all the information and documentation necessary to demonstrate the conformity of an EHR system. They shall cooperate with that authority, at its request, on any action taken to bring their EHR systems in conformity with the essential requirements laid down in Annex II.

Article 21

Cases in which obligations of manufacturers of an EHR system apply to importers and distributors

An importer or distributor shall be considered a manufacturer for the purposes of this Regulation and shall be subject to the obligations laid down in Article 17, where they made an EHR system available on the market under their own name or trademark or modify an EHR system already placed on the market in such a way that conformity with the applicable requirements may be affected.

Article 22

Identification of economic operators

Economic operators shall, on request, identify the following to the market surveillance authorities, for 10 years after the last EHR system covered by the EU declaration of conformity has been placed on the market:

- (a) any economic operator who has supplied them with an EHR system;
- (b) any economic operator to whom they have supplied an EHR system.

SECTION 3

CONFORMITY OF THE EHR SYSTEM

Article 23

Common specifications

1. The Commission shall, by means of implementing acts, adopt common specifications in respect of the essential requirements set out in Annex II, including a time limit for implementing those common specifications. Where relevant, the common specifications shall take into account the specificities of medical devices and high risk AI systems referred to in paragraphs 3 and 4 of Article 14.

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

2. The common specifications referred to in paragraph 1 shall include the following elements:
 - (a) scope;
 - (b) applicability to different categories of EHR systems or functions included in them;

- (c) version;
- (d) validity period;
- (e) normative part;
- (f) explanatory part, including any relevant implementation guidelines.
3. The common specifications may include elements related to the following:
- (a) datasets containing electronic health data and defining structures, such as data fields and data groups for the representation of clinical content and other parts of the electronic health data;
- (b) coding systems and values to be used in datasets containing electronic health data;
- (c) other requirements related to data quality, such as the completeness and accuracy of electronic health data;
- (d) technical specifications, standards and profiles for the exchange of electronic health data;
- (e) requirements and principles related to security, confidentiality, integrity, patient safety and protection of electronic health data;
- (f) specifications and requirements related to identification management and the use of electronic identification.
4. EHR systems, medical devices and high risk AI systems referred to in Article 14 that are in conformity with the common specifications referred to in paragraph 1 shall be considered to be in conformity with the essential requirements covered by those specifications or parts thereof, set out in Annex II covered by those common specifications or the relevant parts of those common specifications.
5. Where common specifications covering interoperability and security requirements of EHR systems affect medical devices or high-risk AI systems falling under other acts, such as Regulations (EU) 2017/745 or [...] [AI Act COM/2021/206 final], the adoption of those common specifications ~~may~~ **shall** be preceded by a consultation with the Medical Devices Coordination Group (MDCG) referred to in Article 103 of Regulation (EU) 2017/745 or the European Artificial Intelligence Board referred to in Article 56 of Regulation [...] [AI Act COM/2021/206 final], as applicable.
6. Where common specifications covering interoperability and security requirements of medical devices or high-risk AI systems falling under other acts such as Regulation (EU) 2017/745 or Regulation [...] [AI Act COM/2021/206 final], impact EHR systems, the adoption of those common specifications shall be preceded by a consultation with the EHDS Board, especially its subgroup for Chapters II and III of this Regulation.

Article 24

Technical documentation

1. The technical documentation shall be drawn up before the EHR system is placed on the market or put into service and shall be kept up-to-date.
2. The technical documentation shall be drawn up in such a way as to demonstrate that the EHR system complies with essential requirements laid down in Annex II and provide market surveillance authorities with all the necessary information to assess the conformity of the EHR system with those requirements. It shall contain, at a minimum, the elements set out in Annex III.
3. The technical documentation shall be drawn up in one of the official languages of the Union. Following a reasoned request from the market surveillance authority of a Member State, the manufacturer shall provide a translation of the relevant parts of the technical documentation into the official language of that Member State.
4. When a market surveillance authority requests the technical documentation or a translation of parts thereof from a manufacturer, it shall set a deadline of 30 days for receipt of such documentation or translation, unless a shorter deadline is justified because of a serious and immediate risk. If the manufacturer does not comply with the requirements of paragraphs 1, 2 and 3, the market surveillance authority may require it to have a test performed by an independent body at its own expense within a specified period in order to verify the conformity with the essential requirements laid down in Annex II and the common specifications referred to in Article 23.

Article 25

Information sheet accompanying the EHR system

1. EHR systems shall be accompanied by an information sheet that includes concise, complete, correct and clear information that is relevant, accessible and comprehensible to users.
2. The information sheet referred to in paragraph 1 shall specify:
 - (a) the identity, registered trade name or registered trademark, and the contact details of the manufacturer and, where applicable, of its authorised representative;
 - (b) the name and version of the EHR system and date of its release;
 - (c) its intended purpose;

- (d) the categories of electronic health data that the EHR system has been designed to process;
 - (e) the standards, formats and specifications and versions thereof supported by the EHR system.
3. The Commission is empowered to adopt ~~delegated~~ **implementing** acts in accordance with Article ~~68~~⁶⁷ to ~~supplement this Regulation by allowing manufacturers to enter the information referred to in paragraph 2 into the EU database of EHR systems and wellness applications referred to in Article 32, as an alternative to supplying the information sheet referred to in paragraph 1 with the EHR system~~ **provided that it has been verified that the EU database of IHR systems technically supports such information.**

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

Article 26

EU declaration of conformity

1. The EU declaration of conformity shall state that the manufacturer of the EHR system has demonstrated that the essential requirements laid down in Annex II have been fulfilled.
2. Where EHR systems are subject to other Union legislation in respect of aspects not covered by this Regulation, which also requires an EU declaration of conformity by the manufacturer that fulfilment of the requirements of that legislation has been demonstrated, a single EU declaration of conformity shall be drawn up in respect of all Union acts applicable to the EHR system. The declaration shall contain all the information required for the identification of the Union legislation to which the declaration relates.
3. The EU declaration of conformity shall, ~~as a minimum,~~ contain the information set out in Annex IV and shall be translated into one or more official Union languages determined by the Member State(s) in which the EHR system is made available.
4. By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for the conformity of the EHR system.

Article 27

CE marking

1. The CE marking shall be affixed visibly, legibly and indelibly to the accompanying documents of the EHR system and, where applicable, to the packaging.
2. The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) 765/2008 of the European Parliament and of the Council⁴.

SECTION 4

MARKET SURVEILLANCE OF EHR SYSTEMS

Article 28

Market surveillance authorities

1. Regulation (EU) 2019/1020 shall apply to EHR systems covered by Chapter III of this Regulation.
2. Member States shall designate the market surveillance authority or authorities responsible for the implementation of this Chapter. They shall entrust their market surveillance authorities with the powers, resources, equipment and knowledge necessary for the proper performance of their tasks pursuant to this Regulation. Member States shall communicate the identity of the market surveillance authorities to the Commission which shall publish a list of those authorities. **The Commission and the Member States shall make this information publicly available.**
3. Market surveillance authorities designated pursuant to this Article may be the digital health authorities designated pursuant to Article 10. Where a digital health authority carries out tasks of market surveillance authority, **Member States shall ensure that any conflict of interest shall be is avoided.**

⁴ Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30).

4. Market surveillance authorities shall report to the Commission on a ~~regular~~ **yearly** basis the outcomes of relevant market surveillance activities.
5. The market surveillance authorities of the Member States shall cooperate with each other and with the Commission. The Commission shall provide for the organisation of exchanges of information necessary to that effect.
6. For medical devices or high-risk AI systems referred to in Article 14 (3) and (4), the responsible authorities for market surveillance shall be those referred to in Article 93 of Regulation (EU) 2017/745 or Article 59 of Regulation [...] [AI act COM/2021/206 final], as applicable.

Article 29

Handling of risks posed by EHR systems and of serious incidents

1. Where a market surveillance authority finds that an EHR system presents a risk to the health or safety of natural persons, **to the protection of personal data**, or to other aspects of public interest protection, it shall require the manufacturer of the EHR system concerned, its authorised representative and all other relevant economic operators to take all appropriate measures to ensure that the EHR system concerned no longer presents that risk when placed on the market to withdraw the EHR system from the market or to recall it within a reasonable period.
2. The economic operator referred to in paragraph 1 shall ensure that corrective action is taken in respect of all the EHR systems concerned that it has placed on market throughout the Union.
3. The market surveillance authority shall immediately inform the Commission and the market surveillance authorities of other Member States of the measures ordered pursuant to paragraph 1. That information shall include all available details, in particular the data necessary for the identification of the EHR system concerned, the origin and the supply chain of the EHR system, the nature of the risk involved and the nature and duration of the national measures taken.
4. Manufacturers of EHR systems placed on the market **or put into service** shall report any serious incident involving an EHR system to the market surveillance authorities of the Member States where such serious incident occurred and the corrective actions taken or envisaged by the manufacturer. **Member States may provide for users of EHR systems placed on the market or put into service to report such incidents.**

Such notification shall be made, without prejudice to incident notification requirements under Directive (EU) 2016/1148, immediately after the manufacturer has established a causal link between the EHR system and the serious incident or the reasonable likelihood of such a link, and, in any event, not later than 15 days after the manufacturer becomes aware of the serious incident involving the EHR system.

5. The market surveillance authorities referred to in paragraph 4 shall inform the other market surveillance authorities, without delay, of the serious incident and the corrective action taken or envisaged by the manufacturer or required of it to minimise the risk of recurrence of the serious incident.
6. Where the tasks of the market surveillance authority are not performed by the digital health authority, it shall cooperate with the digital health authority. It shall inform the digital health authority of any serious incidents and of EHR systems presenting a risk, including risks related to interoperability, security and patient safety, and of any corrective action, recall or withdrawal of such EHR systems.

Article 30

Handling of non-compliance

1. Where a market surveillance authority makes one of the following findings, it shall require the manufacturer of the EHR system concerned, its authorised representative and all other relevant economic operators to put an end to the non-compliance concerned:
 - (a) the EHR system is not in conformity with **the** essential requirements laid down in Annex II;
 - (b) the technical documentation is either not available or not complete;
 - (c) the EU declaration of conformity has not been drawn up or has not been drawn up correctly;
 - (d) the CE marking has been affixed in violation of Article 27 or has not been affixed.
2. Where the non-compliance referred to in paragraph 1 persists, the Member State concerned shall take all appropriate measures to restrict or prohibit the EHR system being placed on the market or ensure that it is recalled or withdrawn from the market.

SECTION 5

OTHER PROVISIONS ON INTEROPERABILITY

Article 31

~~Voluntary~~ Labelling of wellness applications

1. Where a manufacturer of a wellness application claims interoperability with an EHR system and therefore compliance with the essential requirements laid down in Annex II and common specifications in Article 23, such wellness application ~~may~~ shall be accompanied by a label, clearly indicating its compliance with those requirements. The label shall be issued by the manufacturer of the wellness application.
2. The label shall indicate the following information:
 - (a) categories of electronic health data for which compliance with essential requirements laid down in Annex II has been confirmed;
 - (b) reference to common specifications to demonstrate compliance;
 - (c) validity period of the label.
3. The Commission may, by means of implementing acts, determine the format and content of the label. Those implementing acts shall be adopted in accordance with the ~~advisory~~ examination procedure referred to in Article 68(2).
4. The label shall be drawn-up in one or more official languages of the Union or languages determined by the Member State(s) in which the ~~in which the~~ wellness application is placed on the market.
5. The validity of the label shall not exceed 5 years.
6. If the wellness application is embedded in a device, the accompanying label shall be placed on the device. Two-dimensional (2D) barcodes may also be used to display the label.
7. The market surveillance authorities ~~shall~~ may check the compliance of wellness applications with the essential requirements laid down in Annex II.
8. Each supplier of a wellness application, for which a label has been issued, shall ensure that the wellness application that is placed on the market or put into service is accompanied with the label for each individual unit, free of charge.
9. Each distributor of a wellness application for which a label has been issued shall make the label available to customers at the point of sale in electronic form or, upon request, in physical form.

10. The requirements of this Article shall not apply to wellness applications which are high-risk AI systems as defined under Regulation [...] [AI Act COM/2021/206 final].

Article 32

Registration of EHR systems and wellness applications

1. The Commission shall establish and maintain a publicly available database with information on EHR systems for which an EU declaration of conformity has been issued pursuant to Article 26 and wellness applications for which a label has been issued pursuant to Article 31.
2. Before placing on the market or putting into service an EHR system referred to in Article 14 or a wellness application referred to in Article 31, the manufacturer of such EHR system or wellness application or, where applicable, its authorised representative shall register the required data into the EU database referred to in paragraph 1.
3. Medical devices or high-risk AI systems referred to in paragraphs 3 and 4 of Article 14 of this Regulation shall be registered in the database established pursuant to Regulations (EU) 2017/745 or [...] [AI Act COM/2021/206 final], as applicable.
4. The Commission is empowered to adopt delegated acts in accordance with Article 67 to determine the list of required data to be registered by the manufacturers of EHR systems and wellness applications pursuant to paragraph 2.

ANNEX I

MAIN CHARACTERISTICS OF ELECTRONIC HEALTH DATA CATEGORIES

Electronic health data category	Main characteristics of electronic health data included under the category
1. Patient summary	<p>Electronic health data that includes important clinical facts related to an identified person and that is essential for the provision of safe and efficient healthcare to that person. The following information is part of a patient summary:</p> <ol style="list-style-type: none">1. Personal details2. Contact information3. Information on insurance4. Allergies5. Medical alerts6. Vaccination/prophylaxis information, possibly in the form of a vaccination card7. Current, resolved, closed or inactive problems8. Textual information related to medical history9. Medical devices and implants10. Procedures11. Functional status12. Current and relevant past medicines13. Social history observations related to health14. Pregnancy history15. Patient provided data16. Observation results pertaining to the health condition17. Plan of care18. Information on a rare disease such as details about the impact or characteristics of the disease
2. Electronic prescription	Electronic health data constituting a prescription for a medicinal product as defined in Article 3(k) of Directive 2011/24/EU.
3. Electronic dispensation	Information on the supply of a medicinal product to a natural person by a pharmacy based on an electronic prescription.
4. Medical image and image report	Electronic health data related to the use of or produced by technologies that are used to view the human body in order to prevent, diagnose, monitor, or treat medical conditions.

5. Laboratory result	Electronic health data representing results of studies performed notably through in vitro diagnostics such as clinical biochemistry, haematology, transfusion medicine, microbiology, immunology, and others, and including, where relevant, reports supporting the interpretation of the results.
6. Discharge report	Electronic health data related to a healthcare encounter or episode of care and including essential information about admission, treatment and discharge of a natural person.

ANNEX II

ESSENTIAL REQUIREMENTS FOR EHR SYSTEMS AND PRODUCTS CLAIMING INTEROPERABILITY WITH EHR SYSTEMS

The essential requirements laid down in this Annex shall apply *mutatis mutandis* to products claiming interoperability with EHR systems.

1. General requirements

- 1.1. An electronic health record system (EHR system) shall achieve the performance intended by its manufacturer and shall be designed and manufactured in such a way that, during normal conditions of use, it is suitable for its intended purpose and its use does not put at risk patient safety.
- 1.2. An EHR system shall be designed and developed in such a way that it can be supplied and installed, taking into account the instructions and information provided by the manufacturer, without adversely affecting its characteristics and performance during its intended use.
- 1.3. An EHR system shall be designed and developed in such a way that its interoperability, safety and security features uphold the rights of natural persons, in line with the intended purpose of the EHR system, as set out in Chapter II of this Regulation.
- 1.4. An EHR system that is intended to be operated together with other products, including medical devices, shall be designed and manufactured in such a way that interoperability and compatibility are reliable and secure, and personal electronic health data can be shared between the device and the EHR system.

2. Requirements for interoperability

- 2.1. An EHR system shall allow personal electronic health data to be shared between health professionals or other entities from the health system, and between health professionals and patient or health professional portals in a commonly used electronic interoperable format, which includes, inter-alia, dataset content, data structures, formats, vocabularies, taxonomies, exchange formats, standards, specifications, profiles for exchange and code lists, thus enabling system to system communication.

- 2.2. An EHR system shall be interoperable and compatible with the European infrastructures set out in this Regulation for the cross-border sharing of electronic health data.
- 2.3. An EHR system that includes a functionality for entering structured personal electronic health data shall enable the entry of data structured in a structured way that supports the data sharing in a structured, commonly used and machine-readable format, enabling system to system communication.
- 2.4. An EHR system shall not include features that prohibit, restrict or place undue burden on authorised access, personal electronic health data sharing, or use of personal electronic health data for permitted purposes.
- 2.5. An EHR system shall not include features that prohibit, restrict or place undue burden on authorised exporting of personal electronic health data for the reasons of replacing the EHR system by another product.

3. Requirements for security

- 3.1. An EHR system shall be designed and developed in such a way that it ensures safe and secure processing of electronic health data, and that it prevents unauthorised access to such data.
- 3.2. An EHR system designed to be used by health professionals shall provide reliable mechanisms for the identification and authentication of health professionals, including checks on professional rights and qualifications.
- 3.3. An EHR system designed to be used by health professionals shall support the use of information on professional rights and qualifications as part of the access control mechanisms, such as role-based access control.
- 3.4. An EHR system designed to enable access by health professionals or other individuals to personal electronic health data shall provide sufficient logging mechanisms that record, at least the following information on every access event or group of events:
 - (a) identification of the health professional or other individual having accessed electronic health data;
 - (b) identification of the individual;
 - (c) categories of data accessed;
 - (d) time and date of access;
 - (e) origin(s) of data.

- 3.5. An EHR system shall include tools and mechanism to allow natural persons to restrict health professionals' access to their personal electronic health data. It shall also include mechanisms that allow access to personal electronic health data in emergency situations, and ensure that access is strictly logged.
- 3.6. An EHR system shall include tools or mechanisms to review and analyse the log data, or it shall support the connection and use of external software for the same purposes.
- 3.7. An EHR system designed to be used by health professionals shall support digital signatures or similar non-repudiation mechanisms.
- 3.8. An EHR system designed for the storage of electronic health data shall support different retention periods and access rights that take into account the origins and categories of electronic health data.
- 3.9. An EHR system designed to be used by natural persons shall enable their identification using any recognised electronic identification means as defined in Regulation (EU) No 910/2014, regardless of the Member State that has issued it. If the service supports other electronic identification means, they shall be of assurance levels 'substantial' or 'high'.

ANNEX III

TECHNICAL DOCUMENTATION

The technical documentation referred to in Article 24 shall contain at least the following information, as applicable to the relevant EHR system:

1. A detailed description of the EHR system including:
 - (a) its intended purpose, the date and the version of the EHR system;
 - (b) the categories of electronic health data that the EHR system has been designed to process;
 - (c) how the EHR system interacts or can be used to interact with hardware or software that is not part of the EHR system itself;
 - (d) the versions of relevant software or firmware and any requirement related to version update;
 - (e) the description of all forms in which the EHR system is placed on the market or put into service;
 - (f) the description of hardware on which the EHR system is intended to run;
 - (g) a description of the system architecture explaining how software components build on or feed into each other and integrate into the overall processing, including where appropriate, labelled pictorial representations (e.g. diagrams and drawings), clearly indicating key parts/components and including sufficient explanation to understand the drawings and diagrams;
 - (h) the technical specifications, such as features, dimensions and performance attributes, of the EHR system and any variants/configurations and accessories that would typically appear in the product specification made available to the user, for example in brochures, catalogues and similar publications, including a detailed description of the data structures, storage and input/output of data;
 - (i) a description of any change made to the system throughout its lifecycle;
 - (j) the instructions of use for the user and, where applicable, installation instructions.
2. A detailed description of the system in place to evaluate the EHR system performance, where applicable.
3. The references to any common specification used in accordance with Article 23 and in relation to which conformity is declared.

4. The results and critical analyses of all verifications and validation tests undertaken to demonstrate conformity of the EHR system with the requirements laid down in Chapter III of this Regulation, in particular the applicable essential requirements;
5. A copy of the information sheet referred to in Article 25.
6. A copy of the EU declaration of conformity.

ANNEX IV

EU DECLARATION OF CONFORMITY

The EU declaration of conformity shall contain all of the following information:

1. The name of the EHR system, version and any additional unambiguous reference allowing identification of the EHR system.
 2. Name and address of the manufacturer or, where applicable, their authorised representative.
 3. A statement that the EU declaration of conformity is issued under the sole responsibility of the manufacturer.
 4. A statement that the EHR system in question is in conformity with the provisions laid down in Chapter III of this Regulation and, if applicable, with any other relevant EU legislation that provides for the issuing of an EU declaration of conformity.
 5. References to any relevant harmonized standards used and in relation to which conformity is declared.
 6. References to any common specifications used and in relation to which conformity is declared.
 7. Place and date of issue of the declaration, signature plus name and function of the person who signed, and, if applicable, an indication of the person on whose behalf it was signed.
 8. Where applicable, additional information.
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