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CONTRIBUTION

From:	General Secretariat of the Council
To:	Working Party on Public Health (Attachés) Working Party on Public Health (European Health Data Space)
Subject:	Proposal for a regulation on the European Health Data Space - Comments from delegations following the Working Party on Public Health of 9-10 November 2023

Delegations will find enclosed comments from the Austrian, Belgian, Danish, Dutch, Finnish, French, German, Hungarian, Irish, Italian, Latvian, Polish, Slovak, Slovenian and Swedish delegations on the above mentioned subject following the Working Party on Public Health of 9-10 November 2023.

Written contributions from delegations

Comments from the Austrian delegation

EU Member State	AUSTRIA

BLOCK 1: Primary Use of Health Data (1)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 1	X		
[MOD.PU.1] Article 31A moved to recital (35A) • **Article 31A** moved to **recital (35A)**	X		No alternative wording but a general remark: Under Art. 168 para. 7 TFEU, this statement is a matter of course and of a purely declarative nature, which should have no place even in the recitals of a Regulation. It must be noted once again that the CLS opinion on Art. 168/7 TFEU, which was requested more than a year ago, is unfortunately still not available.
[MOD.PU.4.rev1] Modification of chapeau of Article 5(1) • "For the purposes of this Chapter" instead of the previous text in the chapeau of **Article 5(1)**	X		
[MOD.PU.5.rev1] Modification of definition of EHR system • The definition of EHR system is modified in **Article 2(2)(n)**	X		No alternative wording but a still remaining question: The modified definition of EHR systems is still ambiguous and leaves room for interpretation regarding its scope. Especially if it applies to different levels of health information systems, this could be problematic in light of the interoperability requirements laid out in Annex II – on which system level(s) shall interoperability be achieved?
[MOD.PU.18.rev1] Clarification in **Article 5(1A)**	X		

BLOCK 2: Primary Use of Health Data (2)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 2	X		
[MOD.PU.3.rev1] Modification of Article 6 to allow the inclusion of unstructured data • Deletion of "structured" in **Article 6(1)**	X		
[MOD.PU.8.rev1] Clarification, in a recital, about the inclusion of healthcare professionals of primary care teams in the healthcare professionals of **Article 7A [recital (15C)]** • New recital (15AA)	X		
[MOD.PU.12.rev1] Modification **of Article 7A**	X		

BLOCK 3: Primary Use of Health Data (3)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 3		X	
[MOD.PU.13.rev1] Modification of **Article 8A**	X		
[MOD.PU.16.rev1] Modification of **Article 8D**		X	**The whole Article should be deleted from the Regulation.** Para. 2 appears to be a divergence from the prevailing pull-logic (a healthcare provider, who is treating a patient, requests the patient data) in MyHealth@EU to a push-logic. This is not only inconvenient and brings many technical drawbacks, but is simply not supported by MyHealth@EU. As in our opinion, Data Portability already fulfilled by the established pulls of data via MyHealth@EU, we propose the deletion of this provision. Regarding para.3, how shall this transmission be achieved between natural person and healthcare provider? Due to security concerns, healthcare providers are in practice often reluctant to accept data from unknown sources. Will such data, originating from another healthcare provider but transmitted by a patient, count as data generated by a patient or by a healthcare provider in light of Article 8B? Due to all this uncertainty, this provision should also be deleted. And without paras. 2 and 3, para. 1 of this Article no longer has any meaning, so that the whole Article should be completely deleted from the Regulation.
[MOD.PU.14.rev1] Clarification of scope in **Article 8E(1)**	X		No alternative wording proposal but a grammatical remark. The current wording could allow for an interpretation that would only allow an opt-out from the 8G-Services, rather than the primary use itself, as intended. We would therefore appreciate that clarification.
[MOD.PU.2.rev2] Implementing act for harmonised technical specifications in **Article 8E(3)**	X		
[MOD.PU.17.rev1] Modification of **Article 8F**	X		See the grammatical remark on Art. 8E(1) above.

BLOCK 4: Primary Use of Health Data (4)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 4	X		
[MOD.PU.7.rev1] Clarification of relationship between the GDPR and EHDS **in Articles 8A-G and 11A [recitals (5A)-(16)]**	X		
[MOD.PU.9.rev1] Clarification of relationship between the GDPR and EHDS **in Article 12 [recitals (24)-(25)]**	X		
[MOD.PU.6.rev1] Deletion of **Article 12(6a)**	X		

BLOCK 5: Primary Use of Health Data (5)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 5		X	
[MOD.PU.10.rev1] Market harmonization approach for EHR systems based on components & Clarification of definition and scope of cross-border requirements [many articles, **Annexes II-IV, recitals (20), (27), (28A)]**		X	**Delete all references to a "single market" (recital 27) and "internal market" (Art. 70 para. 1 lit. a sublit. aa) from the whole Regulation.** Without a complete harmonization, which the current compromise text is far from achieving, there can naturally be no single/internal market for EHR systems. Also here, the CLS opinion on Art. 168/7 TFEU, which was requested more than a year ago, would serve to clarify such matters.

BLOCK 6: Primary Use of Health Data (6)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 6	X		
[MOD.PU.11.rev1] Creation of a European testing environment for the primary use of health data [**Article 26A]**	X		

BLOCK 7: Primary Use of Health Data (7)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 7	**X**		
[MOD.PU.15.rev1] Clarification of competences of DPAs [**Article 11A and recital (16A)**]	**X**		

Comments from the Belgian delegation

EU Member State	BELGIUM

BLOCK 1: Primary Use of Health Data (1)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 1	X		
[MOD.PU.1] Article 31A moved to recital (35A) • **Article 31A** moved to **recital (35A)**			
[MOD.PU.4.rev1] Modification of chapeau of Article 5(1) • "For the purposes of this Chapter" instead of the previous text in the chapeau of **Article 5(1)**			
[MOD.PU.5.rev1] Modification of definition of EHR system • The definition of EHR system is modified in **Article 2(2)(n)**			
[MOD.PU.18.rev1] Clarification in **Article 5(1A)**			

BLOCK 2: Primary Use of Health Data (2)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 2	X		
[MOD.PU.3.rev1] Modification of Article 6 to allow the inclusion of unstructured data • Deletion of "structured" in **Article 6(1)**			
[MOD.PU.8.rev1] Clarification, in a recital, about the inclusion of healthcare professionals of primary care teams in the healthcare professionals of **Article 7A [recital (15C)]** • New recital (15AA)			
[MOD.PU.12.rev1] Modification **of Article 7A**			

BLOCK 3: Primary Use of Health Data (3)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 3	X		
[MOD.PU.13.rev1] Modification of **Article 8A**			
[MOD.PU.16.rev1] Modification of **Article 8D**			

[MOD.PU.14.rev1] Clarification of scope in **Article 8E(1)**			
[MOD.PU.2.rev2] Implementing act for harmonised technical specifications in **Article 8E(3)**			
[MOD.PU.17.rev1] Modification of **Article 8F**			

BLOCK 4: Primary Use of Health Data (4)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 4		X	
[MOD.PU.7.rev1] Clarification of relationship between the GDPR and EHDS **in Articles 8A-G and 11A [recitals (5A)-(16)]**			
[MOD.PU.9.rev1] Clarification of relationship between the GDPR and EHDS **in Article 12 [recitals (24)-(25)]**			The Commission shall establish a central and interoperability platform for digital health, MyHealth@EU, **and shall establish and operate generally available services** ~~to provide services~~ to support and facilitate the exchange of personal electronic health data.
[MOD.PU.6.rev1] Deletion of **Article 12(6a)**			

Motivation

We agree with DK proposal for art. 8G: This functionality shall be free of charge and shall be facilitated by ~~**the European Digital Identy Wallets**~~ **a central and interoperability platform** ~~**in accordance with COM (2021) 281:**~~

For the proposed change in ar. 12: MS risk a fragmented implementation of proxy services that is costly to develop. The goal is to keep the data exchange process open and not to limit the possibilities. There should be free or charge and voluntary services put to disposition of MS so that not all MS have to develop there own proxy services with the risks that interoperability will be hampered. It would be ideal if these processes could be set up and reused efficiently, without imposing obligations on MS to use these services. In order to reduce the likelihood of multiple, incompatible solutions across Member States and promoting interoperability in the development and deployment of technologies, we need to ensure interoperable solutions across Member States and avoid the development of multiple individual solutions. This requires a coordinated and collaborative approach. Establishing a central coordination platform is a key element in facilitating a coordinated and collaborative approach across Member States. This central coordination platform can reference already existing services that can be reused by other member states.

BLOCK 5: Primary Use of Health Data (5)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 5	X		
[MOD.PU.10.rev1] Market harmonization approach for EHR systems based on components & Clarification of definition and scope of crossborder requirements [many articles, **Annexes II-IV, recitals (20), (27), (28A)]**			

BLOCK 6: Primary Use of Health Data (6)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 6		X	
[MOD.PU.11.rev1] Creation of a European testing environment for the primary use of health data [**Article 26A]**			3. Manufacturers **shall** ~~**may**~~ use the testing environments mentioned in paragraphs 1 and 2 as a supporting element for self-certification. [MOD.PU.12.rev1]

Motivation:

The statement, "*Manufacturers **shall** use the testing environments mentioned*," should be written in a way that conveys a mandatory requirement. The use of "*shall*" is important for enforcement because it makes the requirement binding. If the term "*shall*" is not used, it would leave the choice of whether to use the testing environments up to the discretion of the manufacturers. This could lead to inconsistency and a lack of accountability in the testing process. The statement is emphasizing that when a manufacturer **declares conformity with certain standards or regulations**, it is not acceptable for them to claim conformity if they have not used the specified testing environments or if the tests conducted in those environments all failed. In other words, manufacturers are expected to adhere to the prescribed testing procedures and achieve the required standards for their products to be considered in compliance.

We want to remind everybody that **this BE proposal** to create a testing environment was a **compromise proposal** for those MS that wanted absolutely a **third party assessment** (comparable with notified bodies) and MS that think that this is much to complex and costly. This BE compromise proposal is much cheaper than a third parties assessment, but it gives some extra guarantee. We know that this is not a 100 % guarantee and that of course the manufacturer stays always responsible. But without an **obligation** and **publicity of the resultas** (e.g. in de declaration of conformity: we need to add the results of this testing environment), it will have the same cost and burden but has NO ADDED VALUE at all.

BLOCK 7: Primary Use of Health Data (7)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 7	X		
[MOD.PU.15.rev1] Clarification of competences of DPAs [**Article 11A and recital (16A)**]			

Art. 70 Evaluation and review

Article 70

Evaluation and review

(aa) ~~**contribution**~~ **review and adaptation** to the functioning of the Internal Market for the EHR systems

Motivation:
"*Contribution*" is a broad and open-ended term that can be interpreted in various ways. Using a term like "*review and adaptation*" provides a more precise and clearer description of the intended action. It conveys a specific process that needs to be undertaken. "*review and adaptation*" implies specific actions that need to be taken to improve and refine EHR systems. This aligns with the PDCA cycle, which emphasizes continuous improvement through a structured process

Comments from the Danish delegation

Article 8G ***Electronic health data access services for natural persons and their representatives***	***Article 8G*** ***Electronic health data access services for natural persons and their representatives***
1. Member States shall **ensure that** ~~establish~~ one or more electronic health data access services at national, regional or local level **are established** enabling **natural persons access to their personal electronic health data and** the exercise of rights referred to in ~~paragraphs 1 and 2~~ **Articles 8A to 8F.** MOVED FROM ARTICLE 3(5)(a):	1. Member States shall may **ensure that** ~~establish~~ one or more electronic health data access services at national, regional or local level **are established** enabling **natural persons access to their personal electronic health data and** the exercise of rights referred to in ~~paragraphs 1 and 2~~ **Articles 8A to 8F.** MOVED FROM ARTICLE 3(5)(a):
2. **Member States shall ensure that** ~~establish~~ one or more proxy services **are established as a functionality of health data access services** enabling a natural person**s** to**:** **(a) authorise other natural persons of their choice to access their personal electronic health data, or part thereof, on their behalf; and;** **(d) have access to the personal electronic health data of natural persons whose affairs they administer as legal guardians;** **in an equivalent manner as they access their personal electronic health data and to manage those authorisations.** 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 electronic health data of the natural persons whose affairs they administer.~~ Member States **shall establish rules regarding such authorisations, actions of guardians and representantives** ~~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. MOVED FROM ARTICLE 3(5)(b) AND SUBPARA 2	2. **Member States ~~shall~~ may ~~ensure that~~** ~~establish~~ **establish interoperable rules for the European Health Data Space regarding authorisations, actions of guardians and representatives. In particular, Member States may ensure that** ~~one or more proxy services are established as~~ **a functionality of health data access services is made available** enabling a natural person**s** to**:** **(a) authorise other natural persons of their choice to access their personal electronic health data, or part thereof, on their behalf; and;** **(d) have access to the personal electronic health data of natural persons whose affairs they administer as legal guardians;** **in an equivalent manner as they access their personal electronic health data and to manage those authorisations.** **This functionality shall be free of charge and shall be facilitated by the European Digital Identity Wallets in accordance with [COM(2021) 281 final]. Means for identification and authentication may also be provided on paper or by eID means of Member States' national health care systems.** ~~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 electronic health data of the natural persons whose affairs they administer.~~ ~~Member States **shall establish rules regarding such authorisations, actions of guardians and representantives** 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~~
3. The access to the electronic health data services as referred to in paragraph 1 shall be free of charge for the natural persons and their representatives.	

	~~ethics. The proxy services shall be interoperable among Member States. MOVED FROM ARTICLE 3(5)(b) AND SUBPARA 2~~
	2a. For the purposes of paragraph 2, the Commission shall, by means of an implementing act, lay down the technical specifications for a scheme of a Qualified Electronic Attestation of Attribute to be issued to European Digital Identity Wallets (in accordance with Article 45c and Annex V of eIDAS), that can express relevant authorisations for a given natural person. This implementing act shall be adopted in accordance with the examination procedure referred to in Article 68(2).
	3. The access to the electronic health data services as referred to in paragraph 1 shall be free of charge for the natural persons and their representatives.

Justification of the new wording:

It is important that article 8G is revised to secure viable solutions for proxy services. Digital proxy services should be aligned with the work under the revision of the eIDAS Act. The infrastructure that is going to support the identities for legal and natural persons under the eIDAS Act is not yet mature enough to support the implementation of digital proxy solutions within the scope of the EHDS. As the negotiations of the eIDAS Act are currently still ongoing it is unclear when this will be possible.

It is essential that there is a more horizontal approach in the EHDS that is clearly aligned with the ongoing negotiations of the eIDAS Act. This is the right approach to ensure an interoperable solution across Member States and to avoid the development of multiple individual solutions in different sectors with future data spaces. Firstly, it will reduce the level of user-friendliness for end-users if there is a multitude of solutions across sectors instead of one horizontal solutions. Secondly, it will be an unnecessary burden, both administrative and financially, to Member States. Therefore, article 8G(2) is made voluntary for the Member States, as we support the purpose of having solutions for power of attorney. Additionally, we propose to align this article with eIDAS2 by inserting a reference. This is to ensure an interoperable solution across Member States and to avoid the development of multiple individual solutions in different sectors with future dataspaces.

EU Member State	Denmark

General remark

We encourage the Presidency to ensure that the terminology is consistent throughout the recitals and articles in the regulation. This is especially important in the descriptions of the interplay between EHDS and both national legislations and EU-regulation.

BLOCK 1: Primary Use of Health Data (1)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 1		**x**	
[MOD.PU.1] Article 31A moved to recital (35A) • **Article 31A** moved to **recital (35A)**	x		
[MOD.PU.4.rev1] Modification of chapeau of Article 5(1) • "For the purposes of this Chapter" instead of the previous text in the chapeau of **Article 5(1)**	x		
[MOD.PU.5.rev1] Modification of definition of EHR system • The definition of EHR system is modified in **Article 2(2)(n)**	x		
[MOD.PU.18.rev1] Clarification in **Article 5(1A)**		x	Article 5 1A. Member States may enable access to an exchange of personal electronic health data for primary use pursuant to this Chapter for additional categories of personal electronic health data available in the EHR of natural persons. **Where Member States enable such additional categories of personal electronic heath data in a cross-border context, this Chapter shall fully apply.** Justification This article goes too far in regulating the sharing of health data outside the scope of EHDS in the Member States' national context. The article has to respect Article 168(7) in TFEU. An alternative to our proposed changes is to maintain the wording in the Swedish compromise text.

BLOCK 2: Primary Use of Health Data (2)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 2		**x**	

[MOD.PU.3.rev1] Modification of Article 6 to allow the inclusion of unstructured data • Deletion of "structured" in **Article 6(1)**	x		
[MOD.PU.8.rev1] Clarification, in a recital, about the inclusion of healthcare professionals of primary care teams in the healthcare professionals of **Article 7A [recital (15C)]** • New recital (15C)	x		
[MOD.PU.12.rev1] Modification **of Article 7A**		x	Article 7A 3. Where access to electronic health data has been restricted by the natural person pursuant to Article 8E, the healthcare provider or health professionals shall ~~not~~ be informed of the ~~content~~ existence of restricted ~~the~~ electronic health data. Access to these restricted electronic health data shall be provided with the consent of the natural person or in case of an immediate life-threatening situation where access to the data is of vital importance to the patients' health and survival. ~~without prior authorization by the natural person, including where healthcare provider or health professional is informed of the existence and nature of the restricted electronic health data~~. […]. Justification We support the overall aim of this article, including the "breaking-the-glass"-option for health professionals. However, it is important to include in the paragraph that health professionals shall be informed if data has been restricted by the patient. As we have stated before, Denmark is of the opinion that it represents a tangible and very high risk for both the patient and the health professional, if health professionals are not informed.

BLOCK 3: Primary Use of Health Data (3)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 3		**x**	
[MOD.PU.13.rev1] Modification of **Article 8A**	x		
[MOD.PU.16.rev1] Modification of **Article 8D**		x	Article 8D 1. Natural persons shall have the right to give access to or request a healthcare provider to ~~transmit~~ exchange, all or part of their electronic health data […]. 2. […] the transmitting provider shall ~~transmit~~ exchange the data in the European electronic health record exchange format referred to in Article 12. The receiving healthcare

			provider shall accept such data and be able to read it. 3. […] they shall be able to **~~transmit~~ exchange** that data to healthcare providers of their choice […]. 4. The Commission shall, by means of implementing acts, determine the requirements concerning the technical implementation of the rights **in cross-border context** set out in this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 68(2). Justification We do not agree with only using the word 'transmitted' as it should be up to MS how they will share the data. Furthermore, we find it important to ensure that this article only regulates what is necessary in a cross-border context.
[MOD.PU.14.rev1] Clarification of scope in **Article 8E(1)**		x	Article 8E 2. […] (a) the healthcare provider **or other individuals** who accessed the personal electronic data; Justification Information of the natural person's access should also be logged. This is important for the patient safety as it allows the natural person to notice potential identity-theft. This should also be reflected in Article 2(2)(nd), recital (12A) and be in line with Annex II (3.4). Furthermore, we would like to underline that it is important for Denmark that the formulation remains "healthcare provider" and is not changed to "healthcare professional" in this Article and recital (12A). Denmark recognizes the importance of being able to identify the person who has accessed a person's electronic health data. However, it is necessary to create a balance between patient rights and the need to protect health professionals in situations with conflicts and threats from patients.
[MOD.PU.2.rev2] Implementing act for harmonised technical specifications in **Article 8E(3)**		x	Denmark does not support the addition of the implementing act. It should be up to Member States to determine the requirements for the technical implementation. If Article 8E(3) is maintained, we suggest to clarify that the implementing act only regards logging (in line with recital 12A) and not restrictions: Article 8E 3. The Commission may, by means of implementing acts, determine the requirements for the technical implementation of the rights set out in **paragraph 2 of** this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 68(2).

[MOD.PU.17.rev1] Modification of **Article 8F**	x		

BLOCK 4: Primary Use of Health Data (4)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 4		**x**	
[MOD.PU.7.rev1] Clarification of relationship between the GDPR and EHDS **in Articles 8A-G and 11A [recitals (5A)-(16)]**		x	Recital 12A Moreover, the access to personal health records should be transparent to the natural persons. The health data access services should provide detailed information on accesses to data, such as when which healthcare provider **or other individuals**, accessed which data. To ensure uniform implementation, the Commission should be empowered to lay down detailed elements in an implementing act. Justification Information of the natural person's access should also be logged. This is important for the patient safety as it allows the natural person to notice potential identity-theft. This should also be reflected in Article 2(2)(nd), Article 8E(2) and be in line with Annex II (3.4). Recital 15 We recommend adding 'or share' as we believe it should be up to MS how they will share the data: "[…]. Electronic health data made available in interoperable format, which can be ~~transmit~~ **exchange** between healthcare providers can also reduce the administrative burden on health professionals […]." Recital 15 B Natural persons should be able to provide an authorisation to the natural persons of their choice, such as to their relatives or other close natural persons, enabling them to access or control access to their personal electronic health data or to use digital health services on their behalf. Such authorisations may also be useful for convenience reasons in other situations. Proxy services for enabling such authorisations should be established by Member States to implement these authorisations, and they should be linked to personal health data access services, such as patient portals on patient-facing mobile applications. The proxy services should also enable guardians to act on behalf of their dependent children; in such situations, authorisations could be automatic. In order to take into account cases in which the display of some personal electronic health data of minors to their guardians could be contrary to the interests or will of the minor, Member States should be able to provide for such limitations and safeguards in national law, as well as the necessary technical implementation. Personal health data access services, such as patient portals or mobile applications, should make use of such authorisations and thus enable authorised

			natural persons to access personal electronic health data falling within the remit of the authorisation, in order for them to produce the desired effect. **Digital proxy solutions are to be aligned with eIDAS2 and the technical specifications of the Wallet In order to ensure a horizontal solution with increased user-friendliness for end-users. Furthermore, this will reduce both administrative financial burdens for Member States by reducing the risk of building up parallel systems that are not interoperable across the EU.** Justification In line with our remarks to Article 8G, we suggest this addition for the recital.
[MOD.PU.9.rev1] Clarification of relationship between the GDPR and EHDS **in Article 12 [recitals (24)-(25)]**	x		
[MOD.PU.6.rev1] Deletion of **Article 12(6a)**	x		

BLOCK 5: Primary Use of Health Data (5)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 5		**x**	
[MOD.PU.10.rev1] Market harmonization approach for EHR systems based on components & Clarification of definition and scope of cross-border requirements [many articles, **Annexes II-IV, recitals (20), (27), (28A)]**		x	Article 2(2)(nb) 'software component' or 'component' means a discrete part of software ~~**that is dedicated to specific functions or procedures**~~ **which provides specific functionality and**, which can operate ~~**independently or**~~ in conjunction with other components. Components are designed to be reusable and to integrate seamlessly with other components within a larger software system; Justification We believe that the definition of a "component" is too narrow, since not all systems consist of discrete components. Instead, we suggest focusing on the functions that the systems must support. We will send our written comments. Article 2(2)(nd) 'European logging component for EHR systems' (or 'the logging component') means a discrete software component of the EHR system which provides logging information relating to access of health professionals **or other individuals** to personal electronic health data in the format defined in Annex II.3.4 of this Regulation; […]. Justification Information of the natural person's access should also be logged. This is important for the patient safety as it allows the natural person to

			notice potential identity-theft. This should also be reflected in Article 8E(2), recital (12A) and be in line with Annex II (3.4). Annex II (2.1.a) 2.1.a. ~~Where a~~An EHR system **or a national infrastructure** is designed to store or intermediate personal electronic health data, it shall ~~provide an interface enabling~~ **enable** access to the personal electronic health data processed by it in the European health record exchange format, by means of the European interoperability component ~~for EHR systems~~. Justification We find the requirement for all EHR-systems to provide an interface enabling access to the personal health data too extensive. It would be very costly to change all the systems that do not already have such an interface. In Denmark, we provide access to data through a national infrastructure enabling interoperability between separate systems at the local level. Therefore, we suggest to provide flexibility for Member States to decide how the access to data is provided i.e. directly from the local systems or through a national infrastructure.

BLOCK 6: Primary Use of Health Data (6)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 6	**x**		
[MOD.PU.11.rev1] Creation of a European testing environment for the primary use of health data [**Article 26A]**	x		

BLOCK 7: Primary Use of Health Data (7)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 7		**x**	
[MOD.PU.15.rev1] Clarification of competences of DPAs [**Article 11A and recital (16A)]**			We suggest the following addition to recital (16A): Recital (16A) […]. **The supervisory authority or authorities responsible for monitoring and enforcement of the processing of personal electronic health data for primary use shall be competent to impose administrative fines. In Member States where the legal systems does not provide for administrative fines, the rules on administrative fines may be applied in such a manner that the fines are initiated by the competent supervisory authority and imposed by competent**

			national courts as a criminal penalty, provided that such an application of the rules has an equivalent effect to administrative fines imposed by the supervisory authority. In any event, the fines shall be effective, proportionate and dissuasive. Justification For constitutional reasons it is crucial for Denmark that the administrative fines can be imposed in the manner described in our suggestion.

Comments from the Dutch delegation

Recitals

(19) The level of availability of personal health and genetic data in an electronic format varies between Member States. The EHDS should make it easier for natural persons to have those data available in electronic format. This would also contribute to the achievement of the target of 100% of Union citizens having access to their electronic health records by 2030, as referred to in the Policy Programme "Path to the Digital Decade". In order to make electronic health data accessible and transmissible, such data should be accessed and transmitted in an interoperable common European electronic health record exchange format, at least for certain categories of electronic health data, such as patient summaries, electronic prescriptions and dispensations, medical images and image reports, laboratory results and discharge reports, subject to transition periods. Where personal electronic health data is made available to a healthcare provider or a pharmacy by a natural person, or is transmitted by another data controller in the European electronic health record exchange format, the electronic health data should be read and accepted for the provision of healthcare or for dispensation of a medicinal product, thus supporting the provision of the health care services or the dispensation of the electronic prescription. Commission Recommendation (EU) 2019/243[7] provides the foundations for such a common European electronic health record exchange format. The use of European electronic health record exchange format should become more generalised at EU and national level. While the eHealth Network under Article 14 of Directive 2011/24/EU of the European Parliament and of the Council[8] recommended Member States to use the European electronic health record exchange format in procurements, in order to improve interoperability, uptake was limited in practice, resulting in fragmented landscape and uneven access to and portability of electronic health data. Where it concerns hospital discharge reports, the transmission of such reports only takes place when there is a follow-up treatment, or when the patient concerned agrees to such transmission.

Commented [A1]: *Reference article 5 and article 12*
Explanation:
Refering to the explanation of the EC, the transmission of hospital discharge reports should only take place when there is a basis upon which this transmission can take place. This would be either a situation where there is follow-up treatment, or the patient agrees with the transmission. This addition in a recital is in conformity with the deletion of para 6A of article 12.

{Article 8E, restriction part + Article 7A(3)} Natural persons may not want to allow access to some parts of their personal electronic health data while enabling access to other parts. Such selective sharing of personal electronic health data should be supported. However, such restrictions may have life threatening consequences and, therefore, access to personal electronic health data should be possible to protect vital interests as an emergency override. According to Regulation (EU) 2016/679, vital interests refer to situations in which it is necessary to protect an interest which is essential for the life of the data subject or that of another natural person. Processing of personal electronic health data based on the vital interest of another natural person should in principle take

place only where the processing cannot be manifestly based on another legal basis. More specific legal provisions on the mechanisms of restrictions placed by the natural person on parts of their personal electronic health data ~~should~~ may be provided by Member States in national law. Because the unavailability of the restricted personal electronic health data may impact the provision or quality of health services provided to the natural person, ~~he/she~~ they should assume responsibility for the fact that the healthcare provider cannot take the data into account when providing health services. An emergency override is not possible if a natural persons has exerciced the right, where this is provided by Member States, to object to their personal electronic health data being made available.

Commented [A2]: it is advisable to clairify in this recital what the relationship is between 7A(3) and 8F, as is done in recital 13A

(13A) {8F} ~~In addition~~ Member States may provide for natural persons to have the right to object to their personal electronic health data to be made available ~~a full opt out~~, without an emergency override, both for cross-border access and inside that Member State. If they choose to do so, they should establish the rules and specific safeguards regarding such mechanisms in line with Article 9(4) of Regulation (EU) 2016/67.

Commented [A3]: See explanation suggested alteration of the title of article 8F.

(15) {Article 7B} Timely and full access of health professionals to the medical records of patients is fundamental for ensuring continuity of care and avoiding duplications and errors. However, due to a lack of interoperability, in many cases, health professionals cannot access the complete medical records of their patients and cannot make optimal medical decisions for their diagnosis and treatment, which adds considerable costs for both health systems and natural persons and may lead to worse health outcomes for natural persons. Electronic health data made available in interoperable format, which can be transmitted between healthcare providers can also reduce the administrative burden on health professionals of manually entering or copying health data between electronic systems. Therefore, health professionals should be provided with appropriate electronic means, such as health professional portals, to use personal electronic health data for the exercise of their duties. Providing this service to health professionals , can be considered as a task in the public interest if assigned by national law ~~this Regulation~~ whose performance requires the processing of personal in the sense of Article 6(1)(e) of Regulation (EU) 2016/679. ~~Article 9(2), point (h), of Regulation (EU) 2016/679 provides for exceptions where the processing of senstitive data is necessary for the purposes of preventive or~~

Commented [A4]: *Explanation: (not main position, but considered important)*

1. If article 6(1)(e) should be considered as a the legal base for private legal entities to process personal data, including health care data (health professional access services need to process personal health data in order to be able to allocate to data) additional guarantees should be given in order to make sure these data are processed safely and securely (or MS should have that option) --> see proposition in artikel 7B.
2. This regulation does not assign a task of public interest as stipulated in this phrase.
So it should be noted in the recital that national law should regulate the task carried out in the public interest.
3. We wonder what this legal base means in light with 87 GDPR. In the Netherlands, the processing of a Dutch social security number is only allowed if this is established by national law.
4. Health professional access services will also process personal health data in order to be able to allocate to data. Which base in article 9(2) GDPR should be used? And if 9(2)(h), what does this entail for the right, mentioned in article 17 GDPR?

~~occupational medicine, for the assessment of the working capacity of the employee, medical diagnosis, the provision of health care or treatment or the management of health care systems and services on the basis of Union or Member State law.~~ This Regulation ~~should~~ provide**s** conditions and safeguards for the processing of electronic health data ~~by healthcare providers and health professionals~~ **in the health professional access service** in line with Article 9(2), point (h), of Regulation (EU) 2016/679**, such as detailed provisions on logging to provide transparency towards data subjects.** ~~with the purpose of accessing personal electronic health data provided by the natural person or transmitted from other healthcare providers.~~ However, this Regulation should be without prejudice to the national laws concerning the processing of health data **for the delivery of healthcare**, including the legislation establishing categories of health professionals that can process different categories of electronic health data.

(15A) **{Article 8G(1)}** **In order to facilitate the exercise of the complementary access and portability rights established under this Regulation, Member States should establish technical solutions ~~most fitting to the~~ suitable for their ~~national~~ health information systems that allows ~~for~~ natural persons to access their personal electronic health data ~~one or more electronic health data accecss serveices to provide.~~ These services can for example be provided as an online patient portal or via a mobile application. They should be designed in an accessible way, including for persons with disabilities. Proving such a service to enable natural persons with easy access to their personal electronic health data is a substantial public interest. The processing of personal electronic health data in these services can be considered as ~~is~~ necessary for the performance of that task if assigned by national law ~~this Regulation~~ in the sense of Articles 6(1)(e) and 9(2) of Regulation (EU) 2016/679.**

(25) ~~In the context of~~ MyHealth@EU~~, a central platform should provide~~ **provides** a common infrastructure for the Member States to ensure connectivity and interoperability in an efficient and secure way **to support cross-border healthcare. The Commission should, as a processor on behalf of the Member States, provide this infrastructure.** In order to guarantee compliance with data protection rules and to provide a risk management framework for the transmission of personal electronic

Commented [A5]: We have introduced some amended wording to add clarity that Member States are free to decide the most fitting technical solution to allow citizens to access their personal electronic health data.

Commented [A6]: See previous comment

health data, ~~the Commission should, by means of implementing acts, allocate~~ specific responsibilities ~~among~~ **of** the Member States, as ~~joint~~ controllers, and ~~prescribe its own obligations, as processor.~~ **the Commission's obligations should be laid down in detail in implementing acts. This Regulation requires national law to provide the legal basis for the processing of personal electronic health data in this infrastructure, as a task carried out in the public interest assigned by Union law in the sense of Article 6(1)(e) of Regulation (EU) 2016/679. This processing is necessary for the provision of healthcare, as mentioned in Article 9(2)(h) of that Regulation, in cross-border situations.**

Article 2

Definitions

(…)

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

(d) 'primary use of electronic health data' means the processing of personal electronic health data for the provision of health**care** ~~services~~ to assess, maintain or restore the state of health of the natural person to whom that data relates, including the prescription, dispensation and provision of medicinal products and medical devices. ~~as well as for relevant social security, administrative or reimbursement services.~~

Article 2A

Registration of personal electronic health data [MOVED FROM ARTICLE 7]

1. ~~Memebr States shall ensure that~~ **Where** data is processed in electronic format **for the provision of healthcare, healthcare providers** ~~health professionals~~ shall ~~systematically:~~

(a) register the relevant **personal** health data falling **fully or partially** 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. [MOVED FROM ARTICLE 7(1) AND AMENDED], and;

Commented [A7]: This regulation does not in itself create this task, but requires MS to do so, therefore the addition in the recital

Commented [A8]: The use of these legal bases in the GDPR means that the rights under article 17 GDPR no longer applies. We believe that this should be mentioned in the recital.

Commented [A9]: *Explanation:*

As discussed during our bilateral talk, we believe that the definition of primary use should only entail the use of personal electronic health data for the delivery of care and should not be used for purposes outside the healthcare sector.

(b) ~~**1.A Where they process data in an electronic format, health professional, healthcare providesrs shall**~~ ensure that the personal electronic health data of the natural persons they treat are updated with information related to the health**care** ~~services~~ provided. [MOVED FROM ARTICLE 4(1)(b) AND AMENDED]

Commented [A10]: In the compromise text, the relationship between paragraph 1 and 1A was not clear enough. As a seperate paragraph, 1A was unclear and could be interpreted as a much broader obligation than was intended.

Article 7A

Access by health professionals to personal electronic health data [MOVED FROM ARTICLE 4]

1. **Member States shall ensure that w**~~W~~here ~~they~~ **health professionals** process **personal** **electronic** health data ~~**through the health professional authorised access services referred to in Article 7B**~~ ~~in an electronic form,~~ **they** ~~health professionals~~ shall~~: (a)~~ have access to the **personal** electronic health data of natural persons under their treatment, irrespective of the Member State of affiliation and the Member State of treatment.~~:~~ [MOVED FROM ARTICLE 4(1)(a)]

Commented [A11]: We have moved the reference to article 7B to para 1A. Through this way para 1 describes the right of a person (what), while para 1A describes how this right should be facilitated (how). We believe it creates clarity in article 7A.

1A. Acces to the electronic health data of the natural person under treatment shall be made available for health professionals of the Member States of affiliation through the health professional authorised access services referred to in Article 7B. **Where the Member States of affiliation of the natural person under treatment and the Member States of treatment differ, cross-border access to the electronic health data of the natural person under treatment shall be provided through the infrastructure referred to in Article 12** ~~**via the national contact point**~~**. [MOD.PU.12.rev1]**

2. **The access referred to in paragraphs** ~~**1 and 1A**~~ **shall include at least the priority categories in Article 5** ~~**and in line with the principles provided for in Article 5 of Regulation (EU) 2016/679 and only where there is a valid legal basis under Article 6 and the conditions of Article 9(2) and (3) of the same Regulation are fulfilled.**~~ **[MOD.PU.12.rev1]**. In line with the ~~data minimisation~~ principle**s** provided for in Article 5 of the Regulation (EU) 2016/679, Member States may **also** establish rules providing for the categories of personal electronic health data required by different health professionals. Such rules shall ~~not be based on the source of electronic health data~~ **take into account the possibility of restrictions imposed in according to Article 8E.** [MOVED FROM ARTICLE 4(2) AND AMENDED]

Commented [A12]: Changes to make it in line with amendment in para 1

3~~4~~. Where access to electronic health data has been restricted by the natural person **pursuant to Article 8E**, 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 **as referred to in Article 9(2)(c) of the Regulation (EU) 2016/679**, 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 controller of the personal electronic health data data holder and the natural person concerned or his/her guardians that access to electronic health data had been granted.**~~ **Such events shall be logged in a clear and understandable format. Following such access, het healthcare provider or health professional shall inform the natural person concerned or his/her guardians that access had been granted ~~easily accessible for the natural person.~~ [MOD.PU.12.rev1]** Member States' law may **set out** ~~add~~ additional safeguards. [MOVED FROM ARTICLE 4(4) AND AMENDED]. **This article does not apply ~~if~~ where Member States have provided the right for natural persons to object to their personal electronic health data being made available, and a natural person has exercised this right pursuent to article 8F.**

4. The access referred to in paragraph 1 may be limited if:

a. Member States have provided the right for natural persons to object to their personal electronic health data are made available and exchanged, pursuent to article 8F, and a natural person has exercised this right; or

b. if natural persons have exercised the right, referred to in article 8E, first paragraph.

Article 7B

Health professional authorised access services

1. **For the provision of healthcare,** 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. **Those services shall be accessible only to ~~H~~h**ealth professionals ~~with~~ **who are in possession of** recognised

Commented [A13]: The Netherlands prefers to maintain the obligation to actively inform natural persons in case of breaking-the-glass. This is considered to be an important requirement for the breach of privacy and trust of natural persons in the suggested system in the EHDS.

Commented [A14]: *Explanation:*
It is advisable to clarify that the emergency override is not possible in case a natural person has opted out. This is mentioned in the recitals, but needs in our opinion also mentioning in the articles.

Commented [A15]: *Explanation:*
MS cannot ensure right to access for health care professionals in other Member States, because natural persons may have the right to object to the availability of the data (8F) and have the right to limit access. It is therefore advisable to clarify that the right to access is not absolute. It is also advisable to clarify that breaking-the-glass is not possible in case of an 8F-opt out (right to object).

electronic identification means ~~shall have the right to use those health professional access services,~~ and the access shall be free of charge. [MOVED FROM ARTICLE 4(3) AND AMENDED]

2. **In line with the principles provided for in Article 5 of the Regulation (EU) 2016/679, Member States may establish rules for the technical development of health professional authorised access services, detailed rules concerning the security, confidentiality and protection of personal electronic health data and the conditions and compliance checks necessary to be considered a health professional authorised access services.**

Commented [A16]: *Explanation*
See explanation given at recital 15.

Article 8A

Right of natural persons to access their personal electronic health data

1. Natural persons shall have the right to access their personal electronic health data**, at a minimum ~~such~~ data that belongs the priority categories in Article 5,** processed **for the provision of healthcare** ~~in the context of primary use of electronic health data~~ **~~and other information, in the meaning of Article 15(1) of Regulation (EU) 2016/679,~~ through the electronic health data access services of the Member State of affiliation referred to in Article 8G. The access shall be provided immediately after the personal electronic health data has been registered in an EHR system, while adhering to technological practicability**, free of charge and in an easily readable, consolidated and accessible form. [MOVED FROM ARTICLE 3(1) AND AMENDED]

Commented [A17]: *Explanation:*
As discussed on 12/10/23, NL finds it undesirable that natural persons need several electronic health data access services: if a Dutch natural has had healthcare a few times in Belgium, and that person had an accident in Austria, the person will need to consult 3 different electronic health data access services, and most likely those services will not be available in the languages of all the MS.

Since the aim of the EHDS is to make it easier for natural persons to exercise their rights, it is therefore advisable to regulate that the natural person will only be able to exercise the mentioned right via an electronic health data access services of the Member State of affiliation.

2. Natural persons shall have the right to receive an electronic copy**, free of charge**, **through the electronic health data access services of the Member State of affiliation referred to in Article 8G,** 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. [MOVED FROM ARTICLE 3(2) AMENDED]

3. In accordance with Article 23 of Regulation (EU) 2016/679, Member States may restrict the scope of ~~this~~ **the** right**s referred to in paragraphs 1 and 2, ~~in particular~~** 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 their health. [MOVED FROM ARTICLE 3(3)]

Article 8B

Right of natural persons to insert information in their own EHR

Member States may allow n~~N~~atural persons **or their representatives as referred to in Article 8G(2) to** ~~may~~ insert **information** ~~their electronic health data~~ in their own EHR ~~or in that of natural persons whose health information they can access,~~ through electronic health data access services **of the Member State of affiliation** or applications linked to these services **as referred to in Article 8G**. That information shall **in such cases** 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 electronic health data and related information inserted by health professionals.** [MOVED FROM ARTICLE 3(6)]

Article 8C

Right of natural persons to rectification

~~Member States shall ensure that, w~~**W**hen exercising the right to rectification under Article 16 of tRegulation (EU) 2016/679, natural persons **shall** ~~can~~ **be able to** easily request, **online through the electronic health data access services** services **of the Member State of affiliation referred to in Article 8G, the relevant controller of the personal electronic health data,** ~~rectification online through the electronic health data access services referred to in paragraph 5, point (a), of this Article~~ **to rectify their personal electronic health data**. [MOVED FROM ARTICLE 3(7) AND AMENDED]

Commented [A18]: *Explanation*

In the recital it is clarified that the controller of the data concerns the "relevant controller", not being the legal entity that is the administrator of access services. This needs a translation in article 8C. In the Netherlands it is not unlikely that there are several controllers of data. In other articles the wording is "transmitting provider". Do these terms have different meanings?

Member States may also enable natural persons to exercise other rights pursuant to Chapter III of Regulation (EU) 2016/679 online through the electronic health data access services of the Member State of affiliation referred to in Article 8G.

Article 8E

Right to restrict access and information on access

1. ~~Notwithstanding Article 6(1), point (d), of Regulation (EU) 2016/679, n~~**N**atural persons shall have the right to restrict access of health professionals **and healthcare providers** to ~~all or part of~~ their **personal** electronic health data **refered to in Article**

8A(1) and accessible through the electronic health data access services referred to in Article 8G of the Member State of affiliation. Such restriction of access may be derogated from under the conditions laid down to in Article 7A(3). [MOD.PU.14.rev1]

Member States shall establish the rules and specific safeguards regarding such restriction mechanisms. [MOVED FROM ARTICLE 3(9)]

2. 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 **through the health professional access service or the infrastructure referred to in Article 12 [MOD.PU.14.rev1]** in the context **of** healthcare. The information shall be provided ~~immediately~~ **without delay** and free of charge through electronic health data access services. **The information shall include, at least, the following:**

(a) the healthcare provider who accessed the personal electronic health data;

(b) the date and time of access;

(c) the personal electronic health data that was accessed. [MOVED FROM ARTICLE 3(10)]

3. **The Commission may, by means of implementing acts, determine the requirements for the technical implementation of the rights set out in this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 68(2). [MOD.PU.2.rev1]**

Article 8F

***Right of natural person to ~~object~~ object* [MOD.PU.17.rev1]**

~~1. Member States may provide for natural persons to have the right to object to the access to their personal electronic health data registered in an EHR system by electronic health data access services referred to in Article 8G.~~

~~If a Member State provides for such a right, it shall establish the rules and specific safeguards regarding such objection mechanisms.~~

Commented [A19]: Since access to personal data is also accessible via MyHealth@EU, this right should also be applicable if that data is accessed through that infrastructure. Otherwise it is not necessarily clear for natural persons which healthcare professional has had access.

Commented [A20]: We wonder if the term "Opt out" is correct. This term derives from telecommunication law. In telecommunication law someone can opt out from "assumed permision". However, the EHDS-regulation entails a legal obligation to make data availabel (7A). This means that the ehds- regulation does not lead to "assumed permision" or - in line with this - "opt out".

Commented [A21]: We suggest to delete this paragraph. It is undesirable that natural persons can exclude legal guardians as mentioned in 8G (2) (b) from their eletronic health data access service, because this wil make it impossible for legal guardians to perform their legal duties. For the people, mentioned in 8G (g) (a), this paragraph does not have aditional value; it goes without saying that if a natural person can authorise other natural persons to access their personal electronic health data, they can als withdraw this autorisation (or should be mentioned in 8G).

We assume that the this paragraph was intended to regulate that the objection mat be registered in a electronic data access service. In order to regulate this, we made a suggestion in the second paragraph, sub b.

Commented [A22]: We suggest to delete this paragraph. It is undesirable that natural persons can exclude legal guardians as mentioned in 8G (2) (b) from their eletronic health data access service, because this wil make it impossible for legal guardians to perform their legal duties. For the people, mentioned in 8G (g) (a), this paragraph does not have aditional value; it goes without saying that if a natural person can authorise other natural persons to access their personal electronic health data, they can als withdraw this autorisation (or should be mentioned in 8G).

We assume that the this paragraph was intended to regulate that the objection mat be registered in a electronic data access service. In order to regulate this, we made a suggestion in the second paragraph, sub b.

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1. With regard to ~~cross-border~~ access to personal electronic health data referred to in Article 5, paragraphs 1 and 1A, Member States may provide for natural persons to have the right to object to their personal electronic health data ~~are~~ to be made available for:

a. cross-border access and exchange with Member States, other than the Member State of affiliation, through the cross-border infrastructure as referred to in Article 12;

b. national access and exchange through the health professional authorised access services referred to in Article 7B .

2. If a Member State provides for a right referred to in paragraph 1, it

a. shall establish the rules and specific safeguards regarding such objection mechanisms ; and

b. provide for natural persons to exercise the right to object at least through the electronic health data access services referred to in Article 8G of the Member State of affiliation.

Article 8G

Electronic health data access services for natural persons and their representatives

1. Member States shall **ensure that** ~~establish~~ one or more electronic health data access services at national, regional or local level **are established** enabling **natural persons access to their personal electronic health data and** the exercise of rights referred to in ~~paragraphs 1 and 2~~ **Articles 8A to 8F.** [MOVED FROM ARTICLE 3(5)(a)]

2. Member States shall ensure that ~~establish~~ one or more proxy services **are established as a functionality of health data access services** enabling ~~a~~ natural person**s** to**:**

(a) authorise other natural persons of their choice to access their personal electronic health data, or part thereof, on their behalf; and;

(b) have access to the personal electronic health data of natural persons whose affairs they administer as legal guardians

in an equivalent manner as they access their personal electronic health data and to manage those authorisations.

The proxy services shall provide authorisations free of charge, electronically or on paper. ~~They shall enable guardians or other representatives to be authorised, either~~

Commented [A23]: We suggest to clarify that this right is an option for both prioritised data as the for the data that MS want to bring under the action of Chapter II.

Commented [A24]: We suggest to add this phrase, to clarify that article 8F does not concern access and exchange with countries, other than Member States.

Commented [A25]: We suggest to add this paragraph in line with the newly added recital 13A.

~~automatically or upon request, to access electronic health data of the natural persons whose affairs they administer~~.

Member States **shall establish rules regarding such authorisations, actions of guardians and representantives** ~~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. [MOVED FROM ARTICLE 3(5)(b) AND SUBPARA 2]

3. **The access to the electronic health data services as referred to in paragraph 1 shall be free of charge for the natural persons and their representatives.**

4. **In line with the principles provided for in Article 5 of the Regulation (EU) 2016/679, Member States may establish rules for the technical development of electronic health data access services for natural persons and their representatives, detailed rules concerning the security, confidentiality and protection of personal electronic health data and the conditions and compliance checks necessary to be considered a Health professional authorised access services.**

Commented [A26]: See explanation given at recital 15a.

Article 12

MyHealth@EU

3. Each national contact point for digital health **is vested with the authority to process personal electronic health data referred to in article 5 for the purpose of** ~~shall~~ **enable ing their exchange** ~~of their personal electronic health data referred to in Article 5~~ with ~~all other~~ national contact points **in other Member States through MyHealth@EU**. The exchange shall be based on the European electronic health record exchange format.

Commented [A27]: The proposed text is hard to reconcile with the requirements the GDPR has for a legal basis in articles 6(3) and 9(1) in conjunction with the last sentence of recital 41 as well as recitals 52-54 GDPR. Therefore it is necessary to create a clear basis for processing by the national contact points in the body of the proposal.

This could for example be rectified by making it clear that the designation of a national contact point comes with a basis for processing.

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Article 13

Supplementary cross-border digital health services and infrastructures

2. The Commission and Member States may facilitate the exchange of **personal** 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 field~~ 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).

4. Section I of this Chapter is not applicable for the access and exchange data via supplementary services, infrastructures, a national contact point of a third country or a system established at an international level.

Article 26A

European digital testing environment

3. Manufacturers shall ~~may~~ use the testing environments mentioned in paragraphs 1 and 2 as a supporting element for self-certification. [MOD.PU.12.rev1]

Commented [A28]: It is advisable to clarify that the legal base to access and echange data via supplementary services, infrastructures or with third countries, needs to be found in the in articles 6 and 9 of the GPDR. This entails that consent may be the legal basis if MS decide so. The system that follows from Chapter II, section I (obligation to make data accessible and in line with that, the right to object and limit access) are not therefor not applicable for the options in artikel 13.
In our view, article 63 is insufficient to regulate this.

Commented [A29]: The Netherlands is of the strong opinion that the use of the digital test environment (either at EU level or national) should be made obligatory. The current proposal is already very light for both manufacturers and Member States to implement. Introducing the obligation to use the test environment helps us Member States to achieve the goals of the EHDS, namely interoperability of electronic health data. This report can also then be a tool for the market supervisor to ensure compliance to the specifications of the EHDS.

Comments from the Finnish delegation

EU Member State	Finland

BLOCK 1: Primary Use of Health Data (1)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 1			
[MOD.PU.1] Article 31A moved to recital (35A) □ **Article 31A** moved to **recital (35A)**			
[MOD.PU.4.rev1] Modification of chapeau of Article 5(1) □ "For the purposes of this Chapter" instead of the previous text in the chapeau of **Article 5(1)**		x	Article 5 1. Where data is processed in electronic format, Member States shall implement access to and exchange of personal electronic health data for primary use falling under the following categories
[MOD.PU.5.rev1] Modification of definition of EHR system □ The definition of EHR system is modified in **Article 2(2)(n)**		x	n) 'EHR system'(electronic health record system) means any system where the appliance or software intended by the manufacturer for use by healthcare professionals in providing patient care for to be used for **processing** electronic health records personal electronic health data that belongs to the priority categories of personal electronic health data as referred to in Article 5(1) of this Regulation. EHR systems may also provide electronic health data access services.
[MOD.PU.18.rev1] Clarification in **Article 5(1A)**		x	Member States may enable access to and exchange of personal electronic health data for primary use pursuant to this Chapter for additional other categories of personal electronic health data available in the EHR of natural persons.

Commented [A30]: Has this change been made, because it would be possible for the MS to regulate wellness applications without it being mentioned and it is clarified in the recital, or does this change have some wider effect? It is unclear in relation to Article 31 what is actually the national margin of manoeuvre in this respect.

Commented [A31]: In the recitals: EHR systems may also be used by other persons than healthcare professionals, for example medical students. Processing refers to storing, intermediating, importing, exporting, converting, editing or viewing.

Commented [A32]: We should keep wellbeing applications and other technical solutions which give patients access to their health data separate from the systems that are being used in providing patient care.

BLOCK 2: Primary Use of Health Data (2)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 2			

[MOD.PU.3.rev1] Modification of Article 6 to allow the inclusion of unstructured data □ Deletion of "structured" in **Article 6(1)**	x		
[MOD.PU.8.rev1] Clarification, in a recital, about the inclusion of healthcare professionals of primary care teams in the healthcare professionals of **Article 7A [recital (15C)]** □ New recital (15AA)	x		
[MOD.PU.12.rev1] Modification **of Article 7A**		x	Following such access, the natural person will be informed that access to their electronic health data has been granted through the electronic health data access services. Such events shall also be logged in a clear and understandable format and shall be easily accessible for the natural persons.

Commented [A33]: Article 6 does not seem to be in line with recital 20, which states that "The European electronic health record exchange format should have two profiles: a simple technical specification for national use applicable to EHR systems and a detailed technical specification for cross-border use, which should only apply to the national contact points for eHealth". This Article does not mention these two profiles and it is not explained how they would actually work.

Commented [A34]: It should be ensured that there is a treatment relationship.

Commented [A35]: In a recital: Informing the natural person may be done for example by a notification in the access services.

BLOCK 3: Primary Use of Health Data (3)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 3			
[MOD.PU.13.rev1] Modification of **Article 8A**		x	3. In accordance with Article 23 of Regulation (EU) 2016/679, Member States may restrict the scope of the rights referred to in paragraphs 1 and 2, **in particular** 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 their health.
[MOD.PU.16.rev1] Modification of **Article 8D**			
[MOD.PU.14.rev1] Clarification of scope in **Article 8E(1)**		x	Natural persons shall have the right to restrict access of health professionals and healthcare providers to their personal electronic health data. Member States shall establish the rules and specific safeguards regarding such restriction mechanisms.
[MOD.PU.2.rev2] Implementing act for harmonised technical specifications in **Article 8E(3)**	x		
[MOD.PU.17.rev1] Modification of **Article 8F**		x	Delete this Article.

Commented [A36]: We do not support deleting "in particular", because we would want to restrict this right also in other situations than what are being mentioned here, for example in situations where the information could have a serious negative effect on the mental health of the patient. We would like to keep "in particular" or then move the ending of the paragraph in the recitals.

Commented [A37]: We are not sure if sending copies of the health data to another healthcare provider would be logical, if they would already have access to the data with Article 7A. Maybe it would have made more sense to send some parts of the health data to a provider of reimbursement services for example. But this idea of sending copies to another healthcare provider seems old-fashioned. But are not against this Article as such.

Commented [A38]: In the recitals: referred to in Article 8A(1) and accessible through the electronic health data access services referred to in Article 8G. Restriction of access may be derogated from under the conditions laid down to in Article 7A(3).

BLOCK 4: Primary Use of Health Data (4)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 4			
[MOD.PU.7.rev1] Clarification of relationship between the GDPR and EHDS **in Articles 8A-G and 11A [recitals (5A)-(16)]**		x	Article 8B Right of natural persons to insert information in their own EHR Member States may allow natural persons or their representatives as referred to in Article 8G(2) to insert information **in their personal electronic health record**, through electronic health data access services or applications linked to these services as referred to in Article 8G. That information shall in such cases be 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 electronic health data and related information inserted by health professionals.
[MOD.PU.9.rev1] Clarification of relationship between the GDPR and EHDS **in Article 12 [recitals (24)-(25)]**	x		
[MOD.PU.6.rev1] Deletion of **Article 12(6a)**	x		

Commented [A39]: We support the comments made by SE, that the data flow in primary use should be clarified.

BLOCK 5: Primary Use of Health Data (5)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 5			
[MOD.PU.10.rev1] Market harmonization approach for EHR systems based on components & Clarification of definition and scope of crossborder requirements [many articles, **Annexes II-IV, recitals (20), (27), (28A)**]		x	Annex 2 1.1 There is no reason to refer to mandatory harmonise components every time, could just use "harmonised components". 1.4 The text should use the same terms when referring t components. 2.1.a, 2.1.b and 2.1c could be combined in one sentenc 2.3 How would it be defined what would be sufficient granularity to enable the provision of the entered health data. 3 The title says requirements for security and logging, bu there does not seem to be any other security requireme anymore than logging requirements. 3.8 Does not seem to directly relate to logging or securit

Commented [A40]: We support restricting the harmonization of the requirements of EHR systems. Restricting the harmonization to only two components could be a way forward. The two components should be limited to minimum harmonisation requirements and they should be used to ensure that the priority categories of data are transmitted from one Member State to another reliably and securely through the national contact points. The possibility of laying down national requirements and to require a third party assessment of those requirements should be maintained.
It seems that at the moment these kind of separate components do not exist on the market. Would this Regulation create a common European market for these components?
We are still analysing in more detail what this would mean for our national legislation and national requirements. Finland would prefer if we could implement the interoperability component through our central Kanta system and through the national contact points.
Recital 20 states that "The European electronic health record exchange format should have two profiles. At the national level, the European electronic health record exchange profile should include the technical specifications for the 'European interoperability component for EHR systems." This does not make it clear what should be done at the national level and what should be done at the national contact points. It should be clearly stated in the Articles, what are the obligations at the MS level.
The recital states that these components have a low risk. Taking into account the wide scope of the definition of the EHR systems and the sensitivity of the data that is being transmitted, we do not agree that these would be low risk components. Current MyHealth@EU conventions require external testing and external auditing concerning national connection points, and NCPs need to be able to ensure that EHR systems connected to them can provide necessary connectivity and security features.
We can support the idea of a testing environment. But it should be analysed which of the requirements in Annex 2 can be tested in the testing environment. It would seem that the components would still need external assessment in addition to using the testing environment.
Recital 20 seems to address both the electronic health record exchange format and the two harmonised components. The recital seems to mix these two elements, which makes reading it confusing. We support that the Member States would retain the competence to define any other requirements for EHR systems and the terms and conditions for connection of healthcare providers to their respective national infrastructures, which may be subject to third-party assessment. This should also be clear from the Articles.
The last sentence of recital 20 seems unclear, which implementing act does it refer to.

BLOCK 6: Primary Use of Health Data (6)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 6			
[MOD.PU.11.rev1] Creation of a European testing environment for the primary use of health data [**Article 26A]**	x		

Commented [A41]: We can support the idea of creating a European testing environment. However, it should also be analysed which of the requirements in Annex 2 can be assessed in the testing environment and which of them would require additional external assessment.
The definition of an EHR system is very wide in this compromise text. Will the testing environment have the capabilities to test all of these different kind of systems?

BLOCK 7: Primary Use of Health Data (7)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 7			
[MOD.PU.15.rev1] Clarification of competences of DPAs [**Article 11A and recital (16A)]**			

Commented [A42]: We should make sure that Article 11A does not restrict the competence of the DPAs when it refers only to the specific rights in Chapter 2. It should be made sure, that the DPAs can use all the sanctions in the GDPR, including administrative fines. It should be made clear what are the competences of the digital health authorities in relation to the DPAs.

Comments from the French delegation

EU Member State	FRANCE

BLOCK 1: Primary Use of Health Data (1)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 1	x		
[MOD.PU.1] Article 31A moved to recital (35A) • **Article 31A** moved to **recital (35A)**	x		
[MOD.PU.4.rev1] Modification of chapeau of Article 5(1) • "For the purposes of this Chapter" instead of the previous text in the chapeau of **Article 5(1)**	x		
[MOD.PU.5.rev1] Modification of definition of EHR system • The definition of EHR system is modified in **Article 2(2)(n)**	x		
[MOD.PU.18.rev1] Clarification in **Article 5(1A)**	x		

The French Authorities support Block 1.

However, attention must be paid to the point raised by several delegations during the working party about the new wording of Article 5(1A), regarding additional data categories that can be added by Member States, and its interplay with Article 6, regarding the European electronic health record exchange format and definition of technical specifications. Indeed, it should be clarified how Article 6 can be activated for these non-priority categories at the request of Member States.

BLOCK 2: Primary Use of Health Data (2)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 2	x		
[MOD.PU.3.rev1] Modification of Article 6 to allow the inclusion of unstructured data • Deletion of "structured" in **Article 6(1)**	x		
[MOD.PU.8.rev1] Clarification, in a recital, about the inclusion of healthcare professionals of primary care teams in the healthcare professionals of **Article 7A [recital (15C)]** • New recital (15AA)	x		
[MOD.PU.12.rev1] Modification **of Article 7A**		x	3. Where access to electronic health data has been restricted by the natural person **pursuant to Article 8E**, 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 **as referred to in Article 9(2)(c) of the Regulation (EU) 2016/679** **if the consent of data subject cannot be collected pursuant to Article 9(2)(a) of Regulation (EU) 2016/679**, 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 controller of the personal electronic health data data holder and the natural person concerned or his/her guardians that access to electronic health data had been granted.**~~ **Such events shall be logged in a clear and understandable format and shall be easily accessible for the natural persons.** **[MOD.PU.12.rev1]** Member States' law may **set out** ~~add~~ additional safeguards. [MOVED FROM ARTICLE 4(4) AND AMENDED]

The French authorities support Block 2

However, French Authorities would like to ensure via a small amendment that the wording of [MOD.PU.12.rev1] makes it possible to limit data access in the event of a life-threatening emergency without the patient's consent to the only situation where the patient's consent cannot be obtained (as in the case of an unconscious person arriving at the emergency department). The current wording is not precise enough and leaves too much room for maneuver as regards the cases in which healthcare professionals could dispense care with the restrictions intended by the holder and described above in the article.

BLOCK 3: Primary Use of Health Data (3)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 3		x	
[MOD.PU.13.rev1] Modification of **Article 8A**	x		
[MOD.PU.16.rev1] Modification of **Article 8D**	x		1. Natural persons shall have the right to give access to or request a ~~data holder~~ health**care provider** ~~**or a provider of social administrative or reimbursement services**~~ ~~security sector~~ to transmit, all **or part of** their electronic health data **that belongs to the priority categories as referred to in Article 5** to a**nother provider** ~~data recipient~~ of their choice from **healthcare sector** ~~**or social administrative or reimbursement services**~~ ~~health or social security sector~~, ~~immediately~~ **without delay**, free of charge and without hindrance from the **transmitting** ~~data holder~~ **provider** or from the manufacturers of the systems used by that ~~holder~~ **provider, as appropriate.** [MOVED FROM ARTICLE 3(8) SUBPARA 1] **[MOD.PU.16.rev1]**
[MOD.PU.14.rev1] Clarification of scope in **Article 8E(1)**	x		
[MOD.PU.2.rev2] Implementing act for harmonised technical specifications in **Article 8E(3)**	x		
[MOD.PU.17.rev1] Modification of		x	**Art 8F**

Article 8F			**Right of the natural person to object**

The French authorities support Block 3 but propose two minor amendments:

- [MOD.PU.16.rev1] : there is a Typo mistake : appropriate
- [MOD.PU.17.rev1] : Proposal to change the title of article 8F

With regards to recitals corresponding to the Articles, the following amendments would help clarifying the relationship between the GDPR and Articles 8A to 8F:

- **In recital 8**, the word « complemented » or « specified » should be preferred to « completed »;
- **In recital 13A**, it should also be clarified that this right complements the GDPR.
- **In recital 15A**, there is a typo, the word « proving » should be replaced by « providing ».

BLOCK 4: Primary Use of Health Data (4)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 4	x		
[MOD.PU.7.rev1] Clarification of relationship between the GDPR and EHDS **in Articles 8A-G and 11A [recitals (5A)-(16)]**		x	**Articles :** ***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**, related to the provisions in this Chapter**. Where the complaint concerns the rights of natural persons pursuant to Article**s** ~~3~~ **8A to 8F** of this Regulation, the digital health authority shall ~~send a copy of~~ **transmit 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 **competent** digital health authority with which the complaint has been lodged shall inform the complainant**, in accordance with national law,** of the progress of the proceedings and of the decision taken. 3. Digital health authorities **in different Member States** shall cooperate to handle and resolve complaints **related to the cross-border exchange and access to personal electronic health data**, including by exchanging all relevant information by electronic means, without undue delay. **Article 11A - *Relationship with data protection ~~regulation~~ supervisory authorities*** The supervisory authority or authorities responsible for monitoring **and enforcement** the application of Regulation (EU) 2016/679 **to the processing of personal electronic health data** shall also be ~~**responsible**~~ **competent** for monitoring **and enforcement of** the ~~**processing of personal electronic health data for primary use, in particular the**~~ **[MOD.PU.15.rev1]** application of ~~this~~ Article**s** ~~3~~ **8A**

			to 8F, 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. [MOVED FROM ARTICLE 3(11)] **Recitals :** **(8)** {**Article 8A**} The right of access to data by a natural person, established by Article 15 of Regulation (EU) 2016/679, should be further **developed** completed **complemented** in the health sector. [...] **(10A)** […]**Data** **Such** rectification requests should **then** be **assessed and, where relevant, implemented** **treated** by the **relevant** data controllers **on case by case basis, if necessary involving health professionals** **in** line accordance **with Regulation (EU) 2016/679**. [...] **(12)** [...]For these reasons, the framework laid down by this Regulation **builds on extends** the right to data portability established in Regulation (EU) 2016/679 by ensuring that natural persons as data subjects can transmit their electronic health data, including inferred data **in the European electronic health record exchange format**, irrespective of the legal basis for processing the electronic health data. [...] **(13A)** **{8F} In addition, Member States may provide for a full opt-out without an emergency override, both for cross-border access and inside that Member State. If they choose to do so, they should establish the rules and specific safeguards regarding such mechanisms.** This specific opt-out is independent from Regulation (EU) 2016/679. **(15A)** [...]**Providing such a service to enable natural persons with easy access to their personal electronic health data is a substantial public interest. The processing of personal electronic health data in these services is necessary for the performance of that task assigned by this Regulation in thesense of Articles 6(1)(e) and 9(2) of Regulation (EU) 2016/679.**
[MOD.PU.9.rev1] Clarification of relationship between the GDPR and EHDS **in Article 12 [recitals (24)-(25)]**	x		
[MOD.PU.6.rev1] Deletion of **Article 12(6a)**	X		

The French authorities support Block 4. However, the French Authorities have several wording amendments to make in [MOD.PU.7.rev1], for the following reasons:

- In Article 11A, French Authorities suggest to keep the reference to the processing of health data in general but in another place in the article;
- The Presidency is proposing to remove the notion of processing personal data. The French Authorities propose that the general concept should be kept earlier in the article if the aim is to clarify that there are new rights in this regulation, or to provide more details.
- In Article 11, French Authorities propose two very small changes:

- In paragraph 1, to replace "send a copy of" with "transmit", which would make it clear that it is the data protection supervisory authority that will deal with the complaint and not, alternatively, one or the other depending on who the complainant goes to see;
- In paragraph 2, to add "competent" at the beginning, after "The" and before "digital health authority".

In Recital 8, "complemented" should be used rather than "completed", as it is clear from the comments added at the end of this recital that a specific right is planned for this data and in this context. Stressing "specified" would be better as well.

The French Authorities point out that a separate right of access to data is now enshrined, while at the same time Recital 9 and Article 8A remind that access can be restricted within the framework of the requirements set out in Article 23 of the RGPD. Linking the two in Recital 9 seems rather difficult.

In recital 10A, French Authorities question the use of the expression "in line" with Regulation 2016/679, as this expression may mean applying the RGPD or the spirit of the provision. We have the impression that the meaning now differs between recital 9 and recital 10A. The amendment “in accordance with" has a better fit when we are really applying the GDPR.

In recital 12, "extends" should replace "builds on", otherwise GDPR does not apply but another separate law.

In Recital 13A, this specific opt-out is envisaged independently of the GDPR if that is what we are moving towards, to clarify here too that the GDPR will also apply.

BLOCK 5: Primary Use of Health Data (5)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 5	x		
[MOD.PU.10.rev1] Market harmonization approach for EHR systems based on components & Clarification of definition and scope of cross-border requirements [many articles, **Annexes II-IV, recitals (20), (27), (28A)]**	x		

The French Authorities support Block 5.

BLOCK 6: Primary Use of Health Data (6)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 6		x	
[MOD.PU.11.rev1] Creation of a European testing environment for the primary use of health data [**Article 26A]**		x	**Mandatory use of the testing environment :** ***Article 26A(3)*** **Manufacturers of EHR systems ~~may~~ shall use the**

			testing environments mentioned in paragraphs 1 and 2 as a supporting element to fulfil their obligation set out under article 17, paragaph 1, a) . [MOD.PU.12.rev1] **Obligation to deliver the test result in the EU declaration:** ***Annex IV :*** **5.The result from the testing environment mentioned in article 26A obtained for the EHR system, attesting the assessment of harmonized components.** **Publication of the results by the Commission:** ***Article 26 – EU declaration of conformity*** […] **6. The Commission shall publish EU declarations of conformity drawn up by manufacturers.**

The French authorities cannot support Block 6.

They welcome the provision of the European test environment, which is required to avoid multiple and unnecessary investments across the EU, as well as for its technical ease of use.

However, if the mechanism chosen for compliance with EHDS requirements remains a self-certification, it is essential to ensure safeguards to avoid market distortion and ensure trust from the ecosystem. **Therefore, it is of paramount importance to strengthen the proposed framework by adding three guarantees:**

- (1) **make paragraph 26A(3) and the use of the European test environment** mandatory for software providers wishing to obtain CE marking
- (2) **Require the manufacturer to provide the result of the test platform together with the declaration of conformity;**
- (3) **Require the European Commission to make the results of this compliance test publicly available**.

On this last point, the Commission pointed out during the Working Party that the Regulation already provides for a form of publicity for the content of declarations of conformity. However, the French Authorities have not identified such a provision, neither in Article 26 or in the articles of Section 4 of Chapter 3 about the market surveillance authority

French Authorities would like to stress that while they support this proposal which leads to a minimum level of market harmonization, they believe that this harmonization level should be extended to additional requirements on a later stage - from technical requirements to requirements related to the eco-responsibility of EHR systems. The Annex II should be revised accordingly. The eco-responsibility and sustainability of digital products and services is a fundamental dimension of the European ethical principles for digital health adopted in January 2022, as well as of the European Digital Rights and Principles promoted by the European Commission. Moreover, it would make this regulation consistent with the objective of the EU climate change agenda. They must be translated into concrete requirements for EHR systems, as the provision of an Eco-score for instance.

BLOCK 7: Primary Use of Health Data (7)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 7	x		
[MOD.PU.15.rev1] Clarification of competences of DPAs [**Article 11A and recital (16A)**]	x		

The French authorities support Block 7.

Note of the French authorities
Sovereignty in the EHDS Regulation – Further clarification on data storage in the EU/EEA
20/11/2023

This paper aims to clarify the French proposal concerning the introduction of a requirement to store health data on European territory, to ensure data security and sovereignty in the context of the European Health Data Space (EHDS) Regulation.

As recalled in the explanatory memorandum of the Regulation, the European strategy for data proposed the establishment of domain-specific common European data spaces. As the EHDS will be the first common European data space, the provisions of the text regarding European sovereignty are of paramount importance and must be carefully discussed.

The objective of this Regulation is to address health-specific challenges to electronic health data access and sharing : the promise is that EHDS will create a common space where natural persons can easily control their electronic health data. It will also enable researchers, innovators and policy makers to use this electronic health data in a **trusted** and **secure** way that **preserves privacy**.

In order to ensure a high level of data protection with regard to the large amount of sensitive health personal data in the scope of this Regulation, **France considers it is crucial to provide EU residents with the insurance of an EU storage of such data, at the very least for EU healthcare providers and the priority data categories referred to in Article 5.**

1. Purpose of the proposal to require healthcare data to be stored in the EU/EEA

Why is such a proposal necessary?

The aim of this storage requirement is to ensure a high level of data protection, for particularly sensitive data. The data processed in the context of the EHDS indeed relate to some of the most intimate aspects of the life of the data subjects concerned. They can reveal diseases and illness which may expose them to very high risks of discrimination, they can also reveal their private life-habits, intimate difficulties they are facing or difficult and personal choices they have made. Many of them can also reveal information that is so sensitive that disclosure to the patients themselves is strictly organised to protect them.

This is the reason why these data benefit from various strong protections, ranging from medical secrecy to stronger safeguards from a data protection perspective. Indeed, the European Convention of Human Rights, as well as the Charter of Fundamental Rights, require specific and stronger guarantees for such sensitive data. Within the EU, more specifically, the GDPR provides a higher level of protection for these data categories: it forbids the processing of such data in principle (art. 9), unless the processing is based on limited derogating grounds.

This storage obligation would be without any prejudice of any transfers of data, for any other purposes than data hosting and as long as they comply with the relevant provisions of the GDPR. Indeed, while the transfer operations only concern a limited amount of data, this obligation of storage would be imposed because it concerns all the data relating to the health of all European citizens and residents. **Such a large volume of data in itself presents an even greater degree of sensitivity, requiring specific safeguards.** In terms of data protection, including of the security of the data concerned, it appears all the more appropriate to lay down stricter conditions as the risks in case of data breach, for example, would be much higher.

In the recent Commission's Proposal for a Regulation of the European Parliament and of the Council on information security in the institutions, bodies, offices and agencies of the Union (COM/2022/119 final), for instance, such a requirement is proposed for '*sensitive non-classified information'.* Article 17(1)(c) of this proposal requires that they '*shall be stored and processed in the EU'*. The Committee on Constitutional Affairs in their opinion (AD\1271064EN.docx) even suggested to strengthen this obligation by adding that "*SNC information shall be stored and processed* exclusively *in the Union*". **France believes that the health data of millions of European citizens is just as important and sensitive as this type of data, and should therefore be subject to at least equivalent precautionary measures.**

In this regard, it should be recalled that the EHDS proposal already establishes measures to specify the application of data protection general rules, in order to ensure that specific safeguards are in place for the data covered by the EHDS proposal, for instance concerning data subject rights in Chapter 2 and in Chapter 4. Article 63 of the Proposal, related to personal electronic health data transfers to a third country, also specifies that Member States « *may maintain or introduce further conditions, including limitations, in accordance with and under the conditions of Article 9(4) of the Regulation (EU) 2016/679, in addition to the requirements set out in Articles 13(3) and 52(5) of this Regulation and the requirement laid down in chapter V of GDPR*».

Following this reasoning, it seems necessary to go further than the reference to the application of the GDPR to ensure the effective protection data subject's data under EHDS. The proposal to include additional storage requirements falls within this framework.

What are the objectives of this proposal in terms of data protection?

The obligation to store data collected by players falling within the scope of this Regulation on servers located on European soil seems both appropriate and balanced. Indeed, this measure seems to be at the very least necessary, in this case, to provide enough guarantees to ensure compliance with three essential criteria for a satisfactory level of data protection: **data confidentiality, security and integrity, and availability**. More technical measures could have been envisaged to ensure compliance with one or other of these criteria, but **the physical storage of data seems to be the very minimum to guarantee all three;** for example, requiring data encryption measures may make it possible to guarantee data confidentiality and/or integrity, but would not provide a guarantee of data availability.

Indeed, this measure aims to serve 3 essential goals:

- **Confidentiality**: the strict confidentiality of processed health data may be called into question by certain non-European legislation or new geopolitical situations. The storage of personal data within the EU/EEA also guarantees that at the end of the retention periods, the data will be destroyed and will no longer be retained in application of the foreign legislation applying to the operators storing the data.
- **Data security and integrity**: in the event of a data breach (voluntary, criminal or accidental), including from or by a third country or an entity located in a third country, the initial storage of data on EU/EEA soil guarantees that the data holder will be able to restore it in a full version without losing his or her right and capacity of action. Indeed, to be able to provide safe and efficient care to the patient, any healthcare provider must be able to restore and the integrity and security of each health data referred to in Article 5 of the Regulation, at any moment, and with the highest level of certainty.

- **Data availability**: the frequent cyber-attacks on healthcare facilities by ransomware[1] demonstrate the need to have strong protections, even physical ones, against such risks.

[1] i.e. where hackers block any access to the data until the processor accepts to pay a ransom.

This is particularly relevant for healthcare providers. **Requiring data to be stored on European soil ensures the application of European legislation, including legislation regarding cybersecurity certification requirements for cloud services, and facilitates the physical "recovery" of data**. It is crucial to provide the strongest guarantees to allow the data controller to organise the blocking and recovery of the data (if necessary with the help of the police) in the context of legal proceedings within EU. It also guarantees that the data is always available, whatever the situation; ensuring the physical availability and security of the data of patients/data-subject allows them to exercise their data protection rights, such as access right.

Thus, this obligation to store data within the EU would benefit all players falling within the scope of the Regulation: it would enable data controllers (healthcare providers) to benefit from the highest degree of confidentiality, security, integrity and availability of data that their tasks require; it would allow data subjects to exercise their rights in relation to these types of processing; where appropriate, the supervision authorities would also be able to fully exercise their tasks.

It is in line with the EDPB/EDPS joint opinion 03/2022 of 12 July 2022 on the Regulation, which has considered the need to impose a requirement to store such personal data in EU, regarding i) the processing of a large quantity of personal data, (ii) that are of a highly sensitive nature and (iii) for which there is no objective element to conclude that there is no risk of unlawful access.

Why is this provision different from the notion of third countries data transfers (Art. 45 GDPR)?

This proposal does not concern the transfer of personal health data to third countries, which is addressed by Article 45 of the GDPR and covers different situations where much smaller amounts of data are concerned and processed, for a shorter time. The issue at stake here is the storage of a very large amount of personal sensitive data concerning, in the end, each and every EU/EEA residents, for as long as data can be lawfully stored. It is the general framework that we intend to provide to assure European citizens that, to the extent that personal health data is processed by European healthcare providers under this Regulation, it is stored in Europe.

2. Scope of this storage requirement proposal

Who would be concerned by this requirement?

- **EU healthcare providers storing data referred to in Article 5**, such as public and private hospitals, medical analysis and biology laboratory, radiology practices, pharmacies. It is important to remind that this obligation would cover the storage of personal health data processed by healthcare providers themselves, or by a processor under their authority.

- **National contact points for digital health** designated by the Member States, referred to in Article 12.

- **The Healthdata@EU platform** mentioned in Article 52.9.

- **Specific secure processing environment (SPE) provided by the Commission**, mentioned in Article 52.10, in line with Article 60A of the last Presidency compromise.

Member States may also provide, by national law, strengthened security measures for the personal health data processed by data holders referred to in Article 33 falling within their jurisdiction. This proposal aims to recall, in the Regulation, that Member States who wish to impose some requirement of data storage localisation even for pseudonymised health data processed by data holders falling within their jurisdiction can do so, in line with the joint opinion 03/2022 of the EDPB/EDPS, that does not make any difference between the data falling within the scope of Chapter 2 or Chapter 4.

What would be left outside the scope of this requirement?

- **Healthcare professionals from third countries who would process the data of EU citizens when treating them on the territory of the third country**, whether or not it is connected to the HealthData@EU infrastructure (Article 13);

- Obviously, this requirement also **does not prevent any further data transfer to third countries**, in accordance with chapter V of GDPR.

3. This requirement is in line with EU data protection policy, law and case law

Objectives set out in the European Strategy for Data

The European strategy for data aims at creating a single market for data that will ensure Europe's global competitiveness and data sovereignty. In addition, to develop the full potential of health data, the Regulation **supports individuals to take control of their own health data**, namely, by enhancing trust. The Regulation aims also at strengthening the rights arising from Article 16 TFEU, to ensure a legal framework consisting of trusted EU and Member State governance mechanisms, and a secure processing environment.

Providing for a storage requirement, while allowing transfers of data when in compliance with the GDPR, allows to ensure a balance between these objectives of a single market and global competitiveness on the one hand, and a high data personal protection degree and data sovereignty on the other hand.

In this context, it is all-the-more crucial to ensure that the space created by the EHDS Regulation will benefit from the highest degree of safeguards – in line with the case law of the CJEU with regards to such sensitive and large amounts of personal data. **This is also a key condition to build trust of the patients whose personal data will be stored in the space.**

This is precisely one of the aims of the proposed EHDS Regulation, to clarify and supplement the rights and obligations set out in the GDPR with regard to the primary and secondary use of personal electronic health data.

Respect of the principle of subsidiarity

Under the principle of subsidiarity, the Union shall act only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States, either at central level or at regional and local level, but can rather, by reason of the scale or effects of the proposed action, be better achieved at Union level. **The very aim of the proposal, creating a common space, cannot be led by Member states on their own, but rather by a Regulation.**

Article 5 of the proposal, by circumscribing the data intended to fall within its scope, allows the Union to exercise its powers with due regard to the principle of subsidiarity, since it is at Union level that the obligation to store this data is provided for. Hence, the content of this proposal does not exceed what is necessary to achieve the objectives of the Treaties.

Article 168 (7) TFEU states that Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organization and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them.

In accordance with Article 168(7) TFEU, as interpreted in the CJUE case-law, European Union law does not detract from the power of the Member States to adopt provisions aimed at organizing their health services. The proposal does not interfere with the role of MS in organizing and delivering of

health services at national level, it only provides some additional guaranty applicable to the data that are within the scope of EHDS Regulation referred to in Article 5. In any case, in exercising their power, the Member States must comply with European Union law, in particular the provisions of the TFEU and Charter of Fundamental Rights on the protection of personal data.

CJEU case law on storage of personal data

The CJEU case law already provides examples of cases where the Court deems necessary to store personal data in the EU. In particular, the European court of Justice decided in its judgment of the 21rst of December 2016, Tele2 Sverige AB, that on-line traffic data processed by internet service providers should be retained within the European Union, to "*ensure the effective protection of retained data against risks of misuse and against any unlawful access to that data*".

4. This requirement is compatible with bilateral and multilateral agreements between the EU and third countries

GATS Agreements

The requirement for health data to be stored in the EU or EEA is **in line with the GATS Agreement**.

According to its Article XIV(c)(ii), nothing in the GATS Agreement shall be construed to prevent the adoption or enforcement by any Member of measures necessary to protect the privacy of individuals in relation to the processing and dissemination of personal data and the protection of confidentiality of individual records and accounts, provided such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where like conditions prevail, or a disguised restriction on trade in services. Similar exceptions can be found in EU bilateral trade agreements.

Firstly, such a requirement for data to be stored within the territory of the EU or EEA pursues the objective to ensure the protection of the privacy of individuals in relation to the processing and dissemination of personal data and the protection of confidentiality of individuals records and accounts as foreseen under Article XIV(c)(ii) GATS.

Considering the sensitivity of the data at stake, several arguments can be put forward to support that this requirement is "necessary" to ensure the protection of the right to privacy of individuals and their personal data, in order to achieve the goals of Confidentiality, Data security and integrity and Data availability (see explanations above, in point 1).
It should first be recalled that the protection of the right for private life and the protection of natural persons in relation to the processing of personal data are both fundamental rights. Article 7 of the Charter provides that everyone has the right to respect for their private and family life, home and communications. Article 8 provides that everyone has the right to the protection of personal data concerning them.

Then, such requirement for health data to be stored in the EU or EEA is necessary to ensure the protection of these fundamental rights, as regards the **specific nature of these data**. Indeed, Article 4, paragraph 14, of the GDPR defines 'data concerning health' as personal data related to the physical or mental health of a natural person, including the provision of healthcare services, which reveal information about his or her health status. According to recital 10 and Article 9, paragraph 1, of the GDPR, such data constitute 'sensitive data' and the processing of such data is in principle prohibited, subject to the derogations provided for in Article 9(2) of the GDPR.

Thus, health data holders, who are either public or private actors, act in the very specific context of primary use of electronic health data in which they process such sensitive data in order to provide care. In some other cases, they act in the area of secondary use, processing personal health data for

example for research purposes.

It is on the basis of this consideration that the French delegation considers that is necessary to require that the storage of health data in order to ensure the protection of natural persons in relation to the processing of such sensitive data.

Secondly, this requirement does not constitute a discrimination. Indeed, the requirement for data to be stored in the EU or EEA has neither the object nor the effect of restricting access to the European market to service operators located in third countries based on their country of establishment or the nationality of their managers.

Thirdly, this requirement does not constitute a disguised restriction on trade in services. Indeed, health data holders established in a third countries will still be able to provide their services within the territory of the EU or EEA. The requirement only concerns the localisation of the health's data storage, without undermining the provisions of services in the EU by health data holders, whether they are legally established in the EU or in a third country.

Besides, such requirement is necessary and proportionate in order to ensure the protection of the right for private life and the protection of natural persons in relation to the processing of personal data, in so far as such requirement does not preclude the stakeholders concerned from transferring the data to a third country nor create a remote access under the conditions provided by Chapter 5 of the GDPR.

In addition, the French authorities want to stress that National contact point referred to in Article 12 and the platform HealthData@EU are not in the scope of the GATS, because they cannot be considered as "commercial services" under Article 2 of this Agreement.

Other bilateral agreements (United-Kingdom, New-Zealand, Japan)

T**hese agreements include both provisions to facilitate the exchange of data**, including personal data (Article 201 of the trade and cooperation agreement with the United Kingdom), **and specific provisions to regulate such exchanges** when they specifically concern personal data (Article 202 of the same agreement).

Based on the same arguments as those developed above, we consider that **the measure requested here does not contravene these agreements but builds on the possibilities provided to ensure privacy and the protection of personal data with the relevant measures**. In this regard, the proposed measure should be considered as a measure « on the protection of personal data and privacy, including with respect to cross-border data transfers, provided that the law of the Party provides for instruments enabling transfers under conditions of general application (34) for the protection of the data transferred. », according to Article 202.2 of the trade and cooperation agreement with the United Kingdom.

Amendments proposed by the French delegation

- In **Articles 2A and 12(7)**: to provide the obligation, for the healthcare providers to store the personal health data referred to in Article 5 within the European Union and also for the National contact point for digital health designated by the Member States ;
- In Articles **52(9) and (10)** : to provide, in line with Article 60A, the obligation for the Commission to store the personal health data referred to in Article 33 within the European Union for the platform Healthdata@EU and for the specific SPE mentioned in Article 52.9 and 10 ;
- **A new recital** to explain the global position.

Article 2A	
16th october 2023 compromise redaction	**Amendment proposal**
Article 2A *Registration of personal electronic health data* [MOVED FROM ARTICLE 7] 1. Member States shall ensure that, where data is processed in electronic format **for the provision of healthcare, healthcare providers** ~~health professionals~~ shall ~~systematically~~ register the relevant **personal** health data falling **fully or partially** 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. [MOVED FROM ARTICLE 7(1) AND AMENDED] **1A.** Where they process data in an electronic format, ~~health professionals~~ **healthcare providers** shall ensure that the personal electronic health data of the natural persons they treat are updated with information related to the health**care** ~~services~~ provided. [MOVED FROM ARTICLE 4(1)(b) AND AMENDED] 2. Where **personal** electronic health data ~~of a natural person~~ is registered in a Member State **of treatment** that is not the Member State of affiliation of **the** ~~that~~ person **concerned**, 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. [MOVED FROM ARTICLE 7(2) AND AMENDED] 3. The Commission shall, by means of implementing acts, determine ~~the~~ **data**	(…) **2A. Member States shall ensure that the storage of personal electronic health data processed pursuant to paragraph 1 is located within the European Union.** (…)

quality requirements**, including semantics, uniformity, consistency of data registration, accuracy and completeness,** for the registration of **personal** electronic health data **in EHR system** ~~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). [MOVED FROM ARTICLE 7(3) AND AMENDED]	
Justification: The aim is to require Members States to ensure that personal electronic health data processed for primary use purposes, pursuant to chapter II of the Regulation, is located within the EU.	

Article 12	
16th october 2023 compromise redaction	**Amendment proposal**
1. The Commission shall establish a central **and interoperability** platform for digital health**, MyHealth@EU,** to provide services to support and facilitate the exchange of **personal** 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**. The national contact point shall be an organisational and technical gateway for the provision of cross-border digital health information services in the context of healthcare of personal electronic health data, enabling and** ~~to~~ ensur**eing** the connection to all other national contact points for digital health and to the central platform for	(…) 7. The national contact points for digital health shall act as joint controllers of the **personal** electronic health data communicated through 'MyHealth@EU' for the processing operations in which they are involved. The Commission shall act **upon instructions of national contact points for digital health as processor. The national contact points for digital health shall ensure the storage of personal electronic health data within the European Union.** (…)

	digital health **in cross-border infrastructure MyHealth@EU**. 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 **inform of** ~~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 **inform** ~~communicate to~~ the Commission **of** 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 **in other Member States through MyHealth@EU**. 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 **personal** 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**. Member States** ~~and~~ shall	

	ensure that ~~those~~ connected **healthcare providers** 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 hospital discharge report is exchanged with the Member State of affiliation. The Commission shall ensure that MyHealth@EU is enabled to transmit the hospital discharge report to the Member State of affiliation.~~	
7.	The national contact points for digital health shall act as ~~joint~~ controllers of the **personal** 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**~~T~~he Commission ~~shall, by means of implementing acts, allocateion of responsibilities among controllers and~~ **shall lay down the rules regarding the requirements of cybersecurity, technical interoperability, semantic interoperability, operations and service management in relation to 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). **[MOD.PU.10.rev1]** 9. **The national contact points referred to in paragraph 2 shall be authorised participants in MyHealth@EU, when they fulfil the conditions to join and to remain connected to MyHealth@EU as laid down pursuant to paragraph 4.** The approval for individual authorised participants to join MyHealth@EU for different services, or to disconnect a participant shall be issued by **the Commission** ~~Joint Controllership group~~, based on the results of the compliance checks **performed by the Commission.** **Subject to the outcome of the compliance check, the Commission shall, by means of implementing act, take decisions to connect individual authorised participants to join the infrastructure or to disconnect them. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 68(2).**	
Justification: In line with the amendments proposed to in Articles 2A, and with Article 60A of the draft Regulation, the proposal is to lay down a requirement for the national contact points provided for in Chapter 2 to host health data within the territory of the European Union (in line with the joint opinion of the EDPB/EDPS 03/2022 on the draft EHDS Regulation).	

Article 52	
16th october 2023 compromise redaction	**Amendment proposal**
1. Each Member State shall designate ~~a~~**one** 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 State** ~~and~~ shall **inform** ~~communicate their names and contact details to~~ the Commission	(…) 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 ensure that this platform is located within the European**

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.

1A. The Union Health Data Access Body shall act as the Union Institutions', bodies, offices and agencies' contact point for secondary use of electronic health data and shall be responsible for making electronic health data available for secondary use. **[MOD.SU.7.rev1]**

2. The national contact points referred to in paragraph 1 **and the Union Institutions' contact point referred to in paragraph 1A** shall be authorised participants in the crossborder infrastructure for secondary use of electronic health data (HealthData@EU). The national contact points **and the Union Institutions' contact point** 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 the Union Institutions' contact point** ~~and~~ shall cooperate closely with each other and with the Commission. **[MOD.SU.7.rev1]**

3. ~~**Union institutions, bodies, offices and agencies involved in health- related research, health policy or analysis, shall be authorised participants of HealthData@EU.**~~ **[MOD.SU.7.rev1]**

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 **Union**. 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 **or authorised participants in this infrastructure**, the Commission **shall** ~~may~~ provide a secure processing environment for data from more than one Member State compliant with the requirements of Article 50. **The Commission shall ensure that the secure processing environment is located within the European Union.** ~~**When personal health data are transferred to a third country, the Commission shall ensure that measures are implemented to secure this transfer is compliant with the requirements laid down in Chapter V of Regulation (EU) 2016/679 and to ensure that the controller provides to the data subject all the information required by Articles 13.1 f) and 14.1 f) of Regulation (EU) 2016/679.**~~ 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 act as processor.

(…)

the rules of Chapter IV of this Regulation, **the transfer stemming from such connection would comply 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.	
When adopting the implementing act, the national security interests of Member States shall be taken into account.	
~~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 **or authorised participants in this infrastructure**, the Commission **shall** ~~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 Joint Controllership group, based on the results of the compliance checks concerning the fulfilment of the requirements.~~ **Subject to the outcome of the compliance check performed by the Commission concerning the fulfilment of the requirements in this Article, the Commission shall, by means of implementing act, take decisions to connect individual authorised participants to join the infrastructure or to disconnect them. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 68(2).**	
Justifications:		

In paragraph 9, in order to align the text with proposed amendments to Article 60A, it is necessary to require the Commission to ensure that this platform is hosted on the territory of the European Union.

Paragraph 10 makes this Article consistent with Article60A: since the HDAB is required to host the secure environment on the territory of the EU, it is necessary for the Commission to ensure that the secure processing environment set up pursuant to Article 52(10) is also located on the territory of the EU.

Alternative proposal: this requirement could also be met by completing article 60A and inserting a reference to article 52.10.

Proposed recital

Propose recital to be inserted between recital 15 and 15A:

Data processors targeted in the present Regulation are processing personal health data, often covered by medical secrecy, which are sensitive data. In principle, Article 9 of Regulation (EU) 2016/679 forbids the processing of such data unless the processing is based on some exception. The aim of this disposition is to provide a higher level of protection for these data categories, including health data. Moreover, considering all EU citizen's data such as that covered by this proposal, the volume of data in itself presents an even higher degree of sensitivity, requiring specific safeguards.

Therefore, in order to mitigate the risks of loss of control over the data and in accordance with the general principles of European Union law, which include the general principles and fundamental rights guaranteed by Articles 7 and 8 of the Charter of Fundamental Rights of the European Union, this Regulation shall ensure that, where personal electronic health data are collected and processed by healthcare providers for the provision of healthcare, the storage of data referred to in Article 5 is located within the European Union.

The obligation to store data collected by players falling within the scope of this Regulation on European territory offers the minimum guarantees necessary to ensure compliance with three essential criteria for a satisfactory level of data protection: data confidentiality, security and integrity, and availability. Such a requirement is necessary and proportionate in order to ensure the protection of private life and of natural persons in relation to the processing of personal data.

This localisation requirement does not prevent the possibility of subsequent transfer or remote access from a third country under the conditions of chapter V of Regulation (EU) 2016/679.

The requirement of European localisation for the storage of data is also applicable to the National contact points referred to in Chapter 2. Concerning chapter 4 of the present Regulation, the same obligation is provided by Article 60A for the HDAB and their secure process environment, and also for the platform HealthData@EU.

Member States wishing to provide more security guarantees for the storage of pseudonymised health data referred to in Article 33 may lay down such a storage localisation requirement for health data holders located on their territory.

Comments from the German delegation

EHDS: Secondary use of certain categories of personal electronic health data

Alternative wording for Article 35F:

Article 35F

Natural person's rights ~~Right to opt-out~~ concerning secondary use of certain categories of personal electronic health data ~~and purposes for secondary use~~

Paragraph 1:

1. In addition to the right to object provided by Article 21 of Regulation (EU) 2016/679 and Article 23 of Regulation (EU) 2018/1725, Member States may provide by national legislation for a right of natural persons to opt-out at any time and without stating reasons ~~from~~ of the secondary use of personal electronic health data relating to them falling under ~~any of~~ the data categories of ~~in~~ Article 33(1) points (a), (e), (ea), (f) and (m) for ~~any category~~ all categories of the purposes ~~for secondary use~~ of ~~in~~ Article 34(1) points (d), (e), (f) or (h). Member States may provide for this right to be exercised separately for ~~per each of those data categories and per~~ each of ~~those~~ these purposes ~~for secondary use~~.

New Paragraph 1a:

1a. Member States may maintain or introduce further conditions, including limitations, for the secondary use of human genetic and genomic data. In particular, Member States may provide that processing of such data is only possible with the consent of the data subject.

Para 4 and 5 should be changed analogously:

4. Where a natural person has opted out and relevant personal electronic health data falling under any of the categories in Article 33(1) points (a), (e), (ea), (f) and (m) relating to that person can be identified in a dataset, that data shall not be made available for secondary use under data permits pursuant to Article 46 which are granted after the natural person has opted out. This shall not affect the processing of that person's electronic health data for secondary use in the scope of data permits granted before the natural person has opted out.

5. Where a natural person has opted out from the processing of relevant personal electronic health data falling under any of the categories in Article 33(1), points (a), (e), (ea), (f) and (m) relating to that person can be identified in a dataset, that data shall not be processed for secondary use following a request for electronic health data in a statistical format pursuant to Article 47 approved after the natural person has opted out.

Justification:

For a set of very sensitive personal health data comprising of data from EHRs, human genetic and genomic data and other molecular data from biobanks and associated databases and person generated health data, Article 35F (1) gives the Member States the option to provide a right to opt-out from the secondary use to the data subjects. **The right can only be executed for this set of data as whole** but separately for each of the purposes in Article 34 paragraph 1 letters d, e, f or h. **Further conditions may be introduced or maintained for human genetic and genomic data.**

Additionally DE ist still looking into ways how to reduce the scope of genomic data that member states should have the option to require consent for. We hope to be able to present a new proposal soon. Until that, our previous proposal still applies.

EHDS: Possibility of requiring consent for genomic data - explanation of DE position

DE position

- In complement to the right to opt-out concerning secondary use of certain categories of personal electronic health data and purposes for secondary use according to Article 35F (1) *(3rd presidency compromise proposal),* member States may introduce or maintain further conditions, including limitations, for human genetic and genomic data referred to in Article 33 (1)(e) *(3rd presidency compromise proposal)*.
- For example, Member States may provide that processing of such data is only possible with the consent of the data subject.

Justification

- Genomic and genetic data are of high transformative value for personalised patient care as well as research. DE fully recognizes its high value and is both setting national infrastructures for secondary use of this data and participating in European projects, such as the Genomic Data Infrastructure, in order to contribute to leverage the potential of this data.
- Apart from its high value for healthcare and research, genome data can be used to draw conclusions about personality-relevant characteristics such as hereditary dispositions, character traits or illnesses of the person concerned. Genomic and genetic data can thus be used for creating a personality profile.
- In view of previous decisions of the Federal Constitutional Court, it cannot be ruled out that genome data are covered by the protection of the core area of personal rights and human dignity. However, consent of the data subject in the processing of its data would exclude an encroachment on fundamental rights.
- Under German constitutional law the core area of personal rights and human dignity enjoys absolute protection, which is superior to any other legal provisions. In the event of a constitutional review, the Federal Constitutional Court might therefore conclude that the processing of genomic and genetic data without consent violates German constitutional law. In that event, it would be likely that any processing of genome data under the EHDS regulation would have to be stopped immediately, meaning that this high-value data cannot be used for research and innovation projects.
- It is therefore essential to introduce to the regulation that member states must have the possibility to regulate the secondary use of genome data only by way of consent (member state option). Such further conditions introduced by the member states are also foreseen e. g. in Article 9 paragraph 4 of the GDPR.
- A member state option which allows Germany and other Member States with similar constitutional traditions to enact a consent requirement would provide a solid legal basis for participating in the emerging data space.

EU Member State	Germany

BLOCK 1: Primary Use of Health Data (1)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 1			
[MOD.PU.1] Article 31A moved to recital (35A) • **Article 31A** moved to **recital (35A)**		X, also see Modification of Article 33	
Modification of **Article 33**			*Article 33* *Minimum categories of electronic **health** 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) **health data from** EHRs **processed in a structured form**; (b) **health** data **on** ~~impacting health, including social, environmental behavioural~~ determinants **of health, such as data having an effect on the health status, healthcare needs, resources allocated to healthcare, the provision of and universal access to healthcare as well as healthcare expenditure and financing, and the causes of mortality**; (c) ~~relevant~~ pathogen genomic data, impacting on human health; (d) health**care**-related administrative data, including claims and reimbursement data; (e) human **genomic**, genetic, ~~genomic,~~ ~~and~~ proteomic**, transcriptomic, epigenomic, metabolomic, lipidomic and other omic** data; (f) person generated ~~electronic~~ health data~~, including~~ **through** medical devices~~, wellness applications or other digital health applications~~; (g) ~~identification~~ data **on professional status and role of** ~~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 **fully completed** 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 **associated** ~~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.~~ SEE PARA 9 IN THIS ARTICLE

			~~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[2]~~. MOVED TO ARTICLE 35B(5) AND AMENDED ~~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.~~ SEE ARTICLES 35B(1) AND 35A(1) ~~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 ARTICLE 37(5) ~~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 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.~~ 8. **Member States may provide by national law that additional categories of electronic health data shall be made available for secondary use pursuant to this Regulation.** ~~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.~~ **9. Member States may establish rules for the processing and use of electronic health data containing various improvements related to processing of electronic health data based on a data permit pursuant to Article 46, such as correction, annotation and enrichment.** DELETED IN ARTICLE 33(1)(o) AND AMENDED
[MOD.PU.4.rev1] Modification of chapeau of Article 5(1) • "For the purposes of this Chapter" instead of the	X		

[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).

previous text in the chapeau of **Article 5(1)**			
[MOD.PU.5.rev1] Modification of definition of EHR system • The definition of EHR system is modified in **Article 2(2)(n)**	X		
[MOD.PU.18.rev1] Clarification in **Article 5(1A)**		X	

Justification for new wording:

Recital 35A/Article 33:

- The change in new Recital 35A is welcomed, but is not comprehensive enough.
- If Member States are free to regulate the use of wellness applications, they should also be free to make data from wellness applications available for secondary use.

Article 5 (1A):

we prefer the old wording and would see a harmonization of further data categories in the future

BLOCK 2: Primary Use of Health Data (2)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 2			
[MOD.PU.3.rev1] Modification of Article 6 to allow the inclusion of unstructured data • Deletion of "structured" in **Article 6(1)**	X		
[MOD.PU.8.rev1] Clarification, in a recital, about the inclusion of healthcare professionals of primary care teams in the healthcare professionals of **Article 7A [recital (15C)]** • New recital (15AA)	X		There is no Recital 15AA
New Article prior to Article 2A			**Article x** **EHR systems for access by health professionals and exercise of patient rights** **Member States may decide which specific EHR system(s) in their national health system fall(s) under the provisions of Chapter II of this regulation, in particular under Articles 2A, 7A, 7B and 8A-8G, and thus form a part in the European Health Data Space in their national health system.**
[MOD.PU.12.rev1] Modification **of Article**		X	***Article 7A*** *Access by health professionals to personal electronic health data*

7A			[MOVED FROM ARTICLE 4] 1. **Member States shall ensure that w~~W~~here ~~they~~ health professionals** process **personal** health data in an electronic format, **they** ~~health professionals~~ shall**:** ~~(a)~~ have access to the relevant **personal** electronic health data of natural persons under their treatment, **through the health professional authorised access services referred to in Article 7B**, irrespective of the Member State of affiliation and the Member State of treatment**.** ~~;~~ [MOVED FROM ARTICLE 4(1)(a)] **2. The access referred to in paragraphs 1 and 1A shall include at least the priority categories in Article 5 ~~and in line with the principles provided for in Article 5 of Regulation (EU) 2016/679 and~~ only where there is a valid legal basis under Article 6 and the conditions of Article 9(2) and (3) of ~~the same~~ Regulation (EU) 2016/679 are fulfilled. [MOD.PU.12.rev1]**. In line with the ~~data minimisation~~ principle**s** provided for in Article 5 of the Regulation (EU) 2016/679, Member States may **also** establish rules providing for the categories of personal electronic health data required by different health professionals. Such rules shall ~~not be based on the source of electronic health data~~ **take into account the possibility of restrictions imposed in according to Article 8E.** [MOVED FROM ARTICLE 4(2) AND AMENDED] **3~~4.~~** Where access to electronic health data has been restricted by the natural person **pursuant to Article 8E**, 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 **as referred to in Article 9(2)(c) of the Regulation (EU) 2016/679**, 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 controller of the personal electronic health data data holder and the natural person concerned or his/her guardians that access to electronic health data had been granted.**~~ **Such events shall be logged in a clear and understandable format and shall be easily accessible for the natural persons. [MOD.PU.12.rev1]** Member States' law may **set out** ~~add~~ additional safeguards. **The possibility for Member States according to Article 8F to provide for a full opt-out without an emergency override, both for cross-border access and inside that Member State, remains unaffected.** [MOVED FROM ARTICLE 4(4) AND AMENDED]

Justification for new wording:

New Article prior to Article 2A (the European Commission anticipated that it is intended this way and that a new Article might be an option)**:**

It should be clarified in the text that Member States decide which specific EHR system(s) in their national health system fall(s) under the provisions of Chapter II, in particular under Articles 2A, 7A and 7B as well as under 8A-8G, and thus form(s) a part of the European Health Data Space which is accessible to both patients and healthcare professionals.

As we understood from the WP meeting, AUT, SWE and NLD support this view.

Article 7A Para (1):
Alignment of the wording with Article 2A (1):
registration of the ***relevant*** data (Article 2A) and
access to the ***relevant*** data (Article 7A)

Article 7A Para (2):
The deletion cannot be accepted. Access to electronic health data may only be granted as far as the data is relevant in the sense that there is a valid legal basis under GDPR. If 7 (2) doesn't explicitly state this, it could be understood in a way that it is itself a legal basis under Art. 9 (2) GDPR which grants unlimited access to electronic health data.
This would be contrary to GDPR's general principle according to which data may only be processed where relevant. Additionally, in many cases unlimited access would not be appropriate. The term "health professionals" includes company physicians who should not have unlimited access to employee's health data or medical records. In the case of company physicians, as opposed to medical examiners, the relationship to the patient/employee is not completely voluntarily. Company physician's full knowledge of employee's medical records is neither intended nor necessary. The argument that the amount of references to the GDPR should be reduced, is not convincing as also other provisions reference the GDPR.

Article 7A Para (3):
Recital 13A states that MS may choose not to provide an emergency override, but the current text of Article 7A (3) gives the impression that emergency overrides are always possible. This should not be the case. It must stay in the MS' competence to decide if access and thus also access in an emergency is possible. It therefor has to be clarified in Article 7A (3) that MS may choose not to provide an emergency override via a reference to Article 8F.
As we understood from the WP meeting, AUT, SWE and NLD support this view.

BLOCK 3: Primary Use of Health Data (3)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 3			
[MOD.PU.13.rev1] Modification of **Article 8A**		X	***Article 8A*** ***Right of natural persons to access their personal electronic health data*** [...] 3. In accordance with Article 23 of Regulation (EU) 2016/679, Member States may restrict the scope of ~~this~~ **the** right**s** **referred to in paragraphs 1 and 2, in particular** 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 their health. [MOVED FROM ARTICLE 3(3)]
Modification of **Article 8C**			***Article 8C*** ***Right of natural persons to rectification*** ~~Member States shall ensure that, w~~**W**hen exercising the right to rectification under Article 16 of Regulation (EU) 2016/679, **Member States shall enable** natural persons ~~**shall can be able**~~ **to** easily request, ~~**online,**~~ **ideally through the electronic health data access services**

			referred to in Article 8G, the controller of the personal electronic health data or the health professional who registered the personal electronic health data according to Article 2A, ~~rectification online through the electronic health data access services referred to in paragraph 5, point (a), of this Article~~ **to rectify their personal electronic health data**. [MOVED FROM ARTICLE 3(7) AND AMENDED] **Member States may also enable natural persons to exercise other rights pursuant to Chapter III of Regulation (EU) 2016/679 online through the electronic health data access services referred to in Article 8G.**
[MOD.PU.16.rev1] Modification of **Article 8D**		X	***Article 8D*** ***Right to data portability for natural persons*** 1. Member States may provide a right for n~~N~~atural persons ~~shall have the right~~ to give access to or request a ~~data holder~~ health**care provider** ~~or a provider of social administrative or reimbursement services security sector~~ to transmit, all **or part of** their electronic health data **that belongs to the priority categories as referred to in Article 5** to a**nother provider** ~~data recipient~~ of their choice from **healthcare sector** ~~or social administrative or reimbursement services~~ ~~health or social security sector~~, ~~immediately~~ **without delay**, free of charge and without hindrance from the **transmitting** ~~data holder~~ **provider** or from the manufacturers of the systems used by that ~~holder~~ **provider, as appropiate.** [MOVED FROM ARTICLE 3(8) SUBPARA 1] **[MOD.PU.16.rev1]** 2. Member States may provide a right for n~~N~~atural persons ~~shall have the right~~ that, where ~~the~~ **healthcare providers** ~~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~~ **transmitting provider** shall transmit the data in the European electronic health record exchange format referred to in Article 6 **through the cross border infrastructure as referred to in Article 12.** ~~and the~~ **The receiving healthcare provider** ~~data recipient~~ shall ~~read and~~ accept **such data and shall be able to read** it. [MOVED FROM ARTICLE 3(8) SUBPARA 2] 3. **Where n**~~N~~atural persons **have received an electronic copy of their priority categories of personal electronic health data as referred to in Article 8A(2), they** shall **be able to** ~~have the right that~~ **transmit that data to** ~~a~~ **healthcare providers** ~~or a provider of social, administrative or reimbursement services~~ **of their choice** ~~where priority categories of personal electronic health data referred to in Article 5 are transmitted or made available by the natural person according to~~ **in** the European electronic health record exchange format referred to in Article 6~~, such data shall be read and accepted by.~~ **The receiving provider shall accept such data and be able to read it, as appropiate.** [MOVED FROM ARTICLE 3(8) SUBPARA 4] **[MOD.PU.16.rev1]** 4. 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). [MOVED FROM ARTICLE 3(12)]
[MOD.PU.14.rev1] Clarification of scope in **Article 8E(1)**	X		
[MOD.PU.2.rev2] Implementing act for harmonised technical specifications in **Article**			SCRUTINY RESERVATION

8E(3)			
[MOD.PU.17.rev1] Modification of **Article 8F**		X	***Article 8F*** ***Right of natural person to ~~object~~ opt-out* [MOD.PU.17.rev1]** **1. Member States may provide for natural persons to have the right to opt out of the use of EHR systems that fall under the provisions of this Chapter.** **If a Member State provides for such a right, it shall establish the rules and specific safeguards regarding such opt out mechanisms.** **1A. If a Patient makes use of such a right, this Chapter is not applicable.** **~~1.~~1B. Member States may provide for natural persons to have the right to opt out of ~~object to~~ the access of health professionals to their personal electronic health data registered in an EHR system by electronic health data access services referred to in Article 7B~~8G~~.** **If a Member State provides for such a right, it shall establish the rules and specific safeguards regarding such opt out ~~objection~~ mechanisms.** **1C. If a Patient makes use of such a right, to this extent this Chapter is not applicable.** **2. With regard to cross-border access to personal electronic health data referred to in Article 5, Member States may provide for natural persons to have the right to opt out of ~~object to~~ their personal electronic health data being ~~are~~ made available for cross-border access and exchanged through the cross-border infrastructure as referred to in Article 12.** **If a Member State provides for such a right, it shall establish the rules and specific safeguards regarding such opt out ~~objection~~ mechanisms.**
new Recital 6A (relating to Article 2A new para (1A) [see Block 4] and Article 8F)			(6) **{Articles 8A-G}** Chapter III of Regulation (EU) 2016/679 sets out specific provisions concerning the rights of natural persons in relation to the processing of their personal data. **The** EHDS builds upon these rights and ~~**further develops**~~ **complements** some of them~~**. The EHDS should support the coherent implementation of those rights**~~ as applied to **personal** electronic health data**. These rights apply** regardless of the Member State in which the personal electronic health data are processed, type of healthcare provider, sources of data or Member State of affiliation of the natural person. The rights and rules related to the primary use of personal electronic health data under Chapter II and III of this Regulation concern all categories of those data, irrespective of how they have been collected or who has provided hem, of the legal ground for the processing under Regulation (EU) 2016/679 or the status of the controller as a public or private organisation of the legal ground for their processing. **The enhanced rights of access and portability of personal electronic health data are without prejudice to the rights of access and portability as established under Regulation (EU) 2016/679. Natural persons continue to have those rights under the conditions set out in that regulation.** **Some Member States might provide different opt out possibilities for patients.** **Firstly, national law might provide a right for patients to completely opt out of the use of an EHR system that would allow health professionals to register data according to Article 2A and to access data according to Articles 7A and 7B as well as patients to exercise their rights under Articles 8A to 8G of this regulation. If patients make use of this basic opt out right, an EHR system that can comply with these Articles might simply not exist. In these cases where patients do not want their data to be part of the EHDS, Chapter II of this**

			regulation should not be applicable so that in these cases Member States are not obliged to provide other kinds of EHR systems in order to meet these provisions despite the patient's decision. Secondly, national law might provide a right for patients to decide if and which personal electronic health data are registered in an EHR system according to Article 2A. Finally, national law might provide a right for patients to decide if and which personal electronic health data, that are registered in the EHR system shall be accessible for health professionals. This decision of a patient may again lead to a situation that none or only certain personal electronic health data according to Article 5 form part of the EHDS. Also in these cases Chapter II of this regulation should, to this extent, not be applicable so that the patient's decision not to have certain data registered or accessible is respected.

Justification for new wording:

Article 8A:
we prefer to keep the more broad wording with "in particular"

Article 8C:
In Germany, for the EHR system that will comply with Articles 8 et seq. (ePA), the data controller (statutory health insurance company) cannot access the data stored therein. Only the health professional who registered the personal electronic health data according to Article 2A can and should rectify data registered by himself. Thus, MS should provide a possibility for natural persons to exercise their right to rectification in an easy way – depending on the EHR system construction – vis-à-vis the data controller or the health professional who initially stored the data in an EHR system.

Article 8D:
We prefer a deletion of this Article as health professionals are already given access to data in Article 7A. In case Article 8D remains in the text, the rights stated there should not be regulated in this regulation but by MS.

Article 8F:
1) Additional paras and accompanying Recital (European Commission and Presidency anticipated that the EHDS concept is intended in the way we understand it):
MS decide which EHR systems in their healthcare system comply with Chapter II (in particular with Articles 2A, 7A-8G) (see our new Article x in Block 2)
regarding the specific EHR system that a MS considers appropriate to comply with Chapter II (e.g. the German ePA), this MS might provide patients with the right either to opt out of the mere use of this EHR system or to decide himself which data shall be registered therein and if and to which extent they are accessible for other health professionals
if the patient makes use of (one of) these opt out options/rights, he will simply not use the specific EHR system (ePA) or it is used but not filled with all Article 5 data or, although filled with data, maybe not accessible for health professionals
in these cases, because of the patient's decision, there simply is either
1) no usable EHR system at all or
2) no or not all data according to Article 5 are stored in the EHR system (Article 2A) or,
3) although data are stored there, they or some of them are not accessible by health professionals (Article 7A et seq.)

in all of these scenarios, the patient can simply not exercise his rights (Articles 8 et seq.) (at least concerning certain data according to Article 5),
there can then be no obligation on the MS to provide for a different EHR system in such cases (e.g. obligation in Germany to open local health professional IT systems)

As we understood from the WP meeting, AUT, SWE and NLD support this view.

2) Change of "object" to "opt out" to align the wording with the Article's new heading

BLOCK 4: Primary Use of Health Data (4)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 4			
Modification of **Article 2A**			***Article 2A*** *Registration of personal electronic health data* [MOVED FROM ARTICLE 7] 1. Member States shall ensure that, where data is processed in electronic format **for the provision of healthcare, healthcare providers** ~~health professionals~~ shall ~~systematically~~ register the relevant **personal** health data falling **fully or partially** 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. [MOVED FROM ARTICLE 7(1) AND AMENDED] **1A. Member States may provide for natural persons to have the right to decide if and which personal electronic health data are registered in an EHR system according to paragraph (1).** **If a Member State provides for such a right, it shall establish the rules and specific safeguards regarding such objection mechanisms.** **1B. If a Patient makes use of such a right, to this extent this Chapter is not applicable.** **1C~~A~~. Member States shall ensure that, w~~W~~here they process data in an electronic format, ~~health professionals~~ **healthcare providers** shall ensure that the personal electronic health data of the natural persons they treat are updated with information related to the health**care** ~~services~~ provided. [MOVED FROM ARTICLE 4(1)(b) AND AMENDED] […]
[MOD.PU.7.rev1] Clarification of relationship between the GDPR and EHDS **in Articles 8A-G and 11A [recitals (5A)-(16)]**		X	**Recital 6:** See Block 3 (additional recital 6A) **Recital 9:** (9) **{Article 8A(3)}** At the same time, it should be considered that immediate access to certain types of personal electronic health data may be harmful for the safety of natural persons~~,~~ **or** unethical ~~**or inappropriate**~~. For example, it could be unethical to inform a patient through an electronic channel about a diagnosis with an incurable disease that is likely to lead to their swift passing instead of providing this information in a consultation with the patient first. Therefore, **it should be possible to delay the provision of this access in such situations for a limited amount of time** ~~**a possibility for limited exceptions in the implementation of this right should be ensured**~~.

			Member States may define **S**such an exception ~~may be imposed by the Member States~~ where **it** ~~this exception~~ constitutes a necessary and proportionate measure in a democratic society, in line with the requirements of Article 23 of Regulation (EU) 2016/679. ~~Such restrictions should be implemented by delaying the display of the concerned personal electronic health data to the natural person for a limited period.~~ Where health data is only available on paper, if the effort to make data available electronically is disproportionate, there should be no obligation **for Member States to regulate** that such health data is converted into electronic format ~~by Member States~~. Any digital transformation in the healthcare sector should aim to be inclusive and benefit also natural persons with limited ability to access and use digital services. ~~Natural persons should be able to provide an authorisation to the natural persons of their choice, such as to their relatives or other close natural persons, enabling them to access or control access to their personal electronic health data or to use digital health services on their behalf. Such authorisations may also be useful for convenience reasons in other situations. Proxy services should be established by Member States to implement these authorisations, and they should be linked to personal health data access services, such as patient portals on patient-facing mobile applications. The proxy services should also enable guardians to act on behalf of their dependent children; in such situations, authorisations could be automatic. In order to take into account cases in which the display of some personal electronic health data of minors to their guardians could be contrary to the interests or will of the minor, Member States should be able to provide for such limitations and safeguards in national law, as well as the necessary technical implementation. Personal health data access services, such as patient portals or mobile applications, should make use of such authorisations and thus enable authorised natural persons to access personal electronic health data falling within the remit of the authorisation, in order for them to produce the desired effect.~~ [[MOVED TO RECITAL 15B]] **Recital 10A:** **(10A) {Article 8C}** Enabling natural persons to more easily and quickly access their electronic health data also further enables them to notice possible errors such as incorrect information or incorrectly attributed patient records ~~and have them rectified using their rights under Regulation (EU) 2016/679~~. In such cases, natural person should be enabled to request rectification of the incorrect electronic health data**, ideally** online, immediately and free of charge, for example through ~~the~~ **a** personal health data access service. ~~Data~~ **Such** rectification requests should **then** be ~~assessed and, where relevant, implemented~~ **treated** by the **relevant** data controllers **or health professional who registered the personal electronic health data according to Article 2A**~~on case by case basis, if necessary involving health professionals~~ **in line with Regulation (EU) 2016/679**. **In this situation, the health data access service forwards the request for rectification under Regulation (EU) 2016/679 to the competent controller or health professional. This facilitates the exercise of this right for the natural person, who can submit requests through the health data access service instead of contacting controllers or health professionals individually. It also helps the controller or health professional, who will receive assurance that the requester is in fact the data subject, as the requester will be reliably identified and authenticated by the health data access service. To further facilitate**

			the exercise of existing data subject rights under Regulation (EU) 2016/679, Member States may also provide possibilities to submit requests to exercise them through their health data access services, complementing the possibility to contact the controller or health professional directly. **Recital 13A:** **(13A) {8F} ~~In addition,~~ Member States may provide for a full opt-out without an emergency override, both for cross-border access and inside that Member State. If they choose to do so, they should establish the rules and specific safeguards regarding such mechanisms.** **Recital 15:** (15) **{Article 7B} Timely and full access of health professionals to the medical records of patients is fundamental for ensuring continuity of care and avoiding duplications and errors. However, due to a lack of interoperability, in many cases, health professionals cannot access the complete medical records of their patients and cannot make optimal medical decisions for their diagnosis and treatment, which adds considerable costs for both health systems and natural persons and may lead to worse health outcomes for natural persons. Electronic health data made available in interoperable format, which can be transmitted between healthcare providers can also reduce the administrative burden on health professionals of manually entering or copying health data between electronic systems. Therefore, health professionals should be provided with appropriate electronic means, such as health professional portals, to use personal electronic health data for the exercise of their duties. Providing this service to health professional is a task in the public interest assigned by this Regulation whose performance requires the processing of personal in the sense of Article 6(1)(e) of Regulation (EU) 2016/679. ~~Article 9(2), point (h), of Regulation (EU) 2016/679 provides for exceptions where the processing of senstitive data is necessary for the purposes of preventive or occupational medicine, for the assessment of the working capacity of the employee, medical diagnosis, the provision of health care or treatment or the management of health care systems and services on the basis of Union or Member State law.~~** This Regulation **~~should~~** provide**s** conditions and safeguards for the processing of electronic health data **~~by healthcare providers and health professionals~~ in the health professional access service** in line with Article 9(2), point (h), of Regulation (EU) 2016/679**, such as detailed provisions on logging to provide transparency towards data subjects. ~~with the purpose of accessing personal electronic health data provided by the natural person or transmitted from other healthcare providers.~~** However, this Regulation should be without prejudice to the national laws concerning the processing of health data **for the delivery of healthcare**, including the legislation **regulating which health professionals register patient data in EHR systems and have access to it as well as the legislation** establishing categories of health professionals that can process different categories of electronic health data.
[MOD.PU.9.rev1] Clarification of relationship between the GDPR and EHDS **in Article 12 [recitals (24)-**	X		

(25)]			
Modification of **Article 12 (5)**			5. ~~**Member States shall ensure connection of all healthcare providers to their national contact points for digital health.**~~ **Member States** ~~and~~ shall ensure that ~~**those connected**~~ **all healthcare providers** are enabled to ~~**perform two-way**~~ exchange ~~**of**~~ **all** electronic health data ~~**with**~~ **to be exchanged in cross-border treatment according to this regulation by data transfer directly or indirectly via** the**ir** national contact point for digital health.
[MOD.PU.6.rev1] Deletion of **Article 12(6a)**	X		

Justification for new wording:

Article 2A:
No direct obligation for healthcare providers should be regulated here but – like in para (1) – rather an obligation for MS to regulate this in their national law.

Recital 9:
Not the MS themselves convert data; MS might only regulate who converts them.

Recital 10A:
See Justification for modification in Article 8C (Block 3).

Recital 13A:
The statement of this Recital is not something that is "added" on top of an emergency override but the complete opposite, namely the absence of the possibility of an emergency override (see also our amendment of Article 7A (3) in Block 2).

Recital 15:
This Recital clarifies that the EHDS is "without prejudice to the national laws concerning the processing of health data for the delivery of healthcare, including the legislation establishing categories of health professionals that can process different categories of electronic health data". To be consistent, the aspect of the "regulation which health professionals register patient data in EHR systems and have access to it" should also be mentioned as this also falls in MS competence.

Article 12 (5):
Depending on the overall information infrastructure of the Member State's healtcare system MS-internal part of the cross-border data exchange via the Member State's national contact points eHealth can also be done by indirect connections between healthcare providers and the MS's NCPeH.

BLOCK 5: Primary Use of Health Data (5)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 5			
[MOD.PU.10.rev1] Market harmonization approach for EHR systems based on components & Clarification of definition and scope of cross-border requirements [**many articles**, **Annexes II-IV, recitals (20), (27), (28A)]**		X	**Article 14(1)** Manufacturers of medical devices as defined in Article 2(1) of Regulation (EU) 2017/745 **and manufacturers of in vitro diagnostic medical devices as defined in Article 2(2) of Regulation (EU) 2017/746** that claim interoperability of those medical devices with EHR systems shall prove compliance with the essential requirements on **the European interoperability component for EHR systems and the European logging component for EHR systems,** laid down in Section 2 of Annex II of this Regulation. **The manufacturers shall prove this compliance within the relevant conformity assessment as required under Regulation (EU) 2017/745 and Regulation (EU) 2017/746.** Article 23 of this

			Chapter shall be applicable to those medical devices. **[MOD.PU.10.rev1]** **Where a notified body has to be involved in that assessment, the notified bodies which have been notified under those legal acts shall be entitled to assess the conformity of the medical devices or in vitro diagnostic medical devices set out in the first subparagraph with the requirements laid down in Section 2 of Annex II. Those notified bodies have to demonstrate to the authority responsible for notified bodies under Regulation (EU) 2017/745 and Regulation (EU) 2017/746 that they have the resource and process requirements required for this task according to this regulation.** **Annex II** 2.1.a Where an EHR system is designed to store or intermediate personal electronic health data, it shall provide an interface enabling access to the personal electronic health data ~~**processed by it**~~ in the European health record exchange format **or mapped into the European health record exchange format**, by means of the European interoperability component for EHR systems. 2.1.b. Where an EHR system is designed to **receive and** store or **to receive and** intermediate personal electronic health data, it shall be able to receive personal electronic health data in the European health record exchange format, by means of the European interoperability component for EHR systems. 2.1.c. Where an EHR system is designed to **receive and** provide access to personal electronic health data, it shall be able to receive personal electronic health data in the European health record exchange format, by means of the European interoperability component for EHR systems. 3.6. The mandatory harmonised components of 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**, while the log data shall not be modifiable**. **Recital 20:** (20) While EHR systems are widely spread, the level of digitalisation of health data varies in Member States depending on data categories and on the coverage of healthcare providers that register health data in electronic format. In order to support the implementation of data subjects' rights of access to and exchange of electronic health data, Union action is needed to avoid further fragmentation. In order to contribute to a high quality and continuity of healthcare, certain categories of health data should be registered in electronic format systematically and according to specific data quality requirements. The European electronic health record exchange format should form the basis for specifications related to the registration and exchange of electronic health data. The Commission should be empowered to adopt implementing acts for determining additional aspects related to the registration of electronic health data, such as ~~**categories of healthcare providers that are to register health data electronically,**~~ categories of data to be registered electronically, or data quality requirements. **The European electronic health record exchange format should have two profiles: a simple technical specification for national use**

			applicable to EHR systems and a detailed technical specification for cross-border use, which should only apply to the national contact points for eHealth. At the national level, the European electronic health record exchange profile should include the technical specifications for the 'European interoperability component for EHR systems'. Also, harmonised technical specifications for the 'European logging component for EHR systems' may be defined by means of implementing acts. These two components are mainly focused on data transformation, although they may imply indirect requirements for data registration and data presentation in EHR systems at the national level. Given the low risk of these components and the wide scope of the definition of EHR systems in this Regulation, conformance assessment should be by means of self-certification. The Commission should establish a testing environment to facilitate such self-certification. Member States should retain the competence to define any other requirements to EHR systems and the terms and conditions for connection of healthcare providers to their respective national infrastructures, which may be subject to third-party assessment at the national level. The cross-border specifications of the European electronic health record exchange format should be complemented by further cybersecurity, technical and semantic interoperability, operations and service management specifications for cross-border use in the MyHealth@EU infrastructure, defined by means of implementing acts. [MOD.PU.10]

Justification for new wording:

Article 14(1):

The new wording remains unclear: How do medical device and IVD manufacturers prove compliance with the essential requirements on the "European interoperability component for EHR systems" and "European logging component for EHR systems", laid down in Section II of Annex II?

In accordance with Art. 52 Regulation (EU) 2017/745 (MDR) / Art. 48 Regulation (EU) 2017/746 (IVDR), prior a manufacturer of medical devices or IVDs places a device on the market, they shall undertake an assessment of the conformity of the device. It must be ensured that the interoperability requirements according to Article 14 (1) should be assess as part of the relevant conformity assessment as required under the MDR or IVDR - a second conformity assessment procedure must be avoided. Where a notified body has to be involved in the conformity assessment, the notified body shall be entitled to control the conformity when they demonstrate to their responsible authority that they have the resource and process required for this task.

Annex II:

2.1.a: To our understanding the interoperability component is the mapping tool for all health data into the European health record exchange format, where data is not (yet) stored in the European health record exchange format.

2.1.b and 2.1.c: If an EHR system is not designed to receive data in the European health record exchange format through an interface and will not be used as a system that receives data through an interface, but through other sources, there should be no obligation to receive data in the European health record exchange format. It would still provide access to the data.

3.6. In addition to the review and analysis of the log data within an EHR system, it should not be possible to change the log data.

Recital 20:

The competence to decide which categories of healthcare providers that are to register health data electronically falls in the sole competence of the respective MS.

BLOCK 6: Primary Use of Health Data (6)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 6			
[MOD.PU.11.rev1] Creation of a European testing environment for the primary use of health data [**Article 26A]**	X as long as it is only an option (and not compulsory) for MS		

BLOCK 7: Primary Use of Health Data (7)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 7			
[MOD.PU.15.rev1] Clarification of competences of DPAs [**Article 11A and recital (16A)]**			SCRUTINY RESERVATION

Comments from the Hungarian delegation

EU Member State	HUNGARY

BLOCK 1: Primary Use of Health Data (1)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 1	X		
[MOD.PU.1] Article 31A moved to recital (35A) • **Article 31A** moved to **recital (35A)**			
[MOD.PU.4.rev1] Modification of chapeau of Article 5(1) • "For the purposes of this Chapter" instead of the previous text in the chapeau of **Article 5(1)**			
[MOD.PU.5.rev1] Modification of definition of EHR system • The definition of EHR system is modified in **Article 2(2)(n)**			
[MOD.PU.18.rev1] Clarification in **Article 5(1A)**			

BLOCK 2: Primary Use of Health Data (2)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 2	X		
[MOD.PU.3.rev1] Modification of Article 6 to allow the inclusion of unstructured data • Deletion of "structured" in **Article 6(1)**			
[MOD.PU.8.rev1] Clarification, in a recital, about the inclusion of healthcare professionals of primary care teams in the healthcare professionals of **Article 7A [recital (15C)]** • New recital (15AA)			
[MOD.PU.12.rev1] Modification **of Article 7A**			

BLOCK 3: Primary Use of Health Data (3)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 3			
[MOD.PU.13.rev1] Modification of **Article 8A**	X		
[MOD.PU.16.rev1] Modification of **Article 8D**		X	**Member States shall ensure for** Natural persons ~~**shall have**~~ **either** the right to give access to **or the right to** request a data holder health**care provider** or **a provider of social administrative or reimbursement services** security sector to transmit, all **or part of** their electronic health data **that belongs to the priority categories as referred to in Article 5** to a**nother provider** data recipient of their choice from **healthcare sector or social**

			administrative or reimbursement services health or social security sector, immediately **without delay**, free of charge and without hindrance from the **transmitting** data holder **provider** or from the manufacturers of the systems used by that holder **provider, as appropiate.**
[MOD.PU.14.rev1] Clarification of scope in **Article 8E(1)**	X		
[MOD.PU.2.rev2] Implementing act for harmonised technical specifications in **Article 8E(3)**		X	pls delete this paragprah
[MOD.PU.17.rev1] Modification of **Article 8F**	X		

BLOCK 4: Primary Use of Health Data (4)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 4	X		
[MOD.PU.7.rev1] Clarification of relationship between the GDPR and EHDS **in Articles 8A-G and 11A [recitals (5A)-(16)]**			
[MOD.PU.9.rev1] Clarification of relationship between the GDPR and EHDS **in Article 12 [recitals (24)-(25)]**			
[MOD.PU.6.rev1] Deletion of **Article 12(6a)**			

BLOCK 5: Primary Use of Health Data (5)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 5		X	
[MOD.PU.10.rev1] Market harmonization approach for EHR systems based on components & Clarification of definition and scope of cross-border requirements [many articles, **Annexes II-IV, recitals (20), (27), (28A)]**			Article 27/A (3) **When Member States ~~wishing to~~ adopt regulations in accordance with paragraph 1, after adoption they shall ~~notify to~~ inform thereabout the Commission. ~~their respective national regulations in accordance with~~ In respect of the measures referred to in paragraph (1) Directive (EU) 2015/1535 shall not apply.**

BLOCK 6: Primary Use of Health Data (6)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 6	X		
[MOD.PU.11.rev1] Creation of a European testing environment for the primary use of health data [**Article 26A]**			Compromise proposal **3. When the Manufacturers ~~may~~ uses the testing environments mentioned in paragraphs 1 and 2, the conformity to this regulation, in respect of the elements tested with positive result, shall be presumed~~, as a supporting element for self-certification.~~**

BLOCK 7: Primary Use of Health Data (7)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 7	X		
[MOD.PU.15.rev1] Clarification of competences of DPAs [**Article 11A and recital (16A)]**			

Comments from the Irish delegation

EU Member State	IRELAND

BLOCK 1: Primary Use of Health Data (1)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 1	**X**		
[MOD.PU.1] Article 31A moved to recital (35A) • **Article 31A** moved to **recital (35A)**	X		
[MOD.PU.4.rev1] Modification of chapeau of Article 5(1) • "For the purposes of this Chapter" instead of the previous text in the chapeau of **Article 5(1)**	X		
[MOD.PU.5.rev1] Modification of definition of EHR system • The definition of EHR system is modified in **Article 2(2)(n)**	X		
[MOD.PU.18.rev1] Clarification in **Article 5(1A)**	X		

BLOCK 2: Primary Use of Health Data (2)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 2		X	
[MOD.PU.3.rev1] Modification of Article 6 to allow the inclusion of unstructured data • Deletion of "structured" in **Article 6(1)**	X		
[MOD.PU.8.rev1] Clarification, in a recital, about the inclusion of healthcare professionals of primary care teams in the healthcare professionals of **Article 7A [recital (15C)]** • New recital (15AA)		X	IE believes that all types of multi-disciplinary care teams involved in care and treatment should be granted access to EHRs under Article 7A, not simply care teams centered around general practitioners. **<u>Proposed text amendment to</u>** **<u>Recital 15C</u>** In some Member States, health care is provided by **multi-disciplinary care teams,** ~~primary case management teams~~, defined as groups of healthcare professionals ~~centred on primary care (general practitioners),~~ **who carry out their activities relating to care and treatment based on a healthcare plan**. ~~who carry out their primary care activities based on a healthcare plan drawn up by them~~. In those cases, in the context of primary use of health data in the European Health Data Space, access should be provided to the members of such teams.
[MOD.PU.12.rev1] Modification **of Article 7A**	X		

BLOCK 3: Primary Use of Health Data (3)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 3		X	
[MOD.PU.13.rev1] Modification of **Article 8A**	X		
[MOD.PU.16.rev1] Modification of **Article 8D**		X	IE would prefer that the deleted text in Article 8D ***'a provider of social administrative or reimbursement services'*** is reinstated as ensure patients' rights to data portability covers all relevant bodies.
[MOD.PU.14.rev1] Clarification of scope in **Article 8E(1)**	X		
[MOD.PU.2.rev2] Implementing act for harmonised technical specifications in **Article 8E(3)**	X		
[MOD.PU.17.rev1] Modification of **Article 8F**		X	IE accepts the text amendment in the title of Art 8F. However, in relation to the associated Recital 13A, IE does not support the inclusion of a full opt-out without an emergency override. Member States should have the ability to develop safeguards which include emergency access procedures. To ensure that patients can be treated safely both within a Member State and cross borders, we recommend the deletion of the following text from Recital 13A. **Suggested text amendments for Recital 13A** 'In addition, Member States may provide for a full opt-out ~~**without an emergency override,**~~ both for cross-border access and inside that Member State. If they choose to do so, they should establish the rules and specific safeguards regarding such mechanisms.'

BLOCK 4: Primary Use of Health Data (4)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 4	X		
[MOD.PU.7.rev1] Clarification of relationship between the GDPR and EHDS **in Articles 8A-G and 11A [recitals (5A)-(16)]**	X		
[MOD.PU.9.rev1] Clarification of relationship between the GDPR and EHDS **in Article 12 [recitals (24)-(25)]**	X		

[MOD.PU.6.rev1] Deletion of **Article 12(6a)**	X		

BLOCK 5: Primary Use of Health Data (5)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 5	X		
[MOD.PU.10.rev1] Market harmonization approach for EHR systems based on components & Clarification of definition and scope of cross-border requirements [many articles, **Annexes II-IV, recitals (20), (27), (28A)]**	X		

BLOCK 6: Primary Use of Health Data (6)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 6	X		
[MOD.PU.11.rev1] Creation of a European testing environment for the primary use of health data [**Article 26A]**	X		

BLOCK 7: Primary Use of Health Data (7)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 7	X		
[MOD.PU.15.rev1] Clarification of competences of DPAs [**Article 11A and recital (16A)]**	X		

Comments from the Italian delegation

EU Member State	<IT>

BLOCK 1: Primary Use of Health Data (1)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 1	**X**		
[MOD.PU.1] Article 31A moved to recital (35A) • **Article 31A** moved to **recital (35A)**	**X**		
[MOD.PU.4.rev1] Modification of chapeau of Article 5(1) • "For the purposes of this Chapter" instead of the previous text in the chapeau of **Article 5(1)**	**X**		
[MOD.PU.5.rev1] Modification of definition of EHR system • The definition of EHR system is modified in **Article 2(2)(n)**	**X**		
[MOD.PU.18.rev1] Clarification in **Article 5(1A)**	**X**		

BLOCK 2: Primary Use of Health Data (2)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 2	**x**		
[MOD.PU.3.rev1] Modification of Article 6 to allow the inclusion of unstructured data • Deletion of "structured" in **Article 6(1)**	**x**		
[MOD.PU.8.rev1] Clarification, in a recital, about the inclusion of healthcare professionals of primary care teams in the healthcare professionals of **Article 7A [recital (15C)]** • New recital (15AA)	**X**		
[MOD.PU.12.rev1] Modification **of Article 7A**	**x**		

BLOCK 3: Primary Use of Health Data (3)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 3	**X**		
[MOD.PU.13.rev1] Modification of **Article 8A**	**X**		
[MOD.PU.16.rev1] Modification of **Article 8D**	**X**		
[MOD.PU.14.rev1] Clarification of scope in **Article 8E(1)**	**X**		
[MOD.PU.2.rev2] Implementing act for harmonised technical specifications in **Article 8E(3)**	**X**		

[MOD.PU.17.rev1] Modification of **Article 8F**	**X**		Note: harmonize the wording in the text of the article according to the title ('right to opt-out' instead of 'right to object')

BLOCK 4: Primary Use of Health Data (4)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 4	**X**		
[MOD.PU.7.rev1] Clarification of relationship between the GDPR and EHDS **in Articles 8A-G and 11A [recitals (5A)-(16)]**	**X**		**Notes:** at recital (6) **{Articles 8A-G}**, instead of "enhanced rights" sounds better "The rights of access and portability established under this Regulation"; at recital 8) **{Article 8A},** at the second line, 'complemented' should be instead di completed; at recital 10) **{Article 8B},** line 3, remove: "**to complement the information available to them**."
[MOD.PU.9.rev1] Clarification of relationship between the GDPR and EHDS **in Article 12 [recitals (24)-(25)]**	**X**		
[MOD.PU.6.rev1] Deletion of **Article 12(6a)**	**X**		

BLOCK 5: Primary Use of Health Data (5)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 5	**X**		
[MOD.PU.10.rev1] Market harmonization approach for EHR systems based on components & Clarification of definition and scope of cross-border requirements [many articles, **Annexes II-IV, recitals (20), (27), (28A)**]	**X**		Note: at recital 20 delete the sentence "**~~Given the low risk of these components and the wide scope of the definition of EHR systems in this Regulation,~~**" and change in **"Given the need to guarantee the information security in the EHR system …"**

BLOCK 6: Primary Use of Health Data (6)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 6	**X**		
[MOD.PU.11.rev1] Creation of a European testing environment for the primary use of health data [**Article 26A]**	**X**		Note: adding the obligation for manufacturers at para 3. **3. Manufacturers SHALL use the testing environments mentioned in paragraphs 1 and 2 as a supporting element for self-certification. [MOD.PU.12.rev1]**

BLOCK 7: Primary Use of Health Data (7)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 7	**X**		
[MOD.PU.15.rev1] Clarification of competences of DPAs [**Article 11A and recital (16A)]**	**X**		

Comments from the Latvian delegation

EU Member State	Latvia

BLOCK 1: Primary Use of Health Data (1)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 1	X		
[MOD.PU.1] Article 31A moved to recital (35A) • **Article 31A** moved to **recital (35A)**	X		
[MOD.PU.4.rev1] Modification of chapeau of Article 5(1) • "For the purposes of this Chapter" instead of the previous text in the chapeau of **Article 5(1)**	X		
[MOD.PU.5.rev1] Modification of definition of EHR system • The definition of EHR system is modified in **Article 2(2)(n)**	X		
[MOD.PU.18.rev1] Clarification in **Article 5(1A)**	X		

BLOCK 2: Primary Use of Health Data (2)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 2		X	
[MOD.PU.3.rev1] Modification of Article 6 to allow the inclusion of unstructured data • Deletion of "structured" in **Article 6(1)**	X		
[MOD.PU.8.rev1] Clarification, in a recital, about the inclusion of healthcare professionals of primary care teams in the healthcare professionals of **Article 7A [recital (15C)]** • New recital (15AA)		X	Latvia has no significant objections to the changes included in this block of modifications. At the same time, Latvia is concerned that recital 15C. highlights only primary care personnel. Following the previous discussions, Latvia understands the intention of this recital (to include primary care teams), however, there is a risk that such wording could be interpreted as restrictive to only primary care. The recital should clearly indicate that access to health data should be granted to all relevant healthcare professionals in both primary and secondary care.
[MOD.PU.12.rev1] Modification **of Article 7A**	X		

BLOCK 3: Primary Use of Health Data (3)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 3		X	

[MOD.PU.13.rev1] Modification of **Article 8A**	X		
[MOD.PU.16.rev1] Modification of **Article 8D**	X		
[MOD.PU.14.rev1] Clarification of scope in **Article 8E(1)**	X		
[MOD.PU.2.rev2] Implementing act for harmonised technical specifications in **Article 8E(3)**	X		
[MOD.PU.17.rev1] Modification of **Article 8F**		X	Latvia draws attention to the need to consistently use the replacement of "object" with "opt-out" in the text of the article itself, not only in the title.

BLOCK 4: Primary Use of Health Data (4)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 4	X		
[MOD.PU.7.rev1] Clarification of relationship between the GDPR and EHDS **in Articles 8A-G and 11A [recitals (5A)-(16)]**	X		
[MOD.PU.9.rev1] Clarification of relationship between the GDPR and EHDS **in Article 12 [recitals (24)-(25)]**	X		
[MOD.PU.6.rev1] Deletion of **Article 12(6a)**	X		

BLOCK 5: Primary Use of Health Data (5)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 5	X		
[MOD.PU.10.rev1] Market harmonization approach for EHR systems based on components & Clarification of definition and scope of cross-border requirements [many articles, **Annexes II-IV, recitals (20), (27), (28A)]**	X		

BLOCK 6: Primary Use of Health Data (6)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 6	X		
[MOD.PU.11.rev1] Creation of a European testing environment for the primary use of health data [**Article 26A]**	X		

BLOCK 7: Primary Use of Health Data (7)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 7	X		
[MOD.PU.15.rev1] Clarification of competences of DPAs [**Article 11A and recital (16A)]**	X		

Comments from the Polish delegation

EU Member State	Poland

BLOCK 1: Primary Use of Health Data (1)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	No	Alternative Wording
General Position for Block 1	X		
[MOD.PU.1] Article 31A moved to recital (35A) • **Article 31A** moved to **recital (35A)**		X	PL does not support moving the text from art 31A to the recital – we prefer to keep the provision in the main text of the regulation, with the wording: "Member States shall remain free to regulate the use of wellness applications as referred to in Article 31 in the context of provision of healthcare, provided that such rules are in compliance with Union law.".
[MOD.PU.4.rev1] Modification of chapeau of Article 5(1) • "For the purposes of this Chapter" instead of the previous text in the chapeau of **Article 5(1)**	X		PL accepts the proposed modification of the wording proposed by PRES ES, while indicating that, in PL's view, the part 'where data is processed in electronic format' from the first version of the text should not be deleted. PL proposes the following wording: "For the purposes of this Chapter, **where data is processed in electronic format**, the priority categories of personal electronic health data shall be the following:".
[MOD.PU.5.rev1] Modification of definition of EHR system • The definition of EHR system is modified in **Article 2(2)(n)**		X	In PL's opinion it is recommended to have a closed catalogue of possible activities performed on the data as an open catalogue, therefore PL proposes to delete "in particular" from the current proposal. Proposed wording: "[…]for use by healthcare professionals in providing patient care or for enabling patient access to their health data**, ~~in particular~~** for storing, intermediating, importing, exporting, converting, editing or viewing[…]".
[MOD.PU.18.rev1] Clarification in **Article 5(1A)**	X		

BLOCK 2: Primary Use of Health Data (2)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	No	Alternative Wording
General Position for Block 2	X		
[MOD.PU.3.rev1] Modification of Article 6 to allow the inclusion of unstructured data • Deletion of "structured" in **Article 6(1)**		X	The proposed amendment is to delete 'structured' from the text of paragraph 1 of Article 6: „Such format shall be ~~structured~~, [MOD.PU.3.rev1], commonly used, machine-readable and allow transmission of personal electronic health data between different software applications, devices and healthcare providers." We opt for keeping the word "structured" in the text in para 1 of art 6. We believe that in order for the data to be useful for analysis and making conclusions based on it, particularly in a cross-border context, all data should be in a structured form.

[MOD.PU.8.rev1] Clarification, in a recital, about the inclusion of healthcare professionals of primary care teams in the healthcare professionals of **Article 7A [recital (15C)]** • New recital (15AA)	X		
[MOD.PU.12.rev1] Modification **of Article 7A**	X		

BLOCK 3: Primary Use of Health Data (3)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	No	Alternative Wording
General Position for Block 3	X		
[MOD.PU.13.rev1] Modification of **Article 8A**	X		
[MOD.PU.16.rev1] Modification of **Article 8D**	X		
[MOD.PU.14.rev1] Clarification of scope in **Article 8E(1)**	X		
[MOD.PU.2.rev2] Implementing act for harmonised technical specifications in **Article 8E(3)**	X		
[MOD.PU.17.rev1] Modification of **Article 8F**	X		PL supports the proposal to change the title of the article - direct indication of 'opt-out'. At the same time, in line with the previous position on the issue of the opt-out and the content of Article 7A, PL considers that in life-threatening situations it should be possible to use access to the patient's data, as it may be difficult to make appropriate clinical decisions in the absence of sufficient health information.

Deadline for written comments: 2023-10-27

BLOCK 4: Primary Use of Health Data (4)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	No	Alternative Wording
General Position for Block 4	X		
[MOD.PU.7.rev1] Clarification of relationship between the GDPR and EHDS **in Articles 8A-G and 11A [recitals (5A)-(16)]**	X		PL does not support the content of recital 13A, it is linked to Article 8F (opt-out). In PL's opinion access to information during an emergency (provision of life-saving treatment) should not be limited by the opt-out due to the risk of misdiagnosis based on incomplete patient data, which may endanger patient safety. PL does not object to the remaining recitals indicated in [MOD.PU.7.rev1].
[MOD.PU.9.rev1] Clarification of relationship between the GDPR and EHDS **in Article 12 [recitals (24)-(25)]**	X		
[MOD.PU.6.rev1] Deletion of **Article 12(6a)**	X		

BLOCK 5: Primary Use of Health Data (5)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	No	Alternative Wording
General Position for Block 5	X		
[MOD.PU.10.rev1] Market harmonization approach for EHR systems based on components & Clarification of definition and scope of cross-border requirements [many articles, **Annexes II-IV, recitals (20), (27), (28A)]**	X		PL generally supports the proposed changes by PRES, although it has to be noted that this selective approach to harmonization lowers the overall level of ambition and creates unfavourable dualism of control mechanisms. On one hand, we would have two harmonized elements of EHR system under EHDS regulation together with market surveillance monitoring at the EU level and on the other hand, we would have solutions based on national law pertaining to all remaining elements of an EHR solution. PL does not support para 2 and 3 of article 27A in its current wording.

BLOCK 6: Primary Use of Health Data (6)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	No	Alternative Wording
General Position for Block 6	X		
[MOD.PU.11.rev1] Creation of a European testing environment for the primary use of health data [**Article 26A]**	X		In PL's opinion if such testing environments are established, they should be mandatory and due to the cross-border background of the intervention (mandatory harmonisation) financed by the Commission. In PL's opinion self-certification of EHR systems is the most cost-effective approach and should be maintained.

BLOCK 6: Primary Use of Health Data (7)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	No	Alternative Wording
General Position for Block 7	X		
[MOD.PU.15.rev1] Clarification of competences of DPAs [**Article 11A and recital (16A)]**	X		

Comments from the Slovak delegation

EU Member State	Slovakia

BLOCK 1: Primary Use of Health Data (1)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 1			
[MOD.PU.1] Article 31A moved to recital (35A) • **Article 31A** moved to **recital (35A)**			
[MOD.PU.4.rev1] Modification of chapeau of Article 5(1) • "For the purposes of this Chapter" instead of the previous text in the chapeau of **Article 5(1)**			
[MOD.PU.5.rev1] Modification of definition of EHR system • The definition of EHR system is modified in **Article 2(2)(n)**			
[MOD.PU.18.rev1] Clarification in **Article 5(1A)**			We prefer the previous version of Article 5(1A) wording but do not object to the revised text.

BLOCK 2: Primary Use of Health Data (2)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 2			
[MOD.PU.3.rev1] Modification of Article 6 to allow the inclusion of unstructured data • Deletion of "structured" in **Article 6(1)**			
[MOD.PU.8.rev1] Clarification, in a recital, about the inclusion of healthcare professionals of primary care teams in the healthcare professionals of **Article 7A [recital (15C)]** • New recital (15AA)			Recital 15AA was not included in the revised proposal. We do not object to the text of recital 15C but reserve our decision if the revision refers to recital 15AA, which we did not have an opportunity to review.
[MOD.PU.12.rev1] Modification **of Article 7A**			

BLOCK 3: Primary Use of Health Data (3)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 3			
[MOD.PU.13.rev1] Modification of **Article 8A**			
[MOD.PU.16.rev1] Modification of **Article 8D**			We generally support the revisions. We still have a concern about Article 8D(3) in

			regards to a lack of provisions for ensuring that the electronic copy of the health data from the natural person was not corrupted or modified before it is accepted by the receiving provider. We would, therefore, propose modification of the last sentence to: "The receiving provider shall accept transmissions of such data in its original, unmodified form and be able to read it, as appropiate." If a healthcare provider is suspicious that the documentation is inaccurate or fraudulent, they should not be required to accept and upload the documentation into their system.
[MOD.PU.14.rev1] Clarification of scope in **Article 8E(1)**			We do not object to [MOD.PU.14.rev1] in Article 8E(1) but do object to the modification in Article 8E(2). We do not support the addition of "through the health professional access service". We would like to respectfully submit that natural persons should be able to obtain information about access to their health data not only by health professionals but also by others, including their proxies. We would, therefore, recommend deletion of the newly added phrase and modification and also revision of "the healthcare provider" to "user" or similar broader term in Article 8E(2)(a).
[MOD.PU.2.rev2] Implementing act for harmonised technical specifications in **Article 8E(3)**			
[MOD.PU.17.rev1] Modification of **Article 8F**			We would respectfully submit that the modification of "object" to "opt-out" should be made not only in the title of the article but also in the main body of the text if this was the intention of the authors.

BLOCK 4: Primary Use of Health Data (4)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 4			
[MOD.PU.7.rev1] Clarification of relationship between the GDPR and EHDS **in Articles 8A-G and 11A [recitals (5A)-(16)]**			We are not clear about the use of word "completed" in the first sentence of Recital 8 (page 4) – please, consider using a clearer term. We would recommend deletion of "without an emergency override" from Recital 13A (page 10) and would recommend clarification of the opt-out option in relation to Article 7A(3) and the Article 9(2)(c) of the Regulation (EU) 2016/679.

	[redacted]		There is a small typo in “thesense” in Recital 15A (on page 12)
[MOD.PU.9.rev1] Clarification of relationship between the GDPR and EHDS **in Article 12 [recitals (24)-(25)]**	[redacted]		
[MOD.PU.6.rev1] Deletion of **Article 12(6a)**		[redacted]	We would prefer if Article12(6a) would be included and expanded to not only hospital discharge reports but all of the priority data categories in Article 5.

BLOCK 5: Primary Use of Health Data (5)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 5	[redacted]		
[MOD.PU.10.rev1] Market harmonization approach for EHR systems based on components & Clarification of definition and scope of cross-border requirements [many articles, **Annexes II-IV, recitals (20), (27), (28A)]**			Small typo on page 71 in Article 30(1)(a) “is” should be plural “are”. In general, we would prefer inclusion of several of the removed paragraphs from the Annexes (especially Annex II), but do not have a strong objection to the revised version.

BLOCK 6: Primary Use of Health Data (6)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 6	[redacted]		
[MOD.PU.11.rev1] Creation of a European testing environment for the primary use of health data [**Article 26A]**			In general, we do not object to the revisions but would have a preference for certification or verification of conformity by a qualified external party rather than the manufacturer themselves using a self-certification assessment. We would also prefer if a successful completion of test using the testing environment was mandatory rather than optional.

BLOCK 7: Primary Use of Health Data (7)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 7	[redacted]		

[MOD.PU.15.rev1] Clarification of competences of DPAs [**Article 11A and recital (16A)]**	[redacted]		We would recommend changing the word "enshrined" to a different word in Recital 16A (page 18). We would recommend revising the phrase "competent for monitoring and enforcement of" to "competent to monitor and enforce" in Article 11A (page 47).

Comments from the Slovenian delegation

EU Member State	<Slovenia>

BLOCK 1: Primary Use of Health Data (1)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 1	x		
[MOD.PU.1] Article 31A moved to recital (35A) • **Article 31A** moved to **recital (35A)**	x		
[MOD.PU.4.rev1] Modification of chapeau of Article 5(1) • "For the purposes of this Chapter" instead of the previous text in the chapeau of **Article 5(1)**	x		
[MOD.PU.5.rev1] Modification of definition of EHR system • The definition of EHR system is modified in **Article 2(2)(n)**	x		
[MOD.PU.18.rev1] Clarification in **Article 5(1A)**	x		

BLOCK 2: Primary Use of Health Data (2)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 2	x		
[MOD.PU.3.rev1] Modification of Article 6 to allow the inclusion of unstructured data • Deletion of "structured" in **Article 6(1)**	x		
[MOD.PU.8.rev1] Clarification, in a recital, about the inclusion of healthcare professionals of primary care teams in the healthcare professionals of **Article 7A [recital (15C)]** • New recital (15AA)		x	Deletion because it is redundant. Optionally, a more general wording (e.g. care teams) , not stressing "primary ", and clarify that access can only be granted to each individual member of care team. *Health care may be provided by care teams or case management teams, defined as groups of healthcare professionals who carry out their activities based on a healthcare plan. In those cases, in the context of primary use of health data in the European Health Data Space, access should be provided to the members of such teams on an individual basis.*
[MOD.PU.12.rev1] Modification **of Article 7A**	x		

BLOCK 3: Primary Use of Health Data (3)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 3	x		
[MOD.PU.13.rev1] Modification of **Article 8A**	x		
[MOD.PU.16.rev1] Modification of **Article 8D**	x		
[MOD.PU.14.rev1] Clarification of scope in **Article 8E(1)**		x	*Natural persons ~~shall~~ may have the right to restrict access of health professionals and healthcare providers…*
[MOD.PU.2.rev2] Implementing act for harmonised technical specifications in **Article 8E(3)**	x		
[MOD.PU.17.rev1] Modification of **Article 8F**		x	Deletion of this article. The article undermines goals of EHDS, jeopardizes quality of healthcare service, collides with other regulations in healthcare, encourages distrust to health professionals, and imposes serious health risks (in extreme cases even patient's death).

BLOCK 4: Primary Use of Health Data (4)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 4	x		
[MOD.PU.7.rev1] Clarification of relationship between the GDPR and EHDS **in Articles 8A-G and 11A [recitals (5A)-(16)]**	x		
[MOD.PU.9.rev1] Clarification of relationship between the GDPR and EHDS **in Article 12 [recitals (24)-(25)]**	x		
[MOD.PU.6.rev1] Deletion of **Article 12(6a)**	x		

BLOCK 5: Primary Use of Health Data (5)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 5	x		
[MOD.PU.10.rev1] Market harmonization approach for EHR systems based on components & Clarification of definition and scope of cross-			

border requirements [many articles, **Annexes II-IV, recitals (20), (27), (28A)]**			

BLOCK 6: Primary Use of Health Data (6)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 6	x		
[MOD.PU.11.rev1] Creation of a European testing environment for the primary use of health data [**Article 26A]**	x		

BLOCK 7: Primary Use of Health Data (7)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 7		x	Comment: DPA alone can not be responsible for enforcement of rights. DHA and health authorities shall be involved in defining implementation aspects of rights of the individual. In particular, DPA is not eligible to impose fines to healthcare providers for accessing EHR during healthcare treatment, irrespective of patients' prior prohibition on access. Redundant. DPA have clear authorizations under GDPR, but they (alone) cannot judge implementation of Article 8.
[MOD.PU.15.rev1] Clarification of competences of DPAs [**Article 11A and recital (16A)]**		x	

Comments from the Swedish delegation

EU Member State	SE

BLOCK 1: Primary Use of Health Data (1)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 1			
[MOD.PU.1] Article 31A moved to recital (35A) • **Article 31A** moved to **recital (35A)**	X		
[MOD.PU.4.rev1] Modification of chapeau of Article 5(1) • "For the purposes of this Chapter" instead of the previous text in the chapeau of **Article 5(1)**	X		
[MOD.PU.5.rev1] Modification of definition of EHR system • The definition of EHR system is modified in **Article 2(2)(n)**		X	Comment: SE questions the need to define EHR systems based on the new compromise for Chapter III. The definition of EHR system will give rise to questions of interpretation about which systems, or parts of systems, are covered by the mandatory requirements, especially in light of the rapid development in eHealth. The proposal should instead be as technology neutral as possible and focus on common rules for the functionality of interoperability and security/logging with a focus on the categories in Article 5(1) for the provision of healthcare. The addition "in particular" seems to broaden the scope of the definition to also include other data than article-5-data while the addition "for use by healthcare professional…." seems to narrow the scope - not include "back bone" system – while at the same time keeping "storing" (which often are "back bone" system).
[MOD.PU.18.rev1] Clarification in **Article 5(1A)**		X	Comment: At this stage, SE does not support the amendments in Article 5.1A. as the amendments broaden the scope of Chapter II. Chapter II and III shall only focus on the priority categories in Article 5.1 at this stage. Expanding the scope will give rise to so many other changes in the article (perhaps also for Chapter III). Therefore SE support either deletion of the para

			or change back to the wording in the second compromise.

BLOCK 2: Primary Use of Health Data (2)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 2			
[MOD.PU.3.rev1] Modification of Article 6 to allow the inclusion of unstructured data • Deletion of "structured" in **Article 6(1)**			
[MOD.PU.8.rev1] Clarification, in a recital, about the inclusion of healthcare professionals of primary care teams in the healthcare professionals of **Article 7A [recital (15C)]** • New recital (15AA)	X		
[MOD.PU.12.rev1] Modification **of Article 7A**		X	Para 3, text proposal: Where access to electronic health data has been restricted by the natural person **pursuant to Article 8E**, 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 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 **and in accordance with ~~as referred to in~~ Article 9(2)(c) of the Regulation (EU) 2016/679**, 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 controller of the personal electronic health data and the natural person concerned or his/her guardians that access to electronic health data had been granted~~. **Such events shall be logged in a clear and understandable format and shall be easily accessible for the natural persons through at least a notification in the patient portal**. ~~-~~Member States' law may **set out** additional safeguards. Justification: This para makes no sense. If a health professional shall be able to access to restricted data, they must be informed that there are restricted data (otherwise they may not understand that there are data that is restricted). The health professional shall

			be able to be informed that there are restricted data of patient safety reasons (but no see the restricted data). SE also considers that the patient must be notified in a proper manner if there have been a breaking the glass situation by at least a notification in the patient portal. **Deletion of last sentence in recital 13:** ~~Because the unavailability of the restricted personal electronic health data may impact the provision or quality of health services provided to the natural person, he/she should assume responsibility for the fact that the healthcare provider cannot take the data into account when providing health services.~~ Justification: SE cannot accept having this strong wording in the recital. The sentence should be deleted.

BLOCK 3: Primary Use of Health Data (3)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 3			
[MOD.PU.13.rev1] Modification of **Article 8A**		X	Para 3, text proposal: In accordance with Article 23 of Regulation (EU) 2016/679, Member States may restrict the scope of ~~this~~ **the** right**s referred to in paragraphs 1 and 2,** ~~**in particular**~~ **in particular** 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 their health. Justification: SE cannot accept the deletion of "in particular" as there could be other reasons not giving access to the data through patient portal, such as other ethical reasons and not only by delaying the access. In some cases the access, through patient portal, could be of harm of the patient and there could also be other situation, for instance where a crime has been committed – where access should not be given through a patient portal. For instance could a hospital discharge report content sensitive data that should be protected during for instance a police investigation. Member State shall be able to use Article 23 - as a whole (as that Article sets out

			sufficient safeguards and rules for limitations of rights). See also text proposals for recital 9 below.
[MOD.PU.16.rev1] Modification of **Article 8D**			SE supports the deletions in paras 1 and 3. The scope of Chapter II is therefore also limited to provision of health care so the definition of primary use also needs to be changed as well. SE is still question this right as the health professional anyway shall have access to the data of the patient they are treating, see article 7A, without patient using the right of data portability. So for the patient to exercise this right within healthcare makes no sense as the data shall be accessible anyway. This right to data portability will impose obligations on Member States (administrative burdens) to ensure that there are technical means for this (see recital 11), meaning that all healthcare provider shall enable national persons to send copies of their electronic health data to them by a secured technical means.
[MOD.PU.14.rev1] Clarification of scope in **Article 8E(1)**	X		
[MOD.PU.2.rev2] Implementing act for harmonised technical specifications in **Article 8E(3)**		X	SE doesn´t support an implementing act in this area as it would be very complex as Member States according to para 1 shall set out rules and Member States also shall set out rules regarding access, see Article 7A. SE proposes deletion of para 3.
[MOD.PU.17.rev1] Modification of **Article 8F**		X	SE could support NL´s proposal for this Article. The word object should be used (not opt-out as we should stay within the framework of GDPR – by specifying and complementing the rights in the GDPR). We should not use the word opt-out in this Regulation as this will create legal uncertainty.

BLOCK 4: Primary Use of Health Data (4)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 4			
[MOD.PU.7.rev1] Clarification of relationship between the GDPR and EHDS **in Articles 8A-G and 11A [recitals (5A)-(16)]**			Recital 9, text proposal: At the same time, it should be considered that immediate access to certain types of personal electronic health data may be harmful for the safety of natural persons, unethical or inappropriate. For example, it could be unethical to inform a patient through an electronic channel about a diagnosis with an incurable disease that is likely to lead to their swift passing instead of providing this information in a consultation with the patient first. **There could also be other justified reasons for**

			restrict the scope of the right to access through an electronic channel to the personal electronic health data registered in patients EHR, such as reasons related to harm to the patient, regardless of access to the data has beeng delay or not. Therefore, a possibility for ~~limited~~ exceptions in the implementation of this right should be ensured. Such an exception may be imposed by the Member States where this exception constitutes a necessary and proportionate measure in a democratic society, in line with the requirements of Article 23 of Regulation (EU) 2016/679. ~~Such restrictions should be implemented by delaying the display of the concerned personal electronic health data to the natural person for a limited period~~. Where health data is only available on paper~~, if the effort to make data available electronically is disproportionate,~~ there should be no obligation that such health data is converted into electronic format by Member States…. Justification: See comments for Article 8A. Recital 10, text proposal: … Enabling natural persons to more easily and quickly access their electronic health data also further enables them to notice possible errors such as incorrect information or incorrectly attributed patient records and have them rectified using their rights under Regulation (EU) 2016/679. In such cases, natural person should be enabled to request rectification of the incorrect electronic health data online, immediately and free of charge, for example through the personal health data access service. Data rectification requests should be assessed and, where relevant, implemented by the data controllers on case by case basis **in accordance with article 16 of Regulation (EU) 2016/679 and supplementary national regulation**. Justification: In SE the right to rectification in the EHR is limited as the data of a patient need to be processed so that for instance our supervision authority would investigate the healthcare providers compliance with the requirement in our national law. Recital 13, text proposal: Natural persons may not want to allow access ~~to some parts~~ of their personal electronic health data ~~while enabling access to other parts~~. Such **restriction of access to** ~~selective sharing of~~ personal electronic health data should be supported. However, such restrictions may have life threatening consequences and, therefore, access to personal electronic health data should be possible to protect vital interests as an emergency override **in accordance with Article 9(2)(c) of** ~~. According~~ to Regulation (EU) 2016/679, ~~vital interests refer to situations in which it is necessary to protect an interest which is essential for the life of the data subject or that of another natural person. Processing of personal electronic health data based on the vital interest of another natural person should in principle take place only~~

			~~where the processing cannot be manifestly based on another legal basis~~. More specific legal provisions on the mechanisms of restrictions placed by the natural person ~~on parts~~ of their personal electronic health data, **including potential limitations,** should be provided by Member States in national law. ~~Because the unavailability of the restricted personal electronic health data may impact the provision or quality of health services provided to the natural person, he/she should assume responsibility for the fact that the healthcare provider cannot take the data into account when providing health services.~~ Justification: Member States shall be able to add limitations for restriction, such as for instance that guidance shall not be able to restrict the childrens health data for reasons related to the protection of children. Recital 13A: SE doesn´t support the use of word opt-out, better to use the word object.
[MOD.PU.9.rev1] Clarification of relationship between the GDPR and EHDS **in Article 12 [recitals (24)-(25)]**	X		
[MOD.PU.6.rev1] Deletion of **Article 12(6a)**	X		SE supports the deletion but considers that this regulation also should provide for possibilities to transmit health data from Member State of treatment to Member State of affiliation (if they are different). Therefore SE proposes an implementing act in article 12(6): **The Commission shall, by means of implementing acts, set out rules concerning under what conditions personal electronic health data that belongs to the priority categories in Article 5(1) other than electronic prescriptions shall be transmitted back to the Member State of Affiliation when the personal electronic health data has been registered in a Member State of Treatment that isn´t The Member States of Affiliation of the natural person. The rules shall take into account the requirements of data protection by design and default laid down in Article 25 of Regulation (EU) 2016/679, ensure transparency and control of natural persons concerned and patient safety. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 68(2).** Further text improvements are of course welcomed.

BLOCK 5: Primary Use of Health Data (5)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 5			
[MOD.PU.10.rev1] Market harmonization approach for EHR systems based on components & Clarification of definition and scope of cross-border requirements [many articles, **Annexes II-IV, recitals (20), (27), (28A)]**			General comments: SE supports the limitation of the harmonized area. SE would like to see a clarification that the functions shall be regulated, not the technique. How the requirements in Annex II are fulfilled should be flexible – taking into account the technical development. We do not want to risk creating lock-in effects that inhibit innovation and that increased unjustified costs for both manufacturers and healthcare providers. By regulating based on function, we probably neither need to define EHR systems nor build a proposal based on technical components. SE would also highlight the need to ensure that the proposal harmonizes with other EU regulations and to avoid requirements that are not compatible. Many of the systems that will be connected to EHDS will have requirements from several other EU regulations and directives to take into account. This is not limited to MDR/IVDR and AI. It also includes, for example, requirements for cyber security, information security, data services, consumer products/services. There is also ongoing collaboration between Member States on wellness apps (which includes both wellness apps and MDSW apps). Requirements from these regulations and directives will affect the ability of the affected systems to meet the requirements of the EHDS regulation. Examples of problem areas that need to be solved: - The need for a notified body (EC certificate) and its impact on lead times and requirements for these systems. - Double regulation of similar requirements – such as registration of the same system in several EU databases, incident reporting to several competent authorities, competent authorities need to create several similar reports to the Commission. - Change management for EHDS and for interconnection of systems. - How to attach the CE mark to software, and how to manage associated information. - Deadlines for storage of documentation and information. Proposal for amendments in recital 20: ~~Given the low risk of these components and the wide scope of the definition of EHR systems in this Regulation, conformance assessment should be by means of self-certification~~ Justification: SE opposes to the wording in recital 20 where it states that that the proposed components entail low risk and proposes

			deletion. **Article 27A** SE is still analyzing this article and is general not in favour of creating additional burdens for MS. Guidance from the CLS is needed.

BLOCK 6: Primary Use of Health Data (6)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 6			
[MOD.PU.11.rev1] Creation of a European testing environment for the primary use of health data [**Article 26A]**			SE generally welcomes test environments, but is concerned of the costs and the financing of such environment at EU level (who will bear the cost). SE also is wondering if this requirement will limit MS's opportunities to receive financial support through the allocated funds.

BLOCK 7: Primary Use of Health Data (7)

Does your delegation agree with the wording proposed by the presidency? If no, please, send an alternative proposal for the article / paragraph

	Yes	NO	Alternative Wording
General Position for Block 7			
[MOD.PU.15.rev1] Clarification of competences of DPAs [**Article 11A and recital (16A)]**		X	{Article 11A} ~~In the context of the EHDS, natural persons should be able to exercise their rights as they are enshrined in Regulation (EU) 2016/679.~~ The supervisory authorities established pursuant to Article 51 of Regulation (EU) 2016/679 ~~should remain~~ are competent for the monitoring and enforcement of that Regulation, in particular to monitor the processing of personal electronic health data and to address any complaints lodged by the natural persons. Those supervisory authority shall also be competent for the monitoring and enforcement of the processing of personal electronic health data within this Regulation. ~~This notably includes the forwarding of complaints that falls within the other authorities' competences.~~ The EHDS specifies and complements some of the right in Regulation (EU) 2016/679 ~~establishes additional rights for natural persons~~ in primary use, regarding ~~going beyond~~ the access and portability rights enshrined in Regulation (EU) 2016/679~~, complementing those rights~~. These additional rights should also be enforced by the supervisory authorities established pursuant to Article 51 of Regulation (EU) 2016/679. ~~In order to carry out their tasks in the health sector and uphold the natural persons' rights,~~ Digital health authorities should

			cooperate with the supervisory authorities ~~under~~ **established pursuant to** Regulation (EU) 2016/679. Justification: An important clarification that DPA´s also shall be competent authority regarding all processing of personal electronic health data within this Regulation.