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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 on the presidency compromise proposal on Chapters I, IV, V, VI and specific topics

Delegations will find enclosed comments of the Austrian, Belgian, Czech, Danish, Dutch, Greek, Finnish, French, German, Hungarian, Italian, Irish, Luxembourg, Polish, Portuguese, Slovak and Spanish delegations on the above-mentioned proposal.

Written contributions from delegations

Comments from the Austrian delegation

AT Written Comments on Chapter I, Articles 48 and 49, Specific Topics Discussed in the Meetings on February 23-24 and March 6-7, and Articles 59-65

First Presidency Compromise Proposal (Chapters I and IV) (Dok. 5302/23)	**AT Comments**
Chapter I	
General provisions	
Article 1	
Subject matter and scope	
1. This Regulation establishes the European Health Data Space ('EHDS') by providing for **common** rules, ~~common~~ standards ~~and practices~~, infrastructures and a governance framework ~~for~~ **with a view to facilitating access to electronic health data for** the **purposes of** primary and secondary use of ~~electronic health~~ **these** data.	
2. This Regulation:	
(a) ~~strengthens~~ **specifies and complements, in Chapter II,** the rights **laid down in the Regulation (EU) 2016/679** of natural persons in relation to **primary use** ~~the availability and control~~ of their **personal** electronic health data;	**The amendments are rejected and it is questionable whether the new version is in conflict with paragraph 3A. In any case, the original version should be retained.**
(b) lays down, **in Chapter III, common** rules for ~~the placing on the market, making available on the market or putting into service of~~ electronic health records systems ('EHR systems') ~~and wellness applications that claim interoperability with EHR systems~~ in the Union **for primary use**;	Wellness applications shall be excluded from this regulation for reasons explained in the specific comment on Art. 2 (2) (o) below.
(c) lays down**, in Chapter II and IV, common** rules and mechanisms ~~supporting~~ **for primary and** secondary use of electronic health data;	
(d) establishes a ~~mandatory~~ cross-border infrastructure enabling the primary use of **personal** electronic health data across the Union **according to Chapter II**;	With regard to Art. 168 (7) TFEU, the deletion of the word "mandatory" is fully supported.

(e) establishes a ~~mandatory~~ cross-border infrastructure for the secondary use of electronic health data **according to Chapter IV**;~~.~~	
(f) establishes governance and coordination on national and European level for both primary and secondary use of electronic health data.	**General scrutiny reservation** with regard to the "governance and coordination **on national (…) level for (…) primary (…) use** of electronic health data" due to a potential conflict with the primary Union law enshrined in Art. 168 (7) TFEU.
~~3. This Regulation applies to:~~	
~~(a) manufacturers and suppliers of EHR systems and wellness applications placed on the market and put into service in the Union and the users of such products;~~	
~~(b) controllers and processors established in the Union processing electronic health data of Union citizens and third-country nationals legally residing in the territories of Member States;~~	
~~(c) controllers and processors established in a third country that has been connected to or are interoperable with MyHealth@EU, pursuant to Article 12(5);~~	
~~(d) data users to whom electronic health data are made available by data holders in the Union.~~	
3A. This Regulation shall be without prejudice to Regulations (EU) 2016/679, (EU) 2018/1725, (EU) No 536/2014 and Directive 2022/58/EC.	See the comment on paragraph 2 (a).
4. This Regulation shall be without prejudice to other Union legal acts regarding access to, sharing of or secondary use of electronic health data, or requirements related to the processing of data in relation to electronic health data, in particular Regulations ~~(EU) 2016/679, (EU) 2018/1725,~~ **(EU) 2022/868**[…] ~~[Data Governance Act COM/2020/767 final],~~ and […] [Data Act COM/2022/68 final].	
5. This Regulation shall be without prejudice to Regulations (EU) 2017/745, **(EU) 2017/746** and […] [AI Act COM/2021/206 final], as regards the security of medical devices and AI systems that interact with EHR systems.	

6. This Regulation shall not affect the rights and obligations laid down in Union or national law concerning health data processing for the purposes of reporting, complying with information requests or demonstrating or verifying compliance with legal obligations**, or national law compliant with Article 9 (4) of the Regulation (EU) 2016/679.**	This textual addition is indispensable from a legal and also political perspective (see also the previous comments on paragraphs 2 (a) and 3A.): From a legal perspective, **Art. 9 (4) GDPR**, pursuing to which "*Member States may maintain or introduce further conditions, including limitations, with regard to the processing of genetic data, biometric data or data concerning health.*", is an **essential outflow of the MS' competences in health matters under Art. 168 (7) TFEU** and therefore **to be fully maintained as applicable Union law**. From a political perspective, the **Council**, in its "**Conclusions on the Communication on shaping Europe's digital future from June 2020"**, underlined the potential of the development of an EHDS which requires a common understanding of the use of health data "*in accordance with international, Union and national law, and in full compliance with the specific high level requirements for the protection of personal health data.*" In this regard, the **Council** held already in **January 2020 in its "Position and findings on the application of the General Data Protection Regulation (GDPR)"** that "*the margin the Member States have to maintain or introduce more specific provisions to adapt the application of the rules of the GDPR (...) has been intentional for the specification of certain provisions of the GDPR and a certain fragmentation is therefore justified*". Against this background, instead of stating in the Proposal where Art. 9 (4) GDPR still applies (as it was done in Art. 63), the **Proposal should explicitely state where Art. 9 (4) GDPR does NOT apply anymore, which would however only be lawful in very exceptional cases under Art. 168 (7) TFEU**.
7. This Regulation shall not apply to activitites concerning public security, defence and national security.	While the inclusion of this paragraph is supported in principle, the question arises as to the motivation and background of such a statement, which seems self-evident even without the inclusion of such a paragraph. Therefore, an explanation of the reasoning behind this paragraph would be appreciated.

Article 2	
Definitions	
Definitions in Article 2(2)(d),(f)-(n) and (p)-(t) are not included in this compromise	Clarification requested that the remaining sub-para will be part of later compromise-texts and therefore any further changes on Art. 2 will be discussed in the working party as per usual. It is highly regrettable that especially Article 2 (2) (m) and (n) are not included in this compromise text, since a clear definition of electronic health record systems is necessary for a correct interpretation of the whole chapter III of this regulation, and as such would represent a prerequisite for meaningful discussions on this topic in the council working groups.
1. For the purposes of this Regulation, following definitions shall apply:	
(a) the definitions **of 'personal data', 'processing', 'pseudonymisation', 'controller', 'processor', 'third party', 'consent', 'genetic data', 'data concerning health', 'supervisory authority', 'international organisation' of the** ~~in~~ Regulation (EU) 2016/679;	**The original version should be retained. The list of terms that are defined in the GDPR should be introduced with "in particular" and moved to a recital.**
(b) the definitions of 'healthcare', 'Member State of affiliation', 'Member State of treatment', **'cross-border healthcare',** 'health professional', 'healthcare provider', 'medicinal product' and 'prescription', pursuant to Article 3 (a), (c), (d), **(e),** (f), (g), (i) and (k) of Article 3 of the Directive 2011/24/EU;	Since the notion of "cross-border healthcare" is referred to in Recital (24) and Art. 8 of the proposal, it should be also included in the definitions.
(c) the definitions of 'data', 'access', 'data altruism', 'public sector body' and 'secure processing environment', pursuant to Article 2 (1), (8), (10), (11) and (14) of **Regulation (EU) 2022/868**~~[Data Governance Act COM/2020/767 final]~~;	
(d) the definitions of 'making available on the market', 'placing on the market', 'market surveillance', 'market surveillance authority', 'non-compliance', 'manufacturer', 'importer', 'distributor', 'economic operator', 'corrective action', 'risk', 'recall' and 'withdrawal', pursuant to Article 2 (1), (2), (3), (4), (7), (8), (9), (10), (13), (16), (18), (22) and (23) of the Regulation (EU) 2019/1020;	

(e) the definitions of 'medical device', 'intended purpose', 'instructions for use', 'performance', 'health institution' and 'common specifications', pursuant to Article 2 (1), (12), (14), (22), (36) and (71) of the Regulation (EU) 2017/745;	
(f) the definitions of 'electronic identification', 'electronic identification means' and 'person identification data' pursuant to Article 3 (1), (2) and (3) of the Regulation (EU) No 910/2014.	
2. In addition, for the purposes of this Regulation the following definitions shall apply:	
(a) 'personal electronic health data' means **personal** data concerning health and genetic data as defined in **Art. 4 (1), (13) and (15) of** Regulation (EU) 2016/679 ~~as well as data referring to determinants of health, or data processed in relation to the provision of healthcare services~~, processed in an electronic form;	It is proposed to insert "Art. 4 paragraph 1, 13 and 15". Personal data is defined in paragraph 1, genetic data in paragraph 13 and health data in paragraph 15.
~~(b) 'non-personal electronic health data' means data concerning health and genetic data in electronic format that falls outside the definition of personal data provided in Article 4(1) of Regulation (EU) 2016/679;~~	
(c) 'electronic health data' means personal **health data** or ~~non-personal electronic health~~ data **concerning health or genetic data that do not constitute personal data in the meaning of Article 4(1) of Regulation (EU) 2016/679, processed in electronic form**;	The wording "falls outside the definition of personal data provided in Article 4(1) of Regulation (EU) 2016/679" from the deleted lit. (b) could be used, at least the reference to "Article 4(1) of Regulation (EU) 2016/679" should be inserted. Human genetic and genomic data should only be collected based on informed consent and voluntary data altruism. According to Austrias constitutional high court (Verfassungsgerichtshof), to some genetic data not even the concerned data subject should get access to, e.g. data on the risk of rare, uncureable genetic deseases. For these two reasons, Austria can't support mandatory exposure of genetic, genomic and proteomic data for secondary data use.
(e) 'secondary use of electronic health data' means the processing of electronic health data for purposes set out in **Article 34** ~~Chapter IV~~ of this Regulation. ~~The data used may include personal electronic health data initially collected in the context of primary use, but also electronic health data collected for the purpose of the secondary use;~~	

~~(o) 'wellness application' means any appliance or software intended by the manufacturer to be used by a natural person for processing electronic health data for other purposes than healthcare, such as well-being and pursuing healthy life-styles;~~	Wellness applications shall be excluded from this regulation, and their interoperability with EHR systems not be pursued. Consumers as data subjects neither expect nor should have to expect that such data will be processed for all kinds of purposes via a central access point. In addition, neither the quality of data from wellness applications, nor the processing of health data by the operators of wellness applications can be effectively controlled. Furthermore, where interoperability between EHR systems and wellness application shall be achieved, it is likely to result in challenges that data in EHR systems is typically stored decentrally, while wellness applications typically use centralized databases to store data. The definition should therefore be deleted without replacement.
~~(u) 'national contact point for secondary use of electronic health data' means an organisational and technical gateway enabling the cross-border secondary use of electronic health data, under the responsibility of the Member States;~~	
~~(v) 'central platform for secondary use of electronic health data' means an interoperability platform established by the Commission, providing services to support and facilitate the exchange of information between national contact points for secondary use of electronic health data;~~	
~~(x) 'HealthData@EU' means the infrastructure connecting national contact points for secondary use of electronic health data and the central platform;~~	
(y) '**health** data holder' means a~~ny~~ natural or legal person, which is an entity or a body in the health or care sector, or performing research in relation to these sectors, as well as Union institutions, bodies, offices and agencies who has ~~the right or obligation, in accordance with this Regulation, applicable Union law or national legislation implementing Union law~~ **either:**	

(a) the right or obligation, in accordance with applicable Union law or national legislation, to process personal electronic health data for the provision of health or care or for public health, research, innovation, policy making, official statistics, patient safety or regulatory purposes, in its capacity as a controller; or	The **definition** of the **data holder** is **extremely far reaching** and **far too extensive**. Especially since every data holder who could possibly process electronic health data – for one of the many purposes listed here – is **obliged** to **make** the **very comprehensive data categories listed in Art. 33** (which is also far too extensive and contains e.g. social and environmental elements, genetic data, data from wellness applications, insurance status, professional status, education, lifestyle, wellness and behaviour and many more) **available** upon request to the health data access body (see Art. 35B) according to a **data permit** or data request (which can be issued for one of the **all-encompassing purposes** listed in Art. 34). The result is that the secondary use has de facto no limits.
(b) the ability to make available, including to register, provide, restrict access or exchange electronic health data that do not constitute personal data in the meaning of Article 4 (1) of Regulation (EU) 2016/679~~non-personal data~~, through control of the technical design of a product and related services, ~~the ability to make available, including to register, provide, restrict access or exchange certain data~~;	The question arises, why the **wording "non-personal data"** is not used any longer. The reference to Article 4 (1) of Regulation (EU) 2016/679 is welcomed in any case.
(z) '**health** data user' means a natural or legal person who has lawful access to ~~personal or non-personal~~ electronic health data for secondary use **pursuant to a data permit or a data request pursuant to this Regulation**;	
(aa) 'data permit' means an administrative decision issued to a **health** data user by a health data access body or a **single health** data holder to process the electronic health data specified in the data permit for the secondary use purposes specified in the data permit based on conditions laid down in **Chapter IV of** this Regulation;	
(ab) 'dataset' means a structured collection of electronic health data;	
(ac) 'dataset catalogue' means a collection of datasets descriptions, which is arranged in a systematic manner and consists of a user-oriented public part, where information concerning individual dataset parameters is accessible by electronic means through an online portal;	
(ad) 'data quality' means the degree to which characteristics of electronic health data are suitable for secondary use;	Isn't data quality also an issue for primary use? May such definition maybe also include primary use, although this is not targeted directly in this sense and by this definition in the regulation?
(ae) 'data quality and utility label' means a graphic diagram, including a scale, describing the data quality and conditions of use of a dataset.	
(af) 'ethical aspects' mean …	Suggestion to add a definition of 'ethical aspects'
(ag) 'ethical committees' mean …	Suggestion to add a definition of 'ethical committees'.

CHAPTER IV	
Secondary use of electronic health data	
CHAPTER IV	
Secondary use of electronic health data	
~~*Article 48*~~	
~~*Making data available for public sector bodies and Union institutions, bodies, offices and agencies without a data permit*~~	
~~By derogation from Article 46 of this Regulation, a data permit shall not be required to access the electronic health data under this Article. When carrying out those tasks under Article 37 (1), points (b) and (c), the health data access body shall inform public sector bodies and the Union institutions, offices, agencies and bodies, about the availability of data within 2 months of the data access application, in accordance with Article 9 of Regulation […] [Data Governance Act COM/2020/767 final]. By way of derogation from that Regulation […] [Data Governance Act COM/2020/767 final], the health data access body may extend the period by 2 additional months where necessary, taking into account the complexity of the request. The health data access body shall make available the electronic health data to the data user within 2 months after receiving them from the data holders, unless it specifies that it will provide the data within a longer specified timeframe.~~	The deletion is welcomed and very important. The provision wouldn't have been acceptable.
~~*Article 49*~~	
~~*Access to electronic health data from a single* **health** *data holder*~~	Article 49 should be deleted for reasons of effective control, governance, and security considerations. A data holder may satisfy such applicant's interest by providing anonymized data, which does not require any specific legal basis.
~~1. **Member States may allow** W**w**here an applicant requests access to electronic health data only from a single **health** data holder **in that** in a single Member State, by way of derogation from Article 45(1) **or Article 47(1)**, that applicant may **to** file a data access application or a data request directly to the **health** data holder. The data access application shall comply with the requirements set out in Article 45 and the data request shall comply with requirements in Article 47. Multi-country requests and requests requiring a combination of datasets from several **health** data holders shall be adressed to health data access bodies.~~	The data holder shouldn't be empowered to issue a data permit, since the data holder is no authority and the definition of data holders is very broad, so that a data holder could be anyone in the health or care sector. There has to be an assessment by an authority if the criteria to issue a data permit are met. Otherwise there would be no control and misuse would be easily possible. Also it has to be possible to appeal the decision. We consider it problematic to allow data users to address single data holders, particularly if the group of data holders subject to the stipulations of this Regulation is not reduced (e.g. by excluding SMEs). The processes and technical infrastructure for processing data access applications would result in unjustifiable costs for individual data holders. Also, the quality of the assessment of data access applications would be reduced (given the limited resources of individual data holders for assessing ethics or data protection issues, of auditing data use etc).

	At least, individual data holders should be enabled/required to approach health data access bodies to help with the processes It should be borne in mind that transferring the obligations to individual data holders here places a massive burden on individual data holders who now have to fulfil the same requirements as an access point. The necessity for each data controller to provide the corresponding infrastructure at the level of the access point for a secure processing environment is, among other things, very resource-intensive. In addition, the data controller has to bear all the administrative and other obligations (including liabilities) that would otherwise be provided by the access point. In any case, the reference to Art. 37(1) is too broad and not precise. Additionally, it should be remarked that also the use of metadata standards is important in this point of view. Also the single health data holder should use metadata consistent and coherent with those that apply to the overall data ecosystem.
~~**1A. Where an applicant request access to electronic health data from health data holders which are an Union institution, body, office or agency, by way of derogation from Article 45(1) or Article 47(1), that applicant shall file a data access application or a data request directly to each health data holder. The data access application shall comply with the requirements set out in Article 45 and the data request shall comply with requirements in Article 47.**~~	An authority should also assess data applications regarding data holders which are Union bodies. Also it has to be possible to appeal the decision.
~~2. In such case **situations referred to in paragraphs 1 and 2 in this Article,** the **health** data holder may issue a data permit in accordance with Article 46 or provide an answer to a data request in accordance with Article 47. The **health** data holder shall then provide access to the electronic health data in a secure processing environment in compliance with Article 50 and may charge fees in accordance with Article 42.~~	See the comments above.
~~3. By way of derogation from Article 51, the single data provider and the data user shall be deemed joint controller.~~ SEE ARTICLE 51	
~~4. Within 3 months t**T**he **single health** data holder**, referred to in paragraph 1 of this Article,** shall **within 3 months** inform the relevant health data access body by electronic means of all data access applications filed and all the data permits issued and the data requests fulfilled under this Article in order to enable the health data access body to fulfil its obligations under Article 37(1) and Article 39.~~	Additionally, it should be remarked that metadata standards should be consistent and coherent with those that apply to the overall data ecosystem and it is questionable if this would apply when the access is provided by many single data holders and providing metadata is not coordinated accordingly.

'Specific topics of Chapter IV discussed in the WPPH on February 23 and 24, 2023

1. <u>The rights of natural persons in relation to the secondary use of personal electronic health data, in particular an opt-out-solution</u>

General questions on rights of natural persons a) Is there a need for an article on the rights of natural person in relation to processing of personal electronic health data for secondary use, inspired by Article 3 in Chapter II, and if so, what would this new article need to contain? Are there for example rights in the GDPR that you would like to address in a such article, and in such case, which rights?	Yes, such an article is needed. **At least it should contain an opt-in/opt-out option.**
Questions related to a possible opt-out solution b) Do you see a need for an opt-out for natural person in relation to the secondary use of their personal electronic health data? i. If so, do you see a need to lay down rules on how and to whom, the health data holder or the health data access body, will the natural person exercise its right to opt-out? ii. If so, who would be responsible for removing the information from the data set when a natural person has exercised its right to opt-out, the health data access body and/or the health data holder? iii. And should the natural person be able to opt-out from certain processing of personal electronic health data, for example certain data categories or certain purposes of secondary use?	Yes, <u>preferably an opt-in or at least an opt-out is needed</u>. i) Yes, it should be specified in the regulation itself how and to whom this opt-in/opt-out can be declared. ii) We see the possibility of implementing an opt-in/ opt out at the HDABs where the HDAB holds a list of to-be-excluded pseudonyms that can be applied to incoming pseudonymised datasets. If data for secondary use can also be requested directly at data holders (art 49), a separate solution would be required (either at the data holder(s) or in cooperation with the HDAB). iii) A full opt-in/opt-out regarding all data processing is certainly needed. If there is additionally an opt-out option regarding the processing of certain data categories or for certain purposes that is a welcomed addition. Additionally to secondary use, there should also be an opt-in or opt-out for primary data use.

2. <u>Article 33(1)(a) - electronic health data from EHRs, including the categories in Article 5 of this Regulation</u>

Option 1 – keep current proposal from the Commission Comment: All electronic health data from EHR system are included, both health data in an unstructured form and health data in a structured form.	
Option 2 – amendment **The priority categories listed in Article 5 of this Regulation.** Comment: Only the priority categories in Article 5 are included.	<u>Option 2 is preferred.</u> We are not sure whether the categories in Art 5, which seem to be oriented at health data held by public sector data holders, is the right way to qualify Art 33(1)(a). If health data from private sector digital health applications (e.g. health apps) is to be addressed, there might be relevant structured (and unstructured) data that is not part of Art 5. At the same time, for public sector actors running EHRs (e.g. a clinical information system), it might be impractical or impossible to provide more than the structured data mentioned in Art 5.

	We recommend transition periods where the focus is on specific sets of structured EHR data while exploring inhowfar data from public AND private sector data holders can be mobilised. This proposal goes in the right direction, but the text should provide even more clarity. "Determinants having an impact on the health status" still is far too broad and shall be deleted.
Option 3 – other amendments	

3. Article 33(1)(b) – data on factors impacting on health, including social, environmental behavioural determinants of health

Option 1 – keep current proposal in the first compromise - Data on factors impacting on health, including social, environmental behavioural determinants of health	
Option 2 – closer link to the determinants of health in the public health area - Electronic health data on elements related to health, namely health status, including morbidity and disability, ~~**the determinants having an effect on the health status**~~, health care needs, resources allocated to health care, the provision of and access to health care as well as health care expenditure and financing, and the causes of mortality. Comment: A proposal with a clearer link to the GDPR on the determinants of health in the public health area, see recital in 54 in the GDPR. In the recitals it also states that such processing of data concerning health for reasons of public interest should not result in personal data being processed for other purposes by third parties such as employers or insurance and banking companies. Such purpose could be added in the list of prohibited purposes in Article 35.	The following answers to the questions are subject to the prerequisite that there is an opt-in/opt-out. Option 2 is still too far-reaching, but it is clearly preferred to Option 1. Also it is better defined what data can be used for secondary use and it seems to contain less data regarding other aspects of life, so this is welcomed. Still it includes much personal data that is linked to other aspects of life. This proposal goes in the right direction, but the text should provide even more clarity. "Determinants having an impact on the health status" still is far too broad and shall be deleted and replaced with clearer data categories. As proposed, the described purpose should be included in the list of prohibited purposes. The Austrian national public health institute supports this specification and is convinced of the added value of the possibility of processing these type of data for public health. At the same time, challenges are seen in obtaining and/or enforcing compliance by relevant data holders. E.g., water quality and sanitation are relevant determinants of health, but obtaining data on them would require working with municipalities etc.
Option 3 – other amendment - Amendments you prefer	

4. Article 33(1)(n) – electronic data related to insurance status, professional status, education, lifestyle, wellness and behaviour data relevant to health

Option 1 – keep current proposal from the Commission - Electronic data related to insurance status, professional status, education, lifestyle, wellness and behaviour data relevant to health	See Comment to Option 2.

Option 2 – amendment - Electronic data related to insurance status, professional status and education Comment: A proposal with exclusion of lifestyle, wellness and behaviour data relevant to health	
Option 3 – other amendments - Amendments you prefer	Option 1 is extremely far-reaching; lifestyle, wellness and behaviour data should not be included. In addition, the question arises if the professional and educational status are really needed. We therefore propose deleting the whole (n), as it is far too broad either way. A general permission to process any kind of personal data under this provision must be impeded.

5. Data categories in Article 33(1)(e) – human genetic, genomic and proteomic data

Option 1 – keep current proposal from the Commission - Human genetic, genomic and proteomic data	
Option 2 – set out additional safeguards - Which clarifications and additional safeguards would be necessary to keep this in the proposal, for example consent, limitation of purposes and/or health data users, ethical aspects et cetera?	
Option 3 – other amendments - Amendments you prefer	Since this regards highly sensitive data, additional safeguards are necessary. The mentioned measures may be suitable safeguards, as in particular consent and purpose limitation. However, we suggest to delete the whole (e), as genetic and genomic can not be pseudonymized nor anonymized, and it is far too sensitive to be processed by third parties on such large scale.

6. Data categories in Article 33(1)(j) – data from clinical trials

Option 1 – keep current proposal from the Commission - data from clinical trials	Definitely keep data from clinical trials, as this provides major opportunities for secondary research. At the time of running the trial, the subjects involved are typicaly already well informed and voluntarily participate in such trials, and often are reimbursed. They already give their consent to processing of their data for the clinical trial, which could be extended to cover secondary use.
Option 2 - set out additional safeguards - Which clarifications and additional safeguards, would be necessary to keep this in the proposal, for example consent, limitation of purposes and/or health data users, ethical aspects et cetera?	**General comment:** It was assumed that for participating in clinical trials and the following processing of personal data from clinical trials consent was already necessary. We would appreciate clarification on this matter.
Option 3 – other amendments - Amendments you prefer	

7. Data categories in Article 33(1)(o) – enriched data

Option 1 – keep current proposal from the Commission - health data containing various improvements such as correction, annotation, enrichment received by the health data holder following a processing based on a data permit	
Option 2 – set out additional rules - health data **based on the original dataset** containing various improvements such as correction, annotation, enrichment received by the health data holder following a processing based on a data permit And then add the following in Article 35B(5) on duties for health data holder: - Where a **health** data holder has received enriched datasets following a processing based on a data permit, it shall make ~~available~~ the new dataset **available upon request pursuant to paragraph 1 in this Article and include the new dataset in the description in accordance with Article 55**, unless it considers it unsuitable and notifies the health data access body in this respect. **Before receiving the enriched datasets from the health data access body, the health data holder shall make such that the dataset are based on its original dataset and, if the new dataset include personal data, assess that the processing of personal data is in line with Articles 5, 6 and 9 of Regulation (EU) 2016/679.**	
Option 3 – other amendments - Amendments you prefer	Delete the whole (o), for the following reasons: • It is unlikely that a data user is able to effectively correct datasets at the time of secondary analysis • This results in unnecessary burdens for health data access bodies. Data should not leave the secure processing environments, and additional personal data should not be sent back to data holders under any provision

Specific topics related to the secondary use discussed in the WPPH on March 6 and 7, 2023

8. The Scope and definition of health data holder

Option 1 – Current scope and definition of health data holder with a clarification that also social security is included Article 2(2)(y) • '**health** data holder' means ~~a~~**any** natural or legal person, which is an entity or a body in the health or care sector, **including social security,** or performing research in relation to these sectors, as well as Union institutions, bodies, offices and agencies who has ~~the right or obligation, in accordance with this Regulation, applicable Union law or national legislation implementing Union law~~ **either:** **a) the right or obligation, in accordance with applicable Union law or national legislation, to process personal electronic health data for the provision of health or care or for public health, research, innovation, policy making, official statistics, patient safety or regulatory purposes, in its capacity as a controller; or** b) **the ability to make available, including to register, provide, restrict access or exchange electronic health data that do not constitute personal data in the meaning of Article 4 (1) of Regulation (EU) 2016/679**~~non-personal data~~, through control of the technical design of a product and related services, ~~the ability to make available, including to register, provide, restrict access or exchange certain data~~; Comment: This is a broad definition of health data holder and include all entities in the health and care sector, including the social security sector. As we understand it, the definition as suggested in option 1, would include for example both private and public health and care providers, pharmaceutical companies, entities within social security, public institutions, and public sectors bodies with tasks in these sectors, including bodies that produce official statistics in these sectors, researchers, insurers, EMA and ECDC etc. See recitals 38 to 40 in the Commission´s proposal. The definition could also include tech companies and other companies when their perform within the health and care sector. For processing of personal electronic health data they need to act as a controller and not for example as a processor. Clarifications on this could be provided in the recitals.	Option 1 with amendments in Option 3. General Remarks: It should be remarked that metadata standards should be consistent and coherent with those that apply to the overall data ecosystem. Data that are needed for secondary use in the public interest with a legal basis (e.g. for official statistics) should be free of charge.
Option 3 – other amendments • Please provide us with other amendments and/or clarification on the scope of health data holder.	Like Option 1, but excluding micro- and small-sized enterprises, while medium-sized enterprises may be excluded for a limited time.

9. The scope and definition of health data user and applicant

Option 1 – Current scope and definition of health data user and the scope of applicant Article 2(2)(z) • '**health** data user' means a natural or legal person who has lawful access to ~~personal or non-personal~~ electronic health data for secondary use **pursuant to a data permit in Article 46 or a data request in Article 47 of this Regulation** Article 45(1) and 47(1) • A natural or legal person may submit… Comment: This is a broad definition of health data user and who may submit a data access application or a data request. It is important to keep in mind that the health data user needs to fulfil the requirement stated in Article 46 and 47.	
Option 2 – Limiting the scope and definition of health data user and the scope of applicant Article 2(2)(z) • '**health** data user' means a natural or legal person **within the juridiction of a country or an international organisation which is an authorised participant of the cross border infrastructure for secondary use in Article 52,** who has lawful access to ~~personal or non-personal~~ electronic health data for secondary use **pursuant to a data permit in Article 46 or a data request in Article 47 of this Regulation** Article 45(1) and 47(1) • A natural or legal person, **within the juridiction of a country or an international organisation which is an authorised participant of the cross border infrastructure for secondary use in Article 52,** may submit… Comment: This option would limit the scope of potential health data users and applicants to ensure reciprocity and equal terms for the sharing of electronic health data for secondary use purposes in relation to the cross-border infrastructure. These entities would still need to fulfil the requirements in Articles 46 and 47 et cetera.	The insertion "**within the juridiction of a country or an international organisation which is an authorised participant of the cross border infrastructure for secondary use in Article 52**" in the definition is confusing and the meaning and purpose of the change cannot be discerned. As long as the meaning of the insertion has not been clarified, a scrutiny reservation should be maintained.
Option 3 – other amendments • Please provide us with other amendments and/or clarification on the scope of health data user and applicant.	

AT Written Comments on Articles 59-65

First Presidency Compromise Proposal (Chapters V-VIII)(Doc. 6627/23)	AT Comments
Chapter V	
Additional actions	
Article 59	
Capacity building	
The Commission shall support sharing of best practices and expertise, aimed to build the capacity of Member States to strengthen digital health systems for primary and secondary use of electronic health data. To support capacity building, the Commission shall **in close cooperation and consultation with Member States** ~~draw up~~ **establish indicators for self assessment** ~~benchmarking guidelines~~ for the primary and secondary use of electronic health data.	Whereas the textual amendments, especially the deletion of the word "benchmarking", is fully supported, this Article is still very vague for a binding Regulation and would therefore deserve a more precise formulation, notably an explanation of what "capacity building" is actually about, preferably in the text but at least in the recitals.
Article 60	
Additional requirements for public procurement and Union funding	
1. **Contracting authorities** ~~Public procurers, national competent authorities~~, including digital health authorities and health data access bodies and **Union institutions, bodies, offices or agencies, including** the Commission**,** shall make reference to the applicable technical specifications, standards and profiles as referred to in Articles 6, **12,** 23, 50, **52,** 56, **as well as to the requirements laid down in Regulations (EU) 2016/679 and (EU) 2018/1725,** as relevant, as points of orientation for public procurements and when formulating their tender documents or calls for proposals, as well as when defining the conditions for Union funding regarding this Regulation, including enabling conditions for the structural and cohesion funds.	This provision as such is fully supported. Also the textual amendments, aiming to include data protection aspects as funding criteria, can be supported. However, such selective references to individual articles of legal acts must not give the impression to those subject to the law that the non-referenced articles of the said legal acts would not apply, which should therefore be clarified (more explicitely than by the wording "in particular") preferably in the text but at least in the recitals.
2. **The criteria for obtaining funding from the Union** ~~The ex-ante conditionality for Union funding~~ shall take into account**:**	
a) the requirements developed in Chapters II, III and IV**;**	
b) the requirements laid down in Regulations (EU) 2016/679 or (EU) 2018/1725, where applicable, in particular:	
(i) the requirements laid down in Article 35 or 39 respectively of these Regulations by requiring a documented data protection impact assessment,	

including where Chapter V of these Regulations apply, an assessment of the impact of the transfer to third countries or international organisations.	
(ii) where Article 28 or 29 respectively of these Regulations is applicable, by requiring a contract or other legal act between the controller and the processor pursuant to Article 28 paragraph 3 or Article 29 paragraph 3 respectively.	
Article 61	
~~*Third country*~~ ***T***~~*t*~~*ransfer* ***to a third country*** *of* ***anonymous electronic health data*** ~~*non-personal electronic data*~~ ***presenting a risk of re-identification***	
1. ~~Non-personal~~ **Anonymous** electronic data made available by health data access bodies **to a health data user in a third country according to a data permit pursuant to Article 46 or a data request pursuant to Article 47 or to an authorisated participants in a third country or an international organisation**, that are based on a natural person's electronic **health** data falling within one of the categories of Article 33 ~~[(a), (e), (f), (i), (j), (k), (m)]~~ shall be deemed highly sensitive within the meaning of Article 5(13) of Regulation **(EU) 2022/868**[…] ~~[Data Governance Act COM/2020/767 final]~~, provided that their transfer to third countries presents a risk of re-identification through means going beyond those **reasonably** likely ~~reasonably~~ to be used, **in particular** in view of the limited number of natural persons involved in that data, the fact that they are geographically scattered or the technological developments expected in the near future.	We support the clarification of only including anonymous data as a legal term of the GDPR, rather then a new category of data as suggested with the term "non-personal data". The use of the term "anonymous" is welcomed. According to the GDPR if a person can be identified, it is personal data. As soon as the data becomes re-identifiable, it becomes personal data within the meaning of the GDPR and the data protection regime of the GDPR, including the provisions of Chapter V regarding third country transfers, becomes applicable. For the qualification as personal data it is sufficient that the possibility is created to re-identify the data, the data does not actually have to be re-identified.
2. The protective measures for the categories of data mentioned in paragraph 1 shall depend on the nature of the data and anonymization techniques and shall be detailed in the Delegated Act under the empowerment set out in Article 5(13) of Regulation **(EU) 2022/868** […] ~~[Data Governance Act COM/2020/767 final]~~.	
Article 62	
~~*International access and*~~ ***T***~~*t*~~*ransfer of* ***anonymous*** ~~non-personal~~ *electronic health data* ***to a third country or an international organisation***	
1. The digital health authorities, health data access bodies, the authorised participants in the cross-border infrastructures provided for in Articles 12 and 52 and **health** data users shall take all reasonable technical, legal and organisational measures, including contractual arrangements, in order to prevent ~~international~~ transfer **to a third country or an international organisation, including** ~~or~~ governmental access **in a third country** **of**~~to~~ **anonymous** ~~non-personal~~ electronic health data held in the Union where such transfer ~~or access~~ would create a conflict with Union law or the national law of the relevant Member State,	

without prejudice to paragraph 2 or 3 of this Article.	
2. Any judgment of a third-country court or tribunal and any decision of a third-country administrative authority requiring a digital health authority, **a** health data access body or **a health** data user~~s~~ to transfer~~ or give access to~~ **anonymous**~~ non-personal~~ electronic health data within the scope of this Regulation held in the Union shall be recognised or enforceable in any manner only if based on an international agreement, such as a mutual legal assistance treaty, in force between the requesting third country and the Union or any such agreement between the requesting third country and a Member State.	We are unsure what exactly this provision implies. We believed that stakeholders in the MS would not be bound by any instruction of courts or tribinals of third countries. This would cleary undermine the EU-position and would open national datasets to the jursidiction of third countries, which we cannot support for the following reasons: The EHDS is a position of strength in contrast to third countries, which intends to facilitate the data economy in the EU. Integrating third-country jurisdiction without being a MS,and therefore not being bound by decisions of the CJEU, third countries would gain all the advantages of the EHDS without having to take any extra steps towards (esp. legal) integration into the EU. Reciprocity is therefore of even greater value and needs to be evaluated and closely monitored before accepting third countries into the EHDS.
3. In the absence of an international agreement as referred to in paragraph 2 of this Article, where a digital health authority, a health data access body, **a health** data user~~s~~ is the addressee of a decision or judgment of a third-country court or tribunal or a decision of a third-country administrative authority to transfer ~~or give access to~~ **anonymous** data within the scope of this Regulation held in the Union and **in** compliance with such a decision would risk putting the addressee in conflict with Union law or with the national law of the relevant Member State, transfer **of** ~~to or access to~~ such data **to** ~~by~~ that third-country authority shall take place only where:	Same as para 2.
(a) the third-country system requires the reasons and proportionality of such a decision or judgment to be set out and requires such a decision or judgment to be specific in character, for instance by establishing a sufficient link to certain suspected **natural or legal** persons or infringements;	How can a reference to a specific person be established if anonymised data is concerned? In what context can it even happen that an anonymous database is to be queried due to a court decision in a third country? What are the use cases?
(b) the reasoned objection of the addressee is subject to a review by a competent third-country court or tribunal; and	
(c) the competent third-country court or tribunal issuing the decision or judgment or reviewing the decision of an administrative authority is empowered under the law of that third country to take duly into account the relevant legal interests of the provider of the data protected under Union law or the national law of the relevant Member State	
4. If the **criteria** ~~conditions~~ laid down in paragraph 2 or 3 are met, **a** digital health authority, a health data access body or a **health data user** ~~data altruism body~~ shall provide the minimum amount of data permissible in response to a request, based on a reasonable interpretation of the request.	
5. The digital health authorities, health data access bodies, **health** data users shall inform the **health** data holder about the existence of a request of a third-country administrative authority to access its data before complying with that request, except where the request serves law enforcement purposes and for as long as this is necessary to preserve the effectiveness of the law enforcement activity.	

Article 63	
*~~International access and~~ **Tt**ransfer of personal electronic health data **to a third country or an international organisation***	
In the context of ~~international access and~~ transfer of personal electronic health data **to a third country or an international organisation,** Member States may maintain or introduce further conditions, including limitations, in accordance with and under the conditions of **A**~~a~~rticle 9(4) of Regulation (EU) 2016/679, **in addition to the requirements set out in Articles 13 paragraph 3 and 52 paragraph 5 of this Regulation and the requirements laid down in Chapter V of Regulation (EU) 2016/679**.	The reference to the requirements laid down in Chapter V of the GDPR is welcomed (and important).
Chapter VI	
European governance and coordination	**General Remarks:** General scrutiny reservation on Chapter VI with regard to the primary use of health data: The proposed abolition of the voluntary eHealth Network (representing the MS' competences under Art. 14 of Directive 2011/24/EU) and its proposed replacement by a "European Digital and Health Data Board" is in potential conflict with the primary Union law enshrined in Art. 168 (7) TFEU. Although some essential changes in the present compromise text go in the right direction, a few textual changes are still needed as far as the primary use of health data is concerned, in order to comply with Art. 168 (7) TFEU.
Article 64	
European Health Data Space Board (EHDS Board)	
1. A European Health Data Space Board (EHDS Board) is hereby established to facilitate cooperation and the exchange of information among Member States. The EHDS Board shall be composed of ~~the high level~~ representatives**, one each** of digital health authorities and health data access bodies**,** of all the Member States. ~~Other national authorities, including market surveillance authorities referred to in Article 28, European Data Protection Board and European Data Protection Supervisor, may be invited to the meetings, where the issues discussed are of relevance for them. The Board may also invite experts and observers to attend its meetings, and may cooperate with other external experts as appropriate. Other Union institutions, bodies, offices and agencies, research infrastructures and other similar structures, shall have an observer role.~~ (SECOND, THIRD AND LAST SENTENCES AMENDED AND MOVED TO PARA 1(B)-1(E))	

1a. A representative of ~~T~~the Commission **and a representative of the Member States** shall **co-**chair the meetings of the EHDS Board. (MOVED FROM PARA 6)	With regard to Art. 168 (7) TFEU, the textual amendment is very important and therefore fully supported.
1b. ~~Other national authorities, including~~**M**~~m~~arket surveillance authorities referred to in Article 28, European Data Protection Board and European Data Protection Supervisor, **shall** ~~may~~ be invited to the meetings, where the issues discussed are of relevance for them. (MOVED FROM PARA 1 AND AMENDED)	The textual amendment, especially the replacement of the word "may" by the word "shall", is fully supported. If data protection issues are concerned, the EDPS and EDPB must be consulted.
1c. The Board may also invite **other national authorities,** experts and observers to attend its meetings, and may cooperate with other external experts as appropriate. (MOVED FROM PARA 1 AND AMENDED)	
1d. Other Union institutions, bodies, offices and agencies, research infrastructures and other similar structures **shall** have an observer role **when invited to participate in the meetings**. (MOVED FROM PARA 1 AND AMENDED)	
1e. Stakeholders and relevant third parties, including patients' representatives, **may** ~~shall~~ be invited to attend meetings of the EHDS Board and to participate in its work, depending on the topics discussed and their degree of sensitivity. (MOVED FROM PARA 4)	
2. Depending on the functions related to the use of electronic health data, the EHDS Board may work in subgroups **for certain topics**, where digital health authorities or health data access bodies ~~for a certain area~~ shall be represented. The subgroups may have joint meetings, as required.	
3. The ~~composition, organisation, functioning and cooperation of subgroups shall be set out in~~ rules of procedures **of the EHDS Board shall be adopted by its members and** put forward by the Commission. **They shall include rules pertaining to the composition, structure, operation and cooperation of the sub-groups and shall regulate the role of invitees referred to in paragraphs 1b to 1e, taking into account the topics under discussion and the level of confidentiatlity involved.**	With regard to Art. 168 (7) TFEU, the textual amendment (especially of the first sentence) is very important and therefore fully supported.
~~4. Stakeholders and relevant third parties, including patients' representatives, shall be invited to attend meetings of the EHDS Board and to participate in its work, depending on the topics discussed and their degree of sensitivity.~~ MOVED TO PARA 1E	
5. The EHDS Board shall cooperate with other relevant bodies, entities and experts, such as the European Data Innovation Board referred to in Article ~~26~~ **29** of Regulation **2022/868** ~~[Data Governance Act COM/2020/767 final]~~, competent bodies set up under Article 7 of Regulation […] [Data Act COM/2022/68 final], supervisory bodies set up under Article 17 of Regulation […] [eID Regulation], European Data Protection Board referred to in Article 68 of	

Regulation (EU) 2016/679 and cybersecurity bodies.	
~~6. The Commission shall chair the meetings of the EHDS Board.~~ MOVED TO PARA 1A	
7. The EHDS Board shall be assisted by a secretariat provided by the Commission.	
8. The Commission shall, by means of implementing acts, adopt the necessary measures for the establishment~~,~~ **and** management ~~and functioning~~ of the EHDS Board. Those implementing acts shall be adopted in accordance with the ~~advisory~~ **examination** procedure referred to in Article 68(2).	The replacement of the advisory by the examination procedure is fully supported.
Article 65	
Tasks of the EHDS Board	
1. The EHDS Board shall have the following tasks relating to the primary use of electronic health data in accordance with Chapters II and III:	
(a) to assist Member States **who so desire** in coordinating practices of digital health authorities;	See the General Remarks/Scrutiny Reservation.
(b) to issue written **non-binding** contributions and to exchange best practices on matters related to the coordination of the implementation at Member State level of this Regulation and of the delegated and implementing acts adopted pursuant to it, in particular as regards:	See the General Remarks/Scrutiny Reservation.
(i) the provisions set out in Chapters II and III;	
(ii) development of online services facilitating secure access, including secure electronic identification, to electronic health data for health professionals and natural persons.~~;~~	
~~(iii) other aspects of the primary use of electronic health data~~.	
(c) to facilitate **voluntary** cooperation between digital health authorities through capacity-building, establishing the structure for **biennial** ~~annual~~ activity reporting, **and exchange of information in those reports** ~~peer review of annual activity reports and exchange of information~~;	See the General Remarks/Scrutiny Reservation.
(d) to share information concerning risks posed by EHR systems and serious incidents as well as their handling;	
(e) to facilitate the exchange of views on the primary use of electronic health data with the relevant stakeholders, including representatives of patients, health professionals, researchers, regulators and policy makers in the health sector.	
2. The EHDS Board shall have the following tasks related to the secondary use of electronic health data in accordance with Chapter IV:	

(a) to assist Member States, in coordinating practices of health data access bodies,–in the implementation of provisions set out in Chapters IV, to ensure a consistent application of this Regulation;	
(b) to issue written contributions and to exchange best practices on matters related to the coordination of the implementation at Member State level of this Regulation and of the delegated and implementing acts adopted pursuant to it, in particular as regards:	
(xi) implementation of rules for access to electronic health data;	
(xii) technical specifications or existing standards regarding the requirements set out in Chapter IV;	
(xiii) incentives policy for promoting data quality and interoperability improvement;	
(xiv) policies concerning fees to be charged by the health data access bodies and **health** data holders;	
(xv) the establishment and application of penalties~~;~~	
~~(xvi) other aspects of the secondary use of electronic health data~~.	
(c) to facilitate cooperation between health data access bodies through capacity-building, establishing the structure for **biennial** ~~annual~~ activity reporting, **and** ~~peer-review of annual activity reports and~~ exchange of information **in those reports**;	
(d) to share information concerning risks and data protection incidents related to secondary use of electronic health data, as well as their handling;	
~~(e) to contribute to the work of the European Data Innovation Board to be established in accordance with Article 29 of the Regulation […] [Data Governance Act COM/2020/767 final];~~ (SEE ARTICLE 65~~4~~(5))	Editorial error.
(f) to facilitate the exchange of views on the secondary use of electronic health data with the relevant stakeholders, including **health data holders, health data users,** representatives of patients, health professionals, researchers, regulators and policy makers in the health sector.	

Comments from the Belgian delegation

BE Comments and proposals Working Party 6 & 7 March: Chapter I and IV EHDS

1) **Chapter I: Examination of the first compromise: Examination of Articles 1 and 2 (2) letter o, u, v, x, aa, ab, ac, ad and ae**

Article 1 Subject matter and scope

1. …

2. This Regulation:
…

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

BE didn't agreed with the deletion of "mandatory" because it is important that the same infrastructure is used everywhere. After listening to the legal service (no added value) and the comments of some MS, we propose to add "interoperable".

…
Article 2 Definitions

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

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

We think that also a definition of "Meta data catalogue" could be useful.

(ad) 'data quality' means the degree to which **a set of inherent** characteristics of ~~electronic health~~ data **fulfils requirements** ~~are suitable~~ ~~for secondary use~~

Also in primary us (e.g. in art 7, 23, 37,39, 41) "data quality" is used. This definition should be more generic as the other definitions.

2) Chapter IV: Secundary use: Continuing the discussion on specific topics related to the secondary use

Article 45

Data access applications

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

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

(aa) a description of the applicant identity, professional function and operation, including the identity of who will have access to the electronic health data. ***In case the data user makes use of one or more processors, these shall be described in sufficient detail"*:**

About (aa): does this include processors as wel? That is sometimes almost impossible (e.g. when using IaaS, SaaS or PaaS cloud architecture solutions)

Text suggestion: addition in (aa): ***In case the data user makes use of one or more processors, these shall be described in sufficient detail"*:**

...

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

About "(d) This should be worded stronger: "(d) where applicable, a~~n~~ ~~explanation~~ ~~of the reasons~~ for seeking access to electronichealth data in a 27seudonymized format;"

…

Article 46

Data permit

3. Where the health data access bodies shall make their decisions to grant or refuse access to electronic health data they shall assess if the applicant fulfils the following criterias:

To what extent is the assessment of criteria specified in (b), (c) and (d) compatible or subsidiary to the competences of the data protection authorities? This should be clarified in the text, depending on the answer

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

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

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

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

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

(f) other requirements in this Chapter.

2. …

Article 47

Data request

…

Article 50

Secure processing environment

….

Article 52

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

….

Article 66

Joint controllership groups for Union infrastructures

…

3) Chapter V : Additional actions

Article 59

Capacity building

…

Article 60

Additional requirements for public procurement and Union funding

...

Article 61

...

Article 62

Transfer of anonymous electronic health data to a third country or an international organisation

…

4. If the criteria laid down in paragraph 2 or 3 are met, a digital health authority, a health data access body or a health data ~~user~~ **holder** shall provide the minimum amount of data permissible in response to a request, based on a reasonable interpretation of the request.

Should this not be “data holder” instead of a data user? Or just delete health data user.

5. The digital health authorities, health data access bodies, health data ~~users~~ **holder** shall inform the health data holder about the existence of a request of a third-country administrative authority to access its data before complying with that request, except where the request serves law enforcement purposes and for as long as this is necessary to preserve the effectiveness of the law enforcement activity.

Same comment: "data holder" of delete health data user.

Article 63

….

4) Chapter VI: European governance and coordination

Article 64

European Health Data Space Board (EHDS Board)

2. A European Health Data Space Board (EHDS Board) is hereby established to facilitate cooperation and the exchange of information among Member States. The EHDS Board shall be composed of **one representatives and one alternate**, ~~**one each** of digital health authorities and health data access bodies~~, of all the Member States. (SECOND, THIRD AND LAST SENTENCES AMENDED AND MOVED TO PARA 1(B)-1(E))

Structure is too complexe. We should limit the number of participants to 1 or 2 per MS.

…

1a. A representative of the Commission and a representative of the Member States shall co-chair the meetings of the EHDS Board. (MOVED FROM PARA 6) Positief faitashisme

1b. Market surveillance authorities referred to in Article 28, European Data Protection Board and European Data Protection Supervisor, shall be invited to the meetings, where the issues discussed are of relevance for them. (MOVED FROM PARA 1 AND AMENDED)

1c. The Board may also invite other national authorities, experts and observers to attend its meetings, and may cooperate with other external experts as appropriate. (MOVED FROM PARA 1 AND AMENDED)

1d. Other Union institutions, bodies, offices and agencies, research infrastructures and other similar structures shall have an observer role when invited to participate in the meetings. (MOVED FROM PARA 1 AND AMENDED)

1e. Stakeholders and relevant third parties, including patients' representatives, ~~may~~ **shall have an observer role when invited to participate in the** ~~be invited to attend~~ meetings of the EHDS Board and to participate in its work, depending on the topics discussed and their degree of sensitivity. (MOVED FROM PARA 4)

This brings it more in line with the previous para's.

…

Article 65
Tasks of the EHDS Board

Comments from the Czech delegation

Comments of the Czech Republic
on Chapter of Swedish Presidency compromise of draft EHDS Regulation

Chapter I

General provisions

Article 1

Subject matter and scope

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

2. This Regulation:

Suggestion:

CZ believes that there is no need to explicitely list specific chapters in this paragrap, because it could lead to misinterpretation of the general provisions. It is therefore proposed not to list the chapters directly in Article 1(2) or, on the contrary, to create additional point(s) to cover the remaining chapters V, VII, VIII and IX that are not included in the paragraph, but are still important for the Regulation.

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

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

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

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

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

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

~~3. This Regulation applies to:~~

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

~~(b) controllers and processors established in the Union processing electronic health data of Union citizens and third-country nationals legally residing in the territories of Member States;(c) controllers and processors established in a third country that has been connected to or are interoperable with MyHealth@EU, pursuant to Article 12(5);~~

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

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

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

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

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

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

Suggestion:

It is not certain that paragraph 7 is necessary in the Regulation, especially in the context of the division of powers under the Treaty on the Functioning of the European Union.

Article 2

Definitions

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(y) '**health** data holder' means any natural or legal person, which is an entity or a body in the health or care sector, **including social security,** or performing research in relation to these sectors, as well as Union institutions, bodies, offices and agencies who has the right or obligation, in accordance with this Regulation,

Comment:
CZ supports the compromise proposal of SE PRES that includes data from social security sector, which are valuable and have several common points in the context of health care. The social security data have a number of common points. Thus, they can be useful for use in health policy development and research in particular.

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

Justification:

In Article 2 para 2 letter (y)(a), the Czech Republic proposes to add an additional activity where personal health data is processed, namely 'reimbursement'. Reimbursement data is also one of the minimum categories for disclosure for secondary use set out in Article 33 of the draft Regulation.

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

Justification:

CZ sees a lack of reference also to company data and its protection. CZ therefore proposes to add the reference to this type of data.

Comment regarding the whole „health data holder" definition:

The definition of health data holder includes, inter alia, natural and legal persons conducting research. In the context of the obligations of the data holder, in particular to provide data in the defined categories, the question arises how to apply this obligation to different legal entities operating e.g. in the Czech Republic. An example could be pharmaceutical companies. These companies may have different levels of multinational operations and also different levels of representation in Member States, ranging from the simple case of a company registered only in one or more MS to global firms with a centre overseas, which either do or do not conduct research in MS (but coordinate e.g. innovation trials on the territory of MS), either by acting as a branch of the company or by being merely represented by another company. Such companies may carry out similar activities in several European countries at the same time. There are many combinations. This raises the question, which entities in which country or according to which key is used to determine the entity that will have obligations as data holder in the case of a multinational company?

(z) 'health data user' means a natural or legal **person use in Article 52, who has lawful access to personal or non-personal electronic health data for secondary use pursuant to a data permit in Article 52** who has lawful access to ~~personal or non-personal~~ electronic health data for secondary use **pursuant to a data permit in Article 46 or a data request in Article 47 pursuant to this Regulation**;

Comment:

CZ prefers option 2 from the flash (WK 2846/2023) that limits the scope of potential health data users and applicants in order to ensure reciprocity and equal terms for sharing of electronic health data for secondary purposes in relation to the cross-border infrastructure

However, it is not clear if this version of health data users definition includes also users that are authorised participants in the HealthData@EU infrastructure (in particular health research infrastructures under Article 52) who do not need to apply for permission to access the data. Is it possible that in this case they would not be considered as health data users? This aspect needs to be clarified.

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

Justification:

The need for a reference to Chapter IV in the definition does not appear necessary. It makes the definition more complicated.

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

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

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

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

(af) „synthetic data“ means information that's artificially manufactured rather than generated by real-world events.“

Justification:

CZ proposed in Article 44 to introduce the possibility of providing synthetic data, i.e. artificially produced information that does not represent events or objects in the real world, as part of enabling access to health data. In this context, a definition of synthetic data needs to be introduced in the Regulation. It is therefore proposed to consider adding a new definition in (af) (definition could include all 3 known categories of synthetic data - fully synthetic, partially synthetic and hybrid).

However, synthetic data cannot be fully substituted for e.g. genetic and genomic data in particular, therefore CZ supports further search for solutions so that even very sensitive data can be used in the EHDS to certain extent. In our opinion, solutions have to be sought in the context of discussions about "opt-out" system.

Comments of the Czech Republic
on Article 48, 49, 59 - 65 of Swedish Presidency compromise of draft EHDS Regulation

~~*Article 48*~~

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

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

Article 49

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

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

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

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

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

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

4A "When requested, HDAB shall provide support by its expertise and capabilities to data holders that are not available to them."

Comment:

CZ in general supports the compromise version of this Article proposed by SE PRES, which allows for MS to decide whether the access to electronic health data only from a single health data holder will be introduced.

Despite the above we would like to point out several conrencs and points for clarification. The provisions in Article 49 imply that an applicant can only request access to electronic health data from a single data holder in a single Member State. Therefore, all the expertise, facilities and functions of the HDAB should be available to smaller data holders. This creates a burden on smaller health service providers and other entities and creates confusion as to what all they will have to do and provide. Under the current form of the article, small single health data holders would have to provide all the infrastructure according to the EHDS rules (data catalogue, SPE, administrative support). They would also be obliged to anonymise and make the data available. However, this would place a huge burden on them. In the case of accessing data from a single health data holder, it is also unclear how the data will be protected and secured, unlike accessing data through HDAB where this is provided for. In addition to the burden of the new agenda on smaller data holders, there is also the issue of citizen confidence in the proposed system under the regulation given that personal and corporate data accessed directly by data holders in this case does not have clear terms and conditions. It may be a source of confusion in practice and could create a chaotic environment within the EHDS, if each MS treats this differently.

CZ points out that this provision should be clarified, espeacilly what obligations under Article 37 apply to the single health data holders and what is the relationship of the data files made available by single health data holders to the data catalogue managed by HDAB. During the WPPH on March 6, the EC has confirmed that the datasets of single health data holders should be part of the catalogue managed by HDAB, but it is not clear how it would be performed.

CZ further proposes to include a new provision in point 4A ensuring that the single health data holders would receive sufficient support from HDAB.

Chapter V

Additional actions

Article 59

Capacity building

The Commission shall support sharing of best practices and expertise, aimed to build the capacity of Member States to strengthen digital health systems for primary and secondary use of electronic health data. To support capacity building, the Commission shall **in close cooperation and consultation with Member States** ~~draw up~~ **establish indicators for self assessment** ~~benchmarking guidelines~~ for the primary and secondary use of electronic health data.

Comment:

It should be clarified what is the difference between the "benchmarking guidelines", which it has replaced in its compromise proposal with "indicators for self-assessment". Currently, self-assessment based on KPIs is done within the existing MyHealth@EU infrastructure. Is SE PRES in this case trying to build on the current monitoring framework in the primary use of health data? At the same time, the article does not propose the representation of stakeholders who are also part of the secondary use of health data system (e.g. patient organisations, research institutions, etc.) and who may have suggestions for improving the infrastructure.

Article 60

Additional requirements for public procurement and Union funding

Comment:

Regarding art. 60, CZ refers to the joint opinion of the European Data Protection Board and the European Data Protection Supervisor, in which they recommend that Article 60 of the Proposal also refers, as a condition to procure or fund services provided by controllers and processors established in the EU processing personal electronic health data, that such controllers and processors (i) will store this data in the EU and (ii) have duly demonstrated that they are not subject to third country legislations conflicting with EU data protection rules.

In this regard CZ proposes to consider option for a new Article 60a, which would provide that for the purposes of primary and secondary use of electronic health data, MS shall ensure that the storage, processing and analysis of electronic health data shall only take place in a secure location or locations within the EU, without prejudice to the transfer of personal electronic health data in accordance with Chapter V of the GDPR.

1. **Contracting authorities** ~~Public procurers, national competent authorities~~, including digital health authorities and health data access bodies and **Union institutions, bodies, offices or agencies, including** the Commission**,** shall make reference to the applicable technical specifications, standards and profiles as referred to in Articles 6, **12,** 23, 50, **52,** 56, **as well as to the requirements laid down in Regulations (EU) 2016/679 and (EU) 2018/1725,** as relevant, as points of orientation for public procurements and when formulating their tender documents or calls for proposals, as well as when defining the conditions for Union funding regarding this Regulation, including enabling conditions for the structural and cohesion funds.

2. **The criteria for obtaining funding from the Union** ~~The ex-ante conditionality for Union funding~~ shall take into account**:**

   a) the requirements developed in Chapters II, III and IV**;**

   b) the requirements laid down in Regulations (EU) 2016/679 or (EU) 2018/1725, where applicable, in particular:

   (i) the requirements laid down in Article 35 or 39 respectively of these Regulations by requiring a documented data protection impact assessment, including where Chapter V of these Regulations apply, an assessment of the impact of the transfer to third countries or international organisations.

   (ii) where Article 28 or 29 respectively of these Regulations is applicable, by requiring a contract or other legal act between the controller and the processor pursuant to Article 28 paragraph 3 or Article 29 paragraph 3 respectively.

   (iii) intellectual property rights and trade secrets requirements when appropriate.

Justification:

As proposed in other parts of the Regulation, reference to the protection of intellectual property rights and trade secrets should also be included. According to paragraph 2, the criteria for obtaining EU funding should take into account in particular the requirements set out in the GDPR or Regulation (EU) 2018/1725. However, these legislations talk about the protection of intellectual property and trade secrets in the performance of work, but this should also apply to public procurement. CZ therefore proposes to include new point (iii) in the Article.

Article 61

~~*Third country*~~ ***T****~~t~~ransfer* ***to a third country*** *of* ***anonymous electronic health data*** ~~*non-personal electronic data*~~ ***presenting a risk of re-identification***

Comment:

In general, CZ supports Spain's proposal regarding access to data by third countries and international organisations, but we will provide more detailed position after the envisaged discussion on reciprocity with third countries.

1. ~~Non-personal~~ **Anonymous** electronic data made available by health data access bodies **to a health data user in a third country according to a data permit pursuant to Article 46 or a data request pursuant to Article 47 or to an authorisated participants in a third country or an international organisation**, that are based on a natural person's electronic **health** data falling within one of the categories of Article 33 ~~[(a), (e), (f), (i), (j), (k), (m)]~~ shall be deemed highly sensitive within the meaning of Article 5(13) of Regulation **(EU) 2022/868**~~[…] [Data Governance Act COM/2020/767 final]~~, provided that their transfer to third countries presents a risk of re-identification through means going beyond those **reasonably** likely ~~reasonably~~ to be used, **in particular** in view of the limited number of natural persons involved in that data, the fact that they are geographically scattered or the technological developments expected in the near future.

2. The protective measures for the categories of data mentioned in paragraph 1 shall depend on the nature of the data and anonymization techniques and shall be detailed in the Delegated Act under the empowerment set out in Article 5(13) of Regulation **(EU) 2022/868** ~~[…] [Data Governance Act COM/2020/767 final]~~.

Article 62

*~~International access and~~ **T**~~t~~ransfer of **anonymous** ~~non-personal~~ electronic health data **to a third country or an international organisation***

1. The digital health authorities, health data access bodies, the authorised participants in the cross-border infrastructures provided for in Articles 12 and 52 and **health** data users shall take all reasonable technical, legal and organisational measures, including contractual arrangements, in order to prevent ~~international~~ transfer **to a third country or an international organisation, including** ~~or~~ governmental access **in a third country** **of**~~to~~ **anonymous** ~~non-personal~~ electronic health data held in the Union where such transfer ~~or access~~ would create a conflict with Union law or the national law of the relevant Member State, without prejudice to paragraph 2 or 3 of this Article.

2. Any judgment of a third-country court or tribunal and any decision of a third-country administrative authority requiring a digital health authority, **a** health data access body or **a health** data user~~s~~ to transfer ~~or give access to~~ **anonymous** ~~non-personal~~ electronic health data within the scope of this Regulation held in the Union shall be recognised or enforceable in any manner only if based on an international agreement, such as a mutual legal assistance treaty, in force between the requesting third country and the Union or any such agreement between the requesting third country and a Member State.

3. In the absence of an international agreement as referred to in paragraph 2 of this Article, where a digital health authority, a health data access body, **a health** data user~~s~~ is the addressee of a decision or judgment of a third-country court or tribunal or a decision of a third-country administrative authority to transfer ~~or give access to~~ **anonymous** data within the scope of this Regulation held in the Union and **in** compliance with such a decision would risk putting the addressee in conflict with Union law or with the national law of the relevant Member State, transfer **of** ~~to or access to~~ such data **to** ~~by~~ that third-country authority shall take place only where:

   (a) the third-country system requires the reasons and proportionality of such a decision or judgment to be set out and requires such a decision or judgment to be specific in character, for instance by establishing a sufficient link to certain suspected **natural or legal** persons or infringements;

   (b) the reasoned objection of the addressee is subject to a review by a competent third-country court or tribunal; and

   (c) the competent third-country court or tribunal issuing the decision or judgment or reviewing the decision of an administrative authority is empowered under the law of that third country to take duly into account the relevant legal interests of the provider of the data protected under Union law or the national law of the relevant Member State

4. If the **criteria** ~~conditions~~ laid down in paragraph 2 or 3 are met, **a** digital health authority, a health data access body or a **health data user** ~~data altruism body~~ shall provide the minimum amount of data permissible in response to a request, based on a reasonable interpretation of the request.

5. The digital health authorities, health data access bodies, **health** data users shall inform the **health** data holder about the existence of a request of a third-country administrative authority to access its data before complying with that request, except where the request serves law enforcement purposes and for as long as this is necessary to preserve the effectiveness of the law enforcement activity.

Article 63

~~International access and~~ T~~t~~ransfer of personal electronic health data to a third country or an international organisation

In the context of ~~international access and~~ transfer of personal electronic health data **to a third country or an international organisation,** Member States may maintain or introduce further conditions, including limitations, in accordance with and under the conditions of **A~~a~~**rticle 9(4) of Regulation (EU) 2016/679, **in addition to the requirements set out in Articles 13 paragraph 3 and 52 paragraph 5 of this Regulation and the requirements laid down in Chapter V of Regulation (EU) 2016/679**.

Chapter VI

European governance and coordination

Article 64

European Health Data Space Board (EHDS Board)

1. A European Health Data Space Board (EHDS Board) is hereby established to facilitate cooperation and the exchange of information among Member States. The EHDS Board shall be composed of ~~the high level~~ representatives**, one each** of digital health authorities and health data access bodies**,** of all the Member States. ~~Other national authorities, including market surveillance authorities referred to in Article 28, European Data Protection Board and European Data Protection Supervisor, may be invited to the meetings, where the issues discussed are of relevance for them. The Board may also invite experts and observers to attend its meetings, and may cooperate with other external experts as appropriate. Other Union institutions, bodies, offices and agencies, research infrastructures and other similar structures, shall have an observer role.~~ (SECOND, THIRD AND LAST SENTENCES AMENDED AND MOVED TO PARA 1(B)-1(E))

1a. **A representative of ~~T~~t**he Commission **and a representative of the Member States** shall **co-**chair the meetings of the EHDS Board. (MOVED FROM PARA 6)

1b. ~~Other national authorities, including~~**M~~m~~**arket surveillance authorities referred to in Article 28, European Data Protection Board and European Data Protection Supervisor, **shall** ~~may~~ be invited to the meetings, where the issues discussed are of relevance for them. (MOVED FROM PARA 1 AND AMENDED)

1c. The Board may also invite **other national authorities,** experts and observers to attend its meetings, and may cooperate with other external experts as appropriate. (MOVED FROM PARA 1 AND AMENDED)

1d. Other Union institutions, bodies, offices and agencies, research infrastructures and other similar structures **shall** have an observer role **when invited to participate in the meetings**. (MOVED FROM PARA 1 AND AMENDED)

1e. Stakeholders and relevant third parties, including patients' representatives, **may** ~~shall~~ be invited to attend meetings of the EHDS Board and to participate in its work, depending on the topics discussed and their degree of sensitivity. (MOVED FROM PARA 4)

2. Depending on the functions related to the use of electronic health data, the EHDS Board may work in subgroups **for certain topics**, where digital health authorities or health data access bodies ~~for a certain area~~ shall be represented. The subgroups may have joint meetings, as required.

3. The ~~composition, organisation, functioning and cooperation of subgroups shall be set out in~~ rules of procedures **of the EHDS Board shall be adopted by its members and** put forward by the Commission. **They shall include rules pertaining to the composition, structure, operation and cooperation of the sub-groups and shall regulate the role of invitees referred to in paragraphs 1b to 1e, taking into account the topics under discussion and the level of confidentiatlity involved.**

~~4. Stakeholders and relevant third parties, including patients' representatives, shall be invited to attend meetings of the EHDS Board and to participate in its work, depending on the topics discussed and their degree of sensitivity.~~ MOVED TO PARA 1E

5. The EHDS Board shall cooperate with other relevant bodies, entities and experts, such as the European Data Innovation Board referred to in Article ~~26~~ **29** of Regulation **2022/868** ~~[Data Governance Act COM/2020/767 final~~], competent bodies set up under Article 7 of Regulation […] [Data Act COM/2022/68 final], supervisory bodies set up under Article 17 of Regulation […] [eID Regulation], European Data Protection Board referred to in Article 68 of Regulation (EU) 2016/679 and cybersecurity bodies.

~~6. The Commission shall chair the meetings of the EHDS Board.~~ MOVED TO PARA 1A

7. The EHDS Board shall be assisted by a secretariat provided by the Commission.

8. The Commission shall, by means of implementing acts, adopt the necessary measures for the establishment~~,~~ **and** management ~~and functioning~~ of the EHDS Board. Those implementing acts shall be adopted in accordance with the ~~advisory~~ **examination** procedure referred to in Article 68(2).

Article 65
Tasks of the EHDS Board

1. The EHDS Board shall have the following tasks relating to the primary use of electronic health data in accordance with Chapters II and III:

   (a) to assist Member States in coordinating practices of digital health authorities;

   (b) to issue written contributions and to exchange best practices on matters related to the coordination of the implementation at Member State level of this Regulation and of the delegated and implementing acts adopted pursuant to it, in particular as regards:

      (i) the provisions set out in Chapters II and III;

      (ii) development of online services facilitating secure access, including secure electronic identification, to electronic health data for health professionals and natural persons.~~;~~

      ~~(iii) other aspects of the primary use of electronic health data~~. **response and proposals for further development of primary use of health data.**

Justification:

CZ believes that the EHDS Board should also address those other aspects. There should be a body that also focuses on developing and elaborating on the suggestions, experiences and ideas that will be provided by the practice and feedback from different actors and stakeholders that will operate in both infrastructures.

   (c) to facilitate cooperation between digital health authorities through capacity-building, establishing the structure for **biennial** ~~annual~~ activity reporting, **and exchange of information in those reports** ~~peer review of annual activity reports and exchange of information~~;

   (d) to share information concerning risks posed by EHR systems and serious incidents as well as their handling;

(e) to facilitate the exchange of views on the primary use of electronic health data with the relevant stakeholders, including representatives of patients, health professionals, researchers, regulators and policy makers in the health sector.

2. The EHDS Board shall have the following tasks related to the secondary use of electronic health data in accordance with Chapter IV:

(a) to assist Member States, in coordinating practices of health data access bodies, in the implementation of provisions set out in Chapters IV, to ensure a consistent application of this Regulation;

(b) to issue written contributions and to exchange best practices on matters related to the coordination of the implementation at Member State level of this Regulation and of the delegated and implementing acts adopted pursuant to it, in particular as regards:

(xi) implementation of rules for access to electronic health data;

(xii) technical specifications or existing standards regarding the requirements set out in Chapter IV;

(xiii) incentives policy for promoting data quality and interoperability improvement;

(xiv) policies concerning fees to be charged by the health data access bodies and **health** data holders;

(xv) the establishment and application of penalties;

~~(xvi) other aspects of the secondary use of electronic health data~~. **response and proposals for further development of primary use of health data.**

Justification:

See justification in para 1 letter b (iii).

(c) to facilitate cooperation between health data access bodies through capacity-building, establishing the structure for **biennial** ~~annual~~ activity reporting, **and** ~~peer review of annual activity reports and~~ exchange of information **in those reports**;

(d) to share information concerning risks and data protection incidents related to secondary use of electronic health data, as well as their handling;

~~(e) to contribute to the work of the European Data Innovation Board to be established in accordance with Article 29 of the Regulation […] [Data Governance Act COM/2020/767 final];~~ (SEE ARTICLE 65(5))

(f) to facilitate the exchange of views on the secondary use of electronic health data with the relevant stakeholders, including **health data holders, health data users,** representatives of patients, health professionals, researchers, regulators and policy makers in the health sector.

Comments from the Danish delegation

Comments Denmark Chapter IV, Article 1 and Article 2(2) litra o, u, v x, aa, ab, ac, ad og ae, as indicated in the flash for 6-7 March

General remarks

Denmark thanks the Presidency for the compromise proposal and acknowledges the Presidency for the work that has been done to take the proposal forward. Especially the effort that has been made to give the member states more competence with regards to the implementation of EHDS and the clarifications that have been made regarding the relation to the General Data Protection Regulation. With these written comments Denmark gives preliminary general remarks and remarks on the compromise text for Chapter I and IV as indicated in the flash for March 6.-7.

Denmark draws attention to the fact that although parties are now in a process of commenting on a large number of detailed issues in the articles of chapter IV, general principles and issues of the scope of the secondary use of health data in the European Health Data Space must simultaneously be considered.

DK supports the objective of establishing a coherent and effective structure for the use of health data for secondary use. DK is positive towards that the infrastructure for secondary use must be established as a decentralized/federated model where the responsibility for access to data for secondary use is anchored in the individual Member States and access to data is granted and facilitated by relevant health data access bodies within the individual member states.

DK suggests that the European Health Data Space for secondary use should be developed in a stepwise matter focusing on creating access to mature and interoperable data-sources and infrastructures in this early phase.

DK believes that it is important to have a pragmatic and realistic scope and implementation time, as we foresee future issues with regards to the short implementation time in relation to the extensive list of datacategories, uncertainties regarding standardisation of infrastructure and safeguards for IP-rights and trade secrets. We appreciate the presidency changes in the proposed text on implementation period but we are still examining this prolonged implementation period..

It is important to focus on a common level of data security in relation to building the federated model for sharing data. It is important that the security and protection of health data is in focus, as it is the foundation for citizens' confidence in the use of health data. DK would like to call for the proposal to make it clearer how data security is created in the EHDS infrastructures.

It is crucial to maintain the trust of citizens in the sharing and accessing of health data. In DK citizens have the possibility to opt out of sharing health data related to their genomes for secondary purposes. It is at present not clear how this type of national regulation in the MS is taken into account in the proposal.

Article 1

Subject matter and scope

According to recital 38, in the context of EHDS, the electronic health data already exists and is being collected by healthcare providers, professional associations, public institutions, regulators, researchers insurers, etc. "… In order to fully unleash the benefits of the secondary use of electronic health data, all data holders should contribute to this effort in making different categories of electronic health data they are holding available for secondary use. If the regulation according to recital 38 also will include data from before the EHDS enters into force this would constitute an obligation for certain MS and other data holders to update data into new standards etc. This would lead to substantial economic costs for some MS – and for private companies in case of both primary and secondary purposes – for example when it comes to clinical research. DK sees a need for further examination of which data sources should be included in order to balance the costs and benefits of including different data sources.

Regarding para 2(a) and para 3(A), DK welcomes the new references to GDPR. However, there is still a need for a further clarification regarding the connection between the EHDS and GDPR e.g. in the relation of the use of the terms data holder and data user in relation to the GDPR terms of data controller.
Regarding para 2(b) and "wellness applications" there is a need to consider the risk in relation to cybersecurity as well as the maturity of the data source.

Article 2(2) litra o, u, v x, aa, ab, ac, ad og ae –

Definitions

DK would prefer a clarification of the terms "health data user" and "health data holder". The terms could be interpreted to include only "health" data and not all the data-categories in article 33 of a natural person.
Re. litra (o) "wellness application". The term is very broad and unclear. The definition should be clarified in order to avoid legal uncertainties.
Regarding the adding of "single health data holder" in litra (aa.) DK would like to state, that it can be costly and resource-intense for a single data holder to provide state data permits and data in a secure processing environment, as required in the EHDS.

Article 32A

Scope

In line with the written comments from FI and LU, DK does not see the need for this additional article on scope in Chapter IV. Usually there is only one article on scope, as set forth in article 1. DK does not see the need for changing the scope in article 1, but if a need for further scoping is deemed necessary, DK suggests amending article 1, so it addresses any needs for further scoping regarding chapter IV.

Article 33

Minimum categories of electronic data for secondary use

In general, DK notes that the number of data categories is extensive and contains data- sources that are complex and data-heavy which place great technical demands on MS to make data available in EHDS. DK therefore suggests an assessment of the proportionality of the list of data categories validating the economic costs, since the implementation could create large economic repercussions for the MS.
The headline of article 33 indicates that as a minimum, the below cited categories of data must be made available. This appears not to be in compliance with the principles of GDPR on data-minimisation and the referral in EHDS to data-minimisation and purpose limitation in article 44. It should be clearly stated that the article includes the categories of data available in each Member State. We consider this list to be very comprehensive and we propose that the title should be 'categories of health data that may be included', instead of a list of minimum categories.
DK agrees on the remark from LU regarding article 33 (f) to (o) stating that categories should focus on the type of data and not where the data comes from.
Re. article 33, para. 1.: DK supports written comments from DE and SK that the list on data categories continues to be very broad.

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

It is still unclear whether EHR data includes data from the general practitioners and municipalities? These entities also keep electronic records in Denmark.
Furthermore, DK supports the DE comments to Article 33 1. a regarding the need for clarification regarding minimum categories of electronic data for secondary use: The list is too broad and we support the DE comment stating that priority categories for secondary use should first be defined and made available, and that Member States should be allowed to specify which relevant data holders hold these data in their respective MS and should be obliged to make them available according to Chapter IV. DK finds this important because it is within the remit of GDPR and the subsequent National legislation to decide the purposes for secondary uses of health data collected via consent. In order to respect the provisions of GDPR and National legislation, the EDPB and EDPS joint opinion paragraphs 83- 92 should be taken into account.

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

These types of data can't be defined as electronic health data, as neither are initially formed in the context of patient care and therefore will be subject to different regulation in the Member States. We support the suggestion from SI

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

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

(e) human genetic, genomic and proteomic data;

DK agrees with the commentary from DE underlining the broadness of the data-categories and stressing the need for investigating whether the right of privacy of data-subjects is infringed by the use of the term "human genetic data" in (e) and in case of said infringement, how safeguards can be adequately be inserted in the text.
DK would like to emphasize that DK has drawn up special regulation regarding genome data stored at the Danish National Genome Centre. Here citizens have the possibility to deny (opt out) that information derived from their genome can be used for secondary purposes. It is at present not clear how this type of national regulation in the MS is taken into account.

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

DK proposes to insert "data from"
Re. "wellness applications". There is a need for a discussion regarding the maturity of the data source. There is a very low level of maturity in terms of being able to extract and use person-generated health data from wellness applications for secondary use.
DK agrees with the arguments regarding wellness applications stated in EDPB-EDPS Joint Opinion paragraph 72-81.

(g) identification data related to health professionals involved in the treatment of a natural person;
(h) population wide health data registries (public health registries);

Very relevant in EHDS

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

Very relevant in EHDS

(j) electronic health data from clinical trials;

DK agrees that electronic health data from clinical trials should be available for secondary use. However, this stresses the need for further clarification and safeguards regarding protection of IP-rights and trade secrets in Article 35A. To foster innovation, it is key to maintain the high confidentiality for clinical trials-data for products which has not been approved in EMA. If there is found uncertainties in the safeguards, it could be relevant to discuss if data from clinical trials should be protected against requests for data sharing, referring to the comment above to rephrase the headline from "minimum categories" to "categories of health data that may be included'.
Furthermore, DK would like to highlight that data from clinical trials are available (with different access levels) in the EU Clinical Trials Information System, CTIS, and this should be the primary data source (with respect of GDPR intellectual property rights and trade secrets) for secondary use.
DK suggest that the Commission and EMA assess the maturity of data in relation to making it available for secondary use as well as assess the time perspective.

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

DK agrees that electronic data from registries for medicinal products and medical devices should be available for secondary use. However, this also stresses the need for further clarification and safeguards regarding protection of IP-rights and trade secrets in Article 35A.
There are various EU registers on medicinal products and medical devices. In this regard the following registers can be highlighted: Eudravigilance database, Archieve of periodic safety updates and associated assessment reports, the EMA article 57-database regarding medicinal products, CTIS, and EUDAMED (in development). DK suggests that EMA and the Commission assess possibilities (with respect of GDPR, intellectual property rights and trade secrets) and maturity in relation to making data available for secondary use.
DK would like clarification on the understanding of the term "Electronic health data from medical devices"
DK understands the term as covering measurement data from medical devices -We would like further clarification regarding the understanding of the term and this could be clarified.

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

DK is of the opinion that these data typically are of low maturity. Making these data available will involve a relatively long process, partly due to the amount of research cohorts, questionnaires and surveys, which is quite extensive, and partly due to technical conditions around e.g. translation and interpretation of variables, etc. In this regard, resource considerations in relation to health data holders need to be incorporated

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

DK would like further elaboration on the meaning of "dedicated databases".

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

These types of data are very broad – and might be regulated by other legislation than legislation related 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.

It is difficult to see how this will work in practice i.e. a data holder shall make enriched data available. DK would like to point toward our remarks to article 51. It is a consideration, that the enrichment of data carried out by the data holder might be in conflict with the GDPR, if the data holder uses data only for primary use.

Article 34

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

Denmark would like a clarification of the relationship between EHDS and GDPR as the list of allowed purposes for use of electronic health data for research will result in more narrow purposes than the purposes in GDPR. This is the same concern expressed in the EDPB-EDPS joint opinion [section 7]. DK would like a clarification on the need to narrow the allowed purposes [article 34 1. (a)- to (h)] for which electronic health data can be processed for secondary use?

Article 35

Prohibited secondary use of electronic health data

Re. 35 (a): DK would like clarification on the scope of article 35 (a), in particular in relation to situations where national public bodies in accordance with national law make decisions based on health data.
Furthermore, is not clear how "detrimental to a natural person or group of natural persons" is defined.

Article 35A

IP-rights and trade secrets

It is our opinion that many companies want to share data to a greater extent, but this requires a setup which at the same time allows them to protect their own business and IP rights. At this point, companies are required to share data covered by IP rights and trade secrets, but without a clear description of how data with IP rights and trade secrets is secured. Therefore, it is necessary to

clarify which parties will be obligated to ensure protection of IP-rights and trade secrets in article 35 A (2), as uncertainties could reduce incentives for private companies to invest in innovation and ultimately stay in EU.
As it is a complex matter, Denmark requests further dialogue between the Commission, the European-Parliament and the Council on the one hand, and data owners on the other, to clarify which measures are needed to ensure protection, alternatively a voluntary/agreement model can be suggested.
Re. Para 2: It is not clear who is responsible for "preserve the confidentiality of such data". Will it be the health data holder who has the knowledge of the data, and thus knowledge if the data contains IP rights and trade secrets? Also, it is necessary to specify the phrase “all specific measures” to ensure IP-rights and trade-secrets.

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

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

DK support the added reference in 35B (1)(b) to the legal obligations in GDPR, Article 6 and 9, as this makes the scope of the article much clearer.
Regarding Para 1a. The requirement to deliver data within 3 months may lead to ambiguity, as the term month may mean a calendar month beginning on the 1. or three months from the data of the request. For better precision Denmark suggests that the term 90 calendar days from the date of the request is used.
Regarding Para 5.: DK would like to bring attention to our remark on enriched data above – and the interplay between the GDPR and EHDS.

Article 35C

Duties of health data users

DK finds it positive, that it is now up to MS to decide the handling of clinically significant findings.

Article 36

Health data access bodies

DK sees great potential in the establishment of central bodies responsible for access to data including a coordinating one in the case of several HDAB's.
However, in the current proposal and compromise proposal, the framework for the establishment of these bodies is very detailed in the EHDS, which imposes a high level of complexity regarding the establishment in the MS. DK acknowledges the need for establishing a mandate and structure for the HDAB's securing a common structure for access to data and the interoperability between HDABs.
However, DK finds it unclear whether HDAB, as defined in Article 36, are competent bodies under Article 7 of the Data Governance Act, and thus must comply with the requirements of the DGA and with tasks performed by data protection authorities under the GDPR.
The detailed and extensive requirement for HDAB risks imposing MS costs in establishing health data access bodies and the underlying necessary infrastructure as suggested – and the costs will probably be significantly greater than what is possible to apply for EU funding for and it will require some national costs.

Article 37

Tasks of health data access bodies

This article is very specific and comprehensive regarding establishment of the tasks of an HDAB. It would be preferable if the regulation instead creates a common framework setting up a more general level of requirements in order to distinguish between necessary tasks and desirable tasks of the HDABs and in order to create a system that is less resource-heavy.
The article introduces tasks that can potentially become highly resource-heavy; especially for those MS who process a relatively large number of health data for secondary use. There is a need for distinguishing between the necessary tasks and desirable tasks. Some examples for resource-heavy tasks could be 37(1) (p), (q), (t). Based on the DK experience of sharing data among authorities, data users often ask for guidance regarding e.g. techniques and best practices for secondary use of data from different authorities. Does the proposal include an opportunity for data users to obtain any guidance on data across national borders?
Re. (1)(b) and (c): As mentioned above it is unclear what kind of support the Regulation provides, and at the same time it should be noted that this support is not covered by Article 42 on fees.
Furthermore, it is unclear whether 37.1(b) only covers support for public health sector bodies in health data access bodies in one's own country or also for other countries.

Re. Para 1(ab): A clarification on EHDS-compliance and the scope of the responsibilities of the Data Protection Authorities according to GDPR is needed
Re. Para 1(i) regarding the development of AI systems: Denmark is uncertain about the implications of the provisions regarding AI systems - What obligations and responsibilities will the obligations of "supporting with expertise the development of AI systems" entail for the health data access bodies in terms of co-responsibilities and liabilities for damages, if the AI systems are faulty?
Re. Para 1 (n) DK would like to stress the importance of utilizing the experiences gained in other EU data sharing initiatives, for example the results from European Open Science Cloud in building a European FAIR data space. Therefore, we would like to draw attention to cooperation with the governance of the European Open Science Cloud in this regard. Dk suggest the following wording added:

(n) cooperate at Union and national level and provide advice to the Commission on techniques and best practices for **secondary use of** electronic health data use and management; **cooperate with the governance of the European Open Science Cloud to build upon the experience in building a European FAIR data space and to elaborate with the research efforts towards the interoperability solutions in the framework of the EOSC**.

Re. Para 5.: It is positive that there is now a clearer link to GDPR

6. ~~Where the consent of the natural person is required by national law~~ **Nothwithstanding national laws requesting the consent pursuant to Article 9(4) of Regulation (EU) 2016/679,** health data access bodies shall rely on the obligations laid down in this Chapter

when requesting and processing personal electronic health data from the health data holder and disclose ~~provide access to~~ pseudonymized electronic health data to the health data user. (MOVED FROM ARTICLE 33(5)

This provision seems unclear because it opens several scenarios of interpretation. Considering the fact that the concept of consent is not mentioned in other provisions of the Regulation, DK presumes that the aim of this provision is to ensure the enforcement of the provisions in the Regulation regardless of any previously established legal basis (i.e.consent). DK finds the need for further clarification.
DK would like to mention, that different types of research in DK, for instance certain types of register-based research and certain types of research on especially sensitive bioinformatic data are not based on consent but on National legal provision. DK highly recommends clarifying the provision in order to establish the scope of requirements of informed consent for the rights and obligations of the EHDS.

Article 38

Obligations of health data access bodies towards natural persons

Re. Para 2., the obligations in GDPR, article 14, information to natural persons What is the basis for article 38(2) as the data access body already has the same obligations under the provisions of GDPR article 14?
It is positive that it is now up to MS to decide the handling of clinically significant findings in Para 3. In DK, there is a good experience with the fact, that it is the attending physician who has the responsibility of contacting the person.

Article 39

Reporting by health data access bodies

DK supports the concept of reporting by HDAB as this might help creating and maintain public trust. However, there are many requirements as to the content of these reports – and some of these requirements could potentially require an unnecessarily heavy use of resources, especially litra g, h, j, m and n.

Article 42

Fees

General Remarks

Re.: information about fees:

Clarification on the scope of the article is needed. From the article we understand that the health data access bodies may charge fees for making electronic health data available to data users for secondary use. However, MS will have considerable extra costs in order to make existing data already available in national registries compatible with standards for data- handling in EHDS, continuous updating of data in metadata catalog, maturation of data sources, technical access to data, use of analysis platform, ongoing development e.g. in relation to user management etc. Are these costs supposed to be covered by the suggested fees?

It is unclear when information about fees should be available. Should data-users be able to find such information before application or only after the application has been processed? DK finds, that this information should be available for the applicant before the applicant hands over the application.

Specific remarks

Re. Para 2.: DK has difficulty in envisioning how the HDAB would be able to assess whether a health data holders' estimation of the cost of providing health data is fair.

Re. Para 6.: DK is still examining whether the Commission, by means of implementing acts, should be empowered to lay down the principles and rules for the fee policies and fee structures. However, DK is supports the recent suggestion of changing the implementation procedure to the examination procedure instead of the advisory procedure.

Article 43

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

DK would like to ask for a clarification of the nature of the penalties in article 43.

In DK, the imposition of administrative fines (i.e. the imposition by any administrative authority of pecuniary penalties) gives rise to serious constitutional concerns. In Danish law, administratively imposed periodic penalty payments (PPPs) are not considered punitive (and are therefore in compliance with the constitutional ban on administrative fines) under certain conditions. In particular, if part of the penalty payment remains unpaid or has not been forcibly collected by authorities at the time when the legal or natural person concerned has fulfilled the obligation that gave rise to the PPPs, it is a requirement that this non-collected part of the PPP is dropped by authorities. Under such conditions, PPPs are not considered punitive and can be imposed without the involvement of judicial authorities.

However, if that condition is not met, it is highly likely that Danish courts – ultimately the Supreme Court – would consider PPPs to be administrative fines and therefore strike them down as unconstitutional.

Reference is made to the answers send to the Presidency on 24 March 2023 regarding administrative penalties in Denmark.
Re.: The Danish system of administrative fines
DK would also like to ask for the reasoning behind the 5 years period mentioned in article 43(4), and for a clarification of whether the provision requires health data bodies to be able to revoke a data permit or exclude the health data user from any access to electronic health data within the EHDS for a period longer than the period of non-compliance referred to in article 43(3).
Reference is again made to the answers send to the Presidency on 24 March 2023 regarding administrative penalties in Denmark

Article 44

Data minimisation and purpose limitation

DK finds it important to bring to mind the main objective of EHDS article 1: The protection of data-subjects and the data-safety. Therefore, these objectives will have to be primary priorities for the scope of Article 44, and in recitals 49, 54 and 64.
Re. Para 2: DK agrees with the requirement that the HDAB provide the electronic health data in an anonymized form, where the purpose of processing by the health data user can be achieved with such data. However, the article does not consider that there might be cases where the health data holder will only be able to provide the data in either anonymized or pseudonymized form.
This would be the case where the specific datatype determines whether the data can be anonymized or not, for example in case of genomic data.
Re. Para 3: It is unclear what is meant by the added term “body that acts as a trusted third party”. What kind of body could be considered to be “a trusted third party”

Article 45

Data access applications

DK would like a clarification on the relation between EHDS and the possibility of national law regulating ethical assessment - we acknowledge the referrals to ethical assessments in cases where they are requested by national law in article 45, 4. b, and in recital 46 and 50 regarding the criteria for issuing permits.
We think that the possibility of obtaining an ethical evaluation according to national law is a very important contribution to the decision-making process of the health data access bodies especially with regards to secondary use of genetic and genomic data.
We would like to have further clarification on where the ethical evaluation according to national law is deemed important in relation to other tasks of the health data access bodies According to the proposal.

Article 46

Data permit

Denmark supports the added reference in Para 1. (e) to the obligation of evaluating whether an assessment of ethical aspects of processing where applicable, is in line with national law.
DK recommends that the article also includes an obligation for the HDAB to check whether a data user has previously been sanctioned.
It follows from Article 46(2), that the health data access body shall issue a data permit if it concludes that the requirements in paragraph 1 are met. As stated in Article 35(A) it is important that the criteria in EHDS protects intellectual property and trade secrets in an adequate way and see a need for further clarification on this matter.
We support that the sentence: "Where a health data access body fails to provide a decision within the time limit, the data permit shall be issued" has been deleted in Para 3.
For many research-projects a time-restriction on 5 years for a data permit will be to short.

Article 47

Data request

General remark
Fulfilling data requests can be a comprehensive task for a HDAB. Therefore, it is important to stress, that HDAB does not have the obligation to carry out research-tasks. The task should be limited to carrying out "few and limited transactions in order to extract the data". It could possibly clarified in a recital.
Does the possibility of requesting data according to article 47 apply to natural and legal persons outside EU/third countries or is it reserved for natural and legal persons within the EU/EHDS? DK would like this to be clearer in the text.

~~*Article 48*~~

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

DK supports that this article is deleted.

Article 49

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

DK suggests a specific reference to article 45, 4. (a) and (b) be added to article 49. This would make it clear for the single data holder and the applicant that the obligations in other EU- and national data protection law regarding transfer of data should be adhered to.

There is a significant difference between the content of article 45 and article 47 - in regards to gaining access to data (45), and having an answer provided to you via request (47). This difference should be addressed in this article as well.
Is there a need for addressing the risk of different practices between applications/requests reviewed by the MS access body, and a single health data holder?
Re. Para 2: It should be clarified in the text, that single data holders can delegate competences to HDAB. It can be costly for single data holders to have to provide a secure processing environment as stated in the article.

Article 50

Secure processing environment

It should be clearly stated in in this article or a recital, that it will be possible for health data users to import their own data and/or enriched data sets to the secure environment.
Re. Para 2: DK would like to make it a point, that the wording throughout this Regulation is consistent, making it clear whether the data is anonymized, the data is considered anonymous or something else entirely.
Re. Para 4: DK assumes, that like in GDPR the existing public body will have to supervise that the health data access bodies (HDAB) comply with the implementing acts.

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

DK appreciate that the roles of controllership is described with more detail. However, we believe that there should be a clearer reference to the GDPR regarding the responsibilities of a party acting in the capacity of data controller – e.g. Article 24 on data controller. In addition, one should consider whether the more detailed description belongs in a recital rather than in the legal text.
DK believes that it would be useful to clarify who is responsible for the transferal of enriched data back to the original data holder. As mentioned above it should be considered if the transferal of enriched data is in accordance with the GDRP regarding purposes of processing at the original data holder.

Article 52

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

General remark

DK would like to refer to the EDPB-EDPS Joint Opinion on EHDS, [section 120] on shared data responsibility. In case there is a data breach, shared data responsibility will mean that there can be considerable doubt as to which jurisdiction the breach and its handling will fall under, and who the competent authority is. Will the same rules as in GDPR apply here?

If shared data responsibility is maintained, it must be specified in the text which duties different parties involved in the shared data controllership will be responsible for, as well as which authorities will be competent.

Specific remarks

Re. Para 5: DK support the reference to the rules in Chapter V of GDPR and the change to examination procedure.

Re. Para 9: DK notes that it is unclear if more services are included in the sentence "information technology services needed to support and facilitate the exchange of information". E.g. will there be any support function for data users?

Re Para10: It should be made clear, that the decision of putting in electronic health data in the secure processing environment is made "project by project" and not on a general level, as this is not in accordance with the GDPR.

Re. Para 11: It is unclear whether in the instances where there is two or more MS participating, will all MS be separate controllers or does the Commission determine the relation between MS as controllers?

Re. Para 12: DK would like to draw attention to cooperation with the governance of the European Open Science Cloud in this regard. DK will also send in written comments on this paragraph. DK suggest the following wording added:

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], **and with the European Open Science Cloud referred to in the EU Council conclusion 14126/2021.**

Article 53

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

Re. Para 1: It is unclear whether a Health Data Access Body in a 3rd country could be considered to be a joint controller and have the competence to decide access to electronic health data in the EU. If that is the case, DK would like to stress that the decision of secondary use of health data in this regard will not be taken within the EU.

Article 56

Data quality and utility label

Some of criteria might lead to processes that will require quite a lot of resources – we believe that we should narrow this down. DK suggest a questionnaire/survey in line with the discussion on article 10(2) and 39.

Article 57

EU Datasets Catalogue

DK would like to state that when implementing this article, the default should be to reuse of existing infrastructure/platform – such as data.europe.eu – instead of establishing and operating multiple, parallel platforms with very similar functionality. Reusing a single platform also has the benefit of making it easier to find datasets from different sectors in order to combine health data with e.g. environmental, geospatial or mobility data.

It is therefore important that the wording of the article does not compel the Commission to establish a new, separate platform for health data metadata or preclude it from reusing an existing system for the purpose of making metadata available to health data users.

Article 58

Minimum dataset specifications

It is unclear, what is meant with "minimum dataset specifications. Is this for example in regards to the technical specifications of metadata? The broadness of this term and standards may entail large costs in order to comply with this article. Especially if MS have already dataset specifications in national systems that risk having to be changed – which can be costly.

Comments from the Dutch delegation

NL input on the first compromise text for Chapter IV and I of the EHDS
Articles 48, 49, 1(2)(a)-(c) and options discussed in the CWP.
General comments:

- We will refrain from commenting parts related to art 51 for the time being, including rights of natural persons, maintaining a scrutiny reservation.

ARTICLE 48

~~*Article 48*~~
~~*Making data available for public sector bodies and Union institutions, bodies, offices and agencies without a data permit*~~
~~By derogation from Article 46 of this Regulation, a data permit shall not be required to access the electronic health data under this Article. When carrying out those tasks under Article 37 (1), points (b) and (c), the health data access body shall inform public sector bodies and the Union institutions, offices, agencies and bodies, about the availability of data within 2 months of the data access application, in accordance with Article 9 of Regulation […] [Data Governance Act COM/2020/767 final]. By way of derogation from that Regulation […] [Data Governance Act COM/2020/767 final], the health data access body may extend the period by 2 additional months where necessary, taking into account the complexity of the request. The health data access body shall make available the electronic health data to the data user within 2 months after receiving them from the data holders, unless it specifies that it will provide the data within a longer specified timeframe.~~

Article 48
Making data available for public sector bodies and Union institutions, bodies, offices and agencies through an expedient data permit process
The health data access bodies may set out prioritisation rules for the treatment of applications or request, but they shall not make any discrimination between the national applicants or requestors and those from other Member States within the same category of priorities, ~~when~~if providing access to electronic health data.

We understand the deletion of this article but do recognise that the EMA and ECDC (as well as national bodies) would need fast-track access as they should be enabled to perform their regulatory duties and/or duties in the public interest. However, we do not support a complete bypassing of the permit-system for any health data user; instead public and Union entities as health data users should be prioritised where this is justified, as described already in recital 51. This is more appropriate because: • The national HDAB will have some discretion in that regard, but the permits for the execution of a task based on law (such as regulatory or public health tasks) should benefit from an expedient processing of applications for access or requests. • The HDAB may already take into account the applicant's or requestor's purpose when scrutinising their submission. To sum up: we suggest to reformulate Article 48, we urge for a fast-track application review when it concerns specific purposes in the public interest (such as during a pandemic or when there is reason to believe there is considerable health risks). This fast-track lane should include fast-tracking any alterations to the permit to ensure the user does not have to go to the back of the queue.

ARTICLE 49

Article 49
*Access to electronic health data from a single **health** data holder*

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

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

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

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

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

We have made text suggestions with two main objectives. One is to ensure that the choice for allowing single data users to operate is not binary (this article applies or it does not) but rather it can be applied to fit the specific situations and needs of that MS. Two to ensure that the data holders referred to in Article 52 para 3 and 4 are accounted for as single data holders that are under the supervision of the Commission and not the MS where they are located.
Specifically:

- Para 1 now provides for MS to allow for specific data holders to operate as single data holders.
- Para 1A now includes reference to the data holders in Article 52 para 4.
- Para 2 was in our view ambiguously worded since the issuance of a permit or a result is a discretionary possibility; the word may could be interpreted in several ways and indeed we have heard different interpretations. In our view, the single data holder should not respond to applicants or requestors at will, which allows single data holders to discriminate, going against a core principle of this Chapter. At the same time, it should not be up to the data users to decide who can be addressed as a single data holder, hence our suggested amendment in para 1.

Moreover, to ensure a consistent application of these provisions across Member States, providing for a definition of 'single health data holder' would be helpful.
A review of this particular provision may be explicitly included in Article 70, on review of the EHDS.
Finally, to ensure coordination of applications and requests to, and supervision of permits and results issued by, single data holders under para 1A, a new article will be needed that requires the European Commission to act as the coordinating health data access body, responsible for article 37 tasks related to coordination, services and supervision, but not the issuance of permits or providing results upon requests. It is undesirable to have fully fledged HDABs at the level of the Commission because these would in turn require a supervisory mechanism. Instead, single data holders under para 1A are overwhelmingly unique, large data holders (already bringing together data for secondary purposes) that can be addressed as such.

SUBJECT 5 - DATA CATEGORIES IN ARTICLE 33(1)(E) – HUMAN GENETIC, GENOMIC AND PROTEOMIC DATA

We prefer option 2, to set out additional safeguards for this particular category. We urge for this category of data to only be made available for secondary use after explicit consent of the natural person has been obtained.
The Netherlands urges for this category of data to only be made available for secondary use after explicit consent of the data subject has been obtained. This does not go against the Data Governance Act (DGA), which provides the basic framework for the EHDS proposal. The DGA relies on the EHDS to provide a legal basis for (further) processing of personal electronic health data but does provide for the possibility where intermediaries can support potential users in obtaining consent, where other legal bases cannot be relied upon, through the intermediaries and not directly (see DGA rec 15). In DGA recital 26, it is further clarified that data subjects should be supported to provide consent for specific areas of scientific research. This possibility for obtaining consent has been operationalised, for example, in DGA art. 5(6); art. 7(4)(d); and art. 12(m) and (n).
It would be difficult to think of a more sensitive data category than genetic and genomic data. Within category (e) fall data that are 1) particularly sensitive due to the nature of the detailed information they contain, 2) difficult to anonymise/pseudonymise in practice, and 3) whose analysis has a particular likelihood of producing (accidental) insights concerning the health of the data subject and their family. At the same time, we do note that within this category there are potentially many different variations of molecular data, some of which with a higher sensitivity (such as whole genome sequencing) than others. Nevertheless, with the current formulation of this category, it should be linked to a consent requirement, in line with possible exceptions regarding the consent requirement, where they exist based on the GDPR or relevant national legislation.

SUBJECTS 2, 3, 4, 6 AND 7

As a general note, *all* categories should be better circumscribed. This goes for the categories (a) EHRs, (b) data on factors impacting on health, (n) data related to insurance status, professional status, education, lifestyle, wellness and behaviour data, (j) clinical trials data, and (o) enriched datasets, but certainly also for (d) administrative data, (f) data generated by persons, and (m) biobanks and databases. At this stage, we do not have written input for this exercise.
During the WP meeting, a discussion emerged on the format in which the all categories of data should be in scope of the obligations for making them available. We are not against the scope of art. 33(1) applying to both 'raw' and 'structured' data, including 'pre-processed' (currently discussed in the Data Act).

SUBJECT – THE SCOPE AND DEFINITION OF THE HEALTH DATA HOLDER

We support option 2 conditionally:

- We support including: 'excluding social security'
- We do not support including: 'care of elder and persons with disabilities'

Instead, we would like to Cross-border healthcare directive definition for healthcare to be referenced which would then include this. References to 'health or care' should be replaced by 'healthcare' which is already referred to in article 2(1)(b) of the EHDS.
As such healthcare covers: 'health services provided by health professionals to patients to assess, maintain or restore their state of health, including the prescription, dispensation and provision of medicinal products and medical devices'.
We note that 'legal or natural persons performing research in relation to these sectors' are then still included. A recital may clarify when a legal or natural person should be considered as 'performing research in relation to'.
'social security' is a definition of scope stemming from the Social Security Regulation (883/2004), which is very broad, also including data coming from sectors different than the healthcare sector. See for instance art. 3(1).
Finally, we are strongly opposed to option 1, expanding the scope explicitly to the social domain.

SUBJECT – THE SCOPE AND DEFINITION OF THE HEALTH DATA USER AND APPLICANT

We support option 1, no amendments, and are strongly opposed to option 2.
This is because although we do wholeheartedly support the intention to strive for reciprocity, however, we are of the opinion that this can best be achieved through other instruments. Those instruments are best included in other parts of the proposal.
Moreover, the proposed approach is likely to lead to unintended consequences potentially leading to reduced access to data in third countries and reduced access to medicines and medical devices in Europe.
We have provided input on reciprocity separately, and would like to discuss this in a working group setting.

ARTICLES 1 (2) (A)-(C) DEFINITIONS FOR ELECTRONIC HEALTH DATA

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

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

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

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

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

When the EHDS refers to data concerning health and genetic data that is not or no longer identifiable, it should refer to this as 'anonymous' and not as 'non-personal'.
First, specifically referring to anonymous data as opposed to non-personal data creates clarity that this concerns data outside the scope of GDPR Article 4(1) based on the test described in GDPR recital 26.
Second, while no guidelines on non-personal data can be expected from the EDPB and the EDPS, these *are* expected for anonymisation, potentially creating further clarity in the future.
Third, the EHDS relies on a definition for 'data concerning health' and 'genetic data' from the GDPR where the defining characteristics are that they relate to a natural person (reference included underneath). Nowhere in the EHDS are efforts made to define what may constitute 'health data' that, before anonymisation, does not contain 'one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of [a] natural person'. The definitions for data in the EHDS concern data that have had, still have, or may again have, some information related to an identified or identifiable person.
Third, the Data Governance Act (DGA) and the Data Act have a much broader scope. There, definitions for non-personal data can be found. The DGA's definition in art. 2(4) echoes the language in the Free Flow of Data Regulation in art. 2(2), referring to 'data other than personal data'. This makes sense since they include, for instance, purely industrial or environmental data containing no 'factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of [a] natural person'.
Fourth, the requirement for data holders to make available non-personal electronic health data through open trusted databases in Article 41(6) has been removed.
Finally, instead of referring to GDPR recital 26 in the definition text, it should be clarified in a recital:

- (as is the case in the DGA) where personal and anonymous data in a dataset are inextricably linked, this Regulation shall not prejudice the application of Regulation (EU) 2016/679.
- That reference should be made to recital 26 and Article 4(1) of the GDPR and possible Guidelines by the EDPB and the EDPS.

For reference, the GDPR definitions:

- (13) 'genetic data' means personal data relating to the inherited or acquired genetic characteristics of a natural person which give unique information about the physiology or the health of that natural person and which result, in particular, from an analysis of a biological sample from the natural person in question;
- (15) 'data concerning health' means personal data related to the physical or mental health of a natural person, including the provision of health care services, which reveal information about his or her health status;

Comments from the Greek delegation

Comments by Greece on definitions, Art. 33(1)(a), Articles 48 and 49 in Chapter IV, and Articles 59-72

Definitions

Health data user :

Option 2 – Limiting the scope and definition of health data user and the scope of applicant
Article 2(2)(z)
 ‘**health** data user’ means a natural or legal person **within the juridiction of a country or an international organisation which is an authorised participant of the cross border infrastructure for secondary use in Article 52,** who has lawful access to ~~personal or non-personal~~ electronic health data for secondary use **pursuant to a data permit in Article 46 or a data request in Article 47 of this Regulation.**

We prefer option 2, limiting the scope and definition of health data user and the scope of the applicant. We agree that this scope ensures reciprocity and equal terms for the sharing of electronic health data for secondary use purposes in relation to the cross-border infrastructure. We also agree that these entities would still need to fulfil the requirements in Articles 46 and 47 et cetera.

Contracting authorities:

The following definition shall be added to **Article 2(1)**
(g) the definition of ‘contracting authorities’ laid down in Article 2(1)(1) of the Directive 2014/24/EU
We support this definition

Anonymous electronic health data:

The following definition shall be added to **Article 2(2)**
(af) ‘anonymous’ electronic health data means electronic data related to health which does not relate to an identified or identifiable natural person or personal data processed in a such manner that the data subject is not or no longer identifiable.
We support this definition

Minimum data categories in article 33(1):

Article 33(1)(a) - electronic health data from EHRs, including the categories in Article 5 of this Regulation

We support Option 1 and the comments made by Spain.

Articles:

Article 48

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

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

We agree with the deletion of this article as it comes in accordance to the Joint Opinion of the EDPB/EDPS (para 99) : *'(..) The EDPB and the EDPS consider that a permit should also be required, in order to enable verification that all relevant requirements, including lawfulness and necessity, have been complied with. Moreover, the EDPB and EDPS consider such a requirement important to promote transparency, as the Proposal envisages that health data access bodies shall provide general public infor-mation on all the data permits issued pursuant to Article 46.'*

Άρθρο 49

Access to electronic health data from a single health data holder

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

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

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

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

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

- **We support the major change by the Presidency in this article: that the MS may allow a data access application or a data request directly to the single health data holder.**
- **With regard to Art.1A, we wish to state that in our opinion there should be a COM HDAB created as well.**
- **With regard to Art. 2, we ask clarifications on whether the single data holder should have a secure processing environment as well, or access to another SPE will be provided.**

Chapter V

Additional actions

Article 59

Capacity building

The Commission shall support sharing of best practices and expertise, aimed to build the capacity of Member States to strengthen digital health systems for primary and secondary use of electronic health data. To support capacity building, the Commission shall **in close cooperation and consultation with Member States** ~~draw up~~ **establish indicators for self assessment** ~~benchmarking guidelines~~ for the primary and secondary use of electronic health data.

We support the introduction of self-assessment indicators and we strongly agree with the added text "in close cooperation and consultation with Member States". We also support Finland's proposal for clearly defining the indicators for self assessment in the recitals. Moreover, we suggest that indicators should be included to monitor COM as well (services provided for MyHealth@EU and HealthData@EU).

Article 60

Additional requirements for public procurement and Union funding

1. **Contracting authorities** ~~Public procurers, national competent authorities~~, including digital health authorities and health data access bodies and **Union institutions, bodies, offices or agencies, including** the Commission**,** shall make reference to the applicable technical specifications, standards and profiles as referred to in Articles 6, **12,** 23, 50, **52,** 56, **as well as to the requirements laid down in Regulations (EU) 2016/679 and (EU) 2018/1725,** as relevant, as points of orientation for public procurements and when formulating their tender documents or calls for proposals, as well as when defining the conditions for Union funding regarding this Regulation, including enabling conditions for the structural and cohesion funds.

2. **The criteria for obtaining funding from the Union** ~~The ex-ante conditionality for Union funding~~ shall take into account**:**

a) the requirements developed in Chapters II, III and IV**;**

b) the requirements laid down in Regulations (EU) 2016/679 or (EU) 2018/1725, where applicable, in particular:

(i) the requirements laid down in Article 35 or 39 respectively of these Regulations by requiring a documented data protection impact assessment, including where Chapter V of these Regulations apply, an assessment of the impact of the transfer to third countries or international organisations.

(ii) where Article 28 or 29 respectively of these Regulations is applicable, by requiring a contract or other legal act between the controller and the processor pursuant to Article 28 paragraph 3 or Article 29 paragraph 3 respectively.

We support the deletion of "the ex ante conditionality' and the introduction of the term 'contracting authority' - that has been added to the definitions as well.

Article 61

*~~Third country~~ **T**~~t~~ransfer **to a third country** of **anonymous electronic health data** ~~non-personal electronic data~~ **presenting a risk of re-identification***

1. ~~Non-personal~~ **Anonymous** electronic data made available by health data access bodies **to a health data user in a third country according to a data permit pursuant to Article 46 or a data request pursuant to Article 47 or to an authorisated participants in a third country or an international organisation**, that are based on a natural person's electronic **health** data falling within one of the categories of Article 33 ~~[(a), (e), (f), (i), (j), (k), (m)]~~ shall be deemed highly sensitive within the meaning of Article 5(13) of Regulation **(EU) 2022/868**[…] ~~[Data Governance Act COM/2020/767 final]~~, provided that their transfer to third countries presents a risk of re-identification through means going beyond those **reasonably** likely ~~reasonably~~ to be used, **in particular** in view of the limited number of natural persons involved in that data, the fact that they are geographically scattered or the technological developments expected in the near future.
2. The protective measures for the categories of data mentioned in paragraph 1 shall depend on the nature of the data and anonymization techniques and shall be detailed in the Delegated Act under the empowerment set out in Article 5(13) of Regulation **(EU) 2022/868** […] ~~[Data Governance Act COM/2020/767 final]~~.

Given that Articles 61 & 62 are about transfers to third countries and international organizations, we emphasize on the need to have a dedicated discussion on the matter of reciprocity.

We agree with the changes introduced by the Presidency.

Article 62

*~~International access and~~ **T**~~t~~ransfer of **anonymous** ~~non-personal~~ electronic health data **to a third country or an international organisation***

1. The digital health authorities, health data access bodies, the authorised participants in the cross-border infrastructures provided for in Articles 12 and 52 and **health** data users shall take all reasonable technical, legal and organisational measures, including contractual arrangements, in order to prevent ~~international~~ transfer **to a third country or an international organisation, including** ~~or~~ governmental access **in a third country** **of**~~to~~ **anonymous** ~~non-personal~~ electronic health data held in the Union where such transfer ~~or access~~ would create a conflict with Union law or the national law of the relevant Member State, without prejudice to paragraph 2 or 3 of this Article.

2. Any judgment of a third-country court or tribunal and any decision of a third-country administrative authority requiring a digital health authority, **a** health data access body or **a health** data user~~s~~ to transfer ~~or give access to~~ **anonymous** ~~non-personal~~ electronic health data within the scope of this Regulation held in the Union shall be recognised or enforceable in any manner only if based on an international agreement, such as a mutual legal assistance treaty, in force between the requesting third country and the Union or any such agreement between the requesting third country and a Member State.

3. In the absence of an international agreement as referred to in paragraph 2 of this Article, where a digital health authority, a health data access body, **a health** data user~~s~~ is the addressee of a decision or judgment of a third-country court or tribunal or a decision of a third-country administrative authority to transfer ~~or give access to~~ **anonymous** data within the scope of this Regulation held in the Union and **in** compliance with such a decision would risk putting the addressee in conflict with Union law or with the national law of the relevant Member State, transfer **of** ~~to or access to~~ such data **to** ~~by~~ that third-country authority shall take place only where:

   (a) the third-country system requires the reasons and proportionality of such a decision or judgment to be set out and requires such a decision or judgment to be specific in character, for instance by establishing a sufficient link to certain suspected **natural or legal** persons or infringements;

   (b) the reasoned objection of the addressee is subject to a review by a competent third-country court or tribunal; and

   (c) the competent third-country court or tribunal issuing the decision or judgment or reviewing the decision of an administrative authority is empowered under the law of that third country to take duly into account the relevant legal interests of the provider of the data protected under Union law or the national law of the relevant Member State

4. If the **criteria** ~~conditions~~ laid down in paragraph 2 or 3 are met, **a** digital health authority, a health data access body or a **health data user** ~~data altruism body~~ shall provide the minimum amount of data permissible in response to a request, based on a reasonable interpretation of the request.

5. The digital health authorities, health data access bodies, **health** data users shall inform the **health** data holder about the existence of a request of a third-country administrative authority to access its data before complying with that request, except where the request serves law enforcement purposes and for as long as this is necessary to preserve the effectiveness of the law enforcement activity.

Again, we emphasize on the need for reciprocity.

Article 63

*~~International access and~~ **T~~t~~**ransfer of personal electronic health data **to a third country or an international organisation***

In the context of ~~international access and~~ transfer of personal electronic health data **to a third country or an international organisation,** Member States may maintain or introduce further conditions, including limitations, in accordance with and under the conditions of **A~~a~~**rticle 9(4) of Regulation (EU) 2016/679, **in addition to the requirements set out in Articles 13 paragraph 3 and 52 paragraph 5 of this Regulation and the requirements laid down in Chapter V of Regulation (EU) 2016/679**.

It should be made clear that Art. 13(3) applies to international transfers in primary care and Art. 52(5) applies to international transfers in secondary care. Therefore, it could be the case that not

both articles apply at the same time (for example, a third country or an international organization may be part of MyHealth@EU and not part of HealthData@EU and vice versa).

Chapter VI

European governance and coordination

Article 64

European Health Data Space Board (EHDS Board)

1. A European Health Data Space Board (EHDS Board) is hereby established to facilitate cooperation and the exchange of information among Member States. The EHDS Board shall be composed of ~~the high level~~ representatives**, one each** of digital health authorities and health data access bodies**,** of all the Member States. ~~Other national authorities, including market surveillance authorities referred to in Article 28, European Data Protection Board and European Data Protection Supervisor, may be invited to the meetings, where the issues discussed are of relevance for them. The Board may also invite experts and observers to attend its meetings, and may cooperate with other external experts as appropriate. Other Union institutions, bodies, offices and agencies, research infrastructures and other similar structures, shall have an observer role.~~ (SECOND, THIRD AND LAST SENTENCES AMENDED AND MOVED TO PARA 1(B)-1(E))

1a. **A representative of** ~~T~~the Commission **and a representative of the Member States** shall **co-**chair the meetings of the EHDS Board. (MOVED FROM PARA 6)

1b. ~~Other national authorities, including~~**M**~~m~~arket surveillance authorities referred to in Article 28, European Data Protection Board and European Data Protection Supervisor, **shall** ~~may~~ be invited to the meetings, where the issues discussed are of relevance for them. (MOVED FROM PARA 1 AND AMENDED)

1c. The Board may also invite **other national authorities,** experts and observers to attend its meetings, and may cooperate with other external experts as appropriate. (MOVED FROM PARA 1 AND AMENDED)

1d. Other Union institutions, bodies, offices and agencies, research infrastructures and other similar structures **shall** have an observer role **when invited to participate in the meetings**. (MOVED FROM PARA 1 AND AMENDED)

1e. Stakeholders and relevant third parties, including patients' representatives, **may** ~~shall~~ be invited to attend meetings of the EHDS Board and to participate in its work, depending on the topics discussed and their degree of sensitivity. (MOVED FROM PARA 4)

2. Depending on the functions related to the use of electronic health data, the EHDS Board may work in subgroups **for certain topics**, where digital health authorities or health data access bodies ~~for a certain area~~ shall be represented. The subgroups may have joint meetings, as required.

3. The ~~composition, organisation, functioning and cooperation of subgroups shall be set out in~~ rules of procedures **of the EHDS Board shall be adopted by its members and** put forward by the Commission. **They shall include rules pertaining to the composition, structure, operation and cooperation of the sub-groups and shall regulate the role of invitees referred to in paragraphs 1b to 1e, taking into account the topics under discussion and the level of confidentiatlity involved.**

4. ~~Stakeholders and relevant third parties, including patients' representatives, shall be invited to attend meetings of the EHDS Board and to participate in its work, depending on the topics discussed and their degree of sensitivity.~~ MOVED TO PARA 1E

5. The EHDS Board shall cooperate with other relevant bodies, entities and experts, such as the European Data Innovation Board referred to in Article ~~26~~ **29** of Regulation **2022/868** [~~Data Governance Act COM/2020/767 final~~], competent bodies set up under Article 7 of Regulation […] [Data Act COM/2022/68 final], supervisory bodies set up under Article 17 of Regulation […] [eID Regulation], European Data Protection Board referred to in Article 68 of Regulation (EU) 2016/679 and cybersecurity bodies.

~~6. The Commission shall chair the meetings of the EHDS Board.~~ MOVED TO PARA 1A

7. The EHDS Board shall be assisted by a secretariat provided by the Commission.

8. The Commission shall, by means of implementing acts, adopt the necessary measures for the establishment~~,~~ **and** management ~~and functioning~~ of the EHDS Board. Those implementing acts shall be adopted in accordance with the ~~advisory~~ **examination** procedure referred to in Article 68(2).

- **We support the changes made in para 1.**
- **We support the changes made in para 1a. We believe that the way points in the agenda are introduced should also be added here and not be left to be decided in the rules of procedure.**
- **We support the changes made in Para 1b where it is mentioned that EDPB and EDPS may be invited to (some of) the meetings.**
- **We support the changes made in para 1c.**
- **We support the changes made in para 1d and we also need to emphasize that the number of observers to each meeting should be reasonable.**
- **We support the changes made in para 1e.**
- **We support the changes made in para 2.**
- **We support the changes made in para 3 and we wish to emphasize that EEA countries, third countries and international organisations shall NOT have voting rights and any decision power in the EHDS Board. Instead, they may be invited as observers to the meetings, when it is jointly decided by COM and the MS (Same criteria shall apply for the subgroups that may be formed for certain topics).**
- **We support the changes made in para 5.**
- **We support the changes made in para 7.**
- **We welcome the change to examination procedure in para 8.**

We also strongly feel that the voting rules should be laid down in this article and not be decided in the rules of procedure. In our opinion, if consensus cannot be reached, the EHDS Board should deliberate by a majority of two thirds of the Member States representatives. Additionally, each MS should have one vote.

Article 65
Tasks of the EHDS Board

1. The EHDS Board shall have the following tasks relating to the primary use of electronic health data in accordance with Chapters II and III:

(a) to assist Member States in coordinating practices of digital health authorities;

(b) to issue written contributions and to exchange best practices on matters related to the coordination of the implementation at Member State level of this Regulation and of the delegated and implementing acts adopted pursuant to it, in particular as regards:

(i) the provisions set out in Chapters II and III;

(ii) development of online services facilitating secure access, including secure electronic identification, to electronic health data for health professionals and natural persons.~~;~~

~~(iii) other aspects of the primary use of electronic health data~~.

(c) to facilitate cooperation between digital health authorities through capacity-building, establishing the structure for **biennial** ~~annual~~ activity reporting, **and exchange of information in those reports** ~~peer-review of annual activity reports and exchange of information~~;

(d) to share information concerning risks posed by EHR systems and serious incidents as well as their handling;

(e) to facilitate the exchange of views on the primary use of electronic health data with the relevant stakeholders, including representatives of patients, health professionals, researchers, regulators and policy makers in the health sector.

2. The EHDS Board shall have the following tasks related to the secondary use of electronic health data in accordance with Chapter IV:

(a) to assist Member States, in coordinating practices of health data access bodies,~~-~~in the implementation of provisions set out in Chapters IV, to ensure a consistent application of this Regulation;

(b) to issue written contributions and to exchange best practices on matters related to the coordination of the implementation at Member State level of this Regulation and of the delegated and implementing acts adopted pursuant to it, in particular as regards:

(xi) implementation of rules for access to electronic health data;

(xii) technical specifications or existing standards regarding the requirements set out in Chapter IV;

(xiii) incentives policy for promoting data quality and interoperability improvement;

(xiv) policies concerning fees to be charged by the health data access bodies and **health** data holders;

(xv) the establishment and application of penalties~~;~~

~~(xvi) other aspects of the secondary use of electronic health data~~.

(c) to facilitate cooperation between health data access bodies through capacity-building, establishing the structure for **biennial** ~~annual~~ activity reporting, **and** ~~peer-review of annual activity reports and~~ exchange of information **in those reports**;

(d) to share information concerning risks and data protection incidents related to secondary use of electronic health data, as well as their handling;

~~(e) to contribute to the work of the European Data Innovation Board to be established in accordance with Article 29 of the Regulation […] [Data Governance Act COM/2020/767 final];~~ (SEE ARTICLE 65(5))

(f) to facilitate the exchange of views on the secondary use of electronic health data with the relevant stakeholders, including **health data holders, health data users,** representatives of patients, health professionals, researchers, regulators and policy makers in the health sector.

We support the changes made with the exception of deleting (xvi). Other aspects of the secondary use of electronic health data that are not currently listed could arise.

Article 66

~~*Joint controllership groups for Union infrastructures*~~***The Steering Groups for the infrastructures MyHealth@EU and HealthData@EU***-

1. **Two Steering groups are hereby established** ~~The Commission shall establish two groups dealing with joint controllership~~ for the cross-border infrastructures provided for in Articles 12 and 52**; the MyHealth@EU Steering group and the HealthData@EU Steering group. Each** ~~The~~ group~~s~~ shall be composed of **one** ~~the~~ representative~~s~~ **per Member State** of the **respective** national contact points ~~and other authorisated participants in those infrastructures~~.

1A. The **Steering** groups shall take **operational** decisions concerning the development and operation of the cross-border infrastructures pursuant to Chapters II and IV, on changes of infrastructure, adding additional infrastructures or services, or ensuring interoperability with other infrastructures, digital systems or data spaces. ~~The group shall also take decisions to accept individual authorised participants to join the infrastructures or to disconnect them.~~ (MOVED FROM PARA 6 AND AMENDED)

1B. The Steering Groups shall, in principle, take decisions by consensus. Where consensus cannot be reached, the adoption of a decision shall require the support of members representing two-thirds majority.

2. The composition, organisation, functioning and cooperation of the ~~sub~~ **Steering** groups shall be set out in the rules of procedure adopted by those groups.

~~3. Stakeholders and relevant third parties, including patients' representatives, may be invited to attend meetings of the groups and to participate in their work.~~ MOVED TO ARTICLE 66A

4. The groups shall elect chairs for their meetings.

5. The groups shall be assisted by a secretariat provided by the Commission.

~~6. The groups shall take decisions concerning the development and operation of the cross-border infrastructures pursuant to Chapters II and IV, on changes of infrastructure, adding additional infrastructures or services, or ensuring interoperability with other infrastructures, digital systems or data spaces. The groups shall also take decisions to accept individual authorised participants to join the infrastructures or to disconnect them.~~ MOVED TO PARA 1A

- **We welcome the introduction of the 2 steering groups in para 1 but –again- we emphasize that EEA countries, third countries and international organizations that may be authorized participants in the 2 steering groups will not have voting rights.**
- **We disagree with the changes made in para 1a, as we prefer the original wording (that was para 6 before). We support that the steering groups should take decisions to accept individuals authorised participants to join the infrastructures or to disconnect them and we also find the addition of the word 'operational' to be restrictive.**
- **We strongly agree with the addition of para 1b.**

Article 66A

Fora for the infrastructures MyHealth@EU and HealthData@EU-

1. Two fora are hereby established; the MyHealth@EU Forum and the HealthData@EU Forum, with a view to exchange information and views on relevant matters related to the crossborder infrastructures respectively provided for in Articles 12 and 52, excluding any decision making. These Fora shall be convened on a regular basis.
2. The Fora referred to in paragraph 1 shall be composed of members of the Steering groups referred to in Article 66 and of other other participants in the infrastructures provided for in Articles 12 and 52.
3. Stakeholders and relevant third parties, including patients' representatives, may be invited to attend meetings of the respective Forum and to participate in their work.

After thorough examination we have come to believe that the addition of the two fora may not be necessary (there is already the EHDS Board, the Steering Committees, an assisting Committee for COM, it seems too much to add 2 more fora). Therefore, we believe that Art. 66A could be deleted.

Article 12

MyHealth@EU

9. The approval for individual authorised participants to join MyHealth@EU for different services, or to disconnect a participant shall be ~~issued by the Joint Controllership groups,~~ based on the results of the compliance checks **performed by the Commission**.

Subject to the positive outcome of this compliance check the Commission shall, by means of implementing act, take decisions to connect individual authorised participants to join the respective infrastructure or to disconnect them. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 68.

Member States should be involved in the onboarding and offboarding of authorized participants in MyHealth@EU. Therefore, we prefer the original wording.

Article 52

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

14. The approval for individual authorised participant to join HealthData@EU or to disconnect a participant from the infrastructure shall be ~~issued by the~~ **~~Article 66~~** ~~Joint Controllership group,~~ based on the results of the compliance checks **performed by the Commission** concerning the fulfilment of the requirements **referred to in paragraph 13**.

Subject to the positive outcome of this compliance check, the Commission shall, by means of implementing act, take decisions to connect individual authorised participants to join the respective infrastructure or to disconnect them. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 68.

Member States should be involved in the onboarding and offboarding of authorized participants in HealthData@EU. Therefore, we prefer the original wording.

CHAPTER VII

Delegation and Committee

Article 67

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The power to adopt delegated acts referred to in Articles 5(2), 10(3), 25(3), 32(4), 33(7), 37(4), 39(3), 41(7), 45(7), 46(8), 52(7), and 56(4) shall be conferred on the Commission for an indeterminate period of time from the date of entry into force of this Regulation.
3. The power to adopt delegated acts referred to in Articles 5(2), 10(3), 25(3), 32(4), 33(7), 37(4), 39(3), 41(7), 45(7), 46(8), 52(7), and 56(4) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Inter-institutional Agreement of 13 April 2016 on Better Law-Making.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Articles 5(2)~~, 10(3), 25(3),~~ 32(4), ~~33(7), 37(4), 39(3), 41(7), 45(7), 46(8), 52(7),~~ **and** 56(4) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of 3 months of notification of that act to the European Parliament and to the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by 3 months at the initiative of the European Parliament or of the Council.

We support the changes made by the Presidency.

Article 68

Committee procedure

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

We support the changes made by the Presidency.

Chapter VIII
Miscellaneous

Article 69

Penalties

Without prejudice to Articles 30 and 43 of this Regulation and to Chapter VIII of Regulation (EU) 2016/679, Member States shall lay down the rules on penalties applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties shall be effective, proportionate and dissuasive. Member States shall notify the Commission of those rules and measures by date of application of this Regulation and shall notify the Commission without delay of any subsequent amendment affecting them.

We support the changes made by the Presidency.

Article 70

Evaluation and review

1. After ~~5~~ **6** years from the entry into force of this Regulation, the Commission shall carry out a targeted evaluation of this Regulation especially with regards to Chapter III, and submit a report on its main findings to the European Parliament and to the Council, the European Economic and Social Committee and the Committee of the Regions, accompanied, where appropriate, by a proposal for its amendment. The evaluation shall include an assessment of the self-certification of EHR systems and reflect on the need to introduce a conformity assessment procedure performed by notified bodies.

2. After ~~7~~ **8** years from the entry into force of this Regulation, the Commission shall carry out an overall evaluation of this Regulation, and submit a report on its main findings to the European Parliament and to the Council, the European Economic and Social Committee and the Committee of the Regions, accompanied, where appropriate, by a proposal for its amendment.

3. Member States shall provide the Commission with the information necessary for the preparation of that report.

We support the changes made by the Presidency.

Article 71

Amendment to Directive 2011/24/EU

Article 14 of Directive 2011/24/EU is deleted.

Chapter IX

Deferred application and final provisions

Article 72

Entry into force and application

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from ~~12~~ **24** months after its entry into force.

However, Articles 3, 4, 5, 6, 7, 12, 14, 23 and 31 shall apply as follows:

(a) from ~~1~~**3** year after date of entry into application to categories of personal electronic health data referred to in Article 5(1), points (a), (b) and (c), and to EHR systems intended by the manufacturer to process such categories of data;

(b) from ~~3~~**5** years after date of entry into application to categories of personal electronic health data referred to in Article 5(1), points (d), (e) and (f), and to EHR systems intended by the manufacturer to process such categories of data;

(c) from the date established in delegated acts pursuant to Article 5(2) for other categories of personal electronic health data.

Chapter III shall apply to EHR systems put into service in the Union pursuant to Article 15(2) from ~~3~~ **4** years after date of entry into application.

Chapter IV shall apply 36 months after date of entry into force.

We believe that the changes made by the Presidency offer a more realistic timeframe

Comments from the Finnish delegation

MINISTRY OF SOCIAL AFFAIRS AND HEALTH

FINLAND comments on the First Presidency compromise proposal Chapter I, Articles 48 and 49

Article	**Comments**
Article 1 Subject matter and scope	
1. This Regulation establishes the European Health Data Space ('EHDS') by providing for **common** rules, ~~common~~ standards ~~and practices~~, infrastructures and a governance framework ~~for~~ **with a view to facilitating access to electronic health data for** the **purposes of** primary and secondary use of ~~electronic health~~ **these** data.	It should be clarified in the recitals what standards this paragraph refers to.
2. This Regulation: (a) ~~strengthens~~ **specifies and complements, in Chapter II,** the rights **laid down in the Regulation (EU) 2016/679** of natural persons in relation to **primary use** ~~the availability and control~~ of their **personal** electronic health data; (b) lays down, **in Chapter III, common** rules for the placing on the market, making available on the market or putting into service of electronic health records systems ('EHR systems') **and wellness applications that claim interoperability with EHR systems** in the Union **for primary use**; (c) lays down**, in Chapter II and IV, common** rules and mechanisms supporting **for primary and** secondary use of electronic health data; (d) establishes a ~~mandatory~~ cross-border infrastructure enabling the primary use of **personal** electronic health data across the Union **according to Chapter II**; (e) establishes a ~~mandatory~~ cross-border infrastructure for the secondary use of electronic health data **according to Chapter IV**;**.** **(f) establishes governance and coordination on national and European level for both primary and secondary use of electronic health data.**	It should be clarified when this Regulation uses the margin of manoeuvre from the GDPR and when it deviates from the GDPR. The relationship to the rights in the GDPR should be clarified in a recital for example with the wording "The additional rights for natural persons in this Regulation do not affect the rights natural persons have according to the GDPR." We are of the opinion that the references to specific Chapters are not necessary.

~~3. This Regulation applies to:~~ ~~(a)manufacturers and suppliers of EHR systems and wellness applications placed on the market and put into service in the Union and the users of such products;~~ ~~(b)controllers and processors established in the Union processing electronic health data of Union citizens and third country nationals legally residing in the territories of Member States;~~ ~~(c)controllers and processors established in a third country that has been connected to or are interoperable with MyHealth@EU, pursuant to Article 12(5);~~ ~~(d)data users to whom electronic health data are made available by data holders in the Union.~~	We are not necessarily in favor of the deletion of this whole paragraph. If this paragraph would be kept, it should include a reference to all economic operators. EDPB and EDPS Joint Opinion para 34 the EDPB and the EDPS recommend adding manufacturers and suppliers of medical devices in Article 1(3)(a) of the Proposal. (b) The term "legally" could be deleted from this.
3A. This Regulation shall be without prejudice to Regulations (EU) 2016/679, (EU) 2018/1725, (EU) No 536/2014 and Directive 2022/58/EC.	We support this change.
4. This Regulation shall be without prejudice to other Union legal acts regarding access to, sharing of or secondary use of electronic health data, or requirements related to the processing of data in relation to electronic health data, in particular Regulations ~~(EU) 2016/679, (EU) 2018/1725~~, **(EU) 2022/868** ~~[…] [Data Governance Act COM/2020/767 final]~~ and […] [Data Act COM/2022/68 final].	Paragraphs 3A and 4 should be written in a similar way.
5. This Regulation shall be without prejudice to Regulations (EU) 2017/745, **(EU) 2017/746** and […] [AI Act COM/2021/206 final], as regards the security of medical devices and AI systems that interact with EHR systems.	
6. This Regulation shall not affect the rights and obligations laid down in Union or national law concerning data processing for the purposes of reporting, complying with information requests or demonstrating or verifying compliance with legal obligations.	This could be deleted as it does not affect the rights and obligations laid down in Union or national law.
7. This Regulation shall not apply to activitites concerning public security, defence and national security.	It should be defined more clearly what this paragraph means in the recitals. Paragraph could be written "shall not apply to processing of electronic health data in the context of…"

Article 2 Definitions	*Definitions in Article 2(2)(d),(f)-(n) and (p)-(t) are not included in this compromise*
1.For the purposes of this Regulation, following definitions shall apply: (a) the definitions **of 'personal data', 'processing', 'pseudonymisation', 'controller', 'processor', 'third party', 'consent', 'genetic data', 'data concerning health', 'supervisory authority', 'international organisation' of the** in Regulation (EU) 2016/679; (b) the definitions of 'healthcare', 'Member State of affiliation', 'Member State of treatment', 'health professional', 'healthcare provider', 'medicinal product' and 'prescription', pursuant to Article 3 (a), (c), (d), (f), (g), (i) and (k) of Article 3 of the Directive 2011/24/EU; (c) the definitions of 'data', 'access', 'data altruism', 'public sector body' and 'secure processing environment', pursuant to Article 2 (1), (8), (10), (11) and (14) of **Regulation (EU) 2022/868** ~~[Data Governance Act COM/2020/767 final]~~; (d)the definitions of 'making available on the market', 'placing on the market', 'market surveillance', 'market surveillance authority', 'non-compliance', 'manufacturer', 'importer', 'distributor', 'economic operator', 'corrective action', 'risk', 'recall' and 'withdrawal', pursuant to Article 2 (1), (2), (3), (4), (7), (8), (9), (10), (13), (16), (18), (22) and (23) of the Regulation (EU) 2019/1020; (e)the definitions of 'medical device', 'intended purpose', 'instructions for use', 'performance', 'health institution' and 'common specifications', pursuant to Article 2 (1), (12), (14), (22), (36) and (71) of the Regulation (EU) 2017/745; (f)the definitions of 'electronic identification', 'electronic identification means' and 'person identification data' pursuant to Article 3 (1), (2) and (3) of the Regulation (EU) No 910/2014.	

2. In addition, for the purposes of this Regulation the following definitions shall apply: (a)'personal electronic health data' means **personal** data concerning health and genetic data as defined in Regulation (EU) 2016/679, ~~as well as data referring to determinants of health, or data processed in relation to the provision of healthcare services,~~ processed in an electronic form; ~~(b)'non-personal electronic health data' means data concerning health and genetic data in electronic format that falls outside the definition of personal data provided in Article 4(1) of Regulation (EU) 2016/679;~~ (c)'electronic health data' means personal **health data** or ~~non-personal electronic health~~ data **concerning health or genetic data that do not constitute personal data, processed in electronic form**; (d)'primary use of electronic health data' means the processing of personal electronic health data for the provision of health 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; (e)'secondary use of electronic health data' means the processing of electronic health data for purposes set out in **Article 34** ~~Chapter IV~~ of this Regulation. ~~The data used may include personal electronic health data initially collected in the context of primary use, but also electronic health data collected for the purpose of the secondary use~~; (f)'interoperability' means the ability of organisations as well as software applications or devices from the same manufacturer or different manufacturers to interact towards mutually beneficial goals, involving the exchange of information and knowledge without changing the content of the data between these organisations, software applications or devices, through the processes they support; (g)'European electronic health record exchange format' means a structured, commonly used and machine-readable format that allows transmission of personal electronic health data	Article 2, para 2 a has been amended according to EDPB and EDPS Joint Opinion para 40: The EDPB and EDPS recommend to amend the definition in Article 2(2)(a) of the Proposal to simply refer to "data concerning health and genetic data as defined in GDPR that are processed in an electronic form". We agree with this change. Article 2 paragraph 2 e, we support the reference to Article 34, as this makes the purposes for secondary use clear. We also support the deletion of the latter sentence.

between different software applications, devices and healthcare providers; (h)‘registration of electronic health data’ means the recording of health data in an electronic format, through manual entry of data, through the collection of data by a device, or through the conversion of non-electronic health data into an electronic format, to be processed in an EHR system or a wellness application; (i)‘electronic health data access service’ means an online service, such as a portal or a mobile application, that enables natural persons not acting in their professional role to access their own electronic health data or electronic health data of those natural persons whose electronic health data they are legally authorised to access; (j)‘health professional access service’ means a service, supported by an EHR system, that enables health professionals to access data of natural persons under their treatment; (k)‘data recipient’ means a natural or legal person that receives data from another controller in the context of the primary use of electronic health data; (l)‘telemedicine’ means the provision of healthcare services, including remote care and online pharmacies, through the use of information and communication technologies, in situations where the health professional and the patient (or several health professionals) are not in the same location; (m)‘EHR’ (electronic health record) means a collection of electronic health data related to a natural person and collected in the health system, processed for healthcare purposes; (n)‘EHR system’ (electronic health record system) means any appliance or software intended by the manufacturer to be used for storing, intermediating, importing, exporting, converting, editing or viewing electronic health records; (o)‘wellness application’ means any appliance or software intended by the manufacturer to be used by a natural person for processing electronic health data for other purposes than healthcare, such as well-being and pursuing healthy life-styles; (p)‘CE marking of conformity’ means a marking by which the manufacturer indicates that the EHR system is in conformity with the	(o) The definition for wellness application is very wide, the information should be related to health and wellbeing.

applicable requirements set out in this Regulation and other applicable Union legislation providing for its affixing; (q)'serious incident' means any malfunction or deterioration in the characteristics or performance of an EHR system made available on the market that directly or indirectly leads, might have led or might lead to any of the following: (i)the death of a natural person or serious damage to a natural person's health; (ii)a serious disruption of the management and operation of critical infrastructure in the health sector; (r)'national contact point for digital health' means an organisational and technical gateway for the provision of cross-border digital health information services for primary use of electronic health data, under the responsibility of the Member States; (s)'central platform for digital health' means an interoperability platform providing services to support and facilitate the exchange of electronic health data between national contact points for digital health; (t)'MyHealth@EU' means the cross-border infrastructure for primary use of electronic health data formed by the combination of national contact points for digital health and the central platform for digital health; ~~(u)'national contact point for secondary use of electronic health data' means an organisational and technical gateway enabling the cross-border secondary use of electronic health data, under the responsibility of the Member States;~~ ~~(v)'central platform for secondary use of electronic health data' means an interoperability platform established by the Commission, providing services to support and facilitate the exchange of information between national contact points for secondary use of electronic health data;~~ ~~(x)'HealthData@EU' means the infrastructure connecting national contact points for secondary use of electronic health data and the central platform;~~ (y)' **health** data holder' means ~~any~~ natural or legal person, which is an entity or a body in the health or care sector, or performing research in relation to these sectors, as well as Union institutions, bodies, offices and agencies who	We would prefer to keep definitions u, v and x.

has ~~the right or obligation, in accordance with this Regulation, applicable Union law or national legislation implementing Union law~~, **either:** **(a) the right or obligation, in accordance with applicable Union law or national legislation, to process personal electronic health data for the provision of health or care or for public health, research, innovation, policy making, official statistics, patient safety or regulatory purposes, in its capacity as a controller; or** **(b) the ability to make available, including to register, provide, restrict access or exchange electronic health data that do not constitute personal data in the meaning of Article 4 (1) of Regulation (EU) 2016/679** ~~non-personal data,~~ through control of the technical design of a product and related services, ~~the ability to make available, including to register, provide, restrict access or exchange certain data~~; (z)' **health** data user' means a natural or legal person who has lawful access to ~~personal or non-personal~~ electronic health data for secondary use **pursuant to a data permit or a data request pursuant to this Regulation**; (aa)'data permit' means an administrative decision issued to a **health** data user by a health data access body or **single health** data holder to process the electronic health data specified in the data permit for the secondary use purposes specified in the data permit based on conditions laid down **Chapter IV of** in this Regulation; (ab)'dataset' means a structured collection of electronic health data; (ac)'dataset catalogue' means a collection of datasets descriptions, which is arranged in a systematic manner and consists of a user-oriented public part, where information concerning individual dataset parameters is accessible by electronic means through an online portal; (ad)'data quality' means the degree to which characteristics of electronic health data are suitable for secondary use; (ae)'data quality and utility label' means a graphic diagram, including a scale, describing the data quality and conditions of use of a dataset.	(ac) This definition should be checked against Articles 57 and 55.

CHAPTER IV Secondary use of electronic health data	
~~Article 48~~ ~~Making data available for public sector bodies and Union institutions, bodies, offices and agencies without a data permit~~	
~~By derogation from Article 46 of this Regulation, a data permit shall not be required to access the electronic health data under this Article. When carrying out those tasks under Article 37 (1), points (b) and (c), the health data access body shall inform public sector bodies and the Union institutions, offices, agencies and bodies, about the availability of data within 2 months of the data access application, in accordance with Article 9 of Regulation […] [Data Governance Act COM/2020/767 final]. By way of derogation from that Regulation […] [Data Governance Act COM/2020/767 final], the health data access body may extend the period by 2 additional months where necessary, taking into account the complexity of the request. The health data access body shall make available the electronic health data to the data user within 2 months after receiving them from the data holders, unless it specifies that it will provide the data within a longer specified timeframe.~~	We agree with this change and it is according to the Joint Opinion of the EDPB and EDPS. EDPB/EDPS (paragraph 99): "Article 48 of the Proposal provides that, by derogation from Article 46 of the Proposal, a data permit shall not be required to access the electronic health data under the same Article by public sector bodies and Union institutions, bodies, offices and agencies. The EDPB and the EDPS consider that a permit should also be required, in order to enable verification that all relevant requirements, including lawfulness and necessity, have been complied with. Moreover, the EDPB and EDPS consider such a requirement important to promote transparency, as the Proposal envisages that health data access bodies shall provide general public information on all the data permits issued pursuant to Article 46."
Article 49 Access to electronic health data from a single **health** data holder	
1. **Member States may allow** ~~W~~**w**here an applicant requests access to electronic health data only from a single **health** data holder **in that** ~~in a single~~ Member State, by way of derogation from Article 45(1) **or Article 47(1)**, that applicant ~~may~~ **to** file a data access application or a data request directly to the **health** data holder. The data access application shall comply with the requirements set out in Article 45 and the data request shall comply with requirements in Article 47. Multi-country requests and requests requiring a combination of datasets from several **health** data holders shall be adressed to health data access bodies.	We find it very important that there is a possibility for single health data holders to give data permits. In Finland this is possible and in most cases the processing of the data permit is faster in a single data holder than in Findata. The single data holders have the best expertise on their own data and experience on handling data permit applications to their data. The single data holders should have the expertise necessary to handle data access applications and especially for data requests, the anonymization processes.

1A. Where an applicant request access to electronic health data from health data holders which are an Union institution, body, office or agency, by way of derogation from Article 45(1) or Article 47(1), that applicant shall file a data access application or a data request directly to each health data holder. The data access application shall comply with the requirements set out in Article 45 and the data request shall comply with requirements in Article 47.	This process should be mapped out and described clearly. We support the creation of an EU HDAB.
2. In ~~such case~~ **situations referred to in paragraphs 1 and 2 in this Article,** the **health** data holder may issue a data permit in accordance with Article 46 or provide an answer to a data request in accordance with Article 47. The **health** data holder shall then provide access to the electronic health data in a secure processing environment in compliance with Article 50 and may charge fees in accordance with Article 42.	It should be clarified in a recital what secure processing environment does the single data holder provide access to. There was discussion on the fact that a single data holder may reject the data access application, if it does not have the capacity to process it and does not have a secure processing environment. However, this does not show in the Article itself.
~~3. By way of derogation from Article 51, the single data provider and the data user shall be deemed joint controllers.~~ SEE ARTICLE 51	
4. ~~Within 3 months t~~**T**he **single health** data holder**, referred to in paragraph 1 of this Article,** shall **within 3 months** inform the relevant health data access body by electronic means of all data access applications filed and all the data permits issued and the data requests fulfilled under this Article in order to enable the health data access body to fulfil its obligations under Article 37(1) and Article 39.	There is no need to make references to paragraphs within one Article.

FINLAND comments on the definitions of data holder and data user

The definition of a health data holder

Option 1 – Current scope and definition of health data holder with a clarification that also social security is included

- Finland's objective is to enable at least the processing of the data sets that are currently laid down in the Finnish Act on secondary use of Health and Social data, and therefore we support a broad definition of health data holder. The Finnish Act Section 6 lists the relevant authorities who are responsible for providing access to their data.
- In Finland, we prefer a holistic approach, in which case mere health data is not sufficient for research and other purposes. In addition to health data, social welfare and financial information as well as education data are also needed.
- We should be able to get access to all the data categories in Article 33.
- The definition should include public and private social and healthcare providers, and authorities which have the legal right or obligation to collect personal electronic health data for steering, supervision, researching and collecting statistics on the social and health care sector.
- We are not sure if Option 1 will provide us with all the relevant data. We would prefer a wider definition.
- Even though Article 33 gives member states the possibility to provide more data than the data categories, if the definition of data holder is very restricted, this means that in practice these entities will not be able to give access to their data in this infrastructure. How would this definition and Article 33 paragraph 8 work together?

The definition of a health data user

Option 1 – Current scope and definition of health data user and the scope of applicant
Article 2(2)(z)

- In principle, we do not support limiting the scope and definition of health data user, although we agree that all transfers to third countries should be done according to the Chapter 5 of the GDPR. The data access body has the possibility to reject an application if the applicant does not meet the criteria in the Regulation and if the transfer of data would not be according to Chapter 5 of the GDPR.
- Currently the third countries which ensure an adequate level of protection according to Chapter 5 of the GDPR are: Andorra, Argentina, Canada (only commercial organizations), Faroe Islands, Guernsey, Israel, Isle of Man, Jersey, New Zealand, Switzerland, Uruguay, Japan, the United Kingdom and South Korea. There might also be a decision concerning US in the near future.
- We support Option 1.
- Would Option 2 mean that research cooperation with the US would not be possible? For example, at the moment, Findata gives access to US researchers to data in the Findata secure processing environment.

Commented [A1]: Section 6
Authorities and organisations responsible for the services and restrictions on data sets
Chapter 3 contains provisions on the services that are needed for processing the customer data of social and health care services and other personal data referred to in this Act that can be combined with them for the purposes stated in section 2. The responsibility for producing the services lies with the Data Permit Authority and the following authorities and organisations:
1) Ministry of Social Affairs and Health;
2) National Institute for Health and Welfare, notwithstanding the data it has collected for statistical purposes as a statistical authority.
3) Social Insurance Institution of Finland insofar as the data needed for the purposes stated in this Act is personal data stored during the processing of benefits in a customer relationship or concerns drug prescriptions and associated delivery information stored in a prescription centre referred to in section 3, paragraph 4 of the Act on Electronic Prescriptions (61/2007) and in a prescription archive referred to in paragraph 5 of the Act.
4) National Supervisory Authority for Welfare and Health Valvira;
5) Regional State Administrative Agencies insofar as they process matters related to social and health care;
6) Finnish Institute of Occupational Health insofar as the data needed for the purposes stated in this Act comes from occupational disease registers and exposure measurement registers and the Institute's patient registers;
7) Finnish Medicines Agency Fimea;
8) Public service organisers of social and health care;
9) Statistics Finland insofar as the data needed for the purposes stated in this Act is data referred to in the Act on Determining the Cause of Death (459/1973);
10) Finnish Centre for Pensions insofar as the data needed for the purposes stated in this Act is necessary personal data stored in the Finnish Centre for Pensions's registers and concerns employment and earnings information stored during the implementation of earnings-related pension, granted benefits and their justifications, including disability pension diagnoses; and
11) Population Register Centre insofar as the data needed for the purposes stated in this Act comes from the Population Information System and is basic data on individuals, their family relationships and places of residence as well as data on buildings.

Chapter V

Additional actions

Article 59
Capacity building

The Commission shall support sharing of best practices and expertise, aimed to build the capacity of Member States to strengthen digital health systems for primary and secondary use of electronic health data. To support capacity building, the Commission shall **in close cooperation and consultation with Member States** ~~draw up~~ **establish indicators for self assessment** ~~benchmarking guidelines~~ for the primary and secondary use of electronic health data.

Commented [A2]: Indicators for self assessment should be clearly defined and explained in the recitals.

Article 60
Additional requirements for public procurement and Union funding

1. **Contracting authorities** ~~Public procurers, national competent authorities~~, including digital health authorities and health data access bodies and **Union institutions, bodies, offices or agencies, including** the Commission**,** shall make reference to the applicable technical specifications, standards and profiles as referred to in Articles 6, **12,** 23, 50, **52,** 56, **as well as to the requirements laid down in Regulations (EU) 2016/679 and (EU) 2018/1725,** as relevant, as points of orientation for public procurements and when formulating their tender documents or calls for proposals, as well as when defining the conditions for Union funding regarding this Regulation, including enabling conditions for the structural and cohesion funds.

Commented [A3]: It should be checked that the term contracting authorities does not widen the scope and that it contains the earlier wording public procurers and national competent authorities.

Commented [A4]: We support these additions, although it might not be necessary to refer to GDPR and Union institutions Regulation as these should be applied regardless.

2. **The criteria for obtaining funding from the Union** ~~The ex-ante conditionality for Union funding~~ shall take into account**:**

Commented [A5]: The "criteria for obtaining funding from the Union" seems clearer than "ex ante conditionality".

a) the requirements developed in Chapters II, III and IV**;**

b) the requirements laid down in Regulations (EU) 2016/679 or (EU) 2018/1725, where applicable, in particular:

(i) the requirements laid down in Article 35 or 39 respectively of these Regulations by requiring a documented data protection impact assessment, including where Chapter V of these Regulations apply, an assessment of the impact of the transfer to third countries or international organisations.

(ii) where Article 28 or 29 respectively of these Regulations is applicable, by requiring a contract or other legal act between the controller and the processor pursuant to Article 28 paragraph 3 or Article 29 paragraph 3 respectively.

Article 61

*~~Third country~~ **T**~~t~~ransfer **to a third country** of **anonymous electronic health data** ~~non-personal electronic data~~ **presenting a risk of re-identification***

1. ~~Non-personal~~ **Anonymous** electronic data made available by health data access bodies **to a health data user in a third country according to a data permit pursuant to Article 46 or a data request pursuant to Article 47 or to an authorisated participants in a third country or an international organisation**, that are based on a natural person's electronic **health** data falling within one of the categories of Article 33 ~~[(a), (e), (f), (i), (j), (k), (m)]~~ shall be deemed highly sensitive within the meaning of Article 5(13) of Regulation **(EU) 2022/868**~~[…] [Data Governance Act COM/2020/767 final]~~, provided that their transfer to third countries presents a risk of re-identification through means going beyond those **reasonably** likely ~~reasonably~~ to be used, **in particular** in view of the limited number of natural persons involved in that data, the fact that they are geographically scattered or the technological developments expected in the near future.
2. The protective measures for the categories of data mentioned in paragraph 1 shall depend on the nature of the data and anonymization techniques and shall be detailed in the Delegated Act under the empowerment set out in Article 5(13) of Regulation **(EU) 2022/868** ~~[…] [Data Governance Act COM/2020/767 final]~~.

Article 62

*~~International access and~~ **T**~~t~~ransfer of **anonymous** ~~non-personal~~ electronic health data **to a third country or an international organisation***

1. The digital health authorities, health data access bodies, the authorised participants in the cross-border infrastructures provided for in Articles 12 and 52 and **health** data users shall take all reasonable technical, legal and organisational measures, including contractual arrangements, in order to prevent ~~international~~ transfer **to a third country or an international organisation, including** ~~or~~ governmental access **in a third country** **of**~~to~~ **anonymous** ~~non-personal~~ electronic health data held in the Union where such transfer ~~or access~~ would create a conflict with Union law or the national law of the relevant Member State, without prejudice to paragraph 2 or 3 of this Article.

Commented [A6]: These requirements apply regardless of this Regulation and therefore we are of the opinion that these are not necessary additions.

Commented [A7]: The term used in the DGA is "non-personal, anonymised data". The term anonymous data comes from the GDPR recital 26. The term used here should be the same as in DGA and Data Act.

Also transfers between member states can present a risk for highly sensitive categories of non-personal data.

Commented [A8]: We support the change that all the data categories of Article 33 are included.

Commented [A9]: This does not seem necessary.

Commented [A10]: The term used in the Data Act is non-personal data. The changes made to the Data Act should be taken into account, especially the terminology.

Commented [A11]: These sentences and especially terms "transfer and access" should be checked against the compromise proposal of the Data Act.

2. Any judgment of a third-country court or tribunal and any decision of a third-country administrative authority requiring a digital health authority, **a** health data access body or **a health** data user~~s~~ to transfer ~~or give access to~~ **anonymous** ~~non-personal~~ electronic health data within the scope of this Regulation held in the Union shall be recognised or enforceable in any manner only if based on an international agreement, such as a mutual legal assistance treaty, in force between the requesting third country and the Union or any such agreement between the requesting third country and a Member State.
3. In the absence of an international agreement as referred to in paragraph 2 of this Article, where a digital health authority, a health data access body, **a health** data user~~s~~ is the addressee of a decision or judgment of a third-country court or tribunal or a decision of a third-country administrative authority to transfer ~~or give access to~~ **anonymous** data within the scope of this Regulation held in the Union and **in** compliance with such a decision would risk putting the addressee in conflict with Union law or with the national law of the relevant Member State, transfer **of** ~~to or access to~~ such data **to** ~~by~~ that third-country authority shall take place only where:
   (a) the third-country system requires the reasons and proportionality of such a decision or judgment to be set out and requires such a decision or judgment to be specific in character, for instance by establishing a sufficient link to certain suspected **natural or legal** persons or infringements;
   (b) the reasoned objection of the addressee is subject to a review by a competent third-country court or tribunal; and
   (c) the competent third-country court or tribunal issuing the decision or judgment or reviewing the decision of an administrative authority is empowered under the law of that third country to take duly into account the relevant legal interests of the provider of the data protected under Union law or the national law of the relevant Member State
4. If the **criteria** ~~conditions~~ laid down in paragraph 2 or 3 are met, **a** digital health authority, a health data access body or a **health data user** ~~data altruism body~~ shall provide the minimum amount of data permissible in response to a request, based on a reasonable interpretation of the request.
5. The digital health authorities, health data access bodies, **health** data users shall inform the **health** data holder about the existence of a request of a third-country administrative authority to access its data before complying with that request, except where the request serves law enforcement purposes and for as long as this is necessary to preserve the effectiveness of the law enforcement activity.

Article 63

~~International access and~~ T~~t~~ransfer of personal electronic health data to a third country or an international organisation

In the context of ~~international access and~~ transfer of personal electronic health data **to a third country or an international organisation,** Member States may maintain or introduce further conditions, including limitations, in accordance with and under the conditions of **A~~a~~**rticle 9(4) of Regulation (EU) 2016/679, **in addition to the requirements set out in Articles 13 paragraph 3 and 52 paragraph 5 of this Regulation and the requirements laid down in Chapter V of Regulation (EU) 2016/679**.

Commented [A12]: We are of the opinion that this Article is not necessary, as Member States can maintain further conditions in accordance with the GDPR Article 9(4).

See EDPB and EDPS Joint Opinion paras 109-111.

Chapter VI

European governance and coordination

Article 64

European Health Data Space Board (EHDS Board)

1. A European Health Data Space Board (EHDS Board) is hereby established to facilitate cooperation and the exchange of information among Member States. The EHDS Board shall be composed of ~~the high level~~ representatives**, one each** of digital health authorities and health data access bodies**,** of all the Member States. ~~Other national authorities, including market surveillance authorities referred to in Article 28, European Data Protection Board and European Data Protection Supervisor, may be invited to the meetings, where the issues discussed are of relevance for them. The Board may also invite experts and observers to attend its meetings, and may cooperate with other external experts as appropriate. Other Union institutions, bodies, offices and agencies, research infrastructures and other similar structures, shall have an observer role.~~ (SECOND, THIRD AND LAST SENTENCES AMENDED AND MOVED TO PARA 1(B)-1(E))

Commented [A13]: We are of the opinion that the Member States should be able to decide themselves from which authorities the representatives come from, not necessarily from digital health authorities or data access bodies. Two representatives from each MS creates a large group, how would the decision process be possible in this group?

1a. **A representative of ~~T~~t**he Commission **and a representative of the Member States** shall **co-**chair the meetings of the EHDS Board. (MOVED FROM PARA 6)

Commented [A14]: We agree with this change.

1b. ~~Other national authorities, including~~**M~~m~~**arket surveillance authorities referred to in Article 28, European Data Protection Board and European Data Protection Supervisor, **shall** ~~may~~ be invited to the meetings, where the issues discussed are of relevance for them. (MOVED FROM PARA 1 AND AMENDED)

Commented [A15]: We support the change that these authorities will be invited if the issues are relevant to them.

1c. The Board may also invite **other national authorities,** experts and observers to attend its meetings, and may cooperate with other external experts as appropriate. (MOVED FROM PARA 1 AND AMENDED)

Commented [A16]: We support this change.

1d. Other Union institutions, bodies, offices and agencies, research infrastructures and other similar structures **shall** have an observer role **when invited to participate in the meetings**. (MOVED FROM PARA 1 AND AMENDED)

Commented [A17]: The Board may also invite other Union institutions, bodies, offices and agencies, research infrastructures and other similar structures. When these participants are invited, they shall have an observer role.

1e. Stakeholders and relevant third parties, including patients' representatives, **may** ~~shall~~ be invited to attend meetings of the EHDS Board and to participate in its work, depending on the topics discussed and their degree of sensitivity. (MOVED FROM PARA 4)

2. Depending on the functions related to the use of electronic health data, the EHDS Board may work in subgroups **for certain topics**, where digital health authorities or health data access bodies ~~for a certain area~~ shall be represented. The subgroups may have joint meetings, as required.

Commented [A18]: We support this change.

3. The ~~composition, organisation, functioning and cooperation of subgroups shall be set out in~~ rules of procedures **of the EHDS Board shall be adopted by its members and** put forward by the Commission. **They shall include rules pertaining to the composition, structure, operation and cooperation of the sub-groups and shall regulate the role of invitees referred to in paragraphs 1b to 1e, taking into account the topics under discussion and the level of confidentiatlity involved.**

Commented [A19]: This change is positive. The rules of procedure should be decided by the Board.

~~4. Stakeholders and relevant third parties, including patients' representatives, shall be invited to attend meetings of the EHDS Board and to participate in its work, depending on the topics discussed and their degree of sensitivity.~~ MOVED TO PARA 1E

5. The EHDS Board shall cooperate with other relevant bodies, entities and experts, such as the European Data Innovation Board referred to in Article ~~26~~ **29** of Regulation **2022/868** ~~[Data Governance Act COM/2020/767 final]~~, competent bodies set up under Article 7 of Regulation […] [Data Act COM/2022/68 final], supervisory bodies set up under Article 17 of Regulation […] [eID Regulation], European Data Protection Board referred to in Article 68 of Regulation (EU) 2016/679 and cybersecurity bodies.

~~6. The Commission shall chair the meetings of the EHDS Board.~~ MOVED TO PARA 1A

7. The EHDS Board shall be assisted by a secretariat provided by the Commission.

8. The Commission shall, by means of implementing acts, adopt the necessary measures for the establishment~~,~~ **and** management ~~and functioning~~ of the EHDS Board. Those implementing acts shall be adopted in accordance with the ~~advisory~~ **examination** procedure referred to in Article 68(2).

Commented [A20]: We support these changes, positive that functioning has been deleted.

Article 65
Tasks of the EHDS Board

1. The EHDS Board shall have the following tasks relating to the primary use of electronic health data in accordance with Chapters II and III:
   (a) to assist Member States in coordinating practices of digital health authorities;
   (b) to issue written contributions and to exchange best practices on matters related to the coordination of the implementation at Member State level of this Regulation and of the delegated and implementing acts adopted pursuant to it, in particular as regards:
      (i) the provisions set out in Chapters II and III;
      (ii) development of online services facilitating secure access, including secure electronic identification, to electronic health data for health professionals and natural persons.~~;~~
      ~~(iii) other aspects of the primary use of electronic health data~~.
   (c) to facilitate cooperation between digital health authorities through capacity-building, establishing the structure for **biennial** ~~annual~~ activity reporting, **and exchange of information in those reports** ~~peer review of annual activity reports and exchange of information~~;
   (d) to share information concerning risks posed by EHR systems and serious incidents as well as their handling;
   (e) to facilitate the exchange of views on the primary use of electronic health data with the relevant stakeholders, including representatives of patients, health professionals, researchers, regulators and policy makers in the health sector.

Commented [A21]: We support the deletion of (iii)

Commented [A22]: We support these changes.

Commented [A23]: The boundaries are still unclear between the requirements for handling of risk and incident management in this proposal and the rules that are already in the GDPR and the NIS directive. Finland sees a risk of inefficiency and unjustified increased burdens for the Member States in this regard. The purpose and the differences in terms of governance need to be clearly justified.

2. The EHDS Board shall have the following tasks related to the secondary use of electronic health data in accordance with Chapter IV:
   (a) to assist Member States, in coordinating practices of health data access bodies, in the implementation of provisions set out in Chapters IV, to ensure a consistent application of this Regulation;
   (b) to issue written contributions and to exchange best practices on matters related to the coordination of the implementation at Member State level of this Regulation and of the delegated and implementing acts adopted pursuant to it, in particular as regards:
      (xi) implementation of rules for access to electronic health data;
      (xii) technical specifications or existing standards regarding the requirements set out in Chapter IV;
      (xiii) incentives policy for promoting data quality and interoperability improvement;
      (xiv) policies concerning fees to be charged by the health data access bodies and **health** data holders;
      (xv) the establishment and application of penalties~~;~~
      ~~(xvi) other aspects of the secondary use of electronic health data~~.
   (c) to facilitate cooperation between health data access bodies through capacity-building, establishing the structure for **biennial** ~~annual~~ activity reporting, **and** ~~peer review of annual activity reports and~~ exchange of information **in those reports**;
   (d) to share information concerning risks and data protection incidents related to secondary use of electronic health data, as well as their handling;
   ~~(e) to contribute to the work of the European Data Innovation Board to be established in accordance with Article 29 of the Regulation […] [Data Governance Act COM/2020/767 final];~~ (SEE ARTICLE 65(5))

Commented [A24]: We support this deletion.

Commented [A25]: We support these changes.

Commented [A26]: Finland sees a risk of inefficiency and unjustified increased burdens for member states in these respects.

Commented [A27]: We support this change, though the reference should be to Article 64.

(f) to facilitate the exchange of views on the secondary use of electronic health data with the relevant stakeholders, including **health data holders, health data users,** representatives of patients, health professionals, researchers, regulators and policy makers in the health sector.

Commented [A28]: We support the additions, though health data users may include researchers, regulators and policy makers.

2. The power to adopt delegated acts referred to in Articles 5(2), ~~10(3), 25(3),~~ 32(4), ~~33(7), 37(4),~~ ~~39(3), 41(7), 45(7), 46(8), 52(7),~~ **and** 56(4) shall be conferred on the Commission for an indeterminate period of time from the date of entry into force of this Regulation.

Commented [A29]: We support these changes, we prefer less delegated acts. Delegated Acts should be used for technical aspects only.

3. The power to adopt delegated acts referred to in Articles 5(2),~~ 10(3), 25(3),~~ 32(4)~~, 33(7), 37(4), 39(3), 41(7), 45(7), 46(8), 52(7),~~ **and** 56(4) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Inter-institutional Agreement of 13 April 2016 on Better Law-Making.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
6. A delegated act adopted pursuant to Articles 5(2)~~, 10(3), 25(3),~~ 32(4), ~~33(7), 37(4), 39(3), 41(7), 45(7), 46(8), 52(7),~~ **and** 56(4) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of 3 months of notification of that act to the European Parliament and to the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by 3 months at the initiative of the European Parliament or of the Council.

Comments from the French delegation

Objet :commentaires des autorités françaises suite au groupe de travail « Santé publique » des 6 et 7 mars 2023 relatif au règlement pour un espace européen des données de santé.

France would like to thank the Swedish Presidency for giving delegations the opportunity to submit written comments on articles 1-2(2), 59, 60, 61, 62, 63, 64 et 65 (chapters I, V, VI, VII and VIII of the compromises of the Presidency on EHDS proposed regulation) and the transversal topics (data holders and users definitions) discussed during Public Health Working Parties of the 23 and 24 of February as well as 6 and 7 of February.

NB: The comment on articles 48 and 49 have been included in the general comments on chapter IV.

The following comments are only preliminary and made with scrutiny reservation. We reserve the right to make a different assessment later on.

The proposed amendments appear in blue in the body of each article reproduced below.

Cross-cutting issues suggested by the Presidency:

The scope and definition of health data holder in Article 2(2)(y)

To facilitate the discussion, the Presidency has prepared options based on the comments and questions raised during the first reading of the text, of which:

Option 3: other amendment

Art 2(2)(y)

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

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

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

The French authorities propose a new amendment to specify that social security organisms are in scope. The French authorities stress that it is important that this definition includes social security among the bodies which can be qualified as "data holders".

This can be illustrated with the context of the French national health data system (SNDS).

[France has an exhaustive database that covers all available data related the care paths of the French population over a period of nearly 20 years. This database (SNDS) includes reimbursements made by all health insurance schemes for care in the private sector, data from health establishments, medical causes of death, and data relating to disability. This extensive database is widely used for studies and research by all healthcare stakeholders (nearly 550 data access requests have been submitted to the Health Data Hub between January 2020 and February 2023). Data are collected by the French Health Insurance - Caisse Nationale d'Assurance Maladie (CNAM) – and are accessible under the conditions of the national regulation for secondary use of data to any project leader.

If organizations such as the CNAM and its branches, especially local ones (called CPAM), referred to as "social security" were to be excluded from the "data holders":

- The risk would be to considerably reduce the scope of data that could be fed into EHDS;

- This would run counter to Article 33 of the compromise, which includes in the categories of data covered by the EHDS administrative data related to health care, including data on claims and reimbursements].

The French authorities would also like to:

- Stress the importance of not limiting (as option 2 does) the care sector to the sole care of the elderly and people with disabilities, in order to allow an overview of care pathways of the whole population, and therefore to allow general population studies;
- Stress its desire to have the guarantee that all organizations involved in the EU territory in the processing of electronic health data, including digital health companies, platforms and providers (e.g. GAFAM/BATX) are included in the scope of the regulation and the obligation, regardless of where they are headquartered.

Moreover, the French authorities would like to ensure that obligations related to health data holders do consistently apply to their subcontractors. This is a frequent case indeed. For instance, third parties processors for hospitals regarding health data hosting, software providers (for EHRs) or IT maintenance providers are granted access to health data in order to execute their missions. The French authorities will therefore propose additional amendments where appropriate in Chapter IV later on, after having initially considered to specify it here in the definition. A proposition is still in discussion, and will be sent to make this precision.

The scope and definition of health data user in Article 2(2)(z), including the scope of the applicant for a data access application in Article 45(1) or the data request applicant in Article 47(1)

To facilitate the discussion, the Presidency has also prepared options, of which:

Option 1: current scope and definition of health data user and current scope of applicant

Article 2(2)(z)
*'**health** data user' means a natural or legal person who has lawful access to personal or non-personal electronic health data for secondary use **pursuant to a data permit or a data request pursuant to this Regulation**;*
Articles 45(1) et 47(1)
A natural or legal person may submit…

Comment by the Presidency: This is a broad definition of who is a health data user and who can submit a data access application or a data request. It is important to keep in mind that the health data user must meet the conditions set out in Articles 46 and 47.

The French authorities support the proposed option 1, in line with the justification proposed by the Presidency, as conditions set out in Articles 46 and 47 seem sufficient.

Mutual understanding of the lawfulness bases of Articles 6 and 9 of the GDPR and the articulation of the rights of natural persons with respect to secondary use of health data

We have summarized our understanding of the lawfulness bases of Articles 6 and 9 of the GDPR and the articulation of the rights of natural persons with respect to secondary use of health data in an attached table.

The French authorities propose to add to article **38.1 c) a specific provision explaining that the exercice of the right to object (opt-out) to secondary use of their health data by the data subject shall apply according to the GDPR**.

- **The French proposition is to recall in the regulation the principle of a right to object (opt-out),** for data subjects, to their data being reused for secondary purposes by specifying that, by way of exception, and in accordance with the possibility provided by the GDPR to do so, this right to object is excluded in the following two cases:
    1. **Because it does not apply to processing based on a legal obligation.** In accordance with Article 6.1(c) of the GDPR, there is indeed no right to object in such a case. This regulation creates such an obligation for transmissions of data from data holders to data access authorities (Article 33.8 of the Regulation), as well as for processing operations carried out by data access authorities (Article 37.1 of the regulation);
    2. **Because it is desirable to harmonize the mechanism for processing carried out on the basis of the public interest** by data users holding an authorization to do so, when these users are bodies entrusted with a public service mission and this processing is based on the public interest: Articles 23.1(e) and 21.1 and 21.6 of the GDPR in fact make it possible to exclude the application of the right to object (opt out) in such cases, in order to give precedence to reasons of public interest over this right recognized to individuals.
- For processing carried out for secondary purposes by data users who are authorized to do so and who are not entrusted with a public service mission, it is proposed to recall the existence of a right to object (opt out), while leaving to Member States the possibility of excluding, on a case-by-case basis and within the framework set by Article 23 of the GDPR, the right to object for data subjects.
- The proposed solution is based on the experience gained with the current French mechanism that would therefore remain identical (or almost identical), by excluding the opt-out for the processing of health data for secondary purposes for public bodies carrying out data processing for research purposes and necessary for the performance of a public interest mission (Article 21.6° of the RGPD), while leaving a margin of maneuver to Member States to exclude it in other situations, on a case-by-case basis, in accordance with Article 23 of the RGPD.

This proposal meets the objective of enhancing access to data for secondary use while protecting the rights of individuals.

Article 1 - Subject matter and scope

1.

- (amendment to Article 50.1).
- The French authorities point out the sensitive nature of this article, and the communication to be ensured to citizens on its application.

Regarding Articles 64-66A and a new article 66B, the *This Regulation establishes the European Health Data Space ('EHDS') by providing for* ***common*** *rules,* ~~*common*~~ *standards* ~~*and practices*~~*, infrastructures and a governance framework* ~~*for*~~ ***with a view to facilitating access to electronic health data for*** *the* ***purposes of*** *primary and secondary use of* ~~*electronic health*~~ ***these*** *data.*

2. This Regulation:

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

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

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

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

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

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

3. ***This Regulation applies to:***

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

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

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

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

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

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

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

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

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

Regarding Article 1,

- **The French authorities globally support the amendments proposed by the Presidency in Article 1.**

With regard to paragraph 2 (f),

The French authorities stress the importance of clarifying governance and coordination between the national and European levels, for the primary and secondary use of health data.

Article 2 - Definitions

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

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

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

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

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

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

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

Comments from the German delegation

German comments after WPPH 06. and 07. March 2023

The comments and change requests are preliminary.

- The following comments are made on the discussion questions in WK 2846/2023:
- On the scope and the definitions on health data holder in Article 2 (2) (y):

DE prefers option 3.

Option 1 already goes in the right direction. Social security data from the health or care sector should be included in the definition. Accordingly, option 2 is rejected. The definition should also cover entities outside the health and care sector that hold or process health data. The goal is to make health data accessible for secondary use independently of the purpose of data collection.

In addition, in order to ensure that the definition cannot be applied without limits, it should be left to the Member States to decide which data holders they designate to provide the categories of data in Article 33. If necessary, uniform criteria could be established for the designation of data holders. Article 33 could be considered as the place for regulation.

DE proposes the following addition to Article 33(2):

2.

The data holders who are obliged to provide the priority categories of data referred to in the first subparagraph to the health data access bodies are designated by the member state, in which the respective data holder has its domicile.

The member states shall ensure that their designated data holders are able to collectively provide relevant data in at least the priority categories referred to in the first subparagraph.

Member states may designate additional data holders or require their designated data holders to provide additional categories of data related to health according to the provisions of this Chapter.

In our view, the possibility that Article 35B(8) offers to exempt micro enterprises from the duties of health data holders is not equally suitable, since it refers primarily to the size of the company which may not correspond to the ability to provide data. We would favour an approach which focuses on a set of data holders which ensures the availability of representative, structured data, of comparable data quality and security.. A stepwise approach to designate data holders would also make it much easier for many Member States to implement the EHDS within the envisaged timeframe.

- On the scope and the definition on health data user in Article 2(2)(z):
    - The additions to the definition of data user under option 1 should be adopted for reasons of clarification. The other specific additions in Option 2 go in the right direction. Third countries and international organisations should not have access to data without also having to provide data. However, the regulations on reciprocity should not be mixed up with the definition of the data holder. The provisions on access should be regulated in the specific articles. DE therefore supports option 1.

- On the mapping of the applicable legal bases and the interplay of natural persons rights:

    As a sector-specific act, the EHDS should build on the GDPR and specify and supplement it in a sector-specific manner. This means that where the provisions of the EHDS specify those of the GDPR further, the EHDS should prevail over the general regulations of the GDPR. Where the EHDS does not specify the GDPR, the latter should prevail. The requirements for a legal basis according to Art. 6, 9 GDPR must not be circumvented.

    The data subject rights are regulated in the GDPR and the EHDS should build on these. However, the EHDS may contain more specific provisions than GDPR in particular cases. Here, clear rules are necessary to create legal certainty about the data subject rights. Insofar as the EHDS restricts the data subject rights from the GDPR, this must still be discussed in detail, including possibilities for an opt-out option by implementing a right to object. The current European level of data protection should be maintained.

Chapter I

General provisions

Article 1

Subject matter and scope

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

2. This Regulation:

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

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

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

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

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

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

~~3. This Regulation applies to:~~

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

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

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

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

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

Commented [A30]: We welcome this addition.

Commented [A31]: This amendment is welcomed as purposeful and is clear regarding the competing relationship with the GDPR.

Commented [A32]: Wellness applications should be removed from the scope of primary use.

Reason:
- Data of wellness applications currently show an insufficient data quality.
- Essential elements of a product regulation are not foreseen, e.g. implementation of a conformity assessment requirements for notyfing authorities and notified bodies, market surveillance, etc

Commented [A33]: Sufficiently long implementation periods should be included.

Commented [A34]: The deletion of paragraph 3 is welcomed.
The personal scope of application was too general and it is better to regulate this specifically in the respective individual provision.

Commented [A35]: (3a) should be added for reasons of legal clarity. However, the wording « without predjudice » in 3A and 4 does not make it sufficienty clear that the EHDS complements the Data Governance Act and the Data Act. We therefore propose an alternative wording under 4.

4. ~~This Regulation shall be without prejudice to other Union legal acts regarding access to, sharing of or secondary use of electronic health data, or requirements related to the processing of data in relation to electronic health data, in particular Regulations (EU) 2016/679, (EU) 2018/1725, **(EU) 20022/868**[…] [Data Governance Act COM/2020/767 final], and […] [Data Act COM/2022/68 final].~~ This regulation sets forth specific rules regarding, inter alia, access to, sharing of and secondary use of electronic health data, as well as requirements related to the processing of data in relation to electronic health data and, insofar, complements Regulations (EU) 2016/679, (EU) 2018/1725 Regulations (EU) 2022/868 and […] [Data Act COM/2022/68 final].

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

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

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

Commented [A36]: We request that the area of justice be added to the area exception. The collection of health data for the specific purposes of the administration of justice is not related to the objectives of the EHDS. We reserve the right to review and make further comments on other area exceptions.

Article 2

Definitions

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

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

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

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

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

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

Commented [A37]: Wellness applications should be removed from the scope of the regulation.

Reason:
- Data of wellness applications currently show an insufficient data quality.
- Essential elements of a product regulation are not foreseen, e.g. implementation of a conformity assessment requirements for notyfing authorities and notified bodies, market surveillance, etc.

Commented [A38]: On (u), (v), (x)

Deletion is welcomed, as the entities and infrastructures mentioned are already defined as such in the individual regulations. Therefore, no separate definition is necessary.

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

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

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

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

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

CHAPTER IV

Secondary use of electronic health data

SECTION 3

DATA PERMIT FOR THE SECONDARY USE OF ELECTRONIC HEALTH DATA

~~*Article 48*~~

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

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

Article 49

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

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

1A. Where an applicant request access to electronic health data from health data holders which are an Union institution, body, office or agency, by way of derogation from Article 45(1) or Article 47(1), that applicant shall file a data access application or a data request directly to each health

Commented [A39]: We welcome the deletion of Article 48.
The special privileges contained for state agencies are too far-reaching. As a rule, these bodies can also go through an application procedure. However, such a procedure could be accelerated or simplified for state bodies. The special privileges should only apply to certain purposes and for reasons of transparency, it should be possible to see in a database which applications have been made.

Commented [A40]: We agree with the amendment in Art 49 (1).
The fact that it is now left to the Member States to decide whether access can also be requested from single data holders is acceptable to us.
However, the Member States must then also be able to decide which data holders may process requests themselves. A blanket application for all data holders should not be possible, but this should be decided individually for each data holder. However, according to our interpretation of the article, this is the case.

Commented [A41]: DE agrees with the addition.
We had proposed to create an EU-HDAB. However, an application to individual EU data holders is also acceptable.

data holder. The data access application shall comply with the requirements set out in Article 45 and the data request shall comply with requirements in Article 47.

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

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

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

Commented [A42]: Art. 47 only provides for the evaluation of a data set and not for data access. Therefore, the differentiation between Art. 45, 46 (data permit) and Art. 47 (data request) should also be reflected here.

Chapter V

Additional actions

Article 59

Capacity building

The Commission shall support sharing of best practices and expertise, aimed to build the capacity of Member States to strengthen digital health systems for primary and secondary use of electronic health data. To support capacity building, the Commission shall **in close cooperation and consultation with Member States** ~~draw up~~ **establish indicators for voluntary self assessment** ~~benchmarking guidelines~~ for the primary and secondary use of electronic health data.

Commented [A43]: We welcome these adjustments. However, it should be made clear that the envisaged "self-assessment" is voluntary for the member states.

Article 60

Additional requirements for public procurement and Union funding

1. **Contracting authorities** ~~Public procurers, national competent authorities~~, including digital health authorities and health data access bodies and **Union institutions, bodies, offices or agencies, including** the Commission**,** shall make reference to the applicable technical specifications, standards and profiles as referred to in Articles 6, **12,** 23, 50, **52,** 56, **as well as to the requirements laid down in Regulations (EU) 2016/679 and (EU) 2018/1725,** as relevant, as points of orientation for public procurements and when formulating their tender documents or calls for proposals, as well as when defining the conditions for Union funding regarding this Regulation, including enabling conditions for the structural and cohesion funds.

2. **The criteria for obtaining funding from the Union** ~~The ex-ante conditionality for Union funding~~ shall take into account**:**

a) the requirements developed in Chapters II, III and IV**;**

b) the requirements laid down in Regulations (EU) 2016/679 or (EU) 2018/1725, where applicable, in particular:

(i) the requirements laid down in Article 35 or 39 respectively of these Regulations by requiring a documented data protection impact assessment, including where Chapter V of these Regulations apply, an assessment of the impact of the transfer to third countries or international organisations.

(ii) where Article 28 or 29 respectively of these Regulations is applicable, by requiring a contract or other legal act between the controller and the processor pursuant to Article 28 paragraph 3 or Article 29 paragraph 3 respectively.

Article 61

*~~Third country~~ **T**~~t~~ransfer **to a third country** of **anonymous electronic health data** ~~non-personal electronic data~~ **presenting a risk of re-identification***

1. ~~Non-personal~~ **Anonymous** electronic data made available by health data access bodies **to a health data user in a third country according to a data permit pursuant to Article 46 or a data request pursuant to Article 47 or to an authorisated participants in a third country or an international organisation**, that are based on a natural person's electronic **health** data falling within one of the categories of Article 33 ~~[(a), (e), (f), (i), (j), (k), (m)]~~ shall be deemed highly sensitive within the meaning of Article 5(13) of Regulation **(EU) 2022/868**~~[…] [Data Governance Act COM/2020/767 final]~~, provided that their transfer to third countries presents a risk of re-identification through means going beyond those **reasonably** likely ~~reasonably~~ to be used, **in particular** in view of the limited number of natural persons involved in that data, the fact that they are geographically scattered or the technological developments expected in the near future.
2. The protective measures for the categories of data mentioned in paragraph 1 shall depend on the nature of the data and anonymization techniques and shall be detailed in the Delegated Act under the empowerment set out in Article 5(13) of Regulation **(EU) 2022/868** ~~[…] [Data Governance Act COM/2020/767 final]~~.

Article 62

*~~International access and~~ **T**~~t~~ransfer of **anonymous** ~~non-personal~~ electronic health data **to a third country or an international organisation***

1. The digital health authorities, health data access bodies, the authorised participants in the cross-border infrastructures provided for in Articles 12 and 52 and **health** data users shall take all reasonable technical, legal and organisational measures, including contractual arrangements, in order to prevent transfer **to a third country or an international organisation, including** governmental access **in a third country** **of**~~to~~ **anonymous** electronic health data held in the Union where such transfer would create a conflict with Union law or the national law of the relevant Member State, without prejudice to paragraph 2 or 3 of this Article.
2. ~~Any judgment of a third-country court or tribunal and any decision of a third-country administrative authority requiring a digital health authority, **a** health data access body or **a health** data users to transfer or give access to **anonymous** non-personal electronic health data within the scope of this Regulation held in the Union shall be recognised or enforceable in any manner only if based on an international agreement, such as a mutual legal assistance treaty, in force between the requesting third country and the Union or any such agreement between the requesting third country and a Member State.~~

Commented [A44]: The provisions of Article 62 are still subject to further examination, in this respect DE has not yet found a conclusive position. Paragraph 1 should not only stipulate that unlawful transfers are to be prevented by all possible means, but that such unlawful transfers are not admissible.
DE is also critical of the fact that the Article contains provisions on legal assistance. In addition, DE sees collisions with european and national legal assistance regimes, in particular with the E-Evidence Regulation.

Commented [A45]: Legal assistance should be excluded from the scope of the Regulation and references should be deleted accordingly (see the request to exclude the area of justice in Article 1(7)). In addition, Art. 62 (as far as we understand) deals exclusively with the transfer of "anonymous electronic health data". DE does not see any relation to criminal mutual legal assistance, which is why the Regulation should not contain any provisions in this regard. DE would thus highly recommend also to delete Articles 62 (3), 62 (4) and 62 (5)

3. In the absence of an international agreement as referred to in paragraph 2 of this Article, where a digital health authority, a health data access body, **a health** data user~~s~~ is the addressee of a decision or judgment of a third-country court or tribunal or a decision of a third-country administrative authority to transfer ~~or give access to~~ **anonymous** data within the scope of this Regulation held in the Union and **in** compliance with such a decision would risk putting the addressee in conflict with Union law or with the national law of the relevant Member State, transfer **of** ~~to or access to~~ such data **to** ~~by~~ that third-country authority shall take place only where:

(a) the third-country system requires the reasons and proportionality of such a decision or judgment to be set out and requires such a decision or judgment to be specific in character, for instance by establishing a sufficient link to certain suspected **natural or legal** persons or infringements;

(b) the reasoned objection of the addressee is subject to a review by a competent third-country court or tribunal; and

(c) the competent third-country court or tribunal issuing the decision or judgment or reviewing the decision of an administrative authority is empowered under the law of that third country to take duly into account the relevant legal interests of the provider of the data protected under Union law or the national law of the relevant Member State

4. If the **criteria** ~~conditions~~ laid down in 3 are met, **a** digital health authority, a health data access body or a **health data user** ~~data altruism body~~ shall provide the minimum amount of data permissible in response to a request, based on a reasonable interpretation of the request.

5. The digital health authorities, health data access bodies, **health** data users shall inform the **health** data holder about the existence of a request of a third-country administrative authority to access its data before complying with that request, except where the request serves law enforcement purposes and for as long as this is necessary to preserve the effectiveness of the law enforcement activity.

Article 63

~~International access and~~ T~~t~~ransfer of personal electronic health data to a third country or an international organisation

In the context of transfer of personal electronic health data **to a third country or an international organisation,** Member States may maintain or introduce further conditions, including limitations, in accordance with and under the conditions of **A**rticle 9(4) of Regulation (EU) 2016/679, **in addition to the requirements set out in Articles 13 paragraph 3 and 52 paragraph 5 of this Regulation and the requirements laid down in Chapter V of Regulation (EU) 2016/679**.

Commented [A46]: DE is very critical of Art. 62(3), as it is intended to enable direct data access to service providers. Special European regulations already exist here in the area of legal assistance under criminal law in the E-Evidence Regulation.

Commented [A47]: DE continues to support the opening clause to allow Member States to adopt further regulations.

Chapter VI

European governance and coordination

Article 64

European Health Data Space Board (EHDS Board)

1. A European Health Data Space Board (EHDS Board) is hereby established to facilitate cooperation and the exchange of information among Member States and the Commission. The EHDS Board shall be composed of ~~the high level~~ representatives~~, one each of digital health authorities and health data access bodies,~~ of all the Member States. The nomination of the Member States representatives is within the competence of each Member State. ~~Other national authorities, including market surveillance authorities referred to in Article 28, European Data Protection Board and European Data Protection Supervisor, may be invited to the meetings, where the issues discussed are of relevance for them. The Board may also invite experts and observers to attend its meetings, and may cooperate with other external experts as appropriate. Other Union institutions, bodies, offices and agencies, research infrastructures and other similar structures, shall have an observer role.~~ (SECOND, THIRD AND LAST SENTENCES AMENDED AND MOVED TO PARA 1(B)-1(E))

1a. **A representative of** ~~T~~the Commission **and a representative of the Member States** shall **co-**chair the meetings of the EHDS Board. (MOVED FROM PARA 6)

1b. ~~Other national authorities, including~~**M**~~m~~arket surveillance authorities referred to in Article 28, the European Data Protection Board and European Data Protection Supervisor, **shall** ~~may~~ be invited to the meetings, where the issues discussed ~~for~~ relate to their respective area of responsibility ~~for them~~. (MOVED FROM PARA 1 AND AMENDED)

1c. The Board may also invite **other national authorities,** experts and observers to attend its meetings, and may cooperate with other external experts as appropriate. (MOVED FROM PARA 1 AND AMENDED)

1d. Other Union institutions, bodies, offices and agencies, research infrastructures and other similar structures **shall** have an observer role **when invited to participate in the meetings**. (MOVED FROM PARA 1 AND AMENDED)

1e. Stakeholders and relevant third parties, including patients' representatives, **may** ~~shall~~ be invited to attend meetings of the EHDS Board and to participate in its work, depending on the topics discussed and their degree of sensitivity. (MOVED FROM PARA 4)

2. ~~Depending on the functions related to the use of electronic health data, t~~The EHDS Board may work in subgroups **for certain topics**, where responsible national Ministries, digital health authorities or health data access bodies ~~for a certain area~~ shall be represented. At least a subgroup on primary use of health data, a subgroup on secondary use of health data and a technical subgroup shall be established as standing bodies. These subgroups may draft guideline documents and shall support the EHDS Board with specific expertise. The subgroups may have joint meetings, as required.

Commented [A48]: In principle, DE welcomes the revised Article and the adjustments go in the right direction. It is particularly important to us that the Member States are given the opportunity to exert political influence on the EHDS Board. However, there is still a need for further adjustments.

Commented [A49]: It should be up to the Member States to decide which specific representatives to send.

Commented [A50]: DE welcomes this adjustment proposal.

Commented [A51]: The European Data Innovation Board (Data Governance Act) as well as the European Data Protection Board should also be able to participate in the meetings of the EHDS Council if the topics affect them. Participation in the meetings seems to go beyond mere cooperation under Paragraph 5

Commented [A52]: The three standing subgroups are proposed as a lesson learned from the current working structure and MS' demands in the context of the eHealth Network.

3. The ~~composition, organisation, functioning and cooperation of subgroups shall be set out in~~ rules of procedures **of the EHDS Board shall be adopted by its members and** put forward by the Commission. **They shall include rules pertaining to the composition, structure, operation and cooperation of the sub-groups and shall regulate the role of invitees referred to in paragraphs 1b to 1e, taking into account the topics under discussion and the level of confidentiatlity involved.**

4. ~~Stakeholders and relevant third parties, including patients' representatives, shall be invited to attend meetings of the EHDS Board and to participate in its work, depending on the topics discussed and their degree of sensitivity.~~ MOVED TO PARA 1E

5. The EHDS Board shall cooperate with other relevant bodies, entities and experts, such as the European Data Innovation Board referred to in Article ~~26~~ **29** of Regulation **2022/868** ~~[Data Governance Act COM/2020/767 final~~], competent bodies set up under Article 7 of Regulation […] [Data Act COM/2022/68 final], supervisory bodies set up under Article 17 of Regulation […] [eID Regulation], European Data Protection Board referred to in Article 68 of Regulation (EU) 2016/679 and cybersecurity bodies.

6. ~~The Commission shall chair the meetings of the EHDS Board.~~ MOVED TO PARA 1A

7. The EHDS Board shall be assisted by a secretariat provided by the Commission.

8. The Commission shall, by means of implementing acts, adopt the necessary measures for the establishment~~,~~ **and** management ~~and functioning~~ of the EHDS Board. Those implementing acts shall be adopted in accordance with the ~~advisory~~ **examination** procedure referred to in Article 68(2).

Article 65
Tasks of the EHDS Board

1. The EHDS Board shall have the following tasks relating to the primary use of electronic health data in accordance with Chapters II and III:

   (a) to assist Member States in coordinating practices of digital health authorities;

   (b) to issue written contributions and to exchange best practices on matters related to the coordination of the implementation at Member State level of this Regulation and of the delegated and implementing acts adopted pursuant to it, in particular as regards:

      (i) the provisions set out in Chapters II and III;

      (ii) development of online services facilitating secure access, including secure electronic identification, to electronic health data for health professionals and natural persons.~~;~~

      ~~(iii) other aspects of the primary use of electronic health data~~.

   (c) to facilitate cooperation between digital health authorities through capacity-building, establishing the structure for **biennial** ~~annual~~ activity reporting, **and exchange of information in those reports** ~~peer review of annual activity reports and exchange of information~~;

Commented [A53]: We welcome this addition.

Commented [A54]: We welcome this adjustment proposal.

Commented [A55]: The Board should also assist COM, the Council and the Parliament regarding delegated acts and implementing acts. It should provide them with opinions, so that they can draw on the expertise of the Board when making their decisions

Commented [A56]: We welcome this adjustment.

(d) to share information concerning risks posed by EHR systems and serious incidents as well as their handling;

(e) to facilitate the exchange of views on the primary use of electronic health data with the relevant stakeholders, including representatives of patients, health professionals, researchers, regulators and policy makers in the health sector.

2. The EHDS Board shall have the following tasks related to the secondary use of electronic health data in accordance with Chapter IV:

(a) to assist Member States, in coordinating practices of health data access bodies,~~-~~in the implementation of provisions set out in Chapters IV, to ensure a consistent application of this Regulation;

(b) to issue written contributions and to exchange best practices on matters related to the coordination of the implementation at Member State level of this Regulation and of the delegated and implementing acts adopted pursuant to it, in particular as regards:

(xi) implementation of rules for access to electronic health data;

(xii) technical specifications or existing standards regarding the requirements set out in Chapter IV;

(xiii) incentives policy for promoting data quality and interoperability improvement;

(xiv) policies concerning fees to be charged by the health data access bodies and **health** data holders;

(xv) the establishment and application of penalties~~;~~

~~(xvi) other aspects of the secondary use of electronic health data~~.

(c) to facilitate cooperation between health data access bodies through capacity-building, establishing the structure for **biennial** ~~annual~~ activity reporting, **and** ~~peer-review of annual activity reports and~~ exchange of information **in those reports**;

(d) to share information concerning risks and data protection incidents related to secondary use of electronic health data, as well as their handling;

~~(e) to contribute to the work of the European Data Innovation Board to be established in accordance with Article 29 of the Regulation […] [Data Governance Act COM/2020/767 final];~~ (SEE ARTICLE 65(5))

(f) to facilitate the exchange of views on the secondary use of electronic health data with the relevant stakeholders, including **health data holders, health data users,** representatives of patients, health professionals, researchers, regulators and policy makers in the health sector.

Comments from the Hungarian delegation

Hungarian porposals on EHDS compromise proposal (5302/23) after the Working party of 23-24 February and 6-7 March

(please note that our earlier written comments made to Chapter IV set out in 5302/23 are still valid, unless superseded in this paper)

Chapter I

General provisions

Article 2

Definitions

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

1.

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

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

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

Justification: We need to include all the entities (like non healthcare related tech companies) who possess data falling under the data categories referred to in Art 33. On the other hand we propose the exlusion of social security sector.

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

Justification: No need to define data permit.

Comments from Hungary in relation with the draft regulation of European Health Data Space

Chapters I. (doc. 5302/23), Article 48-49. (doc. 5302), Chapter V-VI. (doc. 6627/23., 7353/23.)

Article 60

Additional requirements for public procurement and Union funding

1. **Contracting authorities** ~~Public procurers, national competent authorities~~, including digital health authorities and health data access bodies and **Union institutions, bodies, offices or agencies, including** the Commission**,** shall make reference to the applicable technical specifications, standards and profiles as referred to in Articles 6, **12,** 23, 50, **52,** 56, **as well as to the requirements laid down in Regulations (EU) 2016/679 and (EU) 2018/1725,** as relevant, as points of orientation for public procurements and when formulating their tender documents or calls for proposals, as well as when defining the conditions for Union funding regarding this Regulation, including enabling conditions for the structural and cohesion funds.

2. **The criteria for obtaining funding from the Union** ~~The ex-ante conditionality for Union funding~~ shall take into account**:**

a) the requirements developed in Chapters II, III and IV**;**

~~**b) the requirements laid down in Regulations (EU) 2016/679 or (EU) 2018/1725, where applicable, in particular:**~~

~~**(i) the requirements laid down in Article 35 or 39 respectively of these Regulations by requiring a documented data protection impact assessment, including where Chapter V of these Regulations apply, an assessment of the impact of the transfer to third countries or international organisations.**~~

~~**(ii) where Article 28 or 29 respectively of these Regulations is applicable, by requiring a contract or other legal act between the controller and the processor pursuant to Article 28 paragraph 3 or Article 29 paragraph 3 respectively.**~~

Justification

It is not justified that EHDS introduces conditionality criteria on requirements set out in another legislation.

Article 64

Article 64

European Health Data Space Board (EHDS Board)

1. A European Health Data Space Board (EHDS Board) is hereby established to facilitate cooperation and the exchange of information among Member States. The EHDS Board shall be composed of ~~the high level~~ representatives**,** **one each** of digital health authorities and health data access bodies**,** of all the Member States. ~~Other national authorities, including~~

~~market surveillance authorities referred to in Article 28, European Data Protection Board and European Data Protection Supervisor, may be invited to the meetings, where the issues discussed are of relevance for them. The Board may also invite experts and observers to attend its meetings, and may cooperate with other external experts as appropriate. Other Union institutions, bodies, offices and agencies, research infrastructures and other similar structures, shall have an observer role.~~ (SECOND, THIRD AND LAST SENTENCES AMENDED AND MOVED TO PARA 1(B)-1(E))

1a. **A representative of** ~~T~~**t**he Commission **and a representative of the Member States** shall **co-**chair the meetings of the EHDS Board. (MOVED FROM PARA 6)

1b. ~~Other national authorities, including~~**M**~~m~~arket surveillance authorities referred to in Article 28, European Data Protection Board and European Data Protection Supervisor, **shall** ~~may~~ be invited to the meetings, where the issues discussed are of relevance for them. (MOVED FROM PARA 1 AND AMENDED)

1c. The Board may also invite **other national authorities,** experts and observers to attend its meetings, and may cooperate with other external experts as appropriate. (MOVED FROM PARA 1 AND AMENDED)

1d. Other Union institutions, bodies, offices and agencies, research infrastructures and other similar structures **shall** have an observer role **when invited to participate in the meetings**. (MOVED FROM PARA 1 AND AMENDED)

1e. Stakeholders and relevant third parties, including patients' representatives, **may** ~~shall~~ be invited to attend meetings of the EHDS Board and to participate in its work, depending on the topics discussed and their degree of sensitivity. (MOVED FROM PARA 4)

2. Depending on the functions related to the use of electronic health data, the EHDS Board may work in subgroups **for certain topics**, where digital health authorities or health data access bodies ~~for a certain area~~ shall be represented. The subgroups may have joint meetings, as required.

3. The ~~composition, organisation, functioning and cooperation of subgroups shall be set out in~~ rules of procedures **of the EHDS Board shall be adopted by its members and** put forward by the Commission. **They shall include rules pertaining to the composition, structure, operation and cooperation of the sub-groups and shall regulate the role of invitees referred to in paragraphs 1b to 1e, taking into account the topics under discussion and the level of confidentiatlity involved.**

~~4. Stakeholders and relevant third parties, including patients' representatives, shall be invited to attend meetings of the EHDS Board and to participate in its work, depending on the topics discussed and their degree of sensitivity.~~ MOVED TO PARA 1E

5. The EHDS Board shall cooperate with other relevant bodies, entities and experts, such as the European Data Innovation Board referred to in Article ~~26~~ **29** of Regulation **2022/868** ~~[Data Governance Act COM/2020/767 final]~~, competent bodies set up under Article 7 of Regulation […] [Data Act COM/2022/68 final], supervisory bodies set up under Article 17 of Regulation […] [eID Regulation], European Data Protection Board referred to in Article 68 of Regulation (EU) 2016/679 and cybersecurity bodies.

~~6. The Commission shall chair the meetings of the EHDS Board.~~ MOVED TO PARA 1A

7. The EHDS Board shall be assisted by a secretariat provided by the Commission.

7a. **As far as possible, the EHDS Board shall deliberate by consensus. If consensus cannot be reached the EHDS Board shall deliberate by a majority of two thirds of the Member States representatives. Each Member State shall have one vote.**

8. The Commission shall, by means of implementing acts, adopt the necessary measures for the establishment~~,~~ **and** management ~~and functioning~~ of the EHDS Board. Those implementing acts shall be adopted in accordance with the ~~advisory~~ **examination** procedure referred to in Article 68(2).

Jusfitication:
(7a) We maintain our previous comment that at least the voting rules should be laid down in the basic act.

Article 65

Article 65
Tasks of the EHDS Board

1. The EHDS Board shall have the following tasks relating to the primary use of electronic health data in accordance with Chapters II and III:

(a) to assist Member States in coordinating practices of digital health authorities;

(b) to issue written contributions and to exchange best practices on matters related to the coordination of the implementation at Member State level of this Regulation and of the delegated and implementing acts adopted pursuant to it, in particular as regards:

(i) the provisions set out in Chapters II and III;

(ii) development of online services facilitating secure access, including secure electronic identification, to electronic health data for health professionals and natural persons.~~;~~

~~(iii) other aspects of the primary use of electronic health data~~.

(c) to facilitate cooperation between digital health authorities through capacity-building, establishing the structure for **biennial** ~~annual~~ activity reporting, **and exchange of information in those reports** ~~peer-review of annual activity reports and exchange of information~~;

(d) to share information concerning risks posed by EHR systems and serious incidents as well as their handling;

(e) to facilitate the exchange of views on the primary use of electronic health data with the relevant stakeholders, including representatives of patients, health professionals, researchers, regulators and policy makers in the health sector.

2. The EHDS Board shall have the following tasks related to the secondary use of electronic health data in accordance with Chapter IV:

(a) to assist Member States, in coordinating practices of health data access bodies,~~–~~in the implementation of provisions set out in Chapters IV, to ensure a consistent application of this Regulation;

(b) to issue written contributions and to exchange best practices on matters related to the coordination of the implementation at Member State level of this Regulation and of the delegated and implementing acts adopted pursuant to it, in particular as regards:

(xi) implementation of rules for access to electronic health data;

(xii) technical specifications or existing standards regarding the requirements set out in Chapter IV;

(xiii) incentives policy for promoting data quality and interoperability improvement;

~~(xiv) policies concerning fees to be charged by the health data access bodies and~~ **~~health~~** ~~data holders~~;

(xv) the establishment and application of penalties~~;~~

~~(xvi) other aspects of the secondary use of electronic health data~~.

(c) to facilitate cooperation between health data access bodies through capacity-building, establishing the structure for **biennial** ~~annual~~ activity reporting, **and** ~~peer review of annual activity reports and~~ exchange of information **in those reports**;

(d) to share information concerning risks and data protection incidents related to secondary use of electronic health data, as well as their handling;

~~(e) to contribute to the work of the European Data Innovation Board to be established in accordance with Article 29 of the Regulation […] [Data Governance Act COM/2020/767 final];~~ (SEE ARTICLE 65(5))

(f) to facilitate the exchange of views on the secondary use of electronic health data with the relevant stakeholders, including **health data holders, health data users,** representatives of patients, health professionals, researchers, regulators and policy makers in the health sector.

Jusfitication:
(2) b) xiv) We still do not support implementing acts according to paragraph 6 of Article 42, where the Commission may lay down principles and rules for the fee policies and fee structures, therefore we recommend deleting subpoint xiv. of point (b) of paragraph (2).

Article 66

Article 66

~~Joint controllership groups for Union infrastructures~~The Steering Groups for the infrastructures MyHealth@EU and HealthData@EU

1. **Two Steering groups are hereby established** ~~The Commission shall establish two groups dealing with joint controllership~~ for the cross-border infrastructures provided for in Articles 12 and 52**; the MyHealth@EU Steering group and the HealthData@EU Steering group. Each** ~~The~~ group~~s~~ shall be composed of **one** ~~the~~ representative~~s~~ **per Member State** of the **respective** national contact points ~~and other authorisated participants in those infrastructures~~.

1A. The **Steering** groups shall take **operational** decisions concerning the development and operation of the cross-border infrastructures pursuant to Chapters II and IV, on changes of infrastructure, adding additional infrastructures or services, or ensuring interoperability with other infrastructures, digital systems or data spaces. ~~The group shall also take decisions to accept individual authorised participants to join the infrastructures or to disconnect them.~~ (MOVED FROM PARA 6 AND AMENDED)

1B. The Steering Groups shall, in principle, take decisions by consensus. Where consensus cannot be reached, the adoption of a decision shall require the support of members representing two-thirds majority. *Each Member State shall have one vote.*

2. The composition, organisation, functioning and cooperation of the ~~sub-~~**Steering** groups shall be set out in the rules of procedure adopted by those groups.

3. ~~Stakeholders and relevant third parties, including patients' representatives, may be invited to attend meetings of the groups and to participate in their work.~~ MOVED TO ARTICLE 66A

4. The groups shall elect chairs for their meetings.

5. The groups shall be assisted by a secretariat provided by the Commission.

6. ~~The groups shall take decisions concerning the development and operation of the cross-border infrastructures pursuant to Chapters II and IV, on changes of infrastructure, adding additional infrastructures or services, or ensuring interoperability with other infrastructures, digital systems or data spaces. The groups shall also take decisions to accept individual authorised participants to join the infrastructures or to disconnect them.~~ MOVED TO PARA 1A

Justification:
We suggest to supplement the decision making rules of the steering groups with "each Member State shall have one vote".

Comments from the Italian delegation

Proposal for a Regulation on the European Health Data Space - First Presidency compromise proposal

COMMENTS – ITALY

Chapters I, V, VI AND MAIN TOPICS

Thanks to the Swedish Presidency for the continuing effort to improve the EHDS regulation proposal through the discussion of main topics and the great job done to harmonize the MSs positions in the compromise for Chapter I, V and VI.
This file reports written comments to the Articles in first compromise proposal on Chapter I, Articles 48 and 49 in Chapter IV, Articles 59, 60, 61, 62, 63, 64 and 65 in Chapter V and VI and the discussed main topics (rights of natural persons, opt-out, data categories, definitions on health data holder and health data user), as due on Tuesday the 21th of March.
The specific comments are reported in the table below, in blue for insertions, in gray (~~xxx~~) for deletions.

Chapter I **General provisions** *Article 1* *Subject matter and scope* 1. This Regulation establishes the European Health Data Space ('EHDS') by providing for **common** rules, ~~common~~ standards ~~and practices~~, infrastructures and a governance framework ~~for~~ **with a view to facilitating access to electronic health data for** the **purposes of** primary and secondary use of ~~electronic health~~ **these** data. 2. This Regulation: (a) ~~strengthens~~ **specifies and complements, in Chapter II,** the rights **laid down in the Regulation (EU) 2016/679** of natural persons in relation to **primary use** ~~the availability and control~~ of their **personal** electronic health data; (b) lays down, **in Chapter III, common** rules for ~~the placing on the market, making available on the market or putting into service of~~ electronic health records systems ('EHR systems') **and wellness applications that claim interoperability with EHR systems** in the Union **for primary use**; (c) lays down**, in Chapter II and IV, common** rules and mechanisms ~~supporting~~ **for primary and** secondary use of electronic health data; (d) establishes a ~~mandatory~~ cross-border infrastructure enabling the primary use of **personal** electronic health data across the Union **according to Chapter II**; (e) establishes a ~~mandatory~~ cross-border infrastructure for the secondary use of electronic health data **according to Chapter IV;.** **(f) establishes governance and coordination on national and European level for both primary and secondary use of electronic health data.** ~~3. This Regulation applies to:~~ ~~(a) manufacturers and suppliers of EHR systems and wellness applications placed on the market and put into service in the Union and the users of such products;~~ ~~(b) controllers and processors established in the Union processing electronic health data of Union citizens and third-country nationals legally residing in the territories of Member States;~~ ~~(c) controllers and processors established in a third country that has been connected to or are interoperable with MyHealth@EU, pursuant to Article 12(5);~~ ~~(d) data users to whom electronic health data are made available by data holders in the Union.~~ **~~3A. This Regulation shall be without prejudice to Regulations (EU) 2016/679, (EU) 2018/1725, (EU) No 536/2014 and Directive 2022/58/EC.~~** 4. This Regulation shall be without prejudice to other Union legal acts regarding access to, sharing of or secondary use of electronic health data, or requirements related to the processing of data in relation to electronic health data, in particular Regulations ~~(EU) 2016/679, (EU) 2018/1725,~~ **(EU) 2022/868**[…] ~~[Data Governance Act COM/2020/767 final],~~ and […] [Data Act COM/2022/68 final]. 5. This Regulation shall be without prejudice to Regulations (EU) 2017/745, **(EU) 2017/746** and […] [AI Act COM/2021/206 final], as regards the security of medical devices and AI systems that interact with EHR systems.	**Chapter I** **General provisions** *Article 1* *Subject matter and scope* 1. This Regulation establishes the European Health Data Space ('EHDS') by providing for **common** rules, ~~common~~ standards ~~and practices~~, infrastructures and a governance framework ~~for~~ **with a view to facilitating access to ~~electronic~~ health data processed in electronic form for** the **purposes of** primary and secondary use of ~~electronic health~~ **these** data. 2. This Regulation: (a) ~~strengthens~~ **specifies and complements~~, in Chapter II,~~** the rights **laid down in the Regulation (EU) 2016/679** of natural persons in relation to **primary use** ~~the availability and control~~ of their **personal** electronic health data; (b) lays down, **~~in Chapter III,~~ common** rules for ~~the placing on the market, making available on the market or putting into service of~~ electronic health records systems ('EHR systems') **and wellness applications that claim interoperability with EHR systems** in the Union **for primary use**; (c) lays down**~~, in Chapter II and IV,~~ common** rules and mechanisms ~~supporting~~ **for primary and** secondary use of ~~electronic~~ health data **processed in electronic form**; (d) establishes a ~~mandatory~~ cross-border infrastructure enabling the primary use of **personal** electronic health data across the Union **~~according to Chapter II~~**; (e) establishes a ~~mandatory~~ cross-border infrastructure for the secondary use of electronic health data **~~according to Chapter IV;~~.** **(f) establishes governance and coordination framework on national and European level for both primary and secondary use of ~~electronic~~ health data processed in electronic form.** 3. This Regulation applies to: (a) manufacturers and suppliers of EHR systems and wellness applications placed on the market and put into service in the Union and the users of such products; (b) controllers and processors established in the Union processing electronic health data of Union citizens and third-country nationals legally residing in the territories of Member States; (c) controllers and processors established in a third country that has been connected to or are interoperable with MyHealth@EU, pursuant to Article 12(5); (d) data users to whom electronic health data are made available by data holders in the Union. **~~3A. This Regulation shall be without prejudice to Regulations (EU) 2016/679, (EU) 2018/1725, (EU) No 536/2014 and Directive 2002/58/EC.~~** 4. This Regulation shall be without prejudice to other Union legal acts regarding access to, sharing of or secondary use of electronic health data, or requirements related to the processing of data in relation to ~~electronic~~ health data **processed in electronic form**~~, in particular Regulations (EU) 2016/679, (EU) 2018/1725, (EU) 2022/868[…] [Data Governance Act COM/2020/767 final], and […] [Data Act COM/2022/68 final].~~ 5. This Regulation shall be without prejudice to other Union legal acts regarding ~~Regulations (EU) 2017/745, **(EU) 2017/746** and […] [AI Act COM/2021/206 final], as regards~~ the security of medical devices and AI systems that interact with EHR systems. 6. This Regulation shall not affect the rights and obligations laid down in Union or national law concerning	Comments Art. 1, para 1. The wording has been changed to be consistent with the definitions at Article 2, distinguishing among '*personal electronic health data*' and '*electronic health data'*. Comments Art. 1, para 2.a), b), c), d) e). EHDS proposal recall GDPR in several articles and not only in the mentioned Chapters for both primary and secondary uses. We suggest deleting the specification of the Chapters. Comments Art. 1, para 2, letter c): the wording has been changed to be consistent with the definitions at Art. 2, highlighting the differences between '*personal electronic health data*' and '*electronic health data*' according to primary and secondary use. Comments Art. 1, para 2, letter f): the wording has been changed according to para 1, Article 1. Comments Art. 1, para 3, preferred original version of the proposal. Comments Art. 1, para 3A, preferred original version, more generic considering that the Art.1 is about subject matter and scope. Comments Art. 1, para 4 and 5,, preferred general statements being article 1 on subject and scope, and a general recall to all possibly applicable Union legal acts.

6. This Regulation shall not affect the rights and obligations laid down in Union or national law concerning health data processing for the purposes of reporting, complying with information requests or demonstrating or verifying compliance with legal obligations. **7. This Regulation shall not apply to activitites concerning public security, defence and national security.**	health data processing for the purposes of reporting, complying with information requests or demonstrating or verifying compliance with legal obligations. **7. This Regulation shall not apply to activitites concerning public security, defence and national security.**	

Article 2 *Definitions* *Definitions in Article 2(2)(d),(f)-(n) and (p)-(t) are not included in this compromise* 1. For the purposes of this Regulation, following definitions shall apply: (a) the definitions **of 'personal data', 'processing', 'pseudonymisation', 'controller', 'processor', 'third party', 'consent', 'genetic data', 'data concerning health', 'supervisory authority', 'international organisation' of the** ~~in~~ Regulation (EU) 2016/679; (b) the definitions of 'healthcare', 'Member State of affiliation', 'Member State of treatment', 'health professional', 'healthcare provider', 'medicinal product' and 'prescription', pursuant to Article 3 (a), (c), (d), (f), (g), (i) and (k) of Article 3 of the Directive 2011/24/EU; (c) the definitions of 'data', 'access', 'data altruism', 'public sector body' and 'secure processing environment', pursuant to Article 2 (1), (8), (10), (11) and (14) of **Regulation (EU) 2022/868**~~[Data Governance Act COM/2020/767 final]~~; (d) the definitions of 'making available on the market', 'placing on the market', 'market surveillance', 'market surveillance authority', 'non-compliance', 'manufacturer', 'importer', 'distributor', 'economic operator', 'corrective action', 'risk', 'recall' and 'withdrawal', pursuant to Article 2 (1), (2), (3), (4), (7), (8), (9), (10), (13), (16), (18), (22) and (23) of the Regulation (EU) 2019/1020; (e) the definitions of 'medical device', 'intended purpose', 'instructions for use', 'performance', 'health institution' and 'common specifications', pursuant to Article 2 (1), (12), (14), (22), (36) and (71) of the Regulation (EU) 2017/745; (f) the definitions of 'electronic identification', 'electronic identification means' and 'person identification data' pursuant to Article 3 (1), (2) and (3) of the Regulation (EU) No 910/2014. 2. In addition, for the purposes of this Regulation the following definitions shall apply: (a) 'personal electronic health data' means **personal** data concerning health and genetic data as defined in Regulation (EU) 2016/679 ~~as well as data referring to determinants of health, or data processed in relation to the provision of healthcare services~~, processed in an electronic form; ~~(b) 'non-personal electronic health data' means data concerning health and genetic data in electronic format that falls outside the definition of personal data provided in Article 4(1) of Regulation (EU) 2016/679;~~ (c) 'electronic health data' means personal **health data** or ~~non-personal electronic health~~ data **concerning health or genetic data that do not constitute personal data, processed in electronic form**; (e) 'secondary use of electronic health data' means the processing of electronic health data for purposes set out in **Article 34** ~~Chapter IV~~ of this Regulation. ~~The data used may include personal electronic health data initially collected in the context of primary use, but also electronic health data collected for the purpose of the secondary use;~~ (o) 'wellness application' means any appliance or software intended by the manufacturer to be used by a natural person for processing electronic health data for other purposes than healthcare, such as well-being and pursuing healthy	*Article 2* *Definitions* *Definitions in Article 2(2)(d),(f)-(n) and (p)-(t) are not included in this compromise* 1. For the purposes of this Regulation, following definitions shall apply: (a) the definitions **of 'personal data', 'processing', 'pseudonymisation', 'controller', 'processor', 'third party', 'consent', 'genetic data', 'data concerning health', 'supervisory authority', 'international organisation' pursuant to Article 4 (1), (2), (5), (7), (8), (10), (11), (13), (15), (21) and (26) of the** ~~in~~ Regulation (EU) 2016/679; (b) the definitions of 'healthcare', 'Member State of affiliation', 'Member State of treatment', 'health professional', 'healthcare provider', 'medicinal product' and 'prescription', pursuant to Article 3 (a), (c), (d), (f), (g), (i) and (k) ~~of Article 3 of~~ the Directive 2011/24/EU; (c) the definitions of 'data', 'access', 'data altruism', 'public sector body' and 'secure processing environment', pursuant to Article 2 (1), (8), (10), (11) and (14) of **the Regulation (EU) 2022/868**~~[Data Governance Act COM/2020/767 final]~~; (d) the definitions of 'making available on the market', 'placing on the market', 'market surveillance', 'market surveillance authority', 'non-compliance', 'manufacturer', 'importer', 'distributor', 'economic operator', 'corrective action', 'risk', 'recall' and 'withdrawal', pursuant to Article 2 (1), (2), (3), (4), (7), (8), (9), (10), (13), (16), (18), (22) and (23) of the Regulation (EU) 2019/1020; (e) the definitions of 'medical device', 'intended purpose', 'instructions for use', 'performance', 'health institution' and 'common specifications', pursuant to Article 2 (1), (12), (14), (22), (36) and (71) of the Regulation (EU) 2017/745; (f) the definitions of 'electronic identification', 'electronic identification means' and 'person identification data' pursuant to Article 3 (1), (2) and (3) of the Regulation (EU) No 910/2014. 2. In addition, for the purposes of this Regulation the following definitions shall apply: (a) 'personal electronic health data' means **personal genetic** data **and data** concerning health ~~and genetic data as defined in~~ **pursuant to Article 4 (13) and (15) of the** Regulation (EU) 2016/679, ~~as well as data referring to determinants of health, or data processed in relation to the provision of healthcare services~~, processed in an electronic form; ~~(b) 'non-personal electronic health data' means data concerning health and genetic data in electronic format that falls outside the definition of personal data provided in Article 4(1) of Regulation (EU) 2016/679;~~ (c) 'electronic health data' means ~~personal **health data** or non-personal electronic health~~ **genetic data and** data **concerning health ~~or genetic data~~ pursuant to Article 4 (13) and (15) of the Regulation (EU) 2016/679, that do not constitute personal data, processed in electronic form**; (e) 'secondary use of electronic health data' means the processing of electronic health data for purposes set out in **Article 34** ~~Chapter IV~~ of this Regulation. ~~The data used may include personal electronic health data initially collected in the context of primary use, but also electronic health data collected for the purpose of the secondary use;~~ (o) 'wellness application' means any appliance or software intended by the manufacturer to be used by a natural person for processing ~~electronic~~ health data **in electronic form** for other purposes than healthcare, such	Comments art. 2, para 1 Letter a): the Article 4 of the GDPR on definitions has been inserted with the specifications of the paragraphs Comments art. 2, para 2. Letter a): the Article 4 of the GDPR on definitions has been inserted, and the definition's order changed according to this Article. Letter c): the definition has been simplified according to that available in the Regulation (EU) 2016/679, Article 4, also considering that *personal health data* in general remains not clearly defined. Letter o): Is the definition of wellness application just related to the purpose? So it is possible to have an application that can be used for both health and wellness purposes? Further, the wording has been

life-styles; ~~(u) 'national contact point for secondary use of electronic health data' means an organisational and technical gateway enabling the cross-border secondary use of electronic health data, under the responsibility of the Member States;~~ ~~(v) 'central platform for secondary use of electronic health data' means an interoperability platform established by the Commission, providing services to support and facilitate the exchange of information between national contact points for secondary use of electronic health data;~~ ~~(x) 'HealthData@EU' means the infrastructure connecting national contact points for secondary use of electronic health data and the central platform;~~ (y) '**health** data holder' means a~~ny~~ natural or legal person, which is an entity or a body in the health or care sector, or performing research in relation to these sectors, as well as Union institutions, bodies, offices and agencies who has ~~the right or obligation, in accordance with this Regulation, applicable Union law or national legislation implementing Union law~~ **either:** **(a) the right or obligation, in accordance with applicable Union law or national legislation, to process personal electronic health data for the provision of health or care or for public health, research, innovation, policy making, official statistics, patient safety or regulatory purposes, in its capacity as a controller; or** **(b) the ability to make available, including to register, provide, restrict access or exchange electronic health data that do not constitute personal data in the meaning of Article 4 (1) of Regulation (EU) 2016/679**~~non-personal data~~, through control of the technical design of a product and related services, ~~the ability to make available, including to register, provide, restrict access or exchange certain data~~; (z) '**health** data user' means a natural or legal person who has lawful access to ~~personal or non-personal~~ electronic health data for secondary use **pursuant to a data permit or a data request pursuant to this Regulation**; (aa)'data permit' means an administrative decision issued to a **health** data user by a health data access body or a **single health** data holder to process the electronic health data specified in the data permit for the secondary use purposes specified in the data permit based on conditions laid down in **Chapter IV of** this Regulation; (ab)'dataset' means a structured collection of electronic health data; (ac)'dataset catalogue' means a collection of datasets descriptions, which is arranged in a systematic manner and consists of a user-oriented public part, where information concerning individual dataset parameters is accessible by electronic means through an online portal; (ad)'data quality' means the degree to which characteristics of electronic health data are suitable for secondary use; (ae)'data quality and utility label' means a graphic diagram, including a scale, describing the data quality and conditions of use of a dataset.	as well-being and pursuing healthy life-styles; ~~(u) 'national contact point for secondary use of electronic health data' means an organisational and technical gateway enabling the cross-border secondary use of electronic health data, under the responsibility of the Member States;~~ ~~(v) 'central platform for secondary use of electronic health data' means an interoperability platform established by the Commission, providing services to support and facilitate the exchange of information between national contact points for secondary use of electronic health data;~~ ~~(x) 'HealthData@EU' means the infrastructure connecting national contact points for secondary use of electronic health data and the central platform;~~ (y) '**health** data holder' means a~~ny~~ natural or legal person, which is an entity or a body in the health or care sector, or performing research in relation to these sectors, as well as Union institutions, bodies, offices and agencies who has ~~the right or obligation, in accordance with this Regulation, applicable Union law or national legislation implementing Union law~~ **either:** **(a) the right or obligation, in accordance with this Regulation, applicable Union law or national legislation, to make health data available for processing ~~process personal electronic~~ in electronic form for primary and secondary purposes, ~~the provision of health or care or for public health, research, innovation, policy making, official statistics, patient safety or regulatory purposes, in its capacity as a controller;~~ or** **(b) the ability to make available, including to register, provide, restrict access or exchange ~~electronic~~ health data in electronic form that do not constitute personal data in the meaning of Article 4 (1) of Regulation (EU) 2016/679**~~non-personal data~~, through control of the technical design of a product and related services, ~~the ability to make available, including to register, provide, restrict access or exchange certain data~~; (z) '**health** data user' means a natural or legal person who has lawful access to ~~personal or non-personal~~ electronic health data for secondary use, ~~**pursuant to**~~ **based on a data permit** ~~**or a data request**~~ **pursuant to this Regulation**; (aa)'data permit' means an administrative decision issued to a **health** data user by a health data access body or a **single health** data holder to process the electronic health data specified in the data permit, for the secondary use purposes specified in the data permit, based on conditions laid down in **Chapter IV of** this Regulation; (ab)'dataset' means a structured collection of ~~electronic~~ health data **in electronc form;** (ac)'dataset catalogue' means a collection of datasets descriptions, which is arranged in a systematic manner and consists of a user-oriented public part, where information concerning individual dataset parameters is accessible by electronic means through an online portal; (ad)'data quality' means the degree to which characteristics of electronic health data are suitable for secondary use; (ae)'data quality and utility label' means a graphic diagram, including a scale, describing the data quality and conditions of use of a dataset.	changed according to Article 2, para 2, (a) and (c). Comment on article 2 letter v): to define the central platform meaning, it should be clearly established the provided services and the differences among the different platforms/tools defined at letters u), v), x). These platforms are related but the definitions are not clear to explain how/to what. What about simplifying the wording and adding the references to the specific articles explaining the different functions/roles. Letter (y) point a: the wording has been changed according to the definitions at Article 2 para 2, at the Article 41 (moved to 35B) on *'Duties of health data holders'*, and at the Article 3 on primary use. Letter (y) point b: the wording has been changed according to the definitions at Article 2 para 2 Letter (y) point z: the data request has been deleted according to the process described at article 46 on *Data permit.* Comment para aa): It's not clear how a data holder can issue a Data Permit if the process for making data available is under the control of the Health Data Access Body and shall happen within the Secure Processing Environment. Is it implicit a data holder having a SPE? Comment para ab): a clear/common understanding of the concept of structured data is fundamental for both the meanings reported in article 2 and the interpretation of article 58 (structured data, structured collection of data, structured documents to create datasets, etc?)

~~Article 48~~ ~~Making data available for public sector bodies and Union institutions, bodies, offices and agencies without a data permit~~ ~~By derogation from Article 46 of this Regulation, a data permit shall not be required to access the electronic health data under this Article. When carrying out those tasks under Article 37 (1), points (b) and (c), the health data access body shall inform public sector bodies and the Union institutions, offices, agencies and bodies, about the availability of data within 2 months of the data access application, in accordance with Article 9 of Regulation […] [Data Governance Act COM/2020/767 final]. By way of derogation from that Regulation […] [Data Governance Act COM/2020/767 final], the health data access body may extend the period by 2 additional months where necessary, taking into account the complexity of the request. The health data access body shall make available the electronic health data to the data user within 2 months after receiving them from the data holders, unless it specifies that it will provide the data within a longer specified timeframe.~~	Article 48 Making data available for public sector bodies and Union institutions, bodies, offices and agencies without a data permit By derogation from Article 46 of this Regulation, a data permit shall not be required to access the electronic health data under this Article. When carrying out those tasks under Article 37 (1), points (b) and (c), the health data access body shall inform public sector bodies and the Union institutions, offices, agencies and bodies, about the availability of data within 2 months of the data access application, in accordance with Article 9 of Regulation […] [Data Governance Act COM/2020/767 final]. By way of derogation from that Regulation […] [Data Governance Act COM/2020/767 final], the health data access body may extend the period by 2 additional months where necessary, taking into account the complexity of the request. The health data access body shall make available the electronic health data to the data user within 2 months after receiving them from the data holders, unless it specifies that it will provide the data within a longer specified timeframe.	General comment: It's an important article and shouldn't be deleted. Possibly improved with a light version of a data permit.
Article 49 *Access to electronic health data from a single* ***health*** *data holder* 1. **Member States may allow** ~~W~~**w**here an applicant requests access to electronic health data only from a single **health** data holder **in that** ~~in a single~~ Member State, by way of derogation from Article 45(1) **or Article 47(1)**, that applicant ~~may~~ **to** file a data access application or a data request directly to the **health** data holder. The data access application shall comply with the requirements set out in Article 45 and the data request shall comply with requirements in Article 47. Multi-country requests and requests requiring a combination of datasets from several **health** data holders shall be adressed to health data access bodies. **1A. Where an applicant request access to electronic health data from health data holders which are an Union institution, body, office or agency, by way of derogation from Article 45(1) or Article 47(1), that applicant shall file a data access application or a data request directly to each health data holder. The data access application shall comply with the requirements set out in Article 45 and the data request shall comply with requirements in Article 47.** 2. In ~~such case~~ **situations referred to in paragraphs 1 and 2 in this Article,** the **health** data holder may issue a data permit in accordance with Article 46 or provide an answer to a data request in accordance with Article 47. The **health** data holder shall then provide access to the electronic health data in a secure processing environment in compliance with Article 50 and may charge fees in accordance with Article 42. ~~3. By way of derogation from Article 51, the~~	*2.The* ***health*** *data holder shall then provide access to the electronic health data in a secure processing environment in compliance with Article 50 and may charge fees in accordance with Article 42.*	General comment: Para 2. The Secure Processing Environments are mentioned here about the data holder but the relationship with those of the Health Data Access Bodies are not clear. All the health data Holder shall have SEP? Is it a choice of the single data holder? Who controls the compliance with art. 50?

~~single data provider and the data user shall be deemed joint controller.~~ SEE ARTICLE 51 4. ~~Within 3 months t~~**T**he **single health** data holder**, referred to in paragraph 1 of this Article,** shall **within 3 months** inform the relevant health data access body by electronic means of all data access applications filed and all the data permits issued and the data requests fulfilled under this Article in order to enable the health data access body to fulfil its obligations under Article 37(1) and Article 39.		
Chapter V ***Additional actions*** *Article 59* *Capacity building* *The Commission shall support sharing of best practices and expertise, aimed to build the capacity of Member States to strengthen digital health systems for primary and secondary use of electronic health data. To support capacity building, the Commission shall* ***in close cooperation and consultation with Member States*** *draw up* ***establish indicators for self assessment*** *benchmarking guidelines for the primary and secondary use of electronic health data.*		General comment: Not clear the concept of support sharing and how it will be realized: funds? human resources? Platforms? Services (free for MSs or not)?
Article 61 ~~*Third country*~~ ***T****transfer* ***to a third country*** *of* ***anonymous electronic health data*** ~~*non-personal electronic data*~~ ***presenting a risk of re-identification*** 1. ~~Non-personal~~ **Anonymous** electronic data made available by health data access bodies **to a health data user in a third country according to a data permit pursuant to Article 46 or a data request pursuant to Article 47 or to an authorisated participants in a third country or an international organisation**, that are based on a natural person's electronic **health** data falling within one of the categories of Article 33 ~~[(a), (e), (f), (i), (j), (k), (m)]~~ shall be deemed highly sensitive within the meaning of Article 5(13) of Regulation **(EU) 2022/868**~~[…] [Data Governance Act COM/2020/767 final]~~, provided that their transfer to third countries presents a risk of re-identification through means going beyond those **reasonably** likely ~~reasonably~~ to be used, **in particular** in view of the limited number of natural persons involved in that data, the fact that they are geographically scattered or the technological developments expected in the near future. 2. The protective measures for the categories of data mentioned in paragraph 1 shall depend on the nature of the data and anonymization techniques and shall be detailed in the Delegated Act under the empowerment set out in Article 5(13) of Regulation **(EU) 2022/868** ~~[…] [Data Governance Act COM/2020/767 final]~~.		General Comment: What about the concept of reciprocity here in article 61 (and 62)?

No 1. RIGHTS OF NATURAL PERSONS AND AN OPT-OUT SOLUTION **General questions on rights of natural persons** a) Is there a need for an article on the rights of natural person in relation to processing of personal electronic health data for secondary use, inspired by Article 3 in Chapter II, and if so, what would this new article need to contain? Are there for example rights in the GDPR that you would like to address in a such article, and in such case, which rights?	Yes, it would be appropriate the inclusion of an an article on the rights of natural person in relation to processing of personal electronic health data for secondary use. The example of Article 3 in Chapter II however is not applicable (too complex with contents that are mostly not suitable/adaptable for secondary use). It could be considered rights such as: - Rights related to the consent (i.e. an opt-out system where silence is tantamount to consent), in general and/or about specific purposes at article 34 according to religious, cultural, and ethical considerations, - rights to data protection and privacy - children's rights
Questions related to a possible opt-out solution b) Do you see a need for an opt-out for natural person in relation to the secondary use of their personal electronic health data? **i.** If so, do you see a need to lay down rules on how and to whom, the health data holder or the health data access body, will the natural person exercise its right to opt-out? **ii.** If so, who would be responsible for removing the information from the data set when a natural person has exercised its right to opt-out, the health data access body and/or the health data holder? iii. And should the natural person be able to opt-out from certain processing of personal electronic health data, for example certain data categories or certain purposes of secondary use?	Yes, it would be appropriate to include an opt-out system where silence is tantamount to consent, and which should be expressed considering the different data categories at article 33 according to the different purposes at article 34. i. MSs should choose between the health data holder or the health data access body. ii. Up to MSs iii. Yes, very important: different risks, interests and benefits are related to different types of health data and health purposes. For instance, the risk of person identification related to a genomic/proteomic sequence (human genome) is completely different from that related to a chest imaging result or to blood pressure measures. Further, people benefits deriving from purposes as public health interventions or medical research (clinical trials) are very different from those coming from training of AI algorithms for businesses of one or the other high-tech company.
MINIMUM DATA CATEGORIES IN ARTICLE 33(1) **No 2. Article 33(1)(a) - electronic health data from EHRs, including the categories in Article 5 of this Regulation**	Option 1 – keep current proposal from the Commission Preferred option 1 but paying attention to the concept of structured/unstructured data/documents/record. There is not a clear definition of this concept in the proposal and the risk of misunderstanding is high. (MSs are working for *minimum specifications for cross-border datasets for secondary use of electronic health data, taking into account existing Union infrastructures, standards, guidelines and recommendations)*

No 3. Article 33(1)(b) – data on factors impacting on health, including social, environmental behavioural determinants of health	Preferred Option 2 – closer link to the determinants of health in the public health area
No 4. Article 33(1)(n) – electronic data related to insurance status, professional status, education, lifestyle, wellness and behaviour data relevant to health	Preferred Option 3 (see comments on article 33)
No 5. Data categories in Article 33(1)(e) – human genetic, genomic and proteomic data	Option 2 – set out additional safeguards
No 6. Data categories in Article 33(1)(j) – data from clinical trials	Option 1 – keep current proposal from the Commission
No 7. Data categories in Article 33(1)(o) – enriched data	Option 2 – set out additional rules
The scope and the definitions on **health data holder** in Article 2(2)(y)	Option 1 – Current scope and definition of health data holder with a clarification that also social security is included **Italy supports this Option 1** and highlights that the focus should be what kind of health data to make available (Article 33) for what kind of purposes (Article 34) through a secure processing environment and according to quality, interoperability, etc, requirements. Italy is also open to a possible Option 3 which could be based on an improved Option 1 however including social security sector which is very relevant in the health sector for prevention and health management plans.
The scope and the definition on **health data user** in Article 2(2)(z), including the scope on applicant for a data permit in Article 45(1) or a data request in Article 47(1)	Option 2 – Limiting the scope and definition of health data user and the scope of applicant **Italy supports this Option 2** which is more complete giving more guarantees/protections.

Comments from the Irish delegation

Ireland – Written Comments – March 2023
On first compromise proposal on Chapter I, Articles 48 and 49 in Chapter IV, Articles 59, 60, 61, 62, 63, 64 and 65 in Chapter V and VI of the European Health Data Space Regulation

Chapter I – Article 2

Article 2(2)(o):
'wellness application' means any appliance or software intended by the manufacturer to be used by a natural person for processing electronic health data for other purposes than healthcare, such as well-being and pursuing healthy life-styles, **as determined by Member States**;
Rationale
IE considers it necessary to limit the scope of this proposed broad definition and therefore suggests this addition.

Article 2 (2) (ac)
(ac-1) 'dataset catalogue' means a collection of datasets descriptions, which is arranged in a systematic manner and consists of a user-oriented public part, where information concerning individual dataset parameters is accessible by electronic means through an online portal;
(ac-2) 'national dataset' means a structured collection of population wide electronic health data;
(ac-3) 'national metadata catalogue' means a collection of national datasets descriptions, which is arranged in a systematic manner and consists of a user-oriented public part, where information concerning individual dataset parameters is accessible by electronic means through an online portal;
Rationale
IE recommends that three different definitions are set out separately in Article 2, to ensure that the concepts of datasets is not used interchangeably. For example the text refers to a 'national dataset catalogue' instead of a 'dataset catalogue' in Art 37 (1) (q) and Art 57.

Article 2 (2) (ad)
'data quality' means the degree to which **the elements of electronic health data listed in Article 56 are assessed and considered suitable for secondary use as laid down in Chapter IV of this Regulation;**'
Rationale
IE considers it necessary to clarify the current definition for data quality by referencing the requirements for a data label listed in Art 56.

Article 2(2)(z)
IE places a scrutiny reserve on this definition; we are still reviewing the implications of the proposed changes.

Chapter IV

Article 48 - Making data available for public sector bodies and Union institutions, bodies, offices and agencies without a data permit
Comment
IE supports the deletion of this Article in the compromise text.
Additional arrangements for public sector bodies and Union institutions would infringe upon any flexibility granted to Member States in other Articles regarding providing access to health data for secondary uses.
We are open to exploring the possibility of creating an emergency process for accelerated access to relevant health datasets in urgent circumstances.

Article 49 - Access to electronic health data from a single health data holder
Comment
IE supports the change in the text of the compromise that 'Member States may allow' data users to submit applications directly to single data holders.
IE would prefer that all applications are made via a health data access body within a Member State but if this Article is to be retained in the Regulation, it would be important that Member States have the option of whether to enact it or not.
We note that several HDABs may be put in place within a Member State which single data holders could affiliate with – for example a HDAB for a specialist area of research.

IE is concerned that allowing for single access requests to become the norm, would perpetuate fragmentation and create a costly system in which single holders must fulfil many obligations.

Chapter V
Article 59 - Capacity building
Comment
IE supports the changes in the text to require the Commission to work with Member States to develop indicators for self-assessment instead of benchmarking guidelines.

Article 61 Transfer to a third country of anonymous electronic health data presenting a risk of re-identification
Comment
IE maintains its scrutiny reserve placed on Article 61.

Article 62 - Transfer of anonymous electronic health data to a third country or an international organisation
Comment
IE maintains its scrutiny reserve placed on Article 62.

Article 64 - European Health Data Space Board (EHDS Board)
Comment
IE prefers the original text which stated that relevant third parties, including patient representatives 'shall' be invited to attend EHDS Board meetings.
That wording explicitly involves the patient in the governance structure and allows their voice to be included in the EHDS framework and promote trust and transparency in the overall process.
We would support a provision that requires a patient representative to be invited to the EHDS Board, separate to other relevant third-party stakeholders.

Definitions on health data holder and health data user

IE supports Option 2 from the changes proposed by the Presidency. This would better reflect the health and social care sector in Ireland.

Option 2:

'health data holder' means natural or legal person, which is an entity or a body in the health or care sector, **excluding social security**, or performing research in relation to these sectors, as well as Union institutions, bodies, offices and agencies who has either:

c) the right or obligation, in accordance with applicable Union law or national legislation, to process personal electronic health data for the provision of health or healthcare as well as care of elder and persons with disabilities or for public health, research, innovation, policy making, 5 official statistics, patient safety or regulatory purposes, in its capacity as a controller; or

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

Comments from the Luxembourg delegation

Feedback Luxembourg on Chapter I / IV in the context of the proposal for a new definition for authorised participants and national contact points as well as the proposal to introduce a legal basis for improving data and for transferring responsibility for data holding to authorised participants

Chapter I

Article 2 Definitions

Article	**Comments**
Article 2 ***Definitions***	**Updated comments**
2. In addition, for the purposes of this Regulation the following definitions shall apply: (a)'personal electronic health data' means **personal** data concerning health and genetic data as defined in Regulation (EU) 2016/679, ~~as well as data referring to determinants of health, or data processed in relation to the provision of healthcare services~~ **~~as well as data on factors potentially impacting on health, data that may give information about health and data related to the administration of health and care~~**,~~,~~ processed in an electronic form; ~~(b)'non-personal electronic health data' means data concerning health and genetic data in electronic format that falls outside the definition of personal data provided in Article 4(1) of Regulation (EU) 2016/679;~~ (c)'electronic health data' means personal **health data** or ~~non-personal electronic health~~ data **concerning health or genetic data that do not constitute personal data, processed in electronic form**; (e)'secondary use of electronic health data' means the processing of electronic health data for purposes set out in **Article 34** ~~Chapter IV~~ of this Regulation. ~~The data used may include personal electronic health data initially collected in the context of primary use, but also electronic health data collected for the purpose of the secondary use~~; (o)'wellness application' means any appliance or software intended by the manufacturer to be used by a natural person for processing electronic health data for other purposes than healthcare, such as well-being and pursuing healthy life-styles; (y)' **health** data holder' means ~~any~~ natural or legal person, which is an entity or a body in the health or care sector **including / excluding social security**, or performing research in relation to these sectors, as well as Union institutions, bodies, offices and agencies who has ~~the right or obligation, in accordance with this Regulation, applicable Union law or national legislation implementing Union law~~, **either:** **(a) the right or obligation, in accordance with applicable Union law or national legislation, to process personal electronic health data for the provision of health or care or for public health, research, innovation, policy making, official statistics, patient safety or regulatory purposes, in its capacity as a controller; or**	Article 2, para 2(a) We recommend not to limit the definition of personal electronic health data to the definition in the GDPR (where these data are in electronic form). The envisaged scope in the EHDS is much broader, contrary to the EDPB & EDPS's opinion: the GDPR only covers data *pertaining to the health status* (Rec 35 GDPR). This means cost related to healthcare will not be covered, therefore precluding health economics studies to be performed. The definition would also not cover molecular data beyond genetic data that do not allow to derive conclusions on health. Last not least, determinants of health such as socio-economic or environmental data could not be covered. The limitation to health data as defined in the GDPR would render the EHDS very limited. The change made in Article 2 paragraph 2 (b) and (c) should be updated if the new definition 2(af) is adopted. (y) The addition "including / excluding social security" (marked in yellow) is still not providing sufficient clarity. We wait for Finland's proposition for an improved definition. We would like to point out though that even with the current additional prefix "health" the term is confusing because health data holders (hold data for primary purposes in health, care and research) are exactly not DGA data holders (entities having the right to grant access). This conflicting definition origins admittedly on a weakness in the DGA as "data provider" would have been a more intuitive name for the intentions of the DGA. (z) the changes proposed for "health data user" in the meeting of 7 March do all not reflect an improvement in our eyes. Here, only the changes of Opt. 1 are reflected in yellow (addition of reference to Arts 46 and 47). The references to Arts 46 and 47 mean that a health data user would only be defined in the context of the activities of an HDAB. The health data user would not be defined in the context of data access from other authorised participants and/or (if applicable data holders). We suggest therefore to remove again the additional reference to the articles. The option 2, which refers to an authorised participant, has not been added as option as it seems to build on a misunderstanding of the role of authorised participant. We

(b) the ability to make available, including to register, provide, restrict access or exchange electronic health data that do not constitute personal data in the meaning of Article 4 (1) of Regulation (EU) 2016/~~679~~non-personal data, through control of the technical design of a product and related services, ~~the ability to make available, including to register, provide, restrict access or exchange certain data~~; (z)' **health** data user' means a natural or legal person who has lawful access to ~~personal or non-personal~~ electronic health data for secondary use **pursuant to a data permit ~~in Article 46~~ or a data request ~~in Article 47~~ ~~pursuant~~ to this Regulation**; (aa) 'data permit' means an administrative decision issued to a **health** data user by an authorised participant ~~health data access body or a **single health** data holder~~ to process the electronic health data specified in the data permit for the secondary use purposes specified in the data permit based on conditions laid down in Chapter IV of this Regulation;	would like to propose a dedicated definition that also deviates from the original intention of the European Commission (see below) (aa) the definition was adapted to the proposal of a definition of "authorised participant" below.
(ag) 'authorised participant' means a legal person that is competent by law to decide on access to electronic health data for at least one of the purposes in Art. 34(1). **(ah) 'national contact point' is the health data access body that has the responsibility to serve as an organisational gateway and information provision for secondary use of electronic health data within a Member State.**	The current (implicit) definitions of NCPs and authorised participants are by technical capability rather than by fulfilling a certain role in the EHDS. An alternative proposal is an approach that builds on role and data governance, which should ideally come before technical functionality and that makes it easier to assign to these bodies roles in the governance of the EHDS. (ag) In the current EHDS Proposal, authorised participants are the entities that can connect to the EHDS cross-border infrastructure. These are the NCPs on the national level but also the EU institutions, bodies etc. as well as research and other infrastructures based on Union law. In addition, third countries and international organisations can be authorised participants if they connect to the EHDS cross-border infrastructure to make their data findable through the data catalogue and available for the secondary use defined in the EHDS. We see the intention of the EC to allow different actors who want so give access in a cross-border context to connect to HealthData@EU. However, our proposal is to build the definition on the governance role of giving access to data. The necessity that such authorised participants must be able to connect (either directly or through a technical gateway) can be introduced in Chapter IV. (ah) Currently, the EHDS Proposal requires a single technical gateway per country to connect to HealthData@EU. This is not technical necessity but was aimed to provide a clear responsible body to participate in the Board defined in Art. 66. Such a single gateway into the country can prove to create a vulnerability as all communication would rely on the single institution. We therefore recommend to allow countries to establish several gateways to increase the resilience of the communication network. A national contact point could instead serve as an organisational gateway, not only for health data users but also for other entities that need to understand the national

	setup. Considering that a MS could have several HDABs with different functions, several authorised participants etc., it is important that there is a clear contact for each country that can oversee the multiple stakeholder in that country and that provides central information. The NCP could also provide the technical gateway but this is not required as long as at least one gateway per country is established.

Chapter IV

Article	**Comments**
Article 35AA ***Other purposes for which electronic health data can be processed in the context of secondary use***	**Additional Comments**
	A new article should be introduced that creates a legal basis for the cleaning and structuring of data as well as for the possibility to transfer data to authorised participants for subsequent availability for secondary use. [Provisions are subject to the discussions on Luxembourg's proposal to reduce the strain on health data holders and HDABs]
Article 35D ***Authorised participants other than health data access bodies***	**Additional Comments**
	A new article should be introduced that legitimates legal entities competent by MS or Union law to give access to electronic health data as a participant in the EHDS. The article should confirm the legal mandate but also foresee the obligation of these entities to transmit data to HDABs where a purpose of Art. 34 falls outside their remit or where data are to be linked by the HDAB. [Provisions are subject to the discussions on Luxembourg's proposal to redefine authorised participants and to reduce the strain on health data holders and HDABs]
Article 36 ***Health data access bodies****	**Updated comments** **Art. 36 should be adapted or a new article compiled to foresee also an HDAB on the EU level**
1. Member States shall designate one or more health data access bodies responsible for **fulfilling the tasks set out in Articles 37, 38 and 39** ~~granting access to electronic health data for secondary use~~. Member States may either establish one or more new public sector bodies or rely on existing public sector bodies or on internal services of public sector bodies that fulfil the conditions set out in this Article. **The tasks described in Article 37 may be divided between different health data access bodies.** ~~Where a Member State designates several health data access bodies, it shall designate one health data access body to act as coordinator, with responsibility for coordinating requests **to access to electronic health data** with the other health data access bodies.~~ 5. Each country is required to establish a national contact point in a health data access body that serves as an organisational gateway for the country, provides central information and coordinates the multiple stakeholders, including, where applicable, other health data access	Proposal to redefine a national contact point as an organisational gateway. It could have more responsibilities than just the coordination between HDABs but also provide central information in general.

bodies in that country and that provides central information.	
Article 37 ***Tasks of health data access bodies***	**Additional Comments**
1(p)(a) receive and store electronic health datasets from data holders or corrected, annotated or enriched datasets from users for availability for secondary use	HDABs should also be able to store data where needed to take burden from health data holders and to avoid the loss of value added enriched data from users.
Article 49 ***Access to electronic health data from an authorised participant other than a health data access body ~~single health data holder~~***	**Comments**
1. **Member States may allow ~~W~~w**here an applicant requests access to electronic health data ~~only~~ from an authorised participant competent to give access to electronic health data under Member State law ~~single **health** data holder **in that** in a single Member State~~, by way of derogation from Article 45(1) **or Article 47(1)**, that applicant ~~**may**~~ **to** file a data access application or a data request directly to the ~~**health** data holder~~**authorised participant**. The data access application shall comply at minimum with the requirements set out in Article 45 and the data request shall comply with requirements in Article 47. ~~Multi-country requests and~~ ~~r~~Requests requiring a combination of datasets from several **health** data holders shall be adressed to health data access bodies. **1A. Where an applicant request access to electronic health data from ~~health data holders~~ authorised participants which are competent to give access to electronic health data under Union law~~an Union institution, body, office or agency~~, by way of derogation from Article 45(1) or Article 47(1), that applicant shall file a data access application or a data request directly to each ~~health data holder~~authorised participant. The data access application shall comply at minimum with the requirements set out in Article 45 and the data request shall comply with requirements in Article 47.** 2. In ~~such case~~ **situations referred to in paragraphs 1 and 2 in this Article,** the ~~**health** data holder~~ **authorised participant** may issue a data permit in accordance with Article 46 or provide an answer to a data request in accordance with Article 47. The ~~**health** data holder~~ **authorised participant** shall then provide access ~~to the electronic health data in a secure processing environment in compliance with~~	Data access within the EHDS should only be given by entities that have been equipped for such task and where safeguards are provided by law that meet the requirements of the GDPR and the DGA. Therefore, rather than data holders, the focus should here be on authorised participants. Some entities may fall under the definition of both data holders and authorised participants, e.g., entities that hold data for data availability for secondary use by external users but also provide input into policy development such as disease registries. Authorised participants should be allowed to follow their data governance established by law but should use the application form established by the EHDS; where a stricter data governance is pursued, the application form may be extended to ask for additional information. We do not see the necessity here to limit multi-country requests to an HDAB as authorised participants should be connected to a technical gateway to the HealthData@EU and should therefore be able to respond to a cross-border request as well. The DGA Arts. 5 and 6 provide for the necessity to introduce sufficient safeguards and the possibility of fees. As the legal mandate of the authorised participants that are not HDABs should comply with the DGA, this should be sufficient for participation in the EHDS.

~~Article 50 and may charge fees in accordance with Article 42~~in accordance with Art. 5 and 6 of Regulation (EU) 2022/868. ~~3. By way of derogation from Article 51, the single data provider and the data user shall be deemed joint controller~~. SEE ARTICLE 51 4. ~~Within 3 months t~~**T**he ~~**single health** data holder~~**authorised participant, referred to in paragraph 1 of this Article,** shall **within 3 months** inform the relevant National Contact Point or, where disclosing under Union law, the European Commission, ~~health data access body~~ by electronic means of all data access applications filed and all the data permits issued and the data requests fulfilled under this Article in order to enable the health data access body to fulfil its obligations under Article 37(1) and Article 39.	
Article 52 ***Cross-border infrastructure***	**Comments**
	Art. 52 would have to be updated subject to the discussions proposed by Luxembourg on the definition and responsibility of authorised participants.
Article 53 ***Access to cross-border registries or databases ~~sources~~ of electronic health data for secondary use***	Art. 53 would have to be updated subject to the discussions proposed by Luxembourg on the definition and responsibility of authorised participants.
Article	**Comments**
Article 55 ***Dataset description***	**Updated comments**
1. The health data access bodies shall inform the **health** data users about the available datasets **containing structured electronic health data** and their characteristics through a metadata catalogue. Each dataset shall include information concerning the source, the scope, the main characteristics, **the** nature of electronic health data and **the** conditions for making electronic health data available **according to agreed metadata models**.	The obligation to make data available should be limited to structured data. Luxembourg proposes to make it explicit that metadata should follow agreed content and structure, which allows a machine readable translation of the characterisation and thus an easier findability and administration of the data. The initial cost may be higher but subsequent saving on data management overhead (answering questions repeatedly) will make up for this. The possibility for machine-readability is necessary for feasibility of data administration. That would also allow automatic translation when it comes to transferring from machine readable to human readable. We should aim as much as possible to allow the user to assess the suitability of data for their intended purposes. This means that a rather detailed description is needed. It is suggested therefore to limit the requirement to include data into the data catalogue is limited to structured data, which are fewer and easier to characterise.

LU Proposal on the Feasibility of Data Inclusion and Data Services in the European Health Data Space (EHDS)

Executive summary

All datatypes currently envisaged in the EHDS Proposal under Art. 33 are of high value depending on the purpose for which they are intended. In research, information on lifestyle, environmental exposure and all molecular data are highly relevant to understand disease mechanisms. These datasets help to find out about the influence of genetic and external factors on health, and to find new preventive, diagnostic and therapeutic strategies.
Importantly, data for health research have to be **structured** and **documented**. This is a mandatory prerequisite to find the right data for the envisaged purpose, to process them electronically and to draw valid conclusions from them. Moreover, structured and documented data are cheaper to administer for secondary use and ease of implementation of the data minimisation principle. Finally, such controlled and well-described content prevents accidental data breaches, that can otherwise happen because free text can contain an unforeseeable risk of containing direct or indirect identifiers of a person.

On the contrary, sharing and secondary use of unstructured data carries risks of misinterpreting the included information and thus leading to wrong research conclusions, which at best renders the invested efforts futile but can come at worst at the cost of lives. Moreover, unstructured data generate a high administration cost on all sides, as the effort of data structuring and documentation falls on the health data holder and the health data access body but also a health data user will be repeated going back to the data holder with needs for clarification. As data are structured and documented for the need of a single data use case, new requests focus on new elements and thus generate similar efforts again and again, in particular as datasets are changing over time at the data holder and curated datasets become outdated. In this unfavorable scenario, health data holders will be repeatedly queried for information to make the data fit for purpose, a task that will distract them from their primary mission. .

Luxembourg therefore proposes that it should only be mandatory for Member States to include structured data, which are well documented to allow their use without the need of a dialogue between health data user and health data holder. These data have to be listed in the data catalogue and made available for purposes listed in Art. 35. Any Member State is also free to include unstructured data.

In addition to Art. 35 on purposes for secondary use, a legal basis should be provided to transform unstructured data into structured data and budgets should be made available on the EU and MS level to successively transfer valuable unstructured into structured, well documented data. Ultimately, the legislator should increase the obligation to create structured and well documented data already at the primary source, e.g. through Art. 58, thus creating data already fit for purpose in secondary use.

No obligation must be created for MS to offer data services. Such services should be optional and MS should be free to decide for which data sources and purposes under which conditions aggregated statistics are offered instead of a direct data access.

The proposed approach will significantly decrease the burden on health data holders and health data access bodies (HDABs) and allows a set-wise increase of available data.

Background

- ***Limiting the categories of data in the EHDS limits the impact of the EHDS***

Healthcare data are large-scale real-world data. They could be used to inform healthcare professionals on similar patients and support their diagnosis and treatment. Healthcare data can also serve as a large-scale big data source for finding relations between diseases, side effects of drugs and for a fast response to global health challenges. These data are to be complemented with research data that are more limited in the number of subjects involved but more varied with respect to the datatypes captured. Molecular data are particularly important because they provide a window into the body and the underlying mechanisms that lead to diseases. More datatypes than the ones data listed in Art. 33(1)(e) are relevant when aiming to understand an individual's health and disease. Molecular data increasingly find their way also into personalised medicine in healthcare. Complex diseases, such as most chronic diseases, are influenced not only by the genome of an individual but also lifestyle, environmental exposures, the socio-economic situation and many more. These factors are important components of modern clinical research, and their availability determines progress. Beyond research, sustainable health systems need information on health economics and rely on policy development for which healthcare administration data is vital. Leaving out certain data categories does not only limit the innovative scope and impact of the EHDS, it may close some important avenues entirely. Therefore, we recommend not to exclude any of the envisaged data types.

- ***Structured data support accurate queries and analyses***

Structured data have clearly defined, unique variables. Text values build on "controlled vocabularies", sets of pre-defined terms used in to fill in text fields, with a finctionality similar to a drop-down list. The terms in controlled vocabularies should be clearly defined and adhere to agreed and common data models, eliminating data recording errors.

Accelerated Cure Project Multiple Sclerosis, S. Wicks; http://www.acceleratedcure.org

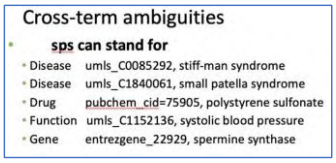
Recording errors appear frequently when free text is used, even in research studies. For instance, a form containing free-text drug names will generate spelling errors (see picture to the right), and the resulting data are not interpretable without prior investment into cleaning. Health data holders who do not pursue secondary use of data themselves will have little incentives to clean their records where, for their own purposes, the existing documentation is sufficient. Where health data users are asking for a certain subset of data, such errors will be missed and the extracted data are not representative. Importantly, extracting unrepresentative or wrong datasets will mask potential biases or errors from the user who is unaware of such bias. A skewed dataset could lead to wrong conclusion, potentially even wrong treatment recommendations in healthcare.

In an electronic health record, uncontrolled and unstructured descriptive terms obscure the meaning further. For instance, a field may contain different observations following the change of drug (box to the right). Here, besides misspellings, one would have to check the meaning of each term, define and consolidate them. For instance, mentioning headache can indicate the ceasing or absence of headaches. Similarly, the reason of the headache

Entry in EHR following change of drug
significantly less pain
unclear headaches
head aches
hedaches
often migraines
pain in the neck and in the head
pain in the neck rather than the head
not complained about nausea or headaches
complaints about a throbbing in the frontal lobes
fewer headaches than before

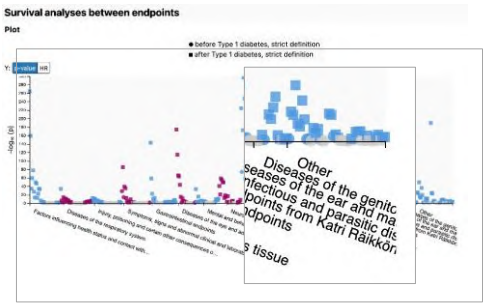
may be inconsistently recorded. Some records may vaguely refer to "patient has…" or "after drug Y" while for a correct interpretation, the information provided should spell out "after changing from drug X to drug Y".

Even with AI applications, it is very difficult to extract knowledge from such text. Successful AI applications in this area had a narrow scope, required training of algorithms first, took place in close interaction with healthcare professionals and required additional "manual" curation. This becomes clear when looking for example into ambiguities found in abbreviations and any other data that requires context interpretation and specific domain knowledge. In summary, AI applications required structured and documented data to be trained on before being able to process similar cases based on unstructured data and only perform for the specific context they were trained in. Thus, there are no AI solutions capable of working on completely unstructured data, without any effort of health data providers.



- ***Structured data support data protection compliance***

Data minimisation requires that health data users only receive access to data needed for their purpose. This task requires the extraction of a subset of a original dataset, and requires structuring the data first. The examples above show that without structuring, such extraction of relevant records is not possible. An important question to ask is whose responsibility it is to extract the data requested. Increasing the load on e.g. a hospital is not desirable but transferring the entire EHR database of patients to HDABs is also not an optimal solution. On the other hand, being able to rely on structured data would make the extraction of relevant datasets straightforward, would reduce cost and avoid an unnecessary transfer of data not required.



Another huge challenge in free text is the inadvertent disclosure of clues to the identity. This can be direct names but also social security numbers, zip codes, phone numbers or indirect give-aways such as names of treating physicians combined with other data. Another real-world example is given on the right.

- ***Structured data have to be documented***

To make structured data useable for few purposes it is essential to document them, which means to describe all the collected fields and their properties. Such documentation, data about data, is also called metadata and provides information on the actual content of data. Why this is important can be derived from the illustration based on a data entry "28/06/68".

Important information in the documentation are for example the data formats used, the data models used, the context in which the data were collected (such as the "change of drug" in the example above), sensitivity of data (e.g. data of minors) and so on.

The picture on the right shows another example, in this case taken from a research project where disease severity assessments were collected across different datasets. Even though these datasets are structured, it is impossible to integrate or even interpret (dataset4) these data points. Documentation is required allowing data users to understand how assessments were made to subsequently adapt datasets before combining them.

Global severity assessment
(value ranges from different cohorts in Biomap)

dataset1	*dataset2*	*dataset3*	*dataset4*
Clear	1 Severe	0 Clear	0
Almost clear	2 Moderate Severe	1 Almost clear	1
Mild	3 Moderate	2 Mild	2
Moderate	4 Mild	3 Moderate	3
Severe	5 Almost Clear	4 Severe	4
	6 Clear	5 Very severe	5
			6
			7

- ***Challenges of data requests (statistics services)***

Even in well documented and structured data, missing values, out of range values (e.g. negative age) and other mistakes are possible. Offering data services following a data request as foreseen in Art. 47 will require HDABs still to do some cleaning tasks before statistics can be generated. The amount of efforts to be invested is impossible to assess before the actual data are consulted, thus making it impossible to foresee the cost associated with a request.

The challenges are even bigger if a request requires the integration of datasets across different sources. The example of the Global Severity Assement above demonstrates associated challenges and efforts that have to be invested into an analysis across datasets. Even worse, it may turn out that the data were generated according to different criteria that cannot be adapted and therefore statistics across datasets would likely lead to wrong conclusions. A well known example from recent times is the reporting of Covid-19 deaths that differs from country to country but also within countries. Documentation of data makes it possible to find out where datasets can or cannot be integrated. However, efforts could be saved where statistics services are only offered for compatible datasets. Quality of the data provided influences not only efforts into a dataset cleaning. Where mistakes are not obvious, domain knowledge is needed to identify them. Such domain knowledge, such as on certain medical fields, will not be available in the HDAB. Statistics leading to wrong conclusions may be created, which can have grave consequences where such statistics are e.g. directly used in healthcare.

Table 1: Definition of COVID-19 deaths in headline figures *Eurohealth* 2020; 26(2).

Country	Diagnosis-based	Test-based	Other issues affecting comparisons
Belgium	✔	–	Only lab-confirmed deaths (largely in hospital) reported until 31st March
Bulgaria	✔	–	All reported deaths had +ve test result
Canada	✔	–	Figures include deaths from other causes "with" COVID
Croatia	✔	–	Those 'probable' can only be included if test +ve
Cyprus	✔	✔	Test result has to be recent
Estonia	✔	–	–
France	✔	–	–
Germany	✔	–	Figures include deaths "with" COVID

- ***Proposed solution***

Member States should be allowed to limit the data made available for secondary use to structured data only. Structured data are easier to document and also to administrate for data access requests, in particular in view of data minimisation, where only necessary data are made available. These data, however, should be accompanied by rich documentation on the content and context of the data generation, which will still provide a challenge for many health data holders but which is necessary for health data users to make sense out of the data for their purposes.

Data services to generate statistics data should be optional for Member States. An optional services will allow Member States to assess which sources can provide reliable data already sufficiently cleaned, where integration is possible or not offered, and also what level of responsibility is taken with respect to the purpose. Data services are significantly more expensive than mere data availability (considering structured and well documented data) and therefore, Member States should be able to determine the prices depending on the complexity of request and the source of the data. As the objective of the EHDS is data availability for secondary use, additional value-added services should not be mandatory for the Member States as these services bear the risk of capacity problems in HDABs that may compete with the issuing of data permits.

- ***No valuable data are lost***

We indeed suggest that unstructured data do not have to be made available for secondary use as this would require substantial and unforeseeable efforts on the side of the data holder and the HDAB to bring the data into a shape that is GDPR compliant and that allows to derive value from them. The likelihood that related cost become prohibitive or that data are not fit for purpose is rather high.

Nevertheless there will be also "gold nuggets" hidden in unstructured data. Therefore, we propose that an explicit legal basis should be provided through the EHDS in a new article to transform these data into structured data and also generate the associated documentation (metadata). Such transformation could then be done either in the context of data users looking for relevant datasets in a specific research context, by the data holders responding to funding offers on the national and EU level or successively planned by the legislator wanting to open up more and more data for reuse and deciding based on objective criteria where the efforts are best invested. This step-wise approach allows countries to develop their own roadmap adapted to the national and / or sector-specific situation.

- ***Maximising impact through a focus on "low hanging fruit"***

In our proposal, the EHDS will focus on those data that are easiest to make administer, easiest to document and best suited already for the health data user. It needs to be considered that even documenting those data will be substantial work for health data holders and HDABs and will already create a major burden for them. Having to respond to requests for data access or statistics related to unstructured data would require a personnel effort and expertise which is likely not available, in particular in the beginning if ever. The EHDS would paralyse itself by aiming to response to such requests, affecting then also the accessibility of more straightforward structured data. At the same time, the access associated cost of having to deal with unstructured data will either make it prohibitive for most health data users or will overload the Member States where these cost cannot be covered by users.

The approach is therefore the traditional one to focus on "low-hanging fruit" with high impact. The data are easier to administer, which means cost will be lower and response times on access requests more competitive. The data are more suitable for reuse and reflect the concept of "high-value datasets" in the European Data Strategy. More complex

challenges can be pursued successively and according to the Member State's priority list, balancing the interest in data and the efforts required to make them available.
In addition, any country would be free to go beyond this approach and offer also unstructured data in the EHDS data catalogue.

- ***Optimisation strategy and feasibility***

For scalability of the EHDS, we strongly recommend that prospective data are collected differently, influenced by obligations of and incentives for the data holders to generate data "**fit for purpose**" with respect to secondary use already in the **primary context**. Art. 5 and Art. 58 can be made use of to define structured datasets on EU level. Creation of structured, well documented data at the primary source should be supported through suitable software that helps the structured data capture as well has the automatic or assisted generation of data documentation (metadata) right at the source. It needs to be considered that datasets reflect in the first place the needs of the stakeholder generating them. Introducing changes will require measures targeted at the respective stakeholder group. Healthcare professionals may be incentivised by automated or semi-automated features that ease their work. Public funding for research should require structured and characterised data in line with EHDS definitions as a precondition to receive funding. Reporting in the regulatory context of clinical trials and medical devices could require information according to pre- defined standards and obligatory data models may be introduced. Successively, the data generated in the EU will be reusable from the beginning, therefore also allowing fast and consistent responses in emergencies such as the Covid-19 pandemic.

Further scalability and financial feasibility could be achieved where health data holders would be allowed to transmit their structured data to HDABs or data infrastructures for administration in the context of secondary use. Health data holders acquire data in their pursuit of a primary task that is driven by their mission. They should be allowed to continue focussing on their core competences. They have neither the capacity nor the expertise for the professional data management needed in secondary use whereas HDABs and data infrastructures do have the mission and the expertise for advanced data management.

Along the same lines, enriched data as foreseen in Art. 33(1)(o) should be assessed for their value by HDABs who administered the access rather than the health data holder. Data holders can and should only assess data usability from the viewpoint of their own purposes, which are likely different from the user's purposes. Further administration could likewise be taken over by the HDAB or a suitable data infrastructure. It is not likely that health data holders such as hospitals will be able to manage a variety of parallel datasets following enrichment. They may nevertheless receive such datasets where the enriched data are relevant for the health data holders own activities and mission but they should not be obliged to manage these datasets, which requires an advanced management of versioned datasets, potentially covering longitudinal changes of their own data as well as additional data sets adapted to different data models, formats and so on.

In general, an investment into IT tools for data administration could optimise workflows and reduce manual efforts to minimum. Nevertheless, it needs to be realised that AI will not be able to replace manual intervention in data cleaning and data management.

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Acknowledgement: input to the text was given by Dr. Marek Ostaszewski, examples were provided by Prof. Dr. Reinhard Schneider and Dr. Venkata Satagopam, Bioinformatics Core, Luxembourg Centre for Systems Biomedicine, University of Luxembourg.

Slides on legal basis

Analysis of the legal situation of the EHDS stakeholders based on the information presented in the slides

HEALTH DATA HOLDERS

Slide 26 & 27 / Arts. 52 and 66

"*The Commission acts as a processor and authorisated participants act as controller in the infrastructure, see Art 52(11).*"

Comment: **following the discussions we see a more granular assignment of roles to reflect all scenarios**

By providing the cross-border infrastructure and a central secure processing environment, the Commission may indeed act as processor but also, as we discussed briefly in the meeting, as subprocessor.

Any role under the GDPR as controller or processor is defined in relation to the processing of personal data that takes place for a specific purpose. The controller is the one who determines the purposes and the (essential) means of the processing.

Therefore, HDABs and authorised participants act as controllers where they decide on access to health data users. Where they utilise the infrastructure provided by the Commission in the context of access provision (handling data applications, permits or access provision), the Commission acts as processor for the access provision. However, authorised participants act as processors where they provide a secure processing environment to the health data user for the health data user's purposes and for which the health data user is controller. If an authorised participant chooses to request the Commission to provide the secure processing environment for the data use for which it has given access, then the Commission will be subprocessor to the HDABs.

An additional aspect is the processing of personal data in the context of organisational and technical measures as safeguards: here, the Commission may even act as controller, e.g. where log files of the processing operations per individual user are stored (see Art. 32 GDPR – responsibility of processors for organisational and technical safeguards).

Slide 32 Data subjects' rights may be more limited than indicated on the slide

After the request by the HDAB, the data are processed by the health data holder based on Art. 6(1)(c) GDPR. Here, the right to erasure may not (no longer) apply nor the right to restrict the processing unless the data are inaccurate, in which case the data subject could delay the disclosure.

Slide 33 Conclusion regarding the health data holder´s processing

"*The EHDS proposal regulates the health data holder´s disclosure of personal electronic health data to be used for secondary use and the legal bases in Article 6 and 9 of the GDPR.*"

Comment: the EHDS proposal does not fully cover the necessary legal bases in Art. 9 GDPR

The EHDS compromise proposal only refers to Art. 9(2)(i) and (j) GDPR. However, the purposes listed under Art. 34(1) go beyond the coverage of these listed exemptions, e.g. the reuse of data in a healthcare context should be covered by Art. 9(2)(h) GDPR. Training and education, if this purpose is to be kept, will likely fall under Art. 9(2)(g) GDPR. It is recommended to extend this scope. The same applies for the processing of HDABs (slide 35).

Comment: obligations of health data holder are insufficiently detailed and will therefore likely require health data holder to structure their data before transmission to HDABs

A legal obligation should provide clear instructions to a controller what processing is or is not required to comply with the legal obligation. The current EHDS proposal specifies, as also stated by the Presidency, that the health data holder must disclose electronic health data following the request by the HDAB. It is not specified to which extent the health data holder has to fulfil the data minimisation in compliance with Art. 5(1)(c) GDPR or to which extent this task of reducing datasets to those data necessary for the user will be down to the HDAB. Where this is not described in the EHDS proposal, the conclusion is that the transmission of data by the health data holder must not exceed the data elements specified by the HDAB in the request. Therefore, the health data holder must limit the data to the amount necessary. Where these data are unstructured, it means that all data must be structured first and reduced to those elements needed.

Comment: health data holder has likely no legal basis to hold on to enriched data

As rightly pointed out by the Presidency, the EHDS proposal does not regulate the situation for the health data holder when receiving enriched data. Where data have been enriched for a secondary use purpose that differs considerably from the primary use purposes for which the data were collected, the data in the enriched format will likely not be necessary for those primary purposes of the health data holder. Unless the health data holder pursues also other purposes that would benefit from the enriched data that the health data user has produced, the enriched data will then not be necessary for the data holder's purposes and, in accordance with Art. 5(1)(c) and 5(1)(e) GDPR, there will be no legal basis for the data holder to process the enriched data.

General comment: necessity and proportionality of invoking Art. 6(1)(c) GDPR for health data holders

The processing of the health data holder to disclose personal data (including directly identifying data from an electronic health record) to an HDAB is a based on a legal obligation. Such law limits the rights of a data subject under the Charter of Fundamental Rights in the EU under Art. 7 and 8 and therefore, according to Art. 52(1) of the Charter, this law must respect the essence of the fundamental rights and observe the principle of proportionality. Under the principle of proportionality, limitations may be made only if they are necessary and genuinely meet objectives of general interest recognised by the European Union or the need to protect the rights and freedoms of others. [See: CJEU C-184/20, CJEU C-140/20, para 52]. They must apply only in so far as is strictly necessary and the legislation which entails the interference must lay down clear and precise rules governing the scope and application of the measure in question. [See: CJEU C-184/20, para 70; CJEU C-439/19, para 105; CJEU C-311/18, para 172 to 176]. In our view, the current EHDS proposal still lacks sufficiently clear and precise rules about the scope and application that limit the restriction of data subjects' rights to what is strictly necessary. We also suggest that an approach is needed that clarifies how the essence of fundamental rights is respected with respect to each envisaged purpose under Art. 34(1), in line with suitable and specific safeguards as required under Art. 9(2)(g,h,i,j) GDPR.

HEALTH DATA ACCESS BODIES

Slide 35 The legal bases in the GDPR for the health data access body´s processing of personal electronic health data

Comment: more specific safeguards should be provided to invoke Art. 9(2)

To rely on Art. 9(2) GDPR exemptions through legal provisions, suitable and specific safeguards are to be foreseen in the legislation that establishes the exemption. The current proposal does seem to consider safeguards specific to purposes, which leads to open questions that may impact the work of HDABs when having to decide on an access request. For example: criteria need to be given when a health data user could be given access for education and training in the health or care sector – is a company wanting to train their employees sufficient? For which cases does the public benefit outweigh the interests of the data subject? Who would be allowed to request access to data for personalised healthcare purposes? How is it ensured that the transfer for scientific research and in particular the

training of AI algorithms is proportionate to the aim pursued and respect the essence of the right to data protection, in particular considering that data as sensitive as electronic health records are provided?

Slide 36/37 The rights of natural persons (health data access body´s processing)

Comment: A systematic overwrite of Art. 14 must respect the essence of the fundamental rights and freedoms and is to be a necessary and proportionate measure in a democratic society to safeguard the objectives pursued

The systematic derogation from the information obligation under Art. 14 GDPR restricts by way of a legislative measure the scope of the obligations and rights provided for in Articles 14 GDPR. As such, requirements of the Charter Article 52(1) and Art. 23(1) GDPR need to be complied with, which postulate that such a restriction respects the essence of the fundamental rights and freedoms and is a necessary and proportionate measure in a democratic society to safeguard the objectives referred to in Article 23(1) GDPR. (See also Opinion 03/2022 of the EDPB and EDPS, para 96) Relevant considerations can also be statements by the CJEU on cost efforts when aiming to invoke Art. 23(1) GDPR (CJEU C-184/20).

Comment: applicability of Art. 21 GDPR is controversially discussed

The Presidency rightly points out that data subjects could object against the processing of their data by the HDABs and that HDABs would have to demonstrate compelling legitimate grounds for the processing which override the interests, rights and freedoms of the data subject. Some argue that in cases of scientific research, Art. 21(6) GDPR would provide the basis for a general exemption from the right to object where the research is pursued under Art. 6(1)(e) GDPR. However, this can be challenged as Art. 21(6) GDPR also refers to scientific research pursuant to Art. 89(1) GDPR. Here, EDPB states in their Guidelines 05/2020 *that 'scientific research' in this context* [i.e. the GDPR recital 159] *means a research project set up in accordance with relevant sector-related methodological and ethical standards, in conformity with good practice*. Ethical standards in research, however, require that data subjects are included into research based on an informed consent and that they should be able to withdraw from the research wherever possible. [OECD Legal Instruments Health Data Governance; CIOMS/WHO, International Ethical Guidelines for Health-related Research Involving Humans; International Bioethics Committee of UNESCO: Report on big data and health; World Medical Association: Declaration of Taipei on Ethical Considerations Regarding Health Databases and Biobanks]

As such, we would like to suggest that Art. 21(6) GDPR should not be seen as a general derogation from the right to object in case of scientific research even if the research is performed in the public interest. Rather, a balancing and case by case decision will be needed.

Comment: Art 38 is not suitable to allow data subjects to exercise their rights

According to Art. 38, the conditions under which data are made available in the EHDS are listed as well as, among others, the applicable rights of natural persons. However, as long as there is no specific information of individual subjects on the use of their data in advance to the data disclosure, this may impact the possibility for data subjects to exercise their rights (see EDPB/EDPS Joint Opinion 03/2022, para 95).

HEALTH DATA USER

Slide 40: The (potential) legal bases in the GDPR for the health data user´s processing

Comment: the assignment of exemptions under Art. 9(2) GDPR seem to be not always the most appropriate choice

We would like to make some alternative propositions:

- Art 34(1)(a) is a verbatim quote of Art. 9(2)(i) GDPR; Art. 9(2)(h) GDPR seems therefore not to be the most appropriate choice.

- Art 34(1)(d) neither falls under scientific research and statistics nor under healthcare provision; therefore the listed exemptions Art. 9(2)(j) and (h) GDPR do not seem to be applicable; Art. 9(2)(g) could be a possible choice.
- Art 34(1)(f) covers a broad range that is going beyond scientific research: ensuring high levels of quality and safety of health care, of medicinal products or of medical devices seems to fall rather under Art. 9(2)(i).

On a different note: the necessity to list Art. 34(1)(b) as separate purpose under Art. 34 is not entirely clear. It is not apparent what purposes the public sector bodies or Union institutions, agencies and bodies pursue that are not covered by the purposes under Art 34(1)(a) and 34(1)(c)-(h)), which makes it difficult to foresee specific and suitable safeguards as required in the GDPR.

Comment: there may be a lack of a legal basis for health data users

Health data users have to provide their own legal basis under Art. 6(1)(e) or 6(1)(f) GDPR. However, public bodies may have problems to establish a valid legal basis where their legal mandate or the national legislative framework does not cover the intended processing. Examples are in the area of healthcare where the legislation may only provide a legal basis for a direct relationship of healthcare professionals with their patients but that do not foresee that data of other patients may be processed in the context. Such a situation could precludes the processing based on Art. 6(1)(e) GDPR. As in some countries, hospitals qualify as public authorities, the alternative of the legal basis under Art. 6(1)(f) GDPR may not easily be possible following Art. 6(1) GDPR, which says that legitimate interest is not available to public authorities in the pursuit of their tasks.

There are ongoing controversial discussions also what legislative provisions are sufficient to provide a legal basis under Art. 6(1)(e) GDPR and weather precisely defined obligations or legislative provisions, which lay down the essential characteristics of processing are necessary or not. Similarly, it is a subject of continued discussions how close a legitimate interest can be to the tasks bestowed on a public authority or also which bodies qualify as public authorities if this is not explicitly provided for in the law.

There is a risk though that the latter solution may still suffer from potentially deviating opinions and restrictions, limiting the scope of users and therefore the impact of the EHDS.

Comment: Art. 9(4) GDPR may interfere with the intentions of the EHDS Regulation

While the potential requirement to process data based on consent has been addressed for health data holders and HDABs in the EHDS consensus proposal, there are no provisions that prevent the applicability of a consent requirement based on Art. 9(4) GDPR to the user. Therefore, health data users may still be subject to consent requirements and/or alternative procedures to be followed to make their processing legitimate. Ideally, the EHDS Regulation should explicitly overwrite such requirements (see also below on Art. 9(4) GDPR).

General comment: data retention requirements of users are not covered

Health data users in scientific research have typically an obligation to keep data available for reproducibility reasons. Where health data users produce their results based on data in the EHDS, they are not able to fulfil this requirement because data are deleted by the HDAB at the end of the processing. Data will subsequently only be available from the health data holder in their original form. However, as many of these datasets evolve longitudinally, including their deletion when the retention time in primary use has ended, it will in many cases not be possible to re-establish the dataset used. The health data users cannot fulfil their obligation under good scientific practice to provide evidence for the validity of their results. This means that strictly speaking, the clauses of the GDPR for scientific research may not be possible to invoke in the EHDS as the conditions required for scientific research cannot always be fulfilled. It is there recommended that the EHDS provides explicitly for retention of data for reproducibility reasons.

GENERAL COMMENT ACROSS ALL STAKEHOLDERS

Comment: possibility of the EHDS regulation to overwrite Art. 9(4) GDPR requirements on the national level is unclear

In the EHDS proposal, it is mentioned that consent requirements based on Art. 9(4) GDPR would not be applicable. However, there are more limitations and conditions applicable to the processing based on Member State law and that are potentially applicable to the processing of health data holders, HDABs and/or health data users.

A possible interpretation of the EHDS legal situation is that the provision of an exemption based on legal provisions in accordance with Art. 9(2) GDPR on the basis of Union law will not only replace the national provisions based on Art. 9(2) GDPR but also the related additional conditions established under Art. 9(4) GDPR.

This needs clarification as otherwise, a large part of the current heterogeneity with respect to the processing of health and genetic data for research will remain. Where the interpretation prevails that the EHDS implementations of Art. 9(2) GDPR overwrite any national provision under Art. 9(4) GDPR, such a clarification in the recitals would be beneficial. In case of any doubt about the situation, an explicit provision through an article within the EHDS Regulation itself would be needed.

Comment: not all processing operations in the context of the EHDS have been analysed in the slides

It may be interesting to have a closer look also to other processing taking place in the context of the EHDS. Examples are the processing of enriched data across the different stakeholders, the processing of the handling of incidental findings or the processing of personal data in the context of technical and organisational measures beyond pseudonymisation.

A closer look into the possible processing operations also reveals that there is no legal basis foreseen that allows a systematic transformation of data into recognised international standards. While there is Art. 58 on requirements on cross-border datasets, there is no role assigned and therefore legal basis provided how such datasets could be generated.

In addition, it needs to be considered that HDABs have no legal basis to hold any data. Nor have data holders a legal basis to store data beyond the necessity for their own mission. Repositories established with a mission to hold data for secondary use and disclose them to users are not explicitly considered in the current EHDS proposal. Correspondingly, there is also no legal basis established that would allow a transfer of data to such entities. These missing elements could be considered to be added in a new consensus to overcome the current weaknesses and missing elements.

Comments from the Polish delegation

PL comments and questions on the proposal for a regulation on European Health Data Space – chapters: IV, V of the PRES SE compromise proposal

General comments:

- It is important to define the roles of different actors in the process of making data available for secondary processing, in particular the role and tasks of the Health Data Access Bodies (HDABs), as this remains still unclear in the current proposal. Health Data Access Bodies are charged with tasks that may be burdensome, e.g. the choice of approach and the activity of anonymising/randomising/pseudonymising data.
- The Health Data Access Body should not be responsible for making the data secure. This process should be done in accordance with a common, established by the EC and worked out with participation of MS approach by each data holder for which the Health Data Access Body (HDAB) receives a request for access.
- The anonymisation of data should be carried out as much as possible by the data holders (health data holders), according to a common methodology, rather than at the level of the Health Data Access Bodies (HDABs), which, due to the expected large number of datasets, could lead to creation of a significant bottleneck.

Specific comments to Chapter IV

Article 33

Minimum categories of electronic data for secondary use

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

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

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

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

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

(e) human genetic, genomic and proteomic data;

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

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

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

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

(j) electronic health data from clinical trials;

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

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

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

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

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

Art. 33 – PL reiterates earlier comments on Article 33: the catalogue in paragraph 1 includes a number of types of sensitive data pertaining to an individual, which are in principle to be made available by the data holders unconditionally. The draft does not envisage a competence for the MS to limit the scope of data made available for secondary processing. MS in order to protect the owners of individual health data, but also with a view to public and national security, should be able to determine the scope of data sharing.
As regards the use of genomic data for the purpose of secondary processing, PL underlines the additional challenges in making such data available: these are the challenges of anonymisation due to the individual character of the data, increased sensitivity of such data and potentially larger risk of genomic data misuse.
With regard to **article 33 para 1a** (electronic health data from the EHR, including the categories defined in Article 5 of the Regulation), in PL's opinion individual health data produced in primary use, i.e. in the processes of diagnosis and treatment of an individual, understood as a set of data of a single person which is made available, should not be part of the catalogue of data subject to secondary processing.
With regard to **article 33(1)(b)** - data on health determinants, including social, environmental and behavioral determinants of health.
PL would rather support option #2 of the PRES SE, which suggests a closer link to the determinants of health in the public health area, with the condition of adding a prohibited use clause in Article 35 on processing by third parties (e.g. employers, companies, banking/insurance sector).
With regard to **article 33(1)(n)** - electronic data on insurance status, professional status, education, lifestyle, well-being and health-relevant behavior, PL would opt for removing the indicated category of data as not directly related to the quality of secondary use.

With regard to **article 33(1)(e)** - Regarding the use of genomic data for secondary use, the PL highlights additional challenges in the area of sharing such data: these are the challenges of anonymization due to the individual nature of the data, the sensitivity of this type of data, and the potentially greater risk of misuse of genomic data. Thus, unless recommendations are made at the EU level on how best to approach safeguarding this type of data from illicit use, consideration should be given to withdrawing this type of data from secondary use and leaving the implementation to the national level (Option 3).

With regard to **article 33(1)(j)** - clinical trial data, In PL's opinion, the release of data from this category could lead to a potential disruption of competitiveness and the functioning of clinical research sector. In PL's view sharing of this type of data should be subject to obtaining an additional positive opinion from an independent ethics committee, as well as the addition of a clause in Article 35 to define additional prohibited purposes of data processing, i.e., those that may lead to an unfair competitive advantage or disrupt those investing in the creation of data sets.
With regard to **article 33(1)(o)** - enriched data, in PL's opinion, in the event that added value is created for a given dataset in the process of its processing under the granted permission, i.e., enrichment, enhancement, editing, etc., this enriched dataset should be added to the dataset catalogue but should function there alongside the original dataset that was made available. The owner of the dataset should make both datasets available in the case of a granted permission, while no further actions (checking for GDPR compliance) should be expected to be performed against the enriched dataset. These possible activities should be performed by the entity enriching the data set in question.
In addition, with regard to categories listed in **art. 33** PL reiterates the opinion that transition periods should be adjusted to the level of maturity of MS. There are certain differences in the e-health development among MS, therefore introducing variable transition periods is justified.

Article 35

Prohibited secondary use of electronic health data

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

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

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

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

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

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

Art. 33&35: All activities resulting from EHDS regulation that could affect negatively competitiveness as regards clinical trials or introducing new drugs or technologies should be avoided. We support adding national security as one of factors that can affect whether the data will be made available. The change introduced in art. 1 by adding: "This Regulation shall not apply to activities concerning public security, defence and national security." seems to respond to this suggestion, however, it might be relevant to introduce it also in art. 35 on Prohibited secondary use of electronic health data.

Article 35A

IP-rights and trade secrets

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

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

Art. 35 A, para 2 – SE PRES has proposed the creation of a new Article 35 A dedicated to the protection of intellectual property and business secrets ("IP-rights and trade secrets"), developed on the basis of the provisions in Articles 33 and 34 of the earlier version of the text. Regarding the current wording of Article 35 A, para 2, in PL's opinion ensuring the confidentiality of data that contains intellectual property or other confidential content should be implemented on the basis of common recommendations developed at the EU level – in our opinion MS should rather not introduce such solutions individually. Given the importance of ensuring the protection of sensitive information, it is reasonable to introduce a unified approach in the EU, based on the highest standards of procedure and with participation of MS.

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

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

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

ART. 35 B, para 1 - in reference to the *Duties of health data holders*, in our opinion, the data that the Health Data Access Body (HDAB) receives should be already anonymized/pseudonymized and in such form transferred to the Health Data Access Body (HDAB). The Health Data Access Body should not be responsible for making the data secure. This process should be done in accordance with a common, established by the EC approach by each data holder for which the Health Data Access Body (HDAB) receives a request for access.

Article 35C

Duties of health data users

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

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

3. Health ~~D~~data users shall make public the results or output of the secondary use of electronic health data, including information relevant for the provision of healthcare, ~~no later than~~ **within** 18 months after the completion of the electronic health data processing in the secure environment or after having received the answer to the data request referred to in Article 47. **This period may in justified cases related to research be extended.** Those results or output shall only contain anonymised data. The **health** data user**s** shall inform the health data access bodies from which a data permit was obtained and support them to also make the **results or output provided by the health data users** ~~information~~ public on

health data access bodies' websites. Whenever the **health** data users have used electronic health data in accordance with this Chapter, they shall acknowledge the electronic health data sources and the fact that electronic health data has been obtained in the context of the EHDS. MOVED FROM ARTICLE 46(11)

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

Art. 35 C, para 1 – A new Article 35 C was added, using partially the previous provisions set in Article 46, with the addition: "This includes a prohibition for health data users to re-identify the natural persons or to process electronic health data for prohibited purposes pursuant to Article 35 or any other misuse of electronic health data." – PL supports the addition of such a provision in the text.
Art. 35 C, para 2 – The paragraph clarifies an earlier provision from Article 35 - its current wording is: „Where processing electronic health data within the secure processing environments referred to in Article 50, the health data users are prohibited to provide access to, or otherwise making the electronic health data available to third parties not mentioned in the data permit." – PL supports the addition of such a clarification.
Art. 35 C, para 3 – with regard to the added wording: "This period may in justified cases related to research be extended." – PL generally supports the addition to the existing wording, but it is worth considering whether justified reasons should be limited only to the area of research.
Art. 35C, para 4 – A new wording was suggested: „Member State law to which the health data access body who granted the data permit is subject may allow the health data users to inform the health data access body of any clinically significant findings that may influence the health status of the natural persons whose data are included in the dataset" – PL would rather recommend a modification of the wording as follows: "MS in which the health data access body who granted the data permit is located may require the health data users to inform the health data access body of any clinically significant findings that may influence the health status of the natural persons whose data are included in the dataset".

Article 36

Health data access bodies

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

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

Art. 36, para 1 – An additional wording was suggested: „Member States shall designate one or more health data access bodies responsible for fulfilling the tasks set out in Articles 37, 38 and 39 (…).The tasks described in Article 37 may be divided between different health data access bodies." - if tasks are specified in the context of Article 37, the text should also clarify that the tasks specified in Articles 38 and 39 remain on the coordinator if there is more than one Health Data Access Body (HDAB) in a given MS.
Art. 36, para 2 – Regarding para 2, we sustain our previous comments that we believe that MS should be financially assisted by the EC in carrying out activities in the part related to cross-border secondary use of data and making data available to EU public authorities.

Article 37

Tasks of health data access bodies

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

…

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

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

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

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

….

6. ~~Where the consent of the natural person is required by national law~~ **Nothwithstanding national laws requesting the consent pursuant to Article 9(4) of Regulation (EU) 2016/679**, health data access bodies shall rely on the obligations laid down in this Chapter

when requesting and processing personal electronic health data from the health data holder and disclose ~~provide access~~ to pseudonymised electronic health data to the health data user.MOVED FROM ARTICLE 33(5)

Art., 37, para1 letter d) – the wording of the paragraph was changed: "process electronic health data referred to in Article 33, including the gathering, combination and compiling of necessary requested data from health data holders, the pseudonymization or anonymization of the data, and the disclosure of those data for secondary use to health data users on the basis of a data permit or a data request" - in PL's opinion, both the performance of complex data gathering, combination and processing operations and pseudonymization and anonymization operations should not be subject to the Health Data Access Body (HDAB). These operations should be performed at the level of data holders. Health data access bodies (HDABs) should not be given overall responsibility for anonymization related approaches regarding data security.
Art. 37, para 1 letter da) – a new paragraph was added to the text: "provide access to electronic health data to health data users pursuant to a data permit in a secure processing environment in accordance with the requirements laid down in Article 50." - in PL's view, it is unjustified for all data to be transferred to the Health Data Access Body (HDAB) before being made available, this should be done pursuant to a permit granted, under which the health data holder should transfer the data directly to the health data user.
Art. 37, para 1(f) - in the context of the changes made in the earlier articles regarding intellectual property, PL considers that the provision in (f): "take all measures necessary to preserve the confidentiality of IP rights and of trade secrets;" is general and not sufficient, guidelines/recommendations should be developed for ensuring intellectual property and corporate confidentiality at the EU level.
Art. 37, para 6 – paragraph moved from Article 33(5), with slightly modified wording: "Nothwithstanding national laws requesting the consent pursuant to Article 9(4) of Regulation (EU) 2016/679, health data access bodies shall rely on the obligations laid down in this Chapter when requesting and processing personal electronic health data from the health data holder and disclose provide access to pseudonymized electronic health data to the health data user." - in our opinion, the timing of the anonymization/pseudonymization of data is important, as we indicated earlier pseudonymization and anonymization operations should not be addressed by the Health Data Access Body (HDAB). The anonymization/pseudonymization process should be of high quality, ensuring the security of data subjects' identities. We would like a clarification whether this paragraph applies only to data for which a decision has been made to pseudonymize (rather than anonymize)?

Article 42

Fees

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

2. Where the data in question are not held by the **health** data access body or a ~~public sector body~~, the fees may also include compensation for part of the costs for collecting the electronic health data ~~specifically under this Regulation~~ in addition to the fees that may be charged pursuant to paragraph 1. The part of the fees linked to the **health** data holder's costs shall be paid to the **health** data holder.

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

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

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

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

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

Art. 42 – In PL's opinion we may reflect on some guidance mechanism to MS as regards the fees, some recommendations for a billing system that would allow to set fees in a transparent, harmonized, simple and fair way for all stakeholders. With regard to para 1, in our opinion, the fees should be based on the value of the data, they should not only reflect the data preparation activities, but also the market value of the data. PL suggests adding in para 1: "and shall also reflect market value of the data in question."

Article 43

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

…

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

Art. 43 para 8 - PL expects recommendations/guidelines from the EC on the billing system for penalties. As for penalties for processing shared data in a way that does not comply with the applicable rules, in PL's opinion they should be determined in a proportionate manner to the user's economic position (e.g., as a percentage of gross annual income earned). Such an approach will achieve the goals inherent in this type of penalties, i.e. penalization of fraudulent behaviour of data users and effective prevention against such actions.

Article 44

Data minimisation and purpose limitation

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

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

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

Art. 44 Data minimisation and purpose limitation – PL reiterates our earlier comments that the Health Data Access Body should not be responsible for making the data secure. This process should be done in accordance with a common, EU established approach by each data holder for which the Health Data Access Body (HDAB) receives a request for access.

Article 45

Data access applications

1. A~~ny~~ natural or legal person may submit a data access application for the purposes referred to in Article 34 with the exception of persons who have breached the rules, according to Article 43 para 4.

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

…

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

Article 45(1) - "A natural or legal person may submit a data access application for the purposes referred to in Article 34." – in the light of the provisions of Article 43(4): "In this regard, the health data access bodies shall be able, where appropriate, to revoke the data permit and to exclude the health data user from any access to electronic health data within the EHDS for a period of up to 5 years" adding a clarification in this paragraph might be worth consideration: "with the exception of persons who have breached the rules, according to Article 43 para 4 ".
In addition, PL reiterates its previous observation that such a broad definition of those entitled to forward secondary access requests increases the risk of unauthorised access to data or the transfer of acquired data to third parties. In PL's view, it would be justified to define the catalogue of entities entitled to this activity.
Article 45(2)(c) - "an indication whether electronic health data need to be made available in a pseudonymised format". - PL underlines that the large-scale availability of health data for secondary use in a pseudonymised format does not ensure sufficient protection of the privacy of the data subject.

Article 49

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

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

Article 49(1) - the wording has been amended: "Member States may allow where an applicant requests access to electronic health data only from a single health data holder in that Member State, by way of derogation from Article 45(1) or Article 47(1), that applicant to file a data access application or a data request directly to the health data holder." - In PL's opinion, adding the provision 'Member States may allow..." and leaving this issue to the MS is a positive change. Nevertheless PL maintains the previous position that offering the possibility to request data directly from the data holder will create some duality in the system. In PL's view, the ability to directly request data imposes an excessive obligation on data holders to comply with the procedures for accessing data, examining the data access application or a data request, issuing consents, collecting fees, and holding and granting access within a secure processing environment. In PL's view, this constitutes an excessive requirement on many entities in the healthcare system. It also creates the potential for abuse, in which the entity requesting the access may opt to deliberately avoid requesting access to multiple data sets through an application to the HDAB by sending a series of requests to single data holders. PL reiterates the earlier comment that consideration should be given to withdrawing the possibility of directly approaching the data holder and obtaining authorisation for data processing.

Article 51

~~Joint~~ Controllership

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

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

Art. 51 para 1 and 1A, in PL's opinion the idea of joint controllership and the data co-management introduced in the first proposal of the draft regulation was not optimal with regard to the adopted model of data exchange, taking into account the relations between multiple MS, as well as the possible challenges in co-administration in the area of both primary and secondary use of health data. In general, PL considers changes introduced in art 51 para 1 and 1A as positive.

Specific comments to Chapter V

Article 59

Capacity building

The Commission shall support sharing of best practices and expertise, aimed to build the capacity of Member States to strengthen digital health systems for primary and secondary use of electronic health data. To support capacity building, the Commission shall **in close cooperation and consultation with Member States** ~~draw up~~ **establish indicators for self assessment** ~~benchmarking guidelines~~ for the primary and secondary use of electronic health data.

Article 59 - An additional wording was suggested: 'in close cooperation and consultation with Member States' - PL supports the amendment.

Article 60
Additional requirements for public procurement and Union funding

…

2. The criteria for obtaining funding from the Union ~~The ex-ante conditionality for Union funding~~ shall take into account**:**

a) the requirements developed in Chapters II, III and IV**;**

b) the requirements laid down in Regulations (EU) 2016/679 or (EU) 2018/1725, where applicable, in particular:

(i) the requirements laid down in Article 35 or 39 respectively of these Regulations by requiring a documented data protection impact assessment, including where Chapter V of these Regulations apply, an assessment of the impact of the transfer to third countries or international organisations.

Article 60(2)(a)(i) - PL asks for clarification on the relevance of indicating third countries and international organisations in the context of applying for EU funding. In PL's view current provision of paragraph 2 causes interpretation difficulties.

Article 61
*~~Third country~~ **T**~~t~~ransfer **to a third country** of **anonymous electronic health data** ~~non-personal electronic data~~ **presenting a risk of re-identification***

1. ~~Non-personal~~ **Anonymous** electronic health data made available by health data access bodies **to a health data user in a third country according to a data permit pursuant to Article 46 or a data request pursuant to Article 47 or to an authorised participants in a third country or an international organisation**, that are based on a natural person's electronic **health** data falling within one of the categories of Article 33 ~~[(a), (e), (f), (i), (j), (k), (m)]~~ shall be deemed highly sensitive within the meaning of Article 5(13) of Regulation **(EU) 2022/868**~~[…] [Data Governance Act COM/2020/767 final]~~, provided that their transfer to third countries presents a risk of re-identification through means going beyond those **reasonably** likely ~~reasonably~~ to be used, **in particular** in view of the limited number of natural persons involved in that data, the fact that they are geographically scattered or the technological developments expected in the near future.

Article 61(1) – In PL's opinion the beginning of the article should be reworded: "Anonymous electronic health data made...'. PL welcomes the change on extending the category of data to entire Article 33 and not just parts of it. At the same time, PL points out that the provision "reasonably likely" is difficult to interpret and should be replaced by a catalogue of characteristics that indicate the risk of re-identification. PL also notes that the definition of the term "Anonymous" provided at the end of the of the compromise proposal (Article 2(2)(af)) contradicts, in PL's view, the wording of Article 61.
According to the definition, anonymous data ('anonymous data') is data which does not identify and make it impossible to identify individuals. According to this definition, it is not possible to re-identify the holder of the data, whereas Article 61 indicates such a risk - PL notes some inconsistency. In PL's view, the definition in para (af) should be reformulated so that it does not conflict with Article 61.

Article 62
*~~International access and~~ **T**~~t~~ransfer of **anonymous** ~~non-personal~~ electronic health data **to a third country or an international organisation***

1. The digital health authorities, health data access bodies, the authorised participants in the cross-border infrastructures provided for in Articles 12 and 52 and **health** data users shall take all reasonable technical, legal and organisational measures, including contractual arrangements, in order to prevent ~~international~~ transfer **to a third country or an international organisation, including** ~~or~~ governmental access **in a third country** **of**~~to~~ **anonymous** ~~non-personal~~ electronic health data held in the Union where such transfer ~~or access~~ would create a conflict with Union law or the national law of the relevant Member State, without prejudice to paragraph 2 or 3 of this Article.

…

3. In the absence of an international agreement as referred to in paragraph 2 of this Article, where a digital health authority, a health data access body, **a health** data user~~s~~ is the addressee of a decision or judgment of a third-country court or tribunal or a decision of a third-country administrative authority to transfer ~~or give access to~~ **anonymous** data within the scope of this Regulation held in the Union and **in** compliance with such a decision would risk putting the addressee in conflict with Union law or with the national law of the relevant Member State, transfer **of** ~~to or access to~~ such data **to** ~~by~~ that third-country authority shall take place only where:
   (a) the third-country system requires the reasons and proportionality of such a decision or judgment to be set out and requires such a decision or judgment to be specific in character, for instance by establishing a sufficient link to certain suspected **natural or legal** persons or infringements;
   (b) the reasoned objection of the addressee is subject to a review by a competent third-country court or tribunal; and
   (c) the competent third-country court or tribunal issuing the decision or judgment or reviewing the decision of an administrative authority is empowered under the law of that third country to take duly into account the relevant legal interests of the provider of the data protected under Union law or the national law of the relevant Member State

Article 62(1) - In PL's view, the provision imposes a significant responsibility on the authorities in MS in terms of compliance and non-compliance with EU law in the area of data processing by third countries and international organisations. The provisions related to the transfer of data to third countries should be structured in such a way that such transfers do not have the potential to create the indicated conflict. Responsibility should not be shifted to MS and in particular, entities such as health data holders (authorised participants...).
Article 62(3) - PL raises concerns about the proposed wording of the criteria in paragraph 3 and the content of this paragraph. The proposed mechanism in the absence of an international agreement with regard to a decision or judgment of a third-country court or tribunal or a decision of a third-country administrative authority is not transparent and raises difficulties of interpretation.

Specific comments to Chapter VI

Article 64
European Health Data Space Board (EHDS Board)

2. A European Health Data Space Board (EHDS Board) is hereby established to facilitate cooperation and the exchange of information among Member States. The EHDS Board shall be composed of ~~the high-level~~ representatives**,** **one each** of digital health authorities and health data access bodies**,** of all the Member States. ~~Other national authorities, including market surveillance authorities referred to in Article 28, European Data Protection Board and European Data Protection Supervisor, may be invited to the meetings, where the issues discussed are of relevance for them. The Board may also invite experts and observers to attend its meetings, and may cooperate with other external experts as appropriate. Other Union institutions, bodies, offices and agencies, research infrastructures and other similar structures, shall have an observer role.~~ (SECOND, THIRD AND LAST SENTENCES AMENDED AND MOVED TO PARA 1(B)-1(E))

1a. **A representative of** ~~T~~the Commission **and a representative of the Member States** shall **co-**chair the meetings of the EHDS Board. (MOVED FROM PARA 6)

1b. ~~Other national authorities, including~~**M**~~m~~arket surveillance authorities referred to in Article 28, European Data Protection Board and European Data Protection Supervisor, **shall** ~~may~~ be invited to the meetings, where the issues discussed are of relevance for them. (MOVED FROM PARA 1 AND AMENDED)**1c.** The Board may also invite **other national authorities,** experts and observers to attend its meetings, and may cooperate with other external experts as appropriate. (MOVED FROM PARA 1 AND AMENDED)

1d. Other Union institutions, bodies, offices and agencies, research infrastructures and other similar structures **shall** have an observer role **when invited to participate in the meetings**. (MOVED FROM PARA 1 AND AMENDED)

1e. Stakeholders and relevant third parties, including patients' representatives, **may** ~~shall~~ be invited to attend meetings of the EHDS Board and to participate in its work, depending on the topics discussed and their degree of sensitivity. (MOVED FROM PARA 4)

…

3. The ~~composition, organisation, functioning and cooperation of subgroups shall be set out in~~ rules of procedures **of the EHDS Board shall be adopted by its members and** put forward by the Commission. **They shall include rules pertaining to the composition, structure, operation and cooperation of the sub-groups and shall regulate the role of invitees referred to in paragraphs 1b to 1e, taking into account the topics under discussion and the level of confidentiatlity involved.**

Article 64(1) – PL supports deletion of 'the high level' from the paragraph on MS representatives in the EHDS Board.
Art. 64 para 1a-1e – PL support changes proposed by the PRES SE. The Commission should not be the chair of the EHDS board, it could be a co-chair with the MS. PL agrees that EHDS Board should be co-chaired.
Art. 64 para 3 – PL support changes proposed by the PRES SE, they reflect our earlier comments.

Article 65
Tasks of the EHDS Board

1. The EHDS Board shall have the following tasks relating to the primary use of electronic health data in accordance with Chapters II and III:

…

(b) to issue written contributions and to exchange best practices on matters related to the coordination of the implementation at Member State level of this Regulation and of the delegated and implementing acts adopted pursuant to it, in particular as regards:

…

~~(iii) other aspects of the primary use of electronic health data~~.

…

2. The EHDS Board shall have the following tasks related to the secondary use of electronic health data in accordance with Chapter IV:

…

~~(xvi) other aspects of the secondary use of electronic health data~~.

(c) to facilitate cooperation between health data access bodies through capacity-building, establishing the structure for **biennial** ~~annual~~ activity reporting, **and** ~~peer review of annual activity reports and~~ exchange of information **in those reports**;

Art. 65 para 1 b(iii) – PL supports deletion
Art. 65 para 2 b(xvi) – PL supports deletion
Art. 65 para 2 c – PL supports changes regarding the reporting.

Additional comments on the rest of the text, relevant to the changes introduced:

Article 69
Penalties

Without prejudice to Articles 30 and 43 of this Regulation and to Chapter VIII of Regulation (EU) 2016/679, Member States shall lay down the rules on penalties applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties shall be effective, proportionate and dissuasive. Member States shall notify the Commission of those rules and measures by date of application of this Regulation and shall notify the Commission without delay of any subsequent amendment affecting them.

Article 69 - PL reiterates an earlier comment. In PL's view, clarification is needed as to how the details of the fees and penalties related to the sharing of health data will be determined for secondary processing. In PL's opinion, the level of penalties should also depend on the value of the data which are subject to secondary processing.

Definitions

Article 1

Subject matter and scope

...

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

Art. 1(7) – provision was added: „This Regulation shall not apply to activities concerning public security, defence and national security." PL supports the addition.

Comments related to other issues:

The opt-out solution

In PL's view, the idea of broad use of health data presented in the draft regulation could be disrupted by an "opt-out" mechanism. If such an entitlement would be introduced, the technical issues (e.g., who would delete the information and to whom the patient's entitlement would be reported) should be left to Member States and national law. Regarding the opt-out option for secondary use, assuming that the data will be anonymized or pseudonymized in an appropriate manner, then the opt-out option does not seem indispensable in PL's view.

Definition of 'Health data holder'

In PL's view, an excessive expansion of the catalogue of entities included in the EHDS may significantly hamper the functioning of the system, it also implies a significant burden in relation to the handling of applications. In PL's view the catalogue of data to be shared is too broadly defined in Art. 33, and the definition of 'health data holder' (both options - option 1 and 2) put forward by PRES SE potentially expands this catalogue even further. This may result in an additional burden on entities becoming a 'health data holder' and the entire EHDS system at national level.

Option two limiting the inclusion of entities only from the care of disabled and elderly may cause interpretation difficulties, inter alia due to the imprecise term 'care of elderly'.

Therefore, PL proposes option 3 - similar to the wording in the first proposal of the first PRES SE compromise proposal:

'health data holder' means a natural or legal person, which is an entity or a body in **health or healthcare sector** or performing research in relation to these sectors, as well as Union institutions, bodies, offices and agencies who has either:

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

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

Definition of 'health data user'

In line with the position presented so far, PL considers that a broad definition of a data user entitled to request access to data as "a natural or legal person" creates the risk of overloading the system and creating excessive burden on the authorities granting consent for secondary data processing (provision in Article 45(1)).

Of the options presented in the PRES SE flash, the first allows for a very broad definition of health data user, the second limits it, but in the PL's view insufficiently. In our interpretation, the provision in line with option two results in the limited possibility of reciprocity.

Therefore, PL requests clarification on the notion of 'within the juridiction of a country' -

which groups of users would be excluded from the definition of 'health data user' under this provision as in option 2, in relation to the proposed definition in the first compromise proposal?

In addition, PL asks for clarification as to how, in terms of the PRES proposal provisions will ensure reciprocity?

Comments from the Portuguese delegation

Written Contributes from the Portuguese Delegation

Chapter IV, V and VI

21-03-2023

Articles 48.º- 49.º

ARTICLE 48.º – MAKING DATA AVAILABLE FOR PUBLIC SECTOR BODIES AND UNION INSTITUTIONS, BODIES, OFFICES AND AGENCIES WITHOUT A DATA PERMIT (DELETED)	
ARTICLE 49.º – ACCESS TO ELECTRONIC HEALTH DATA FROM A SINGLE DATA HOLDER 1. **Member States may allow** where an applicant requests access to electronic **health** data only from a single health data holder **in that** in a single Member State, by way of derogation from Article 45(1) or Article 47(1), that applicant may to file a data access application or a data request directly to the health data holder. The data access application shall comply with the requirements set out in Article 45 and the data request shall comply with requirements in Article 47. Multi-country requests and requests requiring a combination of datasets from several health data holders shall be adressed to health data access bodies. **1A. Where an applicant request access to electronic health data from health data holders which are an Union institution, body, office or agency, by way of derogation from Article 45(1) or Article 47(1), that applicant shall file a data access application or a data request directly to each health data holder. The data access application shall comply with the requirements set out in Article 45 and the data request shall comply with requirements in Article 47.** **2.** ~~In such case~~ **situations referred to in paragraphs 1 and 2 in this Article, the health data holder may issue a data permit in accordance with Article 46 or provide an answer to a data request in accordance with Article 47.** The health data holder shall then provide access to the electronic health data in a secure processing environment in compliance with Article 50 and may charge fees in accordance with Article 42. 3. By way of derogation from Article 51, the single data provider and the data user shall be deemed joint controller. SEE ARTICLE 51 4. Within 3 months tThe single health data holder, referred to in paragraph 1 of this Article, shall within 3 months inform the relevant health data access body by electronic means of all data access applications filed and all the data permits issued and the data requests fulfilled under this Article in order to enable the health data access body to fulfil its obligations under Article 37(1) and Article 39.	Ensuring security requirements are met poses a challenge for many data holders in creating a secure processing environment. Granting the same access powers to data holders as those given to health data access points can create risks in protecting health data if procedural standards are not properly implemented. How will these security requirements be verified?

ARTICLE 61.º- TRANSFER TO A THIRD COUNTRY TRANSFER OF ANONYMOUS NON-PERSONAL ELECTRONIC DATA PRESENTING A RISK OF RE-IDENTIFICATION	
1. Non-personal Anonymous electronic data made available by health data access bodies to a health data user in a third country according to a data permit pursuant to Article 46 or a data request pursuant to Article 47 or to an authorisated participants in a third country or an international organisation, that are based on a natural person's electronic health data falling within one of the categories of Article 33 [(a), (e), (f), (i), (j), (k), (m)] shall be deemed highly sensitive within the meaning of Article 5(13) of Regulation (EU) 2022/868[…] [Data Governance Act COM/2020/767 final], provided that their transfer to third countries presents a risk of re-identification through means going beyond those reasonably likely reasonably to be used, in particular in view of the limited number of natural persons involved in that data, the fact that they are geographically scattered or the technological developments expected in the near future. 2. The protective measures for the categories of data mentioned in paragraph 1 shall depend on the nature of the data and anonymization techniques and shall be detailed in the Delegated Act under the empowerment set out in Article 5(13) of Regulation (EU) 2022/868 […] [Data Governance Act COM/2020/767 final].	Further elaboration of this article is needed to account for reciprocity of data transfer to third countries.
ARTICLE 62.º - INTERNATIONAL ACCESS AND TRANSFER OF NON-PERSONAL ELECTRONIC HEALTH DATA	
1. The digital health authorities, health data access bodies, the authorised participants in the cross-border infrastructures provided for in Articles 12 and 52 and health data users shall take all reasonable technical, legal and organisational measures, including contractual arrangements, in order to prevent international transfer to a third country or an international organisation, including or governmental access in a third country ofto anonymous non-personal electronic health data held in the Union where such transfer or access would create a conflict with Union law or the national law of the relevant Member State, without prejudice to paragraph 2 or 3 of this Article. 2. Any judgment of a third-country court or tribunal and any decision of a third-country administrative authority requiring a digital health authority, a health data access body or a health data users to transfer or give access to anonymous non-personal electronic health data within the scope of this Regulation held in the Union shall be recognised or enforceable in any manner only if based on an international agreement, such as a mutual legal assistance treaty, in force between the requesting third country and the Union or any such agreement between the requesting third country and a Member State. 3. In the absence of an international agreement as referred to in paragraph 2 of this Article, where a digital health authority, a health data access body, a health data users is the addressee of a decision or judgment of a third-country court or tribunal or a decision of a third-country administrative authority to transfer or give access to anonymous data within the scope of this Regulation held in the Union and in compliance with such a decision would risk putting the addressee in conflict with Union law or with the national law of the relevant Member State,	"shall provide the minimum amount of data permissible in response to a request, based on a reasonable interpretation of the request" it Is not clear what constitutes a reasonable interpretation, which could lead to misunderstandings and potential breaches of privacy.

transfer of to or access to such data to by that third-country authority shall take place only where: (a) the third-country system requires the reasons and proportionality of such a decision or judgment to be set out and requires such a decision or judgment to be specific in character, for instance by establishing a sufficient link to certain suspected natural or legal persons or infringements; (b) the reasoned objection of the addressee is subject to a review by a competent thirdcountry court or tribunal; and (c) the competent third-country court or tribunal issuing the decision or judgment or reviewing the decision of an administrative authority is empowered under the law of that third country to take duly into account the relevant legal interests of the provider of the data protected under Union law or the national law of the relevant Member State 4. If the criteria conditions laid down in paragraph 2 or 3 are met, a digital health authority, a health data access body or a health data user data altruism body shall provide the minimum amount of data permissible in response to a request, based on a reasonable interpretation of the request. 5. The digital health authorities, health data access bodies, health data users shall inform the health data holder about the existence of a request of a third-country administrative authority to access its data before complying with that request, except where the request serves law enforcement purposes and for as long as this is necessary to preserve the effectiveness of the law enforcement activity.	
ARTICLE 64 - EUROPEAN HEALTH DATA SPACE BOARD (EHDS BOARD)	
1. A European Health Data Space Board (EHDS Board) is hereby established to facilitate cooperation and the exchange of information among Member States. The EHDS Board shall be composed of the high level representatives, one each of digital health authorities and health data access bodies, of all the Member States. Other national authorities, including market surveillance authorities referred to in Article 28, European Data Protection Board and European Data Protection Supervisor, may be invited to the meetings, where the issues discussed are of relevance for them. The Board may also invite experts and observers to attend its meetings, and may cooperate with other external experts as appropriate. Other Union institutions, bodies, offices and agencies, research infrastructures and other similar structures, shall have an observer role. (SECOND, THIRD AND LAST SENTENCES AMENDED AND MOVED TO PARA 1(B)-1(E)) 1a. A representative of Tthe Commission and a representative of the Member States shall co-chair the meetings of the EHDS Board. (MOVED FROM PARA 6) 1b. Other national authorities, includingMmarket surveillance authorities referred to in Article 28, European Data Protection Board and European Data Protection Supervisor, shall may be invited to the meetings, where the issues discussed are of relevance for them. (MOVED FROM PARA 1 AND AMENDED) 6627/23 MAV/ar 7 ANNEX LIFE.5 LIMITE EN 1c. The Board may also invite other national authorities, experts and observers to attend its meetings, and may cooperate with other external experts as appropriate. (MOVED FROM PARA 1 AND AMENDED) 1d. Other Union institutions, bodies, offices and agencies, research infrastructures and other similar structures shall have an observer role when invited to participate in the meetings. (MOVED FROM PARA 1 AND AMENDED) 1e. Stakeholders and relevant third parties, including patients'	The proposal should clarifythat: - Only one vote for MS will be considered, as such only one high level represenattive for MS should be part of the EHDS board - Minimum rules of procedure for the board should be layed out in this article (eg. The voting procedure for the decisions that are to be taken by the Board)

representatives, may shall be invited to attend meetings of the EHDS Board and to participate in its work, depending on the topics discussed and their degree of sensitivity. (MOVED FROM PARA 4) 2. Depending on the functions related to the use of electronic health data, the EHDS Board may work in subgroups for certain topics, where digital health authorities or health data access bodies for a certain area shall be represented. The subgroups may have joint meetings, as required. 3. The composition, organisation, functioning and cooperation of subgroups shall be set out in rules of procedures of the EHDS Board shall be adopted by its members and put forward by the Commission. They shall include rules pertaining to the composition, structure, operation and cooperation of the sub-groups and shall regulate the role of invitees referred to in paragraphs 1b to 1e, taking into account the topics under discussion and the level of confidentiatlity involved. 4. Stakeholders and relevant third parties, including patients' representatives, shall be invited to attend meetings of the EHDS Board and to participate in its work, depending on the topics discussed and their degree of sensitivity. MOVED TO PARA 1E 5. The EHDS Board shall cooperate with other relevant bodies, entities and experts, such as the European Data Innovation Board referred to in Article 26 29 of Regulation 2022/868 [Data Governance Act COM/2020/767 final], competent bodies set up under Article 7 of Regulation […] [Data Act COM/2022/68 final], supervisory bodies set up under Article 17 of Regulation […] [eID Regulation], European Data Protection Board referred to in Article 68 of Regulation (EU) 2016/679 and cybersecurity bodies. 6. The Commission shall chair the meetings of the EHDS Board. MOVED TO PARA 1A 7. The EHDS Board shall be assisted by a secretariat provided by the Commission. 8. The Commission shall, by means of implementing acts, adopt the necessary measures for the establishment, and management and functioning of the EHDS Board. Those implementing acts shall be adopted in accordance with the advisory examination procedure referred to in Article 68(2).	
ARTICLE 65 TASKS OF THE EHDS BOARD	
The EHDS Board shall have the following tasks relating to the primary use of electronic health data in accordance with Chapters II and III: (a) to assist Member States in coordinating practices of digital health authorities; (b) to issue written contributions and to exchange best practices on matters related to the coordination of the implementation at Member State level of this Regulation and of the delegated and implementing acts adopted pursuant to it, in particular as regards: (i) the provisions set out in Chapters II and III; (ii) development of online services facilitating secure access, including secure electronic identification, to electronic health data for health professionals and natural persons.; (iii) other aspects of the primary use of electronic health data. (c) to facilitate cooperation between digital health authorities through capacity-building, establishing the structure for biennial annual activity reporting, and exchange of information in those reports peer-review of annual activity reports and exchange of information; (d) to share information concerning risks posed by EHR systems and serious incidents as well as their handling; (e) to facilitate the exchange of views on the primary use of electronic health data with the relevant stakeholders, including representatives of patients,	How will EHDS Board carry out these tasks, what are the mechanisms for facilitating cooperation and exchange of information, and how it will ensure the inclusion of diverse stakeholder perspectives? Namely financial and logistic arrangements to pursue these tasks should be clarified. Will countries have to support these tasks? Or the Commission?

health professionals, researchers, regulators and policy makers in the health sector. 2. The EHDS Board shall have the following tasks related to the secondary use of electronic health data in accordance with Chapter IV: (a) to assist Member States, in coordinating practices of health data access bodies, in the implementation of provisions set out in Chapters IV, to ensure a consistent application of this Regulation; (b) to issue written contributions and to exchange best practices on matters related to the coordination of the implementation at Member State level of this Regulation and of the delegated and implementing acts adopted pursuant to it, in particular as regards: (xi) implementation of rules for access to electronic health data; (xii) technical specifications or existing standards regarding the requirements set out in Chapter IV (xiii) incentives policy for promoting data quality and interoperability improvement; (xiv) policies concerning fees to be charged by the health data access bodies and health data holders; (xv) the establishment and application of penalties; (xvi) other aspects of the secondary use of electronic health data. (c) to facilitate cooperation between health data access bodies through capacity-building, establishing the structure for biennial annual activity reporting, and peer-review of annual activity reports and exchange of information in those reports; (d) to share information concerning risks and data protection incidents related to secondary use of electronic health data, as well as their handling; (e) to contribute to the work of the European Data Innovation Board to be established in accordance with Article 29 of the Regulation […] [Data Governance Act COM/2020/767 final]; (SEE ARTICLE 65(5)) (f) to facilitate the exchange of views on the secondary use of electronic health data with the relevant stakeholders, including health data holders, health data users, representatives of patients, health professionals, researchers, regulators and policy makers in the health sector	

Health Data Holder definition

Option 1 – *Current scope and definition of health data holder with a clarification that also social security is included [As we understand it, the definition as suggested in option 1, would include for example both private and public health and care providers, pharmaceutical companies, entities within social security, public institutions, and public sectors bodies with tasks in these sectors, including bodies that produce official statistics in these sectors, researchers, insurers, EMA and ECDC etc. See recitals 38 to 40 in the Commission´s proposal. The definition could also include tech companies and other companies when their perform within the health and care sector. For processing of personal electronic health data they need to act as a controller and not for example as a processor. Clarifications on this could be provided in the recitals.]*

Option 2 – Narrowing the scope and definition of health data holder. [Comment: By explicitly exclude social security and limit the care sector to only include care of elderly and person with disabilities option 2 would mean a narrowed definition of health data holder.]

Analysis:

We agree with option 1.

Considering the two options, it is possible to conclude that option 2 is more restricted that option 1. A narrower definition may provide stronger privacy protections, but it could also limit the use of health data for research and public health purposes.

Otherwise, option 1 allows a more comprehensive approach, ensuring that all relevant entities that handle personal health data are covered by the regulation, However, the requirement that a data holder must act as a controller and not a processor could lead to challenges in granting access to the data. Additionally, monitoring and evaluating compliance with this provision may prove difficult.

Striking a balance between protecting privacy and allowing for the necessary use of health data will be key in ensuring that the regulation is effective and beneficial for all stakeholders involved, but eliminating fundamental data holders from the EHDS will not be the way forward to achieve the objectives of the EHDS.

The Scope and Definition of Health Data User and Applicant

Option 1 – Current scope and definition of health data user and the scope of applicant
Article 2(2)(z)
· 'health data user' means a natural or legal person who has lawful access to personal or non-personal electronic health data for secondary use pursuant to a data permit in Article 46 or a data request in Article 47 of this Regulation Article 45(1) and 47(1)
· A natural or legal person may submit… Comment: This is a broad definition of health data user and who may submit a data access application or a data request. It is important to keep in mind that the health data user needs to fulfil the requirement stated in Article 46 and 47.

Option 2 – Limiting the scope and definition of health data user and the scope of applicant
Article 2(2)(z)
· 'health data user' means a natural or legal person within the juridiction of a country or an international organisation which is an authorised participant of the cross border infrastructure for secondary use in Article 52, who has lawful access to personal or non-personal electronic health data for secondary use pursuant to a data permit in Article 46 or a data request in Article 47 of this Regulation Article 45(1) and 47(1)
· A natural or legal person, within the juridiction of a country or an international organisation which is an authorised participant of the cross border infrastructure for secondary use in Article 52, may submit… Comment: This option would limit the scope of potential health data users and applicants to ensure reciprocity and equal terms for the sharing of electronic health data for secondary use purposes in relation to the cross-border infrastructure. These entities would still need to fulfil the requirements in Articles 46 and 47 et cetera.

Analysis:

Option 1 provides a clearer and wider framework for entities accessing and using health data, which may encourage innovation and scientific discovery, but may also raise concerns about privacy and data protection. Those concerns should be taken care of in the articles that define data permits and application procedures.

Rights of natural persons - opt-out and opt-in

The sharing of health data for primary and secondary purposes involves complex considerations regarding privacy and consent.
When it comes to the primary use of health data, where healthcare providers share data to provide direct care to patients, an opt-out approach may be more advantageous for citizens. With this model, citizens are automatically included in the data-sharing system, and their health information can be accessed quickly and efficiently to support their care. This means that citizens are not required to take any action to authorize the sharing of their data, and healthcare providers can access the necessary information without delay.
However, in the context of secondary use of health data, where data is used for research or public health purposes, an opt-in approach may be more appropriate to ensure that citizens have greater control over how their data is used. However, this may entail challenges for access to data for secondary use.
We agree to continue the discussion on this topic and defer our final considerations to a later date.

Minimum Data Categories

Article 33(1)(a) - electronic health data from EHRs, including the categories in Article 5 of this Regulation
Option 1 – keep current proposal from the Commission
· Electronic health data from EHRs Comment: All electronic health data from EHR system are included, both health data in an unstructured form and health data in a structured form.
Option 2 - amendment
· The priority categories listed in Article 5 of this Regulation Comment: Only the priority categories in Article 5 should are included.
Option 3 – other amendments
· Amendments you prefer
Analysis:
We agree with option 1.
The priority categories included in Article 5 are : (a) patient summaries; (b) electronic prescriptions; (c) electronic dispensations; (d) medical images and image reports; (e) laboratory results; (f) discharge reports, which my lead to restrict the definition of electronic health data and, for instance excluding data on lifestyle habits may limit the ability of researchers and healthcare providers to identify risk factors and develop targeted interventions to improve health outcomes.
The fact that priority categories are defined means that MS will be able to not include other categories if they are not available or are not considered adequate for cross border sharing.

Comments from the Slovak delegation

Comments of the Slovak Republic after the WPPH 6.-7. March

Examination of the first compromise for Chapter I

Examination of Articles 1 and 2 (2) letter o, u, v, x, aa, ab, ac, ad and ae

COMMENT: We have a clarification question about Article 1 (7): would the "public security, defence and national security" activities exclude also health-related data use associated with public health security, biological safety, and drugs/addictions. There is some overlap between health and security data activities which could be foreseeably constrained by Article 1 (7).

Continuing the examination of the first compromise for Chapter IV

Examination of Articles 48 and 49

COMMENT: We would like to thank the EMA for providing additional context for the importance of Articles 48 and 49 for the secondary data use for ensuring safe and effective care in the EU.

We support the deletion of Article 48 in the compromise version. The public sector bodies and Union institutions, bodies, offices and agencies should abide by the same requirements as other data users. Automatic access without the data permit and without cost-recovery fees could impose an unreasonable burden on the health data access bodies and data holders, if used without reasonable constraints by the public sector bodies and Union institutions.

- - - - - - - - - - -

COMMENT: We have a few clarification questions related to Article 49, which are ambiguous in the current proposal:

Can data holder refuse to process individual data application requests and defer this responsibility to the relevant national health data access body? If not, Article 49 would impose an unreasonably large administrative burden especially on smaller health data holders. Will the data catalogue contain information whether applicants can reach out to the health data access body or directly to the individual data holders?

Would individual health data holders also be required to provide the access to health data only through a secure processing environment (Article 50)? Would health data access body still be responsible for auditing health data users if they arranged their data access directly with the individual health data holders?

Continuing the discussion on specific topics related to the secondary use

The scope and the definitions on health data holder in Article 2(2)(y)

COMMENT: We generally support the addition of "health" to the definitions in the compromise version of Article 2. Nonetheless, in relation to Article 2 (2) (y), we would like to stress that the restriction of the definition of "health data holder", if the intent of the EHDS is to link datasets also from non-health data holders (*such as GIS and statistical determinants of health associated with income, employment, education, social services, pollution, crime, etc. as described in Article 33 (1)(b)).* The more restricted "health" data holder term in the compromise could constrain the ability of the health data access bodies to receive and process data from the non-health data holders, who might question whether the new regulation applies to them.

Examination of Articles 59, 60, 61, 62, 63, 64 and 65

COMMENT: For consistency throughout the document, we should consider whether the newly added "anonymous" in Article 60 and 61 should not be changed to "anonymized" or vice versa.

We do not support transfer of individual data to third countries outside of the secure processing environment, even in an anonymized form (as described in Article 61). This is especially relevant to genomic and other sensitive data, which utility and potential for misuse are not currently fully understood. Federated analyses should allow for secondary use of the health data within the EU Member States by qualified users from third countries. We are also concerned about the lack of reciprocity and lack of involvement / expertise transfer from the potential third country data users to the Member States, where the data holders reside.

If Article 63 refers primarily to the ability of Member States to provide additional restrictions to personal data transfer to third countries for primary use, its title could be modified to better reflect this intention and the Article could be numbered with a lower number, ahead of the preceding Articles referring to the secondary data use.

THE SCOPE AND DEFINITION OF HEALTH DATA HOLDER

Option 1 – Current scope and definition of health data holder with a clarification that also social security is included

Article 2(2)(y)

- '**health** data holder' means ~~any~~ natural or legal person, which is an entity or a body in the health or care sector, **including social security,** or performing research in relation to these sectors, as well as Union institutions, bodies, offices and agencies who has ~~the right or obligation, in accordance with this Regulation, applicable Union law or national legislation implementing Union law~~ **either:**
  a) **the right or obligation, in accordance with applicable Union law or national legislation, to process personal electronic health data for the provision of health or care or for public health, research, innovation, policy making, official statistics, patient safety or regulatory purposes, in its capacity as a controller; or**
  b) **the ability to make available, including to register, provide, restrict access or exchange electronic health data that do not constitute personal data in the meaning of Article 4 (1) of Regulation (EU) 2016/679**~~non-personal data~~, through control of the technical design of a product and related services, ~~the ability to make available, including to register, provide, restrict access or exchange certain data~~;

Option 2 – Narrowing the scope and definition of health data holder

Article 2(2)(y)

- '**health** data holder' means a~~ny~~ natural or legal person, which is an entity or a body in the health or care sector, **excluding social security,** or performing research in relation to these sectors, as well as Union institutions, bodies, offices and agencies who has ~~the right or obligation, in accordance with this Regulation, applicable Union law or national legislation implementing Union law~~ **either:**
  c) **the right or obligation, in accordance with applicable Union law or national legislation, to process personal electronic health data for the provision of health or healthcare as well as care of elder and persons with disabilities or for public health, research, innovation, policy making, official statistics, patient safety or regulatory purposes, in its capacity as a controller; or**
  d) **the ability to make available, including to register, provide, restrict access or exchange electronic health data that do not constitute personal data in the meaning of Article 4 (1) of Regulation (EU) 2016/679**~~non-personal data~~, through control of the technical design of a product and related services, ~~the ability to make available, including to register, provide, restrict access or exchange certain data~~;

COMMENT: We support the more restrictive Option 2 or Option 3 with a full exclusion of social services (also excluding elder care facilities). Slovakia does not have a unified system of health and social services. The data is not structured or linked on a national level. Making social services data available for the EHDS could be quite a long process, which could be challenging from legislative, technical, and administrative perspectives.

Option 3 – other amendments

THE SCOPE AND DEFINITION OF HEALTH DATA USER AND APPLICANT

The definition of health data user is central for the secondary use of electronic health data. The health data user are the entities who are able to process electronic health data for the secondary use purposes in Article 34. However, some purposes in Article 34 are reserved for public sector bodies and EUI, see Article 35(2).

COMMENT: Please, refer to our comments about Article 2(2)(y) above.

Option 1 – Current scope and definition of health data user and the scope of applicant

Article 2(2)(z)

- '**health** data user' means a natural or legal person who has lawful access to ~~personal or non-personal~~ electronic health data for secondary use **pursuant to a data permit in Article 46 or a data request in Article 47 of this Regulation**

Article 45(1) and 47(1)

- A natural or legal person may submit…

Option 2 – Limiting the scope and definition of health data user and the scope of applicant

Article 2(2)(z)

- '**health** data user' means a natural or legal person **within the jurisdiction of a country or an international organisation which is an authorised participant of the cross border infrastructure for secondary use in Article 52,** who has lawful access to ~~personal or non-personal~~ electronic health data for secondary use **pursuant to a data permit in Article 46 or a data request in Article 47 of this Regulation**

Article 45(1) and 47(1)

- A natural or legal person, **within the jurisdiction of a country or an international organisation which is an authorised participant of the cross border infrastructure for secondary use in Article 52,** may submit…

Comment: This option would limit the scope of potential health data users and applicants to ensure reciprocity and equal terms for the sharing of electronic health data for secondary use purposes in relation to the cross-border infrastructure. These entities would still need to fulfil the requirements in Articles 46 and 47 et cetera.

COMMENT: We support Option 2 and the intent to promote reciprocity with third country health data users.

Option 3 – other amendments

Comments from the Spanish delegation

Spain's comments on Chapter IV (and extracts of Chapter I) of the Proposal for a Regulation of the European Parliament and the Council on the European Health Data Space

IMPORTANT:

Unless explicitly stated otherwise,

comments in this document refer exclusively to the secondary use of health data,

not to primary use of health data

Glossary and notes

- *the terms **'anonymous (health) data'** and **'non-personal (health) data'** are used interchangeably in these comments. Anonymous dada is define in recital (26) of the GDPR as '…information which does not relate to an identified or identifiable natural person or to personal data rendered anonymous in such a manner that the data subject is not or no longer identifiable (…) To ascertain whether means are reasonably likely to be used to identify the natural person, account should be taken of all objective factors, such as the costs of and the amount of time required for identification, taking into consideration the available technology at the time of the processing and technological developments.'*
- *the term **'current text'** refers to the current compromise proposal of the presidency of the Council at the time of the writing (2023-03-13), i.e. documents 5302/23 and 6627/23 of interinstitutional file 2022/0140(COD) published on the Delegates Portal.*
- ***EHDS** = (proposal for a Regulation of the) European Health Data Space*
- ***SPE** = secure processing environment (defined in article 50 EHDS).*
- ***COM** = EU Commission*
- ***HDAB** = health data access body (defined in articles 36-39 EHDS).*
- ***MS** = Member States*
- ***TFEU** = Treaty of Functioning of the European Union*

General comments

Waiving of opt-in/consent and opt-out

Spain's position

We prefer the waiving consent, opt-in and opt-out, i.e. keeping the text similar to the original proposal of the Commission. We thus propose to keep article 37(6) in the current text as-is.

Justification

1) We believe that the necessary security measures are already in place in the proposal of the presidency of the Council, which justify waiving of consent/opt-in and opt-out in the context of the secondary use of personal data within the EHDS. These security measures are the following:

In the case of a data request (art 47), only anonymized data is provided to the data user. The data user never has access to pseudoanonymized data within the secure processing environment (SPE), or otherwise.

In the case of a data access application (art 45) which leads to a data permit (art 46),
- the data access request must only include the data categories of article 33,
- the data access request has to include the purposes of article 34,
- the data access request must not incur in the prohibited uses of article 35,
- the data user can only export anonymous data from the SPE per article 50(2),
- if there is access to pseudoanonymized data within the SPE, the data access request can be subject to an analysis by a clinical ethics research committee in line with national law, as stated in article 45(4)(b). We believe that this should be extended to anonymized data too (see our "Comments on ethical principles in anonymous health data" below).

2) The actual implementation of opt-out at the national level is highly costly, problematic and is likely to be unreliable in certain datasets.

In particular,
- if opt-out is managed at the HDAB level (general opt-out or purpose-specific opt-out), the HDAB needs to store the status of opt-out for all data subjects in the country and manage the changes therein (i.e. a data subject may change their preferences for opt-out at any time). Then, the HDAB would need to be able to identify each data subject in any dataset used for the provision of information through a data access application (article 45 EHDS) or a data request (article 47 EHDS), in order to decide whether to exclude this data subject's data from the dataset or not. Thus, all datasets in the country would need to include a reference to a national identifier, which could be then linked to the opt-out status of each particular data subject. Also, from a practical point of view, this would also require all secure processing environments (SPEs) in the MS to have a connection to an opt-out verification service provided by the HDAB.

Note: Why can there be several SPEs in a MS? As confirmed by COM in the working party of 2023-02-23, per article 50(1), a MS can have one HDAB and several SPEs. This makes sense since MS already have a significant investment in infrastructure for data processing purposes, which includes supercomputing environments or specialized computing environments for certain data categories, such as genomic or genetic data. Also, for large data holders (even if they are not HDABs) it would make sense to have SPEs for internal and external data users. Also, a MS can have several HDABs per article 36(1).

- If opt-out is introduced at the data holder level, data subjects would need an agile mechanism for opt-out at each data holder, and there may be tens of thousands of data holders in each MS. This would put an additional administrative burden on data holders (which would need to implement this "opt-out from the EHDS service"), but also on data subjects, which would need to contact *each* data holder that may have their data to opt-out from the system.

In both situations, if the patient was misidentified (which sometimes happens, due to administrative errors) at the data holder level or at the HDAB opt-out management system, his/her opt-out decisions would not be taken into account, leading to legal risks for the data holder and the HDAB.

Given the above, an opt-out mechanism would be very costly to implement in most countries.

Reduction of tasks of HDABs in the EHDS

We believe that the mandatory tasks of HDABs (article 37) should be kept to a minimum. This regulation should aim to establish general objectives for HDABs, but not go into the maximum level of detail when explaining their tasks.

Proposal for flexibility of pseudoanonymization and anonymization policies at the national level

The decision on the executing actors and means of pseudoanonymization and anonymization should be a national decision. In the current text (article 37(1)(d) and article 44), these tasks are a responsibility of the HDAB. We believe that, in some cases, these actions could be delegated on specific data holders (for instance, in the case article 49 access to electronic health data from a single data holder) or trusted third parties. We thus propose a different wording of articles 37(1)(d) and article 44:

Justification

There is a significant diversity between MS in their governance model of health data. Some MS may want to apply centralized pseudoanonymization and anonymization policies at the HDABs only. Others may wish to follow a more decentralized approach.

Support for existing wording on single data holders and proposal for delegation of tasks of HDABs

The decision on the handling and existence of single data holders should be a national decision. We thus support the current wording of article 49 (access to electronic health data from a single data holder). However, in these cases, MS should also be able to delegate some (or all) tasks of the HDABs to certain data holders.

Justification

There is a significant diversity between MS in their governance model of health data. It thus a good idea to allow MS to decide if they want to allow single data holders.

Proposal for ethical assessment in access to anonymous health data (Article 45(4))

In the current text, as stated in article 45(4)(b), only when information is accessible is pseudoanonymized format within the SPE, the data access application can be subject to a review based on ethical principles. However, even when data is accessed in anonymous format, unethical usage may occur. For instance, an anti-immigrant association, which could be a data user, could request aggregated (and well-anonymized) data on certain ethnic groups in a very specific way, to show that certain ethnic groups consume more health resources (without taking into account certain confounding variables), which could lead to an unethical use of these results. One solution to avoid this situation would be to prohibit the usage of ethnic groups in the context of the EHDS. However, there are legitimate uses for this variable. For instance, persons of different race and ethnicity react differently to certain medicinal products[1]. Thus, ethnic groups could have a legitimate use in healthcare research. We believe that in cases such as this one, the decision on the ethical risks of certain data access applications (or data requests) must be done by a clinical ethics research committee.

We thus believe that ethical principles should be reviewed not only in the context of usage of pseudoanonymized health data, but also anonymous (non-personal) health data. We thus propose a modification of article 45(4) in that regard (yellow background, underlined):

"4.Where the applicant intends to access the personal electronic health data in a pseudonymised format or non-personal data, the following additional information shall be provided together with the data access application:
(a) a description of how the processing would comply with Article 6(1) of Regulation (EU) 2016/679;
(b) information on the assessment of ethical aspects of the processing, where applicable and in line with national law."

Note: Why are we doing this review of ethical principles at the national level? Why not apply "universal" or EU-wide ethical principles? Because the functioning of clinical ethics research committee at the MS level are a national competence as per article 168(7) TFEU. It would be thus challenging to introduce common legally-binding criteria in the EHDS text.

[1] For example, see: Burroughs, V. J., Maxey, R. W., & Levy, R. A. (2002). Racial and ethnic differences in response to medicines: towards individualized pharmaceutical treatment. *Journal of the National Medical Association*, *94*(10 Suppl), 1. URL: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2594139/

Proposal for merging of data access application (article 45), data permit (article 46) and data request (article 47)

In the current text, the data request (article 47) can have a very high complexity, i.e. a data user can request data on the aggregated number of COVID-19 deaths, which would be fine. However, other data requests can be much more complex and thus much more demanding for the HDAB. For example: "number of COVID-19 deaths of natural persons with certain social determinants, who had 3 or more prior emergency care admissions in the last 5 years with a chief complaint of hypoxia, and certain comorbidities diagnosed in the last 2 years: type II diabetes, etc". The latter data request, while probably interesting, would require very significant resources since it would involve very complex processing of data by the HDAB.

Following the suggestion of HU, we believe that merging data access permit (article 46) and data request (article 47) could help to handle these situations in a more realistic manner.

The idea would be:
- for an HDAB to only receive data access applications (article 45), not data requests.
- an HDAB then decides if to answer with a data access permit (article 46) or with an anonymized (most likely aggregated) answer (which would be equivalent to an answer to a data request in article 47).

Ideas about fees (article 42)

1) Consulting fees are excluded from the EHDS fees right now.
However, consultants are needed for several purposes of the EHDS regulations, for example:
- as stated by Finland, for the practical discoverability of health data, consultants are needed. Why? Because even if the dataset catalogue envisioned in article 55 functions well, it does not provide sufficient information for most data users. Here, a consulting service at the HDAB would be very important, in order to help identify the datasets that would be most beneficial for a data user (examples: hospitals A, B and C -but not D- use a similar data model for their EHRs, and a similar coding system for diagnoses.
- article 37(1)(d) requires consultants with expertise in pseudoanonymization and anonymization.
- article 37(1)(i) requires consultants with AI knowledge.
- et cetera

Right now, the fee structure in article 42(1) is copied from the Data Governance Act (Regulation EU 2022/686) and that fee structure does not include consulting fees. The fee structure in EHDS should be changed to include consulting fees.

2) The general approach to fees is a very challenging aspect of the EHDS: if fees are too high, only certain data users (such as large pharmaceutical companies) would benefit from the system. If the fees are too low, HDABs and data holders would be overflown with data access applications/data requests (not all of which would be producing useful results).

We propose to take the following ideas into account, stated by PT, IT and ES (among other delegations) during the meetings of the EU Council:
- The fees should be dependent on the purposes of article 34(1). For instance, article 34(1)(f) -i.e. development of products and services- could have the highest level of fees.
- The fees should have a baseline cost, which could be increased depending on the budget of the data user.
- The fees as data user could be dependent on the fees charged as data holder.
- When the data is used for the purposes of article 34(1)(f) -i.e. development of products and services- returns could be generated for data holders and/or the public sector as a whole (for example, if a pharmaceutical company develops a new medicinal products with data obtained through the EHDS with public-sector information, a discount could be generated for this medicinal product when sold to the public sector).

Ideas about penalties by HDABs in case of non-compliance (article 43)

Similarly to GDPR article 83, general conditions for imposing fines (such as maximum penalties) can be defined at the EU level in the EHDS. However, anything outside of these conditions must be defined in the national law of the Member States (similarly to GDPR article 84).

Proposal for the enhancement of the role of the Commission in the context of EHDS

1) We propose a modification of article 52(10) in the following manner:
"10. Where requested by two or more health data access bodies, the Commission ~~may~~ shall provide a secure processing environment for data from more than one Member State compliant with the requirements of Article 50. (…)"

Justification

We believe that the Commission must ("shall" instead of "may") provide an SPE for multi-country studies for several reasons:
(i) The obligation of providing an SPE for multi-country studies by the Commission would imply no obligations for the MS. The Commission's SPE would only become available upon request by the MS. i.e. if no MS requests this, the SPE will not be available. Alternatively, if one MS does not want to share data through the Commission's SPE, it will not send this request.

(ii) This approach would be efficient for the EU budget. In multi-country studies involving many MS, it would be more efficient to count on a single SPE.
(iii) This approach could be more cost-efficient for data users, as for certain multi-country data access applications/data requests they would have to pay for a single SPE, instead of several SPEs.

2) We propose a modification of article 36(1) in the following manner:
"1. Member States and the Commission shall designate one or more health data access bodies (…)"

We believe that the Commission should have a Health Data Access Body for several reasons:
(i) The Commission's HDAB would involve no obligations for MS. If the COM's HDAB receives an application for data of a MS, it would simply forward the application to that MS. It would not do anything else.
(ii) Union institutions hold a large amount of relevant health data, which could be reused for the purposes stated in article 34(1) EHDS. More of these data repositories at current and new Union institutions will become available with the advancement of the EU integration process. It would be a good idea to provide a "single point of entry" for data access applications / data requests at the EU level. This point of entry could be an HDAB at the Commission level.
(iii) The existence of this additional HDAB would not increase the EU budget in a significant manner and could actually increase the efficiency of the system (for example, by avoiding several requests to single data holders).

If an HDAB at the Commission level is created, article 49(1A) becomes unnecessary and can thus be deleted, i.e.
~~1A. Where an applicant request access to electronic health data from health data holders which are an Union institution, body, office or agency, by way of derogation from Article 45(1) or Article 47(1), that applicant shall file a data access application or a data request directly to each health data holder. The data access application shall comply with the requirements set out in Article 45 and the data request shall comply with requirements in Article 47.~~

3) The MS have reporting requirements in article 39. Similarly, COM should also have reporting requirements about its HDAB.

4) In the proposal, COM also operates the central interoperability platform for HealthData@EU (article 52(9)). These horizontal services provided to the MS should be subject to Service Level Agreements (SLAs).
Therefore, we propose to add the following sentence at the end of article 52(9):
"The Commission shall develop, deploy and operate a (…) The provision of the aforementioned services by the Commission shall be subject to Service Level Agreements."

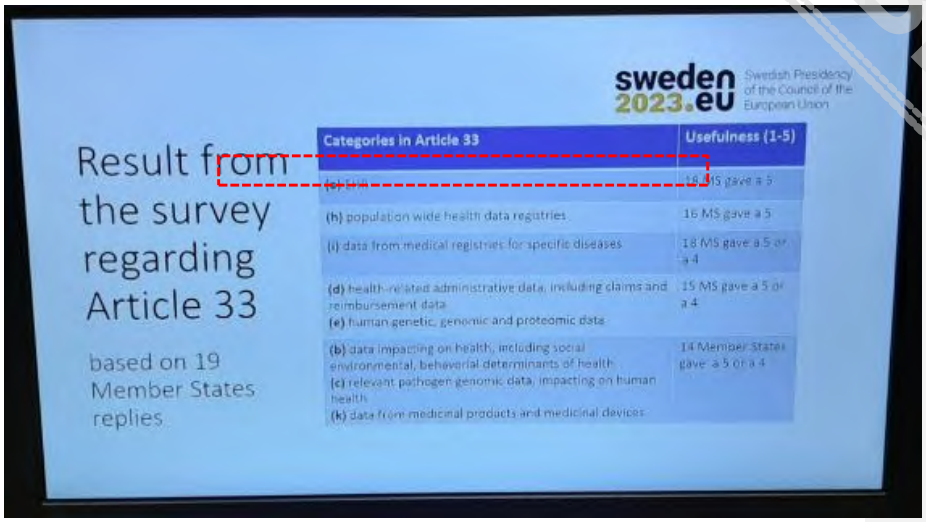
The problems of linking article 33(1)(a) and article 5(1)

On the topics discussed during the working party of 2023-02-24 was the linkage of article 33(1)(a) with the data categories of article 5(1). This was discussed in the following item of the agenda:

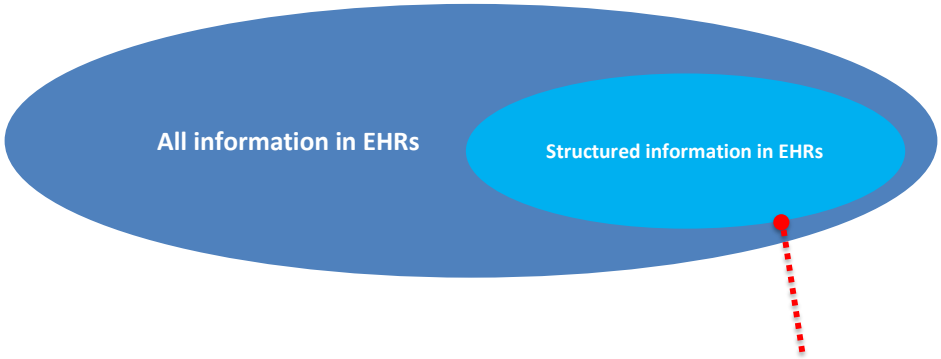
> **No 2. Article 33(1)(a) - electronic health data from EHRs, including the categories in Article 5 of this Regulation**
>
> **Option 1 – keep current proposal from the Commission**
>
> - Electronic health data from EHRs
>
> Comment: All electronic health data from EHR system are included, both health data in an unstructured form and health data in a structured form.
>
> **Option 2 - amendment**
>
> - The priority categories listed in Article 5 of this Regulation
>
> Comment: Only the priority categories in Article 5 should are included.
>
> **Option 3 – other amendments**
>
> - Amendments you prefer

Here, it would be important to clarify several aspects:

1) In the survey sent by the Presidency of the Council to the MS, data from EHRs was identified as the most relevant data category for the secondary use of health data (18 MS rated it in the highest category of usefulness):



However, limiting article 33(1)(a) just to the data categories of article 5(1) would leave this data category almost devoid of content. In fact, this approach would leave significantly less than 1% of the content of an EHR. A detailed explanation on the matter is available at the end of this document.



2) There is much more structured information in EHR systems than the data categories of article 5(1).

3) Unstructured information in EHRs should not be discarded. EHRs information in unstructured format can be very useful. In fact, unstructured can be converted into a structured format using a variety of technologies such as pattern matching, automated coding and natural language processing (NLP) technologies and other AI technologies. The latter have seen strong advances in the last years. Although there are still many issues to be solved, the current results with the processing of clinical information in free information in EHRs is very promising. As an example, we can have a look at this recent article[2]:

> *Hirosawa, T., Harada, Y., Yokose, M., Sakamoto, T., Kawamura, R., & Shimizu, T. (2023). Diagnostic Accuracy of Differential-Diagnosis Lists Generated by Generative Pretrained Transformer 3 Chatbot for Clinical Vignettes with Common Chief Complaints: A Pilot Study. International Journal of Environmental Research and Public Health, 20(4), 3378.*

Full-text available at: https://pubmed.ncbi.nlm.nih.gov/36834073/

Abstract

The diagnostic accuracy of differential diagnoses generated by artificial intelligence (AI) chatbots, including the generative pretrained transformer 3 (GPT-3) chatbot (ChatGPT-3) is unknown. This study evaluated the accuracy of differential-diagnosis lists generated by ChatGPT-3 for clinical vignettes with common chief complaints. General internal medicine physicians created clinical cases, correct diagnoses, and five differential diagnoses for ten common chief complaints. The rate of correct diagnosis by ChatGPT-3 within the ten differential-diagnosis lists was 28/30 (93.3%). The rate of correct diagnosis by physicians was still superior to that by ChatGPT-3 within the five differential-diagnosis lists (98.3% vs. 83.3%, $p = 0.03$). The rate of correct diagnosis by physicians was also superior to that by ChatGPT-3 in the top diagnosis (53.3% vs. 93.3%, $p < 0.001$). The rate of consistent differential diagnoses among physicians within the ten differential-diagnosis lists generated by ChatGPT-3 was 62/88 (70.5%). In summary, this study demonstrates the high diagnostic accuracy of differential-diagnosis lists generated by ChatGPT-3 for clinical cases with common chief complaints. This suggests that AI chatbots such as ChatGPT-3 can generate a well-differentiated diagnosis list for common chief complaints. However, the order of these lists can be improved in the future.

Keywords: AI chatbot; artificial intelligence; clinical decision support; diagnosis; diagnostic accuracy; generative pretrained transformers; natural language processing.

This recent article shows the potential of unstructured data processing of with just clinical information available on the Internet. The accuracy of such systems could be significantly increased with clinical information available in EHRs in free text format.

[2] This article is provided as an example for purely illustrative purposes. There are many more articles on the topic.

Given the above, it would be advisable to avoid restricting article 33(1)(a) only to the data categories of article 5(1) or even to structured data only.

4) Is this approach better from an implementability point of view? Even though this approach may seem simpler from a technical perspective for certain data holders, this is untrue in the general context of article 33.

Why does it seem simpler for certain data holders? Because, it would be possible to design a technical interface for primary uses defined in article 5(1) and this same interface could, in theory, also be used for secondary use in article 33(1)(a). However, from a technical point of view, for many data holders it would be actually easier to provide the information of EHRs as-is[3].

Also, a data request may be for several data categories at once (not just 33(1)(a)). For example, many EHRs contain information about genetic markers (art 33(1)(e)) and environmental factors (art 33(1)(b)) and relevant pathogen genomic data (art 33(1)(c)), as well as other data categories. The restriction of article 33(1)(a) to the data categories article 5(1) would lead to a situation where a data holder has to provide the information of EHRs in the structured formats of article 5(1) and other data for other data categories in other formats. Thus, also for this reason, in most cases, it would be much easier for the data holder to provide all the data together, as-is, without applying transformations at the data holder level (it would then be examined by an HDAB, filtered, etc before providing it to the data user).

Also, generally speaking, it would be much easier for a data user to provide raw data to the HDAB (which would require no transformation of thereof) than to provide a Patient Summary document with structured formats, fields and valuesets in the commonly-agreed clinical terminologies at the EU level.

[3] For instance, let's say that for primary use of health data interfaces are defined based on the HL7 FHIR technical interoperability protocol. This will take a very long time to do, as many MS use *other* exchange formats in the context of primary use, and large-scale access to data (required in the context of secondary use of health data) through FHIR interfaces is actually quite problematic. So, from a technical point of view, it would often be much easier for the data holder to provide the datasets in the format they already have.

5) There are also significant problems for the data users:
   - Very often, the data in art 33(1)(a) is the "linking glue" with the rest of the data categories of this same article. Thus, if this data category is so significantly reduced (by restricting it to the data categories of art 5(1)), the data will be useless for the data user in many instances.
   - As explained in more detail in the next pages, the data provided though the technical interfaces for primary use of health data is rather limited for the secondary use of health data.

6) Restricting article 33(1)(a) to the contents article 5(1) could create unforeseen consequences in the legislative process and further modifications of the EHDS Regulation, or its development through delegated and implementing acts. For example, if Annex I was modified, it would affect both primary and secondary use of healthcare data.

   More importantly, transitionary periods for primary and secondary use of health data may be different. So, some data users may find themselves in a situation where they have to comply with secondary use requirements without having completed the implementation of primary use.

   In the EHDS, primary and secondary uses of health data have different purposes, requirements and scope. This is why these topics are treated in different chapters (Chapters II and III for primary use; Chapter IV for secondary use) and, in the proposal of the Commission, only share certain governance aspects (Chapter VI).

7) Leaving this to a national decision (the baseline is art 33(1)(a) restricted to the contents of art 5(1) but some MS may decide to share all data from EHRs), this, similarly to a lack of harmonization regarding opt-in/opt-out in the secondary use of health data, creates a lack of reciprocity between MS. Some MS would be able to share significantly more information if they keep the original wording of art 33(1)(a), while others would share much less. This would create a clear disincentive for making data available within the EU between MS.

Why would the linkage between article 33(1)(a) just to the data categories of article 5(1) would leave this data category almost devoid of content (this approach would leave significantly less than 1% of the content of an EHR)?

We can examine Annex I of the EHDS Regulation, which defines the main characteristics of electronic health data categories:

Electronic health data category	*Main characteristics of electronic health data included under the category*
1.Patient summary	*Electronic health data that includes important clinical facts related to an identified person and that is essential for the provision of safe and efficient healthcare to that person. The following information is part of a patient summary:* *1.Personal details* *2.Contact information* *3.Information on insurance* *4.Allergies* *5.Medical alerts* *6.Vaccination/prophylaxis information, possibly in the form of a vaccination card* *7.Current, resolved, closed or inactive problems* *8.Textual information related to medical history* *9.Medical devices and implants* *10.Procedures* *11.Functional status* *12.Current and relevant past medicines* *13.Social history observations related to health* *14.Pregnancy history* *15.Patient provided data* *16.Observation results pertaining to the health condition* *17.Plan of care* *18.Information on a rare disease such as details about the impact or characteristics of the disease*
2.Electronic prescription	*Electronic health data constituting a prescription for a medicinal product as defined in Article 3(k) of Directive 2011/24/EU.*
3.Electronic dispensation	*Information on the supply of a medicinal product to a natural person by a pharmacy based on an electronic prescription.*
4.Medical image and image report	*Electronic health data related to the use of or produced by technologies that are used to view the human body in order to prevent, diagnose, monitor, or treat medical conditions.*
5.Laboratory result	*Electronic health data representing results of studies performed notably through in vitro diagnostics such as clinical biochemistry, haematology, transfusion medicine, microbiology, immunology, and others, and including, where relevant, reports supporting the interpretation of the results.*
6.Discharge report	*Electronic health data related to a healthcare encounter or episode of care and including essential information about admission, treatment and discharge of a natural person.*

The categories "1.Patient summary" and "6.Discharge report" (which has been changed to "inpatient discharge reports" in the proposal of the Presidency of the Council) would be the closest link to article 33(1)(a).

In particular, "1.Patient summary" seems to include a lot of potentially useful information. However, this is untrue for the following reasons:

- The patient summary is, as its name says, a summary. It omits a significant amount of clinical information, such as the detailed historical evolution of a patient's conditions.

- Almost all of the fields listed in the table above are optional in practice. Let's see an example: a patient may or may not have allergies. Therefore, that field may be empty, though conformant with the technical specification. Now, from a technical point of view it is impossible to know with complete certainty if the patient actually did not have allergies or if that information was simply not provided in the Patient Summary document[4].

- In some Member States, such as Spain, the Patient Summary document is generated on-the-fly, pulling information from several data sources. In other countries, it should be generated manually by a healthcare professional who may or may not have the time and the incentive to do so in a timely manner (thus keeping the Patient Summary up to date). However, this patient will always have an updated EHR, with all historical information. Therefore, there will be much more information in EHRs than in Patient Summary documents.

In regards to both "1.Patient summary" and "6.Discharge report", the coding systems used in Patient summary and Discharge reports will be, to a large extent and due to legacy databases, administrative coding terminologies such as ICPC, ICD-9, ICD-10 and their variations[5]. Their usefulness for clinical research is limited. Therefore, even if the information is correctly provided in coded format, a significant part shall not be transmitted.

[4] From a technical point of view, it is possible to use a code for "information not available" and another code for "no information", but there is no reliable manner to know if this coding is accurate at the health provider level.

[5] A semantic note: manual coding of healthcare records in ICD-9 and ICD-10 (and their variations, such as ICD-9-CM, ICD-10-CM, ICD-10-PCS, etc) requires significant resources (5-50€ per coded report, perhaps more, depending on the MS and the complexity of the report). It is thus very costly to translate the historical information (millions of citizens with several of healthcare records each) into more modern, clinically rich terminologies such as SNOMED-CT. It is certainly possible to map ICD codes to SNOMED-CT (or other terminologies) automatically, but this would not add clinical information that was not included in the original ICD codes in the first place. For example, transforming a very generic ICD code would not produce a SNOMED-CT code with more information.

However, this information is considered sufficient for primary use (wherein the purpose is the direct delivery of healthcare to the patient), and provides healthcare professionals (most likely, the attending physician) with some notions about the main diagnoses, major surgical procedures, allergies, current medication, et cetera. In the context of primary use of health data, this information can be further complemented in the clinical interview with the patient and/or accompanying persons.

The data categories "2.Electronic prescription" and "3.Electronic dispensation" provide information about active prescriptions (i.e. not yet dispensed medications) and the dispensations of thereof. Therefore, no historical information is provided. Thus, these data categories are not very beneficial in the context of secondary use of data.

The actual data payload and definition of "4.Medical image and image report" and "5.Laboratory result" is yet being defined, but it will most likely follow a similar approach to the already implemented data catalogs, i.e. their purpose will be primary use, they will have few coded fields, with widely available terminologies which are already in use in the MS, which may not provide sufficient granularity and information richness for secondary use.

Proposal for reciprocity and guarantees of compliance with the EHDS principles by third countries and international organizations

1) Modification of article 2(2)(z)

*'health data user' means**, for secondary use of health data, a natural or legal person, within the jurisdiction of a country or an international organization which is an authorised participant of HealthData@EU** (...) pursuant to a data permit or a data request pursuant to this Regulation.*

Justification:

(i) EU Member States are already authorized participants in the HealthData@EU infrastructure, as stated in article 52(2). They are included in this wording.

(ii) With this wording, only data users from third countries or international organizations joining HealthData@EU would be authorized to perform data access applications and data requests.
In the primary use of healthcare data, third countries can only exchange data with the Member States (MS) if they join MyHealth@EU. With this change, we would apply the same criteria to the secondary use (i.e. third countries or international organizations willing to request data from MS must also do so joining the HealthData@EU infrastructure by means of the procedure described in article 52(5)).

(iii) This approach will encourage third countries to join HealthData@EU as a guarantee of reciprocity, which would be further developed in the implementing acts described in article 52(5).

(iv) international organizations (such as the WHO) can also request data from the Member States using the EHDS, but should also be encouraged to offer guarantees of reciprocity.

Note 1:
This modification (or, for the matter, the whole EHDS Regulation) does not modify the existing data flows between the Member States and international organizations, i.e. if a Member State already sends some data to some international organization, it can continue to do so. However, if the international organization wants to request some data from the Member State using the EHDS, then, it must also do so in conditions of reciprocity.

Note 2:
per article 2.1(a) of the compromise proposal, 'international organization' as defined in the GDPR, i.e.
'international organisation' means an organisation and its subordinate bodies governed by public international law, or any other body which is set up by, or on the basis of, an agreement between two or more countries.

2) Modification of articles 64 and 66
In these articles in must be clearly stated that third countries or international organizations joining MyHealth@EU:
- shall not have any decision power (including voting rights) in the governance entities defined in articles 64 and 66.

- may be invited to the meetings of these governance entities as observers, if decided by the Member States and the Commission.
It should be reiterated that the same criteria would also apply to any subgroups created in a temporary or permanent manner by the governance entities defined in articles 64 and 66.

Justification:
This must be explicitly stated in articles 64 and 66. If this is left to be defined in the rules of procedure of these governance groups (and those of their subgroups), this may be omitted later on, and could -eventually- lead to a situation where third countries and international organizations have more decision power that some Member States (this could -of course- be challenged as being contradictory with the EU treaties, but it is better to state this in a clear and non-ambiguous manner in the text of the EHDS to avoid governance confusions and to reinforce legal certainty).

3) Modification of article 66
(new paragraph) 'The Commission shall continuously monitor the compliance to Chapter IV of this Regulation by third countries and international organizations who are authorized participants in HealthData@EU and inform the Member States in a timely manner.'

(new paragraph) 'The Member States may unilaterally decide to disconnect a third country or international organization from HealthData@EU in cases of repeated non-compliance with Chapter IV of this Regulation.'

Justification:

There is a challenge with enforcement of misconduct for data users which are in third countries: it is hard to envisage how a Health Data Access Body located in a Member State could actually impose penalties on a misbehaving data user located in a third country. However, if this third country is part of HealthData@EU, if there are repeated misbehaviors by data users located in their jurisdictions, the whole country could be disconnected from the system. This would create a strong incentives for third countries to ensure the compliance of their data users with the requirements of the EHDS.

4) Modification in article 52.5

5. *Third countries or international organisations may become authorised participants where they comply with the rules of Chapter IV of this Regulation, **the transfer stemming from** **such connection complies with the rules in Chapter V of Regulation (EU) 2016/679** and **they** provide access to **health** data users located in the Union, on equivalent terms and conditions, to the electronic health data available to their health data access bodies. If authorised by the Member States, as envisioned in article 66(6), the Commission ~~may~~ shall 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.*

6. *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 and the Member States. 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.*

Justification:

It is important to emphasize the role of the Member States in:

(i) the compliance checks performed on third countries or international organizations.

(ii) the authorization for those third countries or international organizations to join HealthData@EU.

Note 1:

How would third countries joint HealthData@EU from a legal point of view? As envisioned in the Commission's proposal, the legal basis would be to use implementing decisions similar to those of the EU DCC for third countries: https://commission.europa.eu/strategy-and-policy/coronavirus-response/safe-covid-19-vaccines-europeans/eu-digital-covid-certificate/commission-implementing-decisions-equivalence-covid-19-certificates-issued-non-eu-countries_en

Note 2:

The audit process to allow third countries to join HealthData@EU will include the revision of legal, organizational, semantic and technical requirements (article 52.5), similarly to what has been done with third countries joining the EU DCC system.

As a summary, in this approach:

- MS define the specification of legal, organizational, semantic and technical requirements (third countries and international organizations have no voting power in defining them, as these would be defined in the governance entities defined in articles 64 and especially article 66),
- COM audits (checks for compliance) the third countries and international organizations,
- MS decide if they approve the results of these audits, and can even participate in the audits.

Note 3:

Regarding personal data protection in the relationship with third countries, we believe that the Commission's proposal is sufficient for the following reasons:

(i) a data user can only export data from the secure processing environment (art 50.2 EHDS).

(ii) a data user may access pseudoanonymized data within the secure processing environment (i.e. see the table with the pseudoanonymized data within the SPE). However, if this is allowed for third country users (this would be decided on a case-by-case basis), this could be considered an international data transfer, and thus article 63 EHDS would apply, i.e. additional restrictions may be imposed by the MS. (Actually, article 63 EDHS could be removed since it is almost a literal copy of article 9(4) GDPR, i.e. if article 63 EHDS was removed, article 9(4) GDPR would still apply and impose identical guarantees for the MS.)

5) Modification of article 42

(new paragraph)

'7. Data users from third countries or international organizations may be subject to different fees to those of the data users from Member States, allowing for a compensation of the full cost incurred in making health data available for secondary use. Such fees shall be transparent and proportionate.'

Justification:

For data users from Member States, data can be provided without covering all the costs of making data available (i.e. "at a loss", as a public service) for the HDABs and/or for the data holders.

However, for data users from third countries or international organizations, there should be the possibility for the fees to include in full the costs incurred in the provision of healthcare data for HDABs and data holders.

The justification would be as follows: the Member States participate in the investments for the EHDS infrastructure and obtain benefits from it as a whole, while third countries don't participate in this common investment.

Also, according to Finland's experience, the handling of data access applications by non-EU MS requires much more work. This is why FINDATA applies different fees to non-EEA applicants:

Extensive data permit	You may need an extensive data permit e.g. if one or more of the following is met: – The application concerns the data of more than 15 data controllers – The sampling description is modified at the initiative of the applicant after receiving the cost estimates, ie more than one round of cost estimates is required from one or more controllers – The applicant is established outside the EU or EEA.	3 000,00 EUR

Source: https://findata.fi/en/pricing/

Detailed comments on selected articles

IMPORTANT: Here, we do not re-iterate the comments already made in the general comments.

TEXT OF THE PROPOSAL	COMPROMISE TEXT AND SPAIN'S COMMENTS
Chapter I **General provisions**	
Article 1 **Subject matter and scope**	
1. This Regulation establishes the European Health Data Space ('EHDS') by providing for - rules, - common standards and practices, - infrastructures and a - governance framework … for the primary and secondary use of electronic health data.	1. This Regulation establishes the European Health Data Space ('EHDS') by providing for **common** rules, ~~common~~ standards ~~and practices~~, infrastructures and a governance framework ~~for~~ **with a view to facilitating access to electronic health data for** the **purposes of** primary and secondary use of ~~electronic health~~ **these** data. **Spain's comment:** ok
2. This Regulation: (a) strengthens the rights of natural persons in relation to the availability and control of their electronic health data; (b) lays down rules for the placing on the market, making available on the market or putting into service of electronic health records systems ('EHR systems') in the Union;	2. This Regulation: ~~(a)~~ ~~strengthens~~ **specifies and complements, in Chapter II,** the rights **laid down in the Regulation (EU) 2016/679** of natural persons in relation to **primary use** ~~the availability and control~~ of their **personal** electronic health data; ~~(b)~~ lays down, **in Chapter III, common** rules for ~~the placing on the market, making available on the market or putting into service of~~ electronic health records

TEXT OF THE PROPOSAL	COMPROMISE TEXT AND SPAIN'S COMMENTS
	systems ('EHR systems') **and wellness applications that claim interoperability with EHR systems** in the Union **for primary use**;
	~~(c)~~ lays down**, in Chapter II and IV, common** rules and mechanisms ~~supporting~~ **for primary and** secondary use of electronic health data;
(c) lays down rules and mechanisms supporting the secondary use of electronic health data;	~~(d)~~ establishes a ~~mandatory~~ cross-border infrastructure enabling the primary use of **personal** electronic health data across the Union **according to Chapter II**;
(d) establishes a mandatory cross-border infrastructure enabling the primary use of electronic health data across the Union;	~~(e)~~ establishes a ~~mandatory~~ cross-border infrastructure for the secondary use of electronic health data **according to Chapter IV**;.
(e) establishes a mandatory cross-border infrastructure for the secondary use of electronic health data.	~~(f)~~ establishes governance and coordination on national and European level for both primary and secondary use of electronic health data.
	Spain's comment: Ok
3.This Regulation applies to:	3. ~~This Regulation applies to:~~
(a) manufacturers and suppliers of - EHR systems and - wellness applications placed on the market and put into service in the Union and the users of such products;	~~(g) manufacturers and suppliers of EHR systems and wellness applications placed on the market and put into service in the Union and the users of such products;~~ **Spain's comment:** (a) manufacturers, **authorized representatives, importers and distributors** of - EHR systems and - wellness applications placed on the market and put into service in the Union and the users of such products; Justification

TEXT OF THE PROPOSAL	COMPROMISE TEXT AND SPAIN'S COMMENTS
	It should be clear that all economic operators of Chapter III are included in the scope of the Regulation. Question about this provision: COM has been very insistent in its previous explanations that the requirements are for software vendors, not for healthcare professionals. However, let's suppose a healthcare professional does not use software approved in this Regulation. **Would this have a similar legal liability to a healthcare professional who uses an unauthorized medical device?**
(b) controllers and processors established in the Union processing electronic health data of - Union citizens and - third-country nationals legally residing in the territories of Member States;	~~(b) controllers and processors established in the Union processing electronic health data of Union citizens and third-country nationals legally residing in the territories of Member States;~~ **Spain's comment:** (b) controllers and processors established in the Union processing electronic health data of - Union citizens and - third-country nationals ~~legally~~ residing in the territories of Member States; Justification: In our healthcare systems we sometimes process data from people who are not legal residents in the EU Member States, but who are still provided healthcare services for a variety of reasons (legal provisions, social integration services, charities, etc). We thus believe that their data should be in the scope of the Regulation. Also, from a practical perspective, it would be rather challenging to filter out illegal residents from certain clinical datasets, or in the context of certain healthcare providers (for example, insurance status is usually registered by healthcare providers, but this does not necessarily map to residency status).
(c) controllers and processors established in a third country that has been connected to or are interoperable	~~(c) controllers and processors established in a third country that has been connected to or areinteroperable~~

TEXT OF THE PROPOSAL	COMPROMISE TEXT AND SPAIN'S COMMENTS
with MyHealth@EU, pursuant to Article 12(5);	~~with MyHealth@EU, pursuant to Article 12(5);~~ **Spain's comment:** (c) ~~controllers and processors~~ **data holders and data users** established in a third country that has been connected to or are interoperable with MyHealth@EU, pursuant to Article 12(5); Justification: The terminology for third countries must be aligned with entities residing in the EU. Also, the concept of "data holder" needs to be clarified. **Please, see our comments for article 2(2) letter (y)**
(d) data users to whom electronic health data are made available by data holders in the Union.	~~(d) data users to whom electronic health data are made available by data holders in theUnion.~~ **Spain's comment:** (d) data users to whom electronic health data are made available by data holders in the Union **or third countries or international institutions**. Justification: "Data holders" may be located in third countries or may be part of international institutions. They must be included in the scope of the Regulation.
	3A This Regulation shall be without prejudice to Regulations (EU) 2016/679, (EU)2018/1725, (EU) No 536/2014 and Directive 2022/58/EC. **Spain's comment:** 1) We believe that this should be a reference to Directive 2002/58/EC (

TEXT OF THE PROPOSAL	COMPROMISE TEXT AND SPAIN'S COMMENTS
	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02002L0058-20091219) Why is a reference to the Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications) included here? Which part of this directive would apply in the context of the EHDS Regulation? Which would be the implications? 2) Question about this provision: In regards to the Clinical Trial Regulation (EU) No 536/2014… In the context of secondary data use of the EHDS, in the case of clinical trial (CT) data, it would be very important to clarify the interpretation of the need for consent of art 28(2) of Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:02014R0536-20220131&from=EN) Specifically, the "Question and Answers on the interplay between the Clinical Trials Regulation and the General Data Protection Regulation" (https://health.ec.europa.eu/system/files/2019-04/qa_clinicaltrials_gdpr_en_0.pdf), on its page 9, states *"On the other hand if the aim of using the data for further research outside the protocol of the CT arises after the clinical trial has been completed, the sponsor must go back to the data subjects for specific consent."* Therefore, for secondary use cases, if the data comes from a finished clinical trial, there seems to be a clear need for consent from each data subject. Generally speaking, we believe that clinical trial data should be excluded from the scope of the EHDS proposal for the following reasons: - Data from clinical trials (*) are usually linked to trade secrets and intellectual property. This would make them hard to share

TEXT OF THE PROPOSAL	COMPROMISE TEXT AND SPAIN'S COMMENTS
	through the EHDS mechanism. - If we use text of the Commission, we would be creating contradicting legislation: in EHDS clinical trials would not require consent, but in the Clinical trials Regulation -i.e. Regulation (EU) No 536/2014- they would require consent. So, it would be unclear what to do. - If we use the Presidency's text… the interpretation would be: all data categories of article 33 do not require consent, but clinical trials do. - Now, with this framework, let's imagine what would happen if one large pharmaceutical company requested clinical trial data from another large pharma company. The HDAB could approve the data access request or deny it. In any case, what would happen? There would be a trial, and the HDAB would be potentially liable for damages to one or both pharmaceutical company. (*) Here we mirror the questions comments by FI, related to data from clinical trials. o What is meant by electronic data from clinical trials? Clinical trial reports (CTR), patient level data (PLD), raw data or something else. o It's important to understand that clinical trial results (in the form of the clinical trial report CTR) are aggregated data, and not patient level data (PLD). Both the CTR and PLD are commercially confidential information (CCI) and ownership of the data holders - this cannot be mandated by a regulation to be transferred to public bodies, as indicated in Art 33 (4) for the purposes specified in Art 34. Such mandatory requirement would be detrimental for the attractiveness of pharmaceutical industry to invest in clinical trials conducted within the EU area. Currently, even the European Medicines Agency EMA cannot access the PLD from clinical trials, but only the CTRs, submitted as part of the marketing authorisation applications, with the exception of rare cases. o Needs to be clarified both in terms of definitions and the practical process. Clinical trials are subject to their own extensive regulation, how do they fit together?
4. This Regulation shall be without prejudice to other Union legal acts regarding - access to, - sharing of or	4. This Regulation shall be without prejudice to other Union legal acts regarding access to, sharing of or secondary use of electronic health data, or requirements related to the processing of data in

TEXT OF THE PROPOSAL	COMPROMISE TEXT AND SPAIN'S COMMENTS
- secondary use of electronic health data, or - requirements related to the processing of data in relation to electronic health data, in particular - Regulations (EU) 2016/679, (EU) 2018/1725, […] [Data Governance Act COM/2020/767 final] and […] [Data Act COM/2022/68 final].	relation to electronic health data, in particular Regulations ~~(EU) 2016/679, (EU) 2018/1725,~~ **(EU) 2022/868**[…] ~~[Data Governance Act COM/2020/767 final],~~ and […] [Data Act COM/2022/68 final].
5. This Regulation shall be without prejudice to Regulations (EU) 2017/745 and […] [AI Act COM/2021/206 final], as regards the security of medical devices and AI systems that interact with EHR systems.	5. This Regulation shall be without prejudice to Regulations (EU) 2017/745, **(EU) 2017/746** and […] [AI Act COM/2021/206 final], as regards the security of medical devices and AI systems that interact with EHR systems.
6. This Regulation shall not affect the rights and obligations laid down in Union or national law concerning data processing for the purposes of reporting, complying with information requests or demonstrating or verifying compliance with legal obligations.	6. This Regulation shall not affect the rights and obligations laid down in Union or national law concerning health data processing for the purposes of reporting, complying withinformation requests or demonstrating or verifying compliance with legal obligations.
	7. This Regulation shall not apply to activities concerning public security, defense and national security. **Spain's comment:** Generally speaking, we welcome this change. Would this mean that all military medicine data is excluded from the scope of the Regulation? For instance, data such as numbers of hospital beds in military hospitals would be available or not?
TEXT OF THE PROPOSAL	**COMPROMISE TEXT AND SPAIN'S COMMENTS**
Article 2	Definitions in Article 2(2)(d),(f)-(n) and (p)-(t) are not

TEXT OF THE PROPOSAL	COMPROMISE TEXT AND SPAIN'S COMMENTS
Definitions	included in this compromise
1.For the purposes of this Regulation, following definitions shall apply:	1. For the purposes of this Regulation, following definitions shall apply:
(a) the definitions in Regulation (EU) 2016/679;	(a) the definitions of 'personal data', 'processing', 'pseudonymisation', 'controller', 'processor', 'third party', 'consent', 'genetic data', 'data concerning health', 'supervisory authority', 'international organisation' of the in Regulation (EU) 2016/679; **Spain's comments:** - It would be important to include the definition of anonymous data (*recital (26) of the GDPR*). - In GDPR, 'supervisory authority' means an independent public authority which is established by a Member State pursuant to Article 51 GDPR; The current text of the EHDS compromise proposal should be carefully reviewed to ensure that 'supervisory authority' does not have a different meaning in the context of the EHDS.
(b) the definitions of 'healthcare', 'Member State of affiliation', 'Member State of treatment', 'health professional', 'healthcare provider', 'medicinal product' and 'prescription', pursuant to Article 3 (a), (c), (d), (f), (g), (i) and (k) of the Directive 2011/24/EU;	(b) the definitions of 'healthcare', 'Member State of affiliation', 'Member State of treatment', 'health professional', 'healthcare provider', 'medicinal product' and 'prescription', pursuant to Article 3 (a), (c), (d), (f), (g), (i) and (k) of Article 3 of the Directive 2011/24/EU; **Spain's comments:** *In Directive 2011/24/EU…* *f) 'health professional' means a doctor of medicine, a nurse responsible for general care, a dental practitioner, a midwife or a pharmacist within the meaning of Directive 2005/36/EC (https://eur-lex.europa.eu/legal-*

TEXT OF THE PROPOSAL	COMPROMISE TEXT AND SPAIN'S COMMENTS
	content/EN/TXT/?uri=CELEX%3A02005L0036-20211210), or another professional exercising activities in the healthcare sector which are restricted to a regulated profession as defined in Article 3(1)(a) of Directive 2005/36/EC, or a person considered to be a health professional according to the legislation of the Member State of treatment; *This, in essence, is a MS-specific definition.*
(c) the definitions of 'data', 'access', 'data altruism', 'public sector body' and 'secure processing environment', pursuant to Article 2 (1), (8), (10), (11) and (14) of [Data Governance Act COM/2020/767 final];	(c) the definitions of 'data', 'access', 'data altruism', 'public sector body' and 'secure processing environment', pursuant to Article 2 (1), (8), (10), (11) and (14) of Regulation (EU) 2022/868~~[Data Governance Act COM/2020/767 final]~~;
(d) the definitions of 'making available on the market', 'placing on the market', 'market surveillance', 'market surveillance authority', 'non-compliance', 'manufacturer', 'importer', 'distributor', 'economic operator', 'corrective action', 'risk', 'recall' and 'withdrawal', pursuant to Article 2 (1), (2), (3), (4), (7), (8), (9), (10), (13), (16), (18), (22) and (23) of the Regulation (EU) 2019/1020;	(d) the definitions of 'making available on the market', 'placing on the market', 'marketsurveillance', 'market surveillance authority', 'non-compliance', 'manufacturer', 'importer', 'distributor', 'economic operator', 'corrective action', 'risk', 'recall' and 'withdrawal', pursuant to Article 2 (1), (2), (3), (4), (7), (8), (9), (10), (13), (16), (18), (22) and (23) of the Regulation (EU) 2019/1020;

TEXT OF THE PROPOSAL	COMPROMISE TEXT AND SPAIN'S COMMENTS
(e) the definitions of 'medical device', 'intended purpose', 'instructions for use', 'performance', 'health institution' and 'common specifications', pursuant to Article 2 (1), (12), (14), (22), (36) and (71) of the Regulation (EU) 2017/745;	(e) the definitions of 'medical device', 'intended purpose', 'instructions for use', 'performance', 'health institution' and 'common specifications', pursuant to Article 2 (1), (12), (14), (22), (36) and (71) of the Regulation (EU) 2017/745;
(f) the definitions of 'electronic identification', 'electronic identification means' and 'person identification data' pursuant to Article 3 (1), (2) and (3) of the Regulation (EU) No 910/2014.	(f) the definitions of 'electronic identification', 'electronic identification means' and 'person identification data' pursuant to Article 3 (1), (2) and (3) of the Regulation (EU) No 910/2014.
2.In addition, for the purposes of this Regulation the following definitions shall apply:	**2.**In addition, for the purposes of this Regulation the following definitions shall apply:
(a)'personal electronic health data' means - data concerning health and - genetic data as defined in Regulation (EU) 2016/679, - as well as -- data referring to determinants of health, or -- data processed in relation to the provision of healthcare services, processed in an electronic form;	(a)'personal electronic health data' means **personal** data concerning health and genetic data as defined in Regulation (EU) 2016/679 ~~as well as data referring to determinantsof health, or data processed in relation to the provision of healthcare services~~, processed in an electronic form; **Spain's comments:** **Spain supports the comments made by HU and replicates them verbatim:** (a) 'personal electronic health data' means ~~data concerning health and genetic data as defined in Regulation (EU) 2016/679, as well as data referring to determinants of health, or data processed in relation to the provision of healthcare services,~~

TEXT OF THE PROPOSAL	COMPROMISE TEXT AND SPAIN'S COMMENTS
	~~processed in an electronic form~~ personal data provided in Article 4(1) of Regulation (EU) 2016/679 that fall under the data categories referred to in Article 5(1) and 33 (1);
(b) 'non-personal electronic health data' means data concerning health and genetic data in electronic format that falls outside the definition of personal data provided in Article 4(1) of Regulation (EU) 2016/679;	~~(b) 'non-personal electronic health data' means data concerning health and genetic data in electronic format that falls outside the definition of personal data provided in Article 4(1) of Regulation (EU) 2016/679;~~ **Spain's comments:** **Spain supports the comments made by HU and replicates them verbatim:** (b) 'non-personal electronic health data' means data that fall under the data categories referred to in Article 5(1) and 33 (1) and ~~concerning health and genetic data in electronic format~~ that fall~~s~~ outside the definition of personal data provided in Article 4(1) of Regulation (EU) 2016/679; *Jusfitication* *a)-b) These definitions are crucial therefore should be very specific to provide legal certainity. To this end we propose a simple and functional definition that is restricted to the data categories subject of primary and secondary use, which are the exclusive data to be handled under this regulation.*
(c) 'electronic health data' means - personal or - non-personal electronic health data;	(c) 'electronic health data' means personal **health data** or ~~non-personal electronic health~~data **concerning health or genetic data that do not constitute personal data, processed in electronic form**;
(d) 'primary use of electronic health data' means the processing of personal electronic health data for the provision of health services to assess, maintain or restore the state of health of the natural person to whom that data relates,	**NOT PART OF THE COMPROMISE TEXT** **Spain supports the comments made by HU and replicates them verbatim:** (d) 'primary use of electronic health data' means the processing of personal electronic health data for the

TEXT OF THE PROPOSAL	COMPROMISE TEXT AND SPAIN'S COMMENTS
including the - prescription, dispensation and - provision of medicinal products and medical devices, as well as - for relevant social security, administrative or reimbursement services;	provision of health 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; *Jusfitication* *d) Under the EU legislation (regulation 883/2004) social security does not cover social assistance which might also be relevant for the EHDS regulation.*
(e) 'secondary use of electronic health data' means - the processing of electronic health data for purposes set out in Chapter IV of this Regulation. The data used may include personal electronic health data initially collected in the context of primary use, but also electronic health data collected for the purpose of the secondary use;	(e) 'secondary use of electronic health data' means - the processing of electronic health data for purposes set out in **Article 34** ~~Chapter IV~~ of this Regulation. ~~The data used may include personal electronic health data initially collected in the context of primary use, but also electronic health data collected for the purpose of the secondary use;~~
(f) 'interoperability' means - the ability of organisations as well as software applications or devices from the same manufacturer or different manufacturers to interact towards mutually beneficial goals, involving the exchange of information and knowledge without changing the content of the data between these organisations, software applications or devices, through the processes they support;	**NOT PART OF THE COMPROMISE TEXT** **Spain supports the comments made by HU and replicates them verbatim:** (f) 'interoperability' means the ability of organisations as well as software applications or devices from the same manufacturer or different manufacturers to interact ~~towards mutually beneficial goals~~, involving the exchange of information and knowledge without changing the content of the data between these organisations, software applications or devices, through the processes they support; *Jusfitication* *f) Interoperability requirements should not be circumvented just because the interaction between two operators is not mutually beneficial.*

TEXT OF THE PROPOSAL	COMPROMISE TEXT AND SPAIN'S COMMENTS
(g) 'European electronic health record exchange format' means - a structured, commonly used and machine-readable format that allows transmission of personal electronic health data between different software applications, devices and healthcare providers;	**NOT PART OF THE COMPROMISE TEXT**
(h) 'registration of electronic health data' means - the recording of health data in an electronic format, through manual entry of data, through the collection of data by a device, or through the conversion of non-electronic health data into an electronic format, to be processed in an EHR system or a wellness application;	**NOT PART OF THE COMPROMISE TEXT**
(i) 'electronic health data access service' means - an online service, such as a portal or a mobile application, that enables natural persons not acting in their professional role to access their own electronic health data or electronic health data of those natural persons whose electronic health data they are legally authorised to access;	**NOT PART OF THE COMPROMISE TEXT**
(j) 'health professional access service' means - a service, supported by an EHR system, that enables health professionals to access data of natural persons under their treatment;	**NOT PART OF THE COMPROMISE TEXT**
(k) 'data recipient' means - a natural or legal person that receives data from another controller in the context of the primary use of electronic health data;	**NOT PART OF THE COMPROMISE TEXT** **Spain supports the comments made by HU and replicates them verbatim:** (k) 'health data recipient' means a natural or legal person that receives health data from another controller in the context of the primary use of electronic health data;

TEXT OF THE PROPOSAL	COMPROMISE TEXT AND SPAIN'S COMMENTS
	Jusfitication *k) The definition should be specific to the EHDS regulation in order to avoid overlaps with GDPR.*
(l) 'telemedicine' means - the provision of healthcare services, including remote care and online pharmacies, through the use of information and communication technologies, in situations where the health professional and the patient (or several health professionals) are not in the same location;	**NOT PART OF THE COMPROMISE TEXT** **Spain supports the comments made by HU and replicates them verbatim:** (l) ~~'telemedicine' means the provision of healthcare services, including remote care and online pharmacies, through the use of information and communication technologies, in situations where the health professional and the patient (or several health professionals) are not in the same location;~~ *Justification:* *(l) Further preparation and appropriate impact assessment are required for the introduction of telemedicine rules in the context of cross-border healthcare therefore we recommend the deletion of the concept of telemedicine.*
(m) 'EHR' (electronic health record) means - a collection of electronic health data related to a natural person and collected in the health system, processed for healthcare purposes;	**NOT PART OF THE COMPROMISE TEXT**
(n) 'EHR system' (electronic health record system) means - any appliance or software intended by the manufacturer to be used for storing, intermediating, importing, exporting, converting, editing or viewing electronic health records;	**NOT PART OF THE COMPROMISE TEXT**
(o) 'wellness application' means - any appliance or software intended by the	(o) 'wellness application' means any appliance or software

TEXT OF THE PROPOSAL	COMPROMISE TEXT AND SPAIN'S COMMENTS
manufacturer to be used by a natural person for processing electronic health data for other purposes than healthcare, such as well-being and pursuing healthy life-styles;	intended by the manufacturer to be used by a natural person for processing electronic health data for other purposes than healthcare, such as well-being and pursuing healthy life-styles;
(p) 'CE marking of conformity' means - a marking by which the manufacturer indicates that the EHR system is in conformity with the applicable requirements set out in this Regulation and other applicable Union legislation providing for its affixing;	**NOT PART OF THE COMPROMISE TEXT**
(q) 'serious incident' means - any malfunction or deterioration in the characteristics or performance of an EHR system made available on the market that directly or indirectly leads, might have led or might lead to any of the following: (i) the death of a natural person or serious damage to a natural person's health; (ii) a serious disruption of the management and operation of critical infrastructure in the health sector;	**NOT PART OF THE COMPROMISE TEXT**
(r) 'national contact point for digital health' means - an organisational and - technical gateway for the provision of cross-border digital health information services for primary use of electronic health data, under the responsibility of the Member States;	**NOT PART OF THE COMPROMISE TEXT**
(s) 'central platform for digital health' means - an interoperability platform providing services to	**NOT PART OF THE COMPROMISE TEXT**

TEXT OF THE PROPOSAL	COMPROMISE TEXT AND SPAIN'S COMMENTS
support and facilitate the exchange of electronic health data between national contact points for digital health;	
(t) 'MyHealth@EU' means - the cross-border infrastructure for primary use of electronic health data formed by the combination of national contact points for digital health and the central platform for digital health;	**NOT PART OF THE COMPROMISE TEXT**
(u) 'national contact point for secondary use of electronic health data' means - an organisational and technical gateway enabling the cross-border secondary use of electronic health data, under the responsibility of the Member States;	~~(u) 'national contact point for secondary use of electronic health data' means~~ ~~- an organisational and technical gateway enabling the cross-border secondary use of electronic health data, under the responsibility of the Member States;~~
(v) 'central platform for secondary use of electronic health data' means - an interoperability platform established by the Commission, providing services to support and facilitate the exchange of information between national contact points for secondary use of electronic health data;	~~(v) 'central platform for secondary use of electronic health data' means~~ ~~- an interoperability platform established by the Commission, providing services to support and facilitate the exchange of information between national contact points for secondary use of electronic health data;~~
(x) 'HealthData@EU' means - the infrastructure connecting national contact points for secondary use of electronic health data and the central platform;	~~(x) 'HealthData@EU' means~~ ~~- the infrastructure connecting national contact points for secondary use of electronic health data and the central platform;~~
(y) 'data holder' means - any natural or legal person, which is an entity or a body in the health or care sector, or performing research in relation to these sectors, as well as - Union institutions, bodies, offices and agencies	~~(x)~~ '**health** data holder' means ~~a~~any natural or legal person, which is an entity or a bodyin the health or care sector, or performing research in relation to these sectors, as well as Union institutions, bodies, offices and agencies who has ~~the right or obligation, in accordance with this Regulation, applicable Union law or national legislation implementing Union law~~ **either:**

TEXT OF THE PROPOSAL	COMPROMISE TEXT AND SPAIN'S COMMENTS
who -- has the right or obligation, in accordance with this Regulation, applicable Union law or national legislation implementing Union law, (or in the case of non-personal data, -- through control of the technical design of a product and related services,) the ability to make available (, including to register, provide, restrict access or exchange) certain data;	the right or obligation, in accordance with applicable Union law or national legislation, to process personal electronic health data for the provision of health or care or for public health, research, innovation, policy making, official statistics, patient safety or regulatory purposes, in its capacity as a controller; or **the ability to make available, including to register, provide, restrict access or exchange electronic health data that do not constitute personal data in the meaning of Article 4 (1) of Regulation (EU) 2016/679**~~non- personal data~~, through control of the technical design of a product and related services, ~~the ability to make available, including to register, provide, restrict access or exchange certain data~~; *(y) 'data holder' means* *- any natural or legal person,* ***acting as a data controller,*** *which is an entity or a body in the health or care sector, or performing* ~~*research*~~ *in relation to these sectors,* Justification: - COM (on the meeting of 2022-07-15) explained that a "data holder" was always a "data controller". We believe it's critical to add this to the definition of "data holder". Also, in article 33(2) EHDS, it should be clarified that individual researchers are not included in the current definition of "data holder". **- Replicating HU's comments verbatim,** "The definition ('… research in relation to these sectors…') is too restrictive when non-health and social sector companies are considered data holders if they perform research. We need to be able to request data from tech companies in possession of health data."
(z) 'data user' means a natural or legal person who has lawful access to - personal or	~~(y)~~ '**health** data user' means a natural or legal person, ***, within the jurisdiction of a country or an international organization which is an***

TEXT OF THE PROPOSAL	COMPROMISE TEXT AND SPAIN'S COMMENTS
- non-personal electronic health data for secondary use;	***authorised participant of HealthData@EU***, who has lawful access to ~~personal or non-personal~~ electronic health data for secondary use **pursuant to a data permit or a data request pursuant to this Regulation**; **Justification:** Please, see our general comments on third countries and international organizations.
(aa) 'data permit' means an administrative decision issued to a data user - by a health data access body or data holder to process the electronic health data specified in the data permit for the secondary use purposes specified in the data permit based on conditions laid down in this Regulation;	(aa) 'data permit' means an administrative decision issued to a **health** data user by a health data access body or a **single health** data holder to process the electronic health data specified in the data permit for the secondary use purposes specified in the data permit based on conditions laid down in **Chapter IV of** this Regulation; **Spain's comments:** **Spain supports the comments made by HU and replicates them verbatim:** *(aa) 'data permit' means an administrative decision issued to a data user by a health data access body* ~~***or data holder***~~ *to process the electronic health data specified in the data permit for the secondary use purposes specified in the data permit based on conditions laid down in this Regulation;* *Justification:* *z-aa) Only HDABs can issue data permit and Article 49 should be deleted.*
(ab) 'dataset' means - a structured collection of electronic health data;	

TEXT OF THE PROPOSAL	COMPROMISE TEXT AND SPAIN'S COMMENTS
(ac) 'dataset catalogue' means - a collection of datasets descriptions, which is arranged in a systematic manner and consists of a user-oriented public part, where information concerning individual dataset parameters is accessible by electronic means through an online portal;	
(ad) 'data quality' means - the degree to which characteristics of electronic health data are suitable for secondary use;	
(ae) 'data quality and utility label' means - a graphic diagram, including a scale, describing the data quality and conditions of use of a dataset.	

Article 33 Minimum categories of electronic data for secondary use

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

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

Justification:

Creating a link between primary and secondary use of health data is undesirable. These have different actors, different purposes, different technological implementations and different transition periods.

"including the categories in Article 5 of this Regulation" has no added value.

If, as proposed by some MS in the Council, only the data categories of article 5(1) are available as part of the EHRs, this would be very problematic approach, as explained in the general comments.

(b) data **on factors** impacting health, including social (excluding data relating to criminal convictions and offences), environmental behaviouraldeterminants of health;

Justification: criminal convictions and offenses should be left out of scope of the EHDS per article 10 GDPR.

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

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

(e) extracts from human genetic, genomic and proteomic data, such as genetic markers;

Justification: sharing the full genome or proteome could be challenging and problematic. However, data such as genetic markers is frequently available in EHRs.

Additional analysis is required if the intention is to include the possibility to share the whole genome of a person. Specifically,

- additional safeguards must be introduced when sharing the whole genome or proteome,
- a sufficiently long transitionary period must be implemented.

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

(g) identification data related to health professionals involved in the treatment of a natural person; Member States will define measures to protect the personal data of their health professionals.

Justification: the identity of healthcare professionals must be protected in certain cases. For example, it would be important to avoid the identification of healthcare professionals who prescribe certain medicines

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

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

~~**(j)** electronic health data from clinical trials;~~

Justification: we propose the removal of data from clinical trials for several reasons:
1) legal technique: contradiction with the clinical trials regulation Regulation (EU) No 536/2014. If we use the Presidency's text the interpretation would be: all data categories of article 33(1) do not require consent, but clinical trial data (if not anonymized) do require consent from each data subject.
2) in the survey sent to the MS, this data category was one of the least relevant ones.

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

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

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

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

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

Comment: for (o), it would be important to clarify that enriched datasets can only be returned to the data

holder if the latter has the legal grounds to access all the information in the enriched dataset.

Article 34 Purposes for which electronic health data can be processed for secondary use

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

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

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

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

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

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

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

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

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

Spain's comments

No comments

Article 35 Prohibited secondary use of electronic health data

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

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

This needs to be complemented by a change in article 45(4) and article 47. Right now, the data user can only export anonymous (non-personal) information from the Secure Processing Environment (SPE) (article 50(2)). However, right now, denial of access to data only applies if the data user can have access to pseudoanonymous health data, as stated in article 45(4)(b). However, unethical use may occur with anonymous data. For example, aggregated data on ethnic origin or sexual preferences of a person may has a potential for misuse, but can also have legitimate use. Therefore, ethical principles should apply also for anonymous data, i.e. article 45(4) should read:

"4.Where the applicant intends to access the personal electronic health data in a pseudonymised format or non-personal data, the following additional information shall be provided together with the data access application:
(a)a description of how the processing would comply with Article 6(1) of Regulation (EU) 2016/679;

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

Similarly, article 47 (for aggregated data requests) should also modified in the same manner:

"Article 47. Data request.

1. Any natural or legal person may submit a data request for the purposes referred to in Article 34. Additional information shall be provided on the assessment of ethical aspects of the data request, where applicable and in line with national law. A health data access body shall only provide an answer to a data request in an anonymised statistical format and the data user shall have no access to the electronic health data used to provide this answer.

(…)"

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

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

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

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

(f) ***confidential data used by public bodies which are market regulators.***

Justification: Pharmaceutical market regulators possess confidential databases with information which should not be shared with the pharmaceutical industry for instance.

In the same way that IP rights of private companies need to be protected (art 35A), the confidential data of market regulators also has commercial value and thus should not be directly accessible.

(g) ***data of pharmaceutical prescriptions or medical devices by commercial name, with the exception***

of usage by public authorities.

Justification: access to commercial name data could lead to the of identifying prescription patterns by health professionals, which could lead to undesirable outcomes and incentives. The same reasoning applies to medical devices.

These data can be provided, but without the commercial name. For instance, prescription information can be shared but with the active principle, but not with the commercial name.

There needs to be an exception for the possibility of using these data by public authorities, for instance, for pharmacovigilance purposes.

(h) ***national defense and security.***

Justification: this is a common provision in EU legislation. For example, access to military medicine information could be detrimental to the defense capabilities of the Member States.

Article 35[a] IP-rights and trade secrets

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

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

Spain's comments:

1) Additional clarifications are needed on the measures to protect IP rights and trade secrets. For example, a non-disclosure agreement could be signed between the data user and the data holder. Also, confidential information could be removed from the dataset.

2) The movement of article 33(4) to a new independent article can be problematic as the reference to prior elements of article 33 could be lost. Now the interpretation could be that all kinds of electronic health data (not just the data categories of article 33(1)) subject to IP rights shall be made available for secondary use.

*Article ~~41~~**35B** Duties of **health** data holders* MOVED FROM ARTICLE

(…)

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

Comment:

This is only possible if the data holder has the legal ground to process the new enriched data.

There are two cases here:

- The data user does not add new personal data (for instance, the data user transforms unstructured data into structured data). No action is necessary here by the HDAB and the enriched dataset is sent to the data holder.
- The data user adds new personal data. Then, there needs to be an assessment by the HDAB if the health data holder can process the new data.

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

Comment:

We see little legal value in "A health data holder shall cooperate with the health data access bodies, where relevant".

(…)

(~~8~~) The requirement in ~~the first subparagraph~~ **this Article** shall not apply to **health** data holders that

qualify as micro enterprises as defined in Article 2 of the Annex to Commission Recommendation 2003/361/EC[2]. **Member States may however decide to apply this Chapter to these health data holders.** MOVED FROM ARTICLE 33(2)

Comment:

It is relevant to clarify that individual researchers and small non-profit entities are also not data holders, even though they are not micro-enterprises.

Article 35C Duties of health data users

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

Justification:

We believe it's relevant to clarify this.

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

Comment:

In clinical research there is often anonymous peer review. Sometimes, these reviewers want to access the original clinical data to replicate the results. The problem is that the researcher is the data user, and does not know the identity of the reviewers. Therefore, some exemptions should exist for research.

4. Member State law to which the health data access body who granted the data permit is subject may allow the health ~~D~~**d**ata users ~~shall~~ **to** inform the health data access body ofany clinically significant

findings that may influence the health status of the natural persons whose data are included in the dataset. MOVED FROM ARTICLE 46(12)

Comment:

We should keep this in the Regulation, and even have the possibility of mandating this in the national legislation, using the Finish legislation[6] as an inspiration:

Section 55

Rights, obligations and actions based on significant clinical findings

Notwithstanding the provisions of section 54(3), a data permit holder has the right to notify the person in charge appointed by the Data Permit Authority of a clinically significant finding that would enable the prevention of a risk to a certain patient's health or significant improvements to the quality of care.

If the notification referred to in subsection 1 is based on anonymous data, the person in charge must determine the person or persons to whom the data applies. When the Data Permit Authority's person in charge knows the persons or persons to whom the notification referred to in subsection 1 applies, the person in charge must submit the information without undue delay to the expert appointed by the National Institute for Health and Welfare.

The expert referred to in subsection 2 above must, in collaboration with other experts appointed by the Institute, assess the significance of the information and the expected benefits of actions that can be taken as a result of the information. If the benefit is estimated to be so obvious that the person should be brought in contact with health care, the expert of the National Institute for Health and Welfare referred to in subsection 2 must report the finding to the unit that is regionally responsible for providing health care to the person pursuant to the Health Care Act.

The unit referred to in subsection 3 above must contact the patient and find out whether he/she wants to be informed of a clinically significant finding and the potential examinations and treatment operations carried out as a result, including the benefits of such examinations and treatment.

The patient has the right to prohibit contacts made due to a clinically significant finding. The prohibition is recorded to the patient's information management system referred to in section 14 of the Client Data Act. The patient may set the prohibition in writing on any unit that produces public health care or electronically via the citizen's user interface referred to in section 19 of the Client Data Act.

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

[6] https://www.finlex.fi/fi/laki/ajantasa/2019/20190552

Comment:

We see little legal value in the statement: "Health data users shall cooperate with the health data access bodies, where relevant"

Article 36 Health data access bodies

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

Justification:

Please, see our general comments on the role of the Commission.

Article 37 Tasks of health data access bodies

Comments:

Please, see our general comments on the tasks of health data access bodies.

Article 39 Reporting by health data access bodies

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

(b) a list of data permits involving access to electronic health data processed by the health data access body based on data altruism and a summary description of the general

interests purposes pursued, where applicable, including the outcomes of the data permits granted;

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

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

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

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

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

Justification:

We see little value in this KPI.

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

(i) revenues from data permits and data requests;

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

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

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

Justification:

This KPI is highly relevant, as it is an important indicator of the maturity of the data reuse eco-system.

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

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

Article 42 Fees

Comment:

Please, see our general comments on
- third countries and international organizations.
- fees.

Article 43 Penalties by health data access bodies in case of non-compliance

Comments:

- please, see our general comments on penalties.

Article 45 Data access applications

Article 46 Data permit

Article 47 Data request

Comments:

Please, see our general comments on
- Proposal for ethical assessment in access to anonymous health data (Article 45(4)).
- Proposal for merging of data access application (article 45), data permit (article 46) and data request (article 47)

Article 48 Making data available for public sector bodies and Union institutions, bodies, offices and agencies without a data permit

Comments:

We agree with the deletion of article 48 EHDS.

Article 49 Access to electronic health data from a single data holder

Comments:

- please, see our general comments on single data holders.

Article 50 Secure processing environment

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

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

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

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

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

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

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

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

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

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

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

Comments:

would be important to clarify:

he conditions, roles and responsibilities for transferring data from one SPE to another SPE (from one SPE of one HDAB to the SPE of another HDAB at the national level; or from the SPE of a MS to COM's SPE envisioned in article 52(10)).

hat a secure processing environment can be provisioned by the health data holder.

e minimum infrastructure at the country level would be an HDAB and an SPE.

wever, right now, the HDAB only assesses the request… but does not necessarily have to use that SPE.

an HDAB can assess an application and grant access through the SPE of a health data holder.

is is important since:

e single SPE of the HDAB cannot possibly service all data requests.

ıny data holders (such as large university hospitals) will want to have their own SPE

wever, if there are requests from several data holders, the SPE of the HDAB would be used.

e support the idea of creating several SPEs per country and let the HDABs decide which is the most appropriate environment for the exploitation of specific data.

Article 51 Joint Controllership

(…)

1A. In situations referred to in Article 49,

the single health data holder shall be deemed controller

for its processing of personal electronic health data

related to the providing of electronic health data to the health data user pursuant to a data permit or a data request.

The single health data ~~user~~ holder shall act as a processor for the health data user´s processing

pursuant to a data permit when providing a secure processing environment to the health data user.

(…)

Comments:

There seems to be a typo.

Article 52 Cross-border infrastructure for secondary use of electronic health data (HealthData@EU)

Comments:

Please, see our general comments on

- third countries and international organizations.
- the role of the Commission

Article 55 Dataset description

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

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

Article 56 Data quality and utility label

(…)

3. The data quality and utility label shall comply with **some or all of** the following elements:

Justification:

The data quality label proposed in the EHDS seems to be inspired on the Health Data Research UK research[7].
The data quality level (bronze, silver, gold, platinum) would depend on the number of fields completed from the list. The wording "shall comply with the following elements" would imply that all fields would need to be filled in, while the proposed changed wording allows for some of the elements to be filled in.

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

(b) for assessment of technical quality: completeness, uniqueness, accuracy, validity,

[7] Gordon, B., Barrett, J., Fennessy, C., Cake, C., Milward, A., Irwin, C., ... & Sebire, N. (2021). Development of a data utility framework to support effective health data curation. BMJ Health & Care Informatics, 28(1). URL: https://discovery.ucl.ac.uk/id/eprint/10129971/1/Sebire_Development%20of%20a%20data%20utility%20framework%20to%20support%20effective%20health%20data%20curation_VoR.pdf

timeliness and consistency of the data;

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

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

(…)

Article 57 EU Datasets Catalogue

1. The Commission shall establish an EU Datasets Catalogue connecting the national catalogues of datasets established by the health data access bodies and other authorised participants in HealthData@EU, in the core platform for HealthData@EU operated by the European Commission (Article 52(9))

Justification: it is important to clarify that the deposition in the EU Datasets Catalogue shall be orchestrated in the core platform for HealthData@EU operated by the European Commission (Article 52(9))

If a Member State has designated several Health Data Access Bodies, the one acting as coordinator shall consolidate the national dataset catalogue

Justification: if there are several HDABs in a MS, the coordination of the national catalogues is done through the coordinating health data access body (see proposal for Article 36(1))

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

Article 58 Minimum dataset specifications

he Commission may, by means of implementing acts, determine the minimum specifications for cross-border **specific high-value healthcare** datasets for secondary use of electronic health data, taking into account existing Union infrastructures, standards, guidelines and recommendations. Those implementing acts shall be adopted in accordance

with the ~~advisory~~ **examination** procedure referred to in Article 68(2).

Justification: this article opens the door for dataset normalization at the EU level. While this may be useful for certain dataset such as specific rare diseases, it should not become the norm, as this would be problematic for the MS and could interfere with national competentes. Therefore, the scope should be narrowed down to 'specific high-value healthcare datasets' (which would be different from the 'high-value datasets' of Annex I of *Directive (EU) 2019/1024 of the European Parliament and of the Council of 20 June 2019 on open data and the re-use of public sector information*[8]). Then, it would be important to add a definition of thereof in article 2(2) EHDS.

[8] https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32019L1024&from=EN