The Standing Committee of European Doctors (CPME) represents national medical associations across Europe. We are committed to contributing the medical profession's point of view to EU and European policy-making through pro-active cooperation on a wide range of health and healthcare related issues.

Proposed amendments to the Commission's Proposal for a Regulation on the European Health Data Space

Proposed amendments

CPME's proposed amendments are indicated in ***bold italics and underlined font.***

Recital 2	
Text Proposed by the Commission	**CPME Proposed Amendment**[1]
(2) The COVID-19 pandemic has highlighted the imperative of having timely access to electronic health data for health threats preparedness and response, as well as for diagnosis and treatment and secondary use of health data. Such timely access would have contributed, through efficient public health surveillance and monitoring, to a more effective management of the pandemic, and ultimately would have helped to save lives.	(2) The COVID-19 pandemic has highlighted the imperative of having timely access to ***quality,*** electronic health data for health threats preparedness and response, as well as for ***prevention,*** diagnosis and treatment and secondary use of health data. Such timely access would have contributed, through efficient public health surveillance and monitoring, to a more effective management of the pandemic, and ultimately would have helped to save lives.
Justification	
Prevention needs to be at the core of the primary use of the electronic health data.	

[1] CPME proposed amendments are indicated in bold italics and underlined font.

Recital 7	
Text Proposed by the Commission	**CPME Proposed Amendment**
(7) (...) In order to enable that electronic health data to be accessed, shared and changed by the natural persons or health professionals, some Member States have taken the necessary legal and technical measures and set up centralised infrastructures connecting EHR systems used by healthcare providers and natural persons. Alternatively, some Member States support public and private healthcare providers to set up personal health data spaces to enable interoperability between different healthcare providers. Several Member States have also supported or provided health data access services for patients and health professionals (for instance through patients or health professional portals). They have also taken measures to ensure that EHR systems or wellness applications are able to transmit electronic health data with the central EHR system (some Member States do this by ensuring, for instance, a system of certification). However, not all Member States have put in place such systems, and the Member States that have implemented them have done so in a fragmented manner. In order to facilitate the free movement of personal health data across the Union and avoid negative consequences for patients when receiving healthcare in cross-border context, Union action is needed in order to ensure individuals have improved access to their own personal electronic health data and are empowered to share it.	(7) (...) In order to enable that electronic health data to be accessed, shared and changed by the natural persons or health professionals, some Member States have taken the necessary legal and technical measures and set up centralised infrastructures connecting EHR systems used by healthcare providers and natural persons. Alternatively, some Member States support public and private healthcare providers to set up personal health data spaces to enable interoperability between different healthcare providers. Several Member States have also supported or provided health data access services for patients and health professionals (for instance through patients or health professional portals). They have also taken measures to ensure that EHR systems or wellness applications are able to transmit electronic health data with the central EHR system (some Member States do this by ensuring, for instance, a system of certification). However, not all Member States have put in place such systems, and the Member States that have implemented them have done so in a fragmented manner. In order to facilitate the free movement of personal health data across the Union and avoid negative consequences for patients when receiving healthcare in cross-border context, Union action is needed in order to ensure individuals have improved access to their own personal electronic health data and are empowered to share it. ***The implementation costs for connecting healthcare professionals to the EHDS, including new infrastructure and cybersecurity maintenance, capacity building and additional administrative data workload, cannot be carry by healthcare professionals themselves. Member States must ensure that***

	EU financial incentives are distributed evenly and fairly among those impacted by the proposal. The time spent by healthcare professionals validating and rectifying the electronic health record needs to be accounted for by Member States.
Justification	
The implementation costs of the EHDS Proposal cannot be carried by healthcare professionals themselves. The time spent by healthcare professionals in updating, validating or rectifying the electronic health record needs to be accounted for by Member States.	

Recital 40	
Text Proposed by the Commission	**CPME Proposed Amendment**[2]
(40) The data holders can be public, non for profit or private health or care providers, public, non for profit and private organisations, associations or other entities, public and private entities that carry out research with regards to the health sector that process the categories of health and health related data mentioned above. In order to avoid a disproportionate burden on small entities, micro-enterprises are excluded from the obligation to make their data available for secondary use in the framework of EHDS. […] In some Member States, private entities, including private healthcare providers and professional associations, play a pivotal role in the health sector. The health data held by such providers should also be made available for secondary use.	(40) The data holders can be public, ***~~non~~t-for-profit*** or private health or care providers, public, ***~~non~~t-for-profit*** and private organisations, associations or other entities, public and private entities that carry out research with regards to the health sector that process the categories of health and health related data mentioned above. ***Health professionals contribute to the EHDS by registering the required categories of patient data in the EHR.*** In order to avoid a disproportionate burden on small entities, micro-enterprises ***and small enterprises*** are excluded from the obligation to make their data available for secondary use in the framework of EHDS. ***Medical confidentiality and professional secrecy must be respected during the process.*** […] In some Member States, private entities, including private healthcare providers and professional associations, play a pivotal role in the health sector. The health data held by such providers should also be made available for secondary use, without jeopardising the trust in patient-doctor relationship.

[2] CPME proposed amendments are indicated in bold italics and underlined font.

Justification
Doctors making electronic health data available for secondary use will involve an extraordinary effort from the workforce at the expense of patient's treatment and care. Small medical practices should also be exempted due to the disproportionate effort to their activity. Medical confidentiality and professional secrecy need to be respected during the process, and the trust in the patient-doctor relationship must not be jeopardised.

Recital 53	
Text Proposed by the Commission	**CPME Proposed Amendment[3]**
(53) For requests to access electronic health data from a single data holder in a single Member State and in order to alleviate the administrative burden for heath data access bodies of managing such request, the data user should be able to request this data directly from the data holder and the data holder should be able to issue a data permit while complying with all the requirements and safeguards linked to such request and permit. Multi-country requests and requests requiring combination of datasets from several data holders should always be channelled through health data access bodies. The data holder should report to the health data access bodies about any data permits or data requests they provide.	(53) ~~***For requests to access electronic health data from a single data holder in a single Member State and in order to alleviate the administrative burden for heath data access bodies of managing such request, the data user should be able to request this data directly from the data holder and the data holder should be able to issue a data permit while complying with all the requirements and safeguards linked to such request and permit.***~~ Multi-country requests and requests requiring combination of datasets from several data holders should always be channelled through health data access bodies. The data holder should report to the health data access bodies about any data permits or data requests they provide.
Justification	
This recital needs to be adapted in order to be coherent with the deletion of Article 49. Data access applications under the EHDS should always be addressed to a Health Data Access Body to ensure access through a secure processing environment and uniform application of Section III on data permit for the secondary use of electronic health data in Chapter IV.	

Recital 64 (a) new	
Text Proposed by the Commission	**CPME Proposed Amendment**
–	***Member States should consider criminalising unauthorised re-identification and disclosure of de-identified personal data to serve as a deterrent measure.***

[3] CPME proposed amendments are indicated in bold italics and underlined font.

Justification
The unauthorised re-identification and disclosure of de-identified personal data is a major breach of trust that can put into jeopardy the secondary use system. Member States should consider criminalising these conducts at national level.

Article 2 – paragraph – 2 (b)	
Text Proposed by the Commission	**CPME Proposed Amendment**[4]
2. (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;	2. (b) 'non-personal electronic health data' means data ***relevant for health research*** ~~***concerning health and genetic data***~~ in electronic format that ***have been irreversibly anonymised and data that*** falls outside the definition of personal data provided in Article 4(1) of Regulation (EU) 2016/679;
Justification	
The definition needs to be clarified and coherent with the General Data Protection Regulation (GDPR). Data concerning health and genetic data are 'personal data' pursuant to the GDPR.	

Article 3 – paragraph 6	
Rights of natural persons in relation to the primary use of their personal electronic health data	
Text Proposed by the Commission	**CPME Proposed Amendment**
(6) Natural persons may insert their electronic health data in their own EHR or in that of natural persons whose health information they can access, through electronic health data access services or applications linked to these services. That information shall be marked as inserted by the natural person or by his or her representative.	(6) ***Member States may provide*** natural persons ***the right to*** insert their electronic health data in their own EHR or in that of natural persons whose health information they can access, through electronic health data access services or applications linked to these services. That information shall be marked as inserted by the natural person or by his or her representative ***as non-validated, and information shall only be considered as a clinical fact if validated by an identified, registered health professional with the relevant competence. Natural persons shall not have the possibility to directly change data inserted by healthcare professionals. The process must be secure. Certified digital***

[4] CPME proposed amendments are indicated in bold italics and underlined font.

	applications should only be linked to the EHR with the agreement of the treating medical professional. Applications may not be able to access data in the EHR.
Justification	
The insertion of electronic health data by patients can both enrich the EHR or lead to the file becoming less suitable as a clinical tool. There can be no expectation or obligation for health professionals to consider self-added data by patients or their representatives, including certified digital applications, without their explicit agreement. Natural persons should also not be able to change the EHR as inserted by health professionals.	

Article 3 – paragraph 7	
Rights of natural persons in relation to the primary use of their personal electronic health data	
Text Proposed by the Commission	**CPME Proposed Amendment[5]**
(7) Member States shall ensure that, when exercising the right to rectification under Article 16 of Regulation (EU) 2016/679, natural persons can easily request rectification online through the electronic health data access services referred to in paragraph 5, point (a), of this Article.	(7) Member States shall ensure that, when exercising the right to rectification under Article 16 of Regulation (EU) 2016/679, natural persons can easily request rectification online through the electronic health data access services referred to in paragraph 5, point (a), of this Article. ***The rectification of a clinical fact in the EHR must be validated by an identified, registered health professional with the appropriate competence. The process must be secure.***
Justification	
Patients might dispute a specific diagnosis or treatment, and the right to rectification could imply the obligation to rectify a diagnosis or a prescribed treatment. This addition will ensure that any rectification of a clinical fact is done by identified registered health professionals.	

Article 3 – paragraph 9	
Rights of natural persons in relation to the primary use of their personal electronic health data	
Text Proposed by the Commission	**CPME Proposed Amendment**
(9) Notwithstanding Article 6(1), point (d), of Regulation (EU) 2016/679, natural persons	(9) Notwithstanding Article 6(1), point (d), of Regulation (EU) 2016/679, ***Member States may***

[5] CPME proposed amendments are indicated in bold italics and underlined font.

shall have the right to restrict access of health professionals to all or part of their electronic health data. Member States shall establish the rules and specific safeguards regarding such restriction mechanisms.	***grant*** natural persons ~~***shall have***~~ the right to restrict access of health professionals to all or part of their electronic health data. Member States shall establish the rules and specific safeguards regarding such restriction mechanisms***, including the conditions of medical liability and whether such restrictions apply to health data for research or quality development purposes. The restricted information must be easily identified in the EHR.***
Justification	
Health professionals' liability in diagnosing and treating patients based on incomplete information needs to be clarified, as well as the burden of proof when information is blocked by the patient. Further clarity is required when a patient requests not to include his/her diagnosis in the EHR (e.g. STDs or domestic violence).	

Article 3 – paragraph 10	
Rights of natural persons in relation to the primary use of their personal electronic health data	
Text Proposed by the Commission	**CPME Proposed Amendment[6]**
(10) Natural persons shall have the right to obtain information on the healthcare providers and health professionals that have accessed their electronic health data in the context of healthcare. The information shall be provided immediately and free of charge through electronic health data access services.	(10) Natural persons shall have the right to ~~***obtain information***~~ ***know if*** healthcare providers and health professionals ~~***that***~~ have accessed their electronic health data in the context of healthcare. The information shall be provided ~~***immediately and***~~ free of charge through electronic health data access services. ***Member States may provide that the right to obtain information does not apply whenever necessary for reasons related to the protection and safety of healthcare providers and health professionals.***
Justification	
The right to obtain information on health professionals is very broad and inconclusive. The provision does not establish a mechanism to exercise this right without potentially violating the personality rights of healthcare professionals. The right must not cause dangerous situations for the health professional involved. Doctors have been assaulted or even killed by their patients	

[6] CPME proposed amendments are indicated in bold italics and underlined font.

due to medical orders of psychiatric supervision.[7] Therefore, exceptions should be allowed to protect the integrity of health professionals.

Article 4 – paragraph 3	
Access by health professionals to personal electronic health data	
Text Proposed by the Commission	**CPME Proposed Amendment[8]**
(3) Member States shall ensure that access to at least the priority categories of electronic health data referred to in Article 5 is made available to health professionals through health professional access services. Health professionals who are in possession of recognised electronic identification means shall have the right to use those health professional access services, free of charge.	(3) Member States shall ensure that access to at least the priority categories of electronic health data referred to in Article 5 is made available to health professionals through health professional access services ***and that health professionals can easily select specific relevant information in the EHR***. Health professionals who are in possession of recognised electronic identification means shall have the right to use those health professional access services, free of charge**.**
Justification	
The EHR might be easily saturated with data due to the future interactions of the EHR with medical devices, wellness apps and other software, or result from patient's medical condition which require continuous care. Limited by time constraints, health professionals need to have appropriate tools to deal with different types of health data and to find relevant and useful information.	

Article 4 – paragraph 4	
Access by health professionals to personal electronic health data	
Text Proposed by the Commission	**CPME Proposed Amendment**
(4) Where access to electronic health data has been restricted by the natural person, the healthcare provider or health professionals shall not be informed of the content of the electronic health data without prior authorisation by the natural person, including where the provider or professional is informed of the existence and nature of the restricted electronic health data. In cases	(4) Where access to electronic health data has been restricted by the natural person, the healthcare provider or health professionals shall not be informed of the content of the electronic health data without prior authorisation by the natural person~~***, including where the provider or professional is informed of the existence and nature of the restricted electronic health data***~~. ***The existence of a restriction must be***

[7] Danish doctor in the emergency department killed at home due to information obtained via the EHR, April 2019, <https://www.dr.dk/nyheder/indland/mistaenkt-laegedrab-i-tisvilde-havde-flere-laegers-navne-paa-en-liste>.
[8] CPME proposed amendments are indicated in bold italics and underlined font.

where processing is necessary in order to protect the vital interests of the data subject or of another natural person, the healthcare provider or health professional may get access to the restricted electronic health data. Following such access, the healthcare provider or health professional shall inform the data holder and the natural person concerned or his/her guardians that access to electronic health data had been granted. Member States' law may add additional safeguards.	***clearly indicated in the EHR***. In cases where processing is necessary in order to protect the vital interests of the data subject or of another natural person, the healthcare provider or health professional may get access to the restricted electronic health data. ~~***Following such access, the healthcare provider or health professional shall inform the data holder and the natural person concerned or his/her guardians that access to electronic health data had been granted.***~~ Member States' law may add additional safeguards.
Justification	
Health professionals need to be aware that a restriction is in the file in order to adjust the protocol questions to patients. This is also required to facilitate the burden of proof when healthcare professionals are diagnosing and treating based on incomplete information (medical liability). The obligation to inform the natural person of access to the EHR in case of vital interests is too burdensome for health professionals dealing with patients in life threatening situations everyday.	

Article 5 – paragraph 1 – subparagraph 3	
Priority categories of personal electronic health data for primary use	
Text Proposed by the Commission	**CPME Proposed Amendment[9]**
(1) (…) Access to and exchange of electronic health data for primary use may be enabled for other categories of personal electronic health data available in the EHR of natural persons.	(1) (…) ***Member States may enable*** ~~A~~a***ccess*** to and exchange of electronic health data for primary use ~~***may be enabled***~~ for other categories of personal electronic health data available in the EHR of natural persons.
Justification	
The provision needs to be clear that it will be Member States enabling access to other categories of health data.	

[9] CPME proposed amendments are indicated in bold italics and underlined font.

Article 7 – paragraph 1	
Registration of personal electronic health data	
Text Proposed by the Commission	**CPME Proposed Amendment[10]**
(1) Member States shall ensure that, where data is processed in electronic format, health professionals systematically register the relevant health data falling under at least the priority categories referred to in Article 5 concerning the health services provided by them to natural persons, in the electronic format in an EHR system.	(1) Member States shall ensure that, where data is processed in electronic format, health professionals ~~***systematically***~~ register ***only once*** the relevant health data falling under at least the priority categories referred to in Article 5 concerning the health services provided by them to natural persons, in the electronic format in an EHR system***, and for the primary use purpose pursuant to Chapter II of this Regulation***.
Justification	
Doctors and other health professionals must only provide health data once and register it for the primary use purpose regime. The Once Only Principle is essential to preserve confidentiality and trust in the patient-doctor relationship and respect the principles of medical ethics. It should be up to public authorities to make health data available for secondary use in full respect of different EU and national laws, in particular the GDPR.	

Article 7 – paragraph 3	
Registration of personal electronic health data	
Text Proposed by the Commission	**CPME Proposed Amendment**
(3) The Commission shall, by means of implementing acts, determine the requirements for the registration of electronic health data by healthcare providers and natural persons, as relevant. Those implementing acts shall establish the following: (a) categories of healthcare providers that are to register health data electronically; (b) categories of health data that are to be registered systematically in electronic format by healthcare providers referred to in point (a); (c) data quality requirements pertaining to the	(3) The Commission shall, by means of implementing acts, determine the ***data quality*** requirements for the registration of electronic health data by healthcare providers and natural persons, as relevant. ~~***Those implementing acts shall establish the following:***~~ ~~***(a) categories of healthcare providers that are to register health data electronically;***~~ ~~***(b) categories of health data that are to be registered systematically in electronic format by healthcare providers referred to in***~~

[10] CPME proposed amendments are indicated in bold italics and underlined font.

electronic registration of health data. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2).	~~***point (a);***~~ ~~***(c) data quality requirements pertaining to the electronic registration of health data.***~~ Those implementing acts shall be adopted in accordance with the ~~advisory~~ ***examination*** procedure referred to in Article 68(2).
Justification	
This Article implies regulating over Member States' responsibilities for the organisation and delivery of health services and medical care, including the management of health services.	

Article 8	
Telemedicine	
Text Proposed by the Commission	**CPME Proposed Amendment**[11]
Where a Member State accepts the provision of telemedicine services, it shall, under the same conditions, accept the provision of the services of the same type by healthcare providers located in other Member States.	~~***Where a Member State accepts the provision of telemedicine services, it shall, under the same conditions, accept the provision of the services of the same type by healthcare providers located in other Member States.***~~
Justification	
Telemedicine is a healthcare service which is not harmonised at EU level. There are different rules at national level on when telemedicine services can be used, for which medical conditions and how often, on what can be diagnosed and by whom, on the required professional qualifications, on the reimbursement scheme and insurance, on medication prescriptions (e.g. antibiotics and opiates), on medical liability, and even on how privacy and confidentiality and informed consent are dealt with during the service. This Article implies regulating over Member States' responsibilities for the organisation and delivery of health services and medical care, including the management of health services.	

Article 15 – paragraph 1	
Placing on the market and putting into service	
Text Proposed by the Commission	**CPME Proposed Amendment**
(1) EHR systems may be placed on the market or put into service only if they comply with	(1) EHR systems may be placed on the market or put into service only if they comply with the

[11] CPME proposed amendments are indicated in bold italics and underlined font.

the provisions laid down in this Chapter.	provisions laid down in this Chapter. ***Member States shall introduce a third-party conformity assessment procedure for EHR systems and products claiming interoperability by involving notified bodies in the assessment of the measures, including technical solutions on interoperability and security.***
Justification	
CPME supports the EDPB-EDPS recommendation for the EHR systems to be subject to a third party conformity assessment procedure, involving notified bodies, in the assessment of the technical solutions on interoperability and security.[12]	

Article 33 – paragraph 2	
Minimum categories of electronic data for secondary use	
Text Proposed by the Commission	**CPME Proposed Amendment[13]**
(2) The requirement in the first subparagraph shall not apply to data holders that qualify as micro enterprises as defined in Article 2 of the Annex to Commission Recommendation 2003/361/EC[21].	(2) The requirement in the first subparagraph shall not apply to data holders that qualify as micro ***and small*** enterprises as defined in Article 2 of the Annex to Commission Recommendation 2003/361/EC[21], ***Medical confidentiality and professional secrecy must be respected during the process.***
Justification	
Doctors making electronic health data available for secondary use will involve an extraordinary effort from the workforce at the expense of patient's treatment and care. Small medical practices should also be exempted due to the disproportionate effort to their activity. Medical confidentiality and professional secrecy need to be respected during the process.	

Article 33 – paragraph 5	
Minimum categories of electronic data for secondary use	
Text Proposed by the Commission	**CPME Proposed Amendment**
(5) Where the consent of the natural person is required by national law, health data access bodies shall rely on the obligations laid down	(5) ~~***Where the consent of the natural person is required by national law,***~~ ***Health*** data access bodies shall ~~***rely on the obligations laid down in***~~

[12] EDPB-EDPS Joint Opinion 3/2022 on the Proposal for a Regulation on the European Health Data Space, 12 July 2022, points 72-76, .
[13] CPME proposed amendments are indicated in bold italics and underlined font.

in this Chapter to provide access to electronic health data.	***~~this Chapter to provide~~ ensure that national requirements for access to electronic health data, such as the consent of natural persons, a right to object to the disclosure of their health data or the involvement of ethics committees, are met before providing*** access to electronic health data.
Justification	
This provision risks undermining public trust in the collection, storage and use of healthcare data. National requirements for access to electronic health data, such as consent of natural persons, a right to object to the disclosure of health data or the involvement of ethics committees, must be met before providing access to electronic health data.	

Article 34 – paragraph 1 – (e)	
Purposes for which electronic health data can be processed for secondary use	
Text Proposed by the Commission	**CPME Proposed Amendment[14]**
1. Health data access bodies shall only provide access to electronic health data referred to in Article 33 where the intended purpose of processing pursued by the applicant complies with: (…) (e) scientific research related to health or care sectors;	1. Health data access bodies shall only provide access to electronic health data referred to in Article 33 where the intended purpose of processing pursued by the applicant complies with: (…) (e) scientific research related to health or care sectors ***for prevention, early detection, diagnosis, treatment, rehabilitation or healthcare management, including fundamental, exploratory or applied healthcare research;***
Justification	
The concept of 'scientific research' is too broad and should be narrowed down to use data for specific purposes related to healthcare.	

Article 34 – paragraph 2	
Purposes for which electronic health data can be processed for secondary use	
Text Proposed by the Commission	**CPME Proposed Amendment**

[14] CPME proposed amendments are indicated in bold italics and underlined font.

(2) Access to electronic health data referred to in Article 33 where the intended purpose of processing pursued by the applicant fulfils one of the purposes referred to in points (a) to (c) of paragraph 1 shall only be granted to public sector bodies and Union institutions, bodies, offices and agencies exercising their tasks conferred to them by Union or national law, including where processing of data for carrying out these tasks is done by a third party on behalf of that public sector body or of Union institutions, agencies and bodies.	(2) Access to electronic health data referred to in Article 33 where the intended purpose of processing pursued by the applicant fulfils one of the purposes referred to in points (a) to (c) of paragraph 1 shall only be granted to public sector bodies and Union institutions, bodies, offices and agencies exercising their tasks conferred to them by Union or national law, including where processing of data for carrying out these tasks is done by a third party on behalf of that public sector body or of Union institutions, agencies and bodies. ***This regulation is without prejudice to national legislation where there is a lawful basis for the timely access to and processing of personal electronic health data*.**
Justification	
This regulation must not override national legislation where there is a lawful basis for the timely access to and processing of personal electronic health data.	

Article 35 – paragraph (e)	
Prohibited secondary use of electronic health data	
Text Proposed by the Commission	**CPME Proposed Amendment[15]**
Seeking access to and processing electronic health data obtained via a data permit issued pursuant to Article 46 for the following purposes shall be prohibited: (…) (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.	Seeking access to and processing electronic health data obtained via a data permit issued pursuant to Article 46 for the following purposes shall be prohibited: (…) (e) developing products or services that may harm individuals and societies at large, including, but not limited to illicit drugs, alcoholic beverages, tobacco ***and nicotine*** products, ***weaponries*** or ~~***goods***~~ ***products*** or services which are designed or modified in such a way that they ***incite addiction, including digital addiction***, contravene public order or morality**.**
Justification	

[15] CPME proposed amendments are indicated in bold italics and underlined font.

e-cigarettes and liquids are tobacco products but should be included in the ban. The development of products and services that incite addiction, including digital addiction, or that can be used as a weapon against human beings, or the environment should also be prohibited. Personal health data coming from the EHDS must be designed for the public good and the well being of humans, the society and the environment. This also ensures coherence with the Digital Services Act and the recent Council Conclusions on supporting well-being in digital education[16] when it comes to digital addiction and to which research cannot escape.

Article 38 – paragraph 3	
Obligations of health data access bodies towards natural persons	
Text Proposed by the Commission	**CPME Proposed Amendment[17]**
(3) Where a health data access body is informed by a data user of a finding that may impact on the health of a natural person, the health data access body may inform the natural person and his or her treating health professional about that finding.	(3) Where a health data access body is informed by a data user of a finding that may impact on the health of a natural person, the health data access body may inform the natural person and his or her treating health professional about that finding***, with due regard for the express wish of the natural person not to be contacted. Medical confidentiality and professional secrecy must be respected during the process.***
Justification	
The provision should foresee the situations where a natural person does not wish to be contacted in case of an incidental finding. Medical confidentiality and professional secrecy must be respected during the process.	

Article 46 – paragraph 1	
Health data access bodies	
Text Proposed by the Commission	**CPME Proposed Amendment**
(1) 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.	(1) Health data access bodies shall assess if the application fulfils one of the purposes listed in Article 34(1) of this Regulation, if the requested data is necessary***, adequate, and proportionate*** for the purpose listed in the application***, if it received a favourable opinion***

[16] Council conclusions on supporting well-being in digital education from 28 November 2022, <https://www.consilium.europa.eu/media/60391/st14982-en22.pdf>.
[17] CPME proposed amendments are indicated in bold italics and underlined font.

	<u>from an authorised ethics committee where applicable or after conducting a data protection impact assessment,</u> and if the requirements in this Chapter are fulfilled by the applicant. If that is the case, the health data access body shall issue a data permit.
Justification	
The internal decision making of Health Data Access Bodies (HDAB) needs to be sustained by appropriate organisational structures. Each HDAB needs to ensure that applications are assessed by independent committees or authorities from an ethical, scientific and personal data protection point of view.	

Article 46 – paragraph 3	
Data Permit	
Text Proposed by the Commission	**CPME Proposed Amendment[18]**
(3) A health data access body shall issue or refuse a data permit within 2 months of receiving the data access application. By way of derogation from that Regulation […] [Data Governance Act COM/2020/767 final], the health data access body may extend the period for responding to a data access application by 2 additional months where necessary, taking into account the complexity of the request. In such cases, the health data access body shall notify the applicant as soon as possible that more time is needed for examining the application, together with the reasons for the delay. Where a health data access body fails to provide a decision within the time limit, the data permit shall be issued.	(3) A health data access body shall issue or refuse a data permit within 2 months of receiving the data access application. By way of derogation from that Regulation […] [Data Governance Act COM/2020/767 final], the health data access body may extend the period for responding to a data access application by 2 additional months where necessary, taking into account the complexity of the request. In such cases, the health data access body shall notify the applicant as soon as possible that more time is needed for examining the application, together with the reasons for the delay. ***~~Where a health data access body fails to provide a decision within the time limit, the data permit shall be issued.~~***
Justification	
Tacit data permits should not be allowed when dealing with health data which can be highly sensible. In addition, it would enable the use of health data for prohibited purposes or for unjustified granting of health data in a pseudonymised format.	

[18] CPME proposed amendments are indicated in bold italics and underlined font.

Article 49	
Access to electronic health data from a single data holder	
Text Proposed by the Commission	**CPME Proposed Amendment[19]**
1. Where an applicant requests access to electronic health data only from a single data holder in a single Member State, by way of derogation from Article 45(1), that applicant may file a data access application or a data request directly to the 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 data holders shall be adressed to health data access bodies.	~~***1. Where an applicant requests access to electronic health data only from a single data holder in a single Member State, by way of derogation from Article 45(1), that applicant may file a data access application or a data request directly to the 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 data holders shall be adressed to health data access bodies.***~~
2. In such case, the 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 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.	~~***2. In such case, the 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 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 controllers.	~~***3. By way of derogation from Article 51, the single data provider and the data user shall be deemed joint controllers.***~~
4. Within 3 months the data holder shall 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	~~***4. Within 3 months the data holder shall 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***~~

[19] CPME proposed amendments are indicated in bold italics and underlined font.

access body to fulfil its obligations under Article 37(1) and Article 39.	~~***this Article in order to enable the health data access body to fulfil its obligations under Article 37(1) and Article 39.***~~
Justification	
This provision should be deleted as data access applications under the EHDS should always be addressed to a Health Data Access Body to ensure access through a secure processing environment and uniform application of Section III on data permit for the secondary use of electronic health data in Chapter IV.	

Article 54 – paragraph 2	
Mutual recognition	
Text Proposed by the Commission	**CPME Proposed Amendment**[20]
2. A data permit issued by one concerned health data access body may benefit from mutual recognition by the other concerned health data access bodies.	2. A data permit issued by one concerned health data access body may benefit from mutual recognition by the other concerned health data access bodies***, <u>if provided for by national law</u>***.
Justification	
The implementation of this provision will be a challenge due to the fragmentation of the ethical and data protection requirements in healthcare. The rollout of mutual recognition should be provided by national law.	

Article 63 – new paragraph	
International access and transfer of personal electronic health data	
Text Proposed by the Commission	**CPME Proposed Amendment**
In the context of international access and transfer of personal electronic health data, Member States may maintain or introduce further conditions, including limitations, in accordance with and under the conditions of article 9(4) of the Regulation (EU) 2016/679.	In the context of international access and transfer of personal electronic health data, Member States may maintain or introduce further conditions, including limitations, in accordance with and under the conditions of article 9(4) of the Regulation (EU) 2016/679.

[20] CPME proposed amendments are indicated in bold italics and underlined font.

	<u>Controllers and processors established in the EU processing personal electronic health data within the scope of this Regulation shall store this data in the EU.</u>
Justification	
Pursuant to the recommendations of the EDPS and EDPB, in order to mitigate the risk of unlawful access and to ensure effective supervision, personal electronic health data needs to be stored in the EU in view of its highly sensitive nature.[21]	

ANNEX I			
MAIN CHARACTERISTICS OF ELETRONIC HEALTH DATA CATEGORIES			
Text Proposed by the Commission		**CPME Proposed Amendment[22]**	
Electronic health data category		Electronic health data 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	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. ***<u>Medical</u>*** Procedures 11. Functional status 12. Current and relevant past medicines 13. Social history observations

[21] EDPB-EDPS Joint Opinion 03/2022 on the Proposal for a Regulation on the European Health Data Space, adopted on 12 July 2022, <https://edps.europa.eu/data-protection/our-work/publications/edps-edpb-joint-opinions/european-health-data-space_en>, points 100-111

[22] CPME proposed amendments are indicated in bold italics and underlined font.

	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		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
(…)		***7. Patient provided data marked as such***	***Documentation on living will.***
Justification			
The patient summary is very wide and encompasses categories of data that are unclear, unstructured, not concise or validated by a registered health professional. Some could also lead to discriminatory practices (e.g. information on insurance). The patient summary must only include important clinical facts.			

ANNEX II	
Essential requirements for EHR systems and products claiming interoperability with EHR SYSTEMS	
Text Proposed by the Commission	**CPME Proposed Amendment[23]**
1.4 An EHR system that is intended to be operated together with other products, including medical devices, shall be designed and manufactured in such a way that interoperability and compatibility are reliable and secure, and personal electronic health data can be shared between the device and the EHR system.	1.4 An EHR system that is intended to be operated together with other products, including medical devices, shall be designed and manufactured in such a way that interoperability and compatibility are reliable and secure, and personal electronic health data can be shared between the device and the EHR system. ***Only certified digital applications which comply with ISO/TS 82304-2 on Health and wellness apps – Quality and reliability and are CE approved can be integrated into the EHR***

[23] CPME proposed amendments are indicated in bold italics and underlined font.

	systems. Wellness applications must not be able to access data in the EHR.
Justification	
Health data generated by wellness applications and other digital health applications do not have the same data quality requirements and characteristics of those generated by medical devices.	