The 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.

CPME Feedback on European Health Data Space

CPME congratulates the European Commission for presenting an innovative framework that addresses specific challenges to electronic health data access and sharing. The proposal for a regulation of the European Parliament and of the Council on a European Health Data Space ('the Proposal')[1] brings new possibilities to use health data for medical diagnosis, the provision of health, social care and treatment, or the management of health care systems and services.

CPME welcomes the clear distinction between the use of health data for the provision of health services (the so-called 'primary use'), and the use beyond the individual care of patients, in particular for research (the so-called secondary use').[2]

European doctors welcome that the Proposal attempts to respect Member States' public health competence, as many points are left for Member States to decide, in particular the possibility to restrict the scope of the rights of natural persons to access personal electronic health data (Article 3(3) of the Proposal), or of their guardians or other representatives, based on patient safety and ethics (Article 3(5) second paragraph of the Proposal); to establish rules and specific safeguards on the restriction mechanisms to be applied to health professionals when accessing electronic health data of natural persons (Article 3(9) of the Proposal); and to allow other categories of personal electronic health data to be available in the EHR (Article 5(1) third paragraph of the Proposal).

European Doctors call your attention to the following challenges stemming from the Proposal:

1. Cultural shift and high impact for European Doctors

The Proposal implies a cultural shift on health data sharing. It will generate a high impact for European doctors in relation to the primary use of electronic health data, with increased obligations costs, and administrative burdens. European doctors warn that, at present, neither the practicing health professionals nor the generation in training are adequately prepared.[3]

[1] COM(2022) 197 final.

[2] A precision should be made in relation to research that uses electronic health data from biobanks and dedicated databases. Biobanks are created for research purposes - this is their primary purpose, and thus do not fit well within the secondary use system concept.

[3] CPME Policy on Digital Competencies for Doctors, November 2020, www.cpme.eu/api/documents/adopted/2020/11/CPME_AD_Board_21112020_100.FINAL_.CPME_.Policy.Digital.Competencies.for_.Doctors.pdf.

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The Proposal will require doctors to be responsible for semantic interoperability, adapt to digital infrastructures, and improve their digital health literacy and digital competencies. While doing so, European doctors must not be obliged to provide health data in disregard to the principles of medical ethics,[4] particularly when that implies increasing the risk-of infringing medical confidentiality and patient's privacy.

2. Categories and purposes for secondary use of electronic health data

Article 33 of the Proposal lists categories of 'electronic data' that 'data holders' will have 'to make available' for secondary use. This list is wide and extensive, comprising very sensitive data that cannot be anonymised. For example, i) genetic, genomic and proteomic data (Article 33(1)(e) of the Proposal), and ii) electronic health data from biobanks and dedicated databases (Article 33(1)(m) of the Proposal). In certain Member States, natural persons are accustomed to exercising rights over their data, in particular they can opt-out or opt-in into the collection and usage of such data.

For CPME, it is important to respect national culture on health data sharing and the principle of data minimisation, as well as specific safeguards and derogations for data protection pursuant to article 89 of the General Data protection Regulation. For this reason, CPME recommends:

- adopting a differentiated approach for certain categories of data, such as 'human genetic, genomic and proteomic data' and 'electronic health data from biobanks and dedicated databases', allowing flexibility for Member States to decide which categories of electronic data for secondary use should belong under an opt-out regime, an opt-in regime, or when the absence of consent would be allowed. These two categories must only be made available with patient's informed consent.

- detailing in the Proposal a clear regime in relation to the role and involvement of ethics committees or review boards.[5] Ethics committees or review boards need to verify, among other, whether the data requested is indeed necessary, if the research in question is worthy, if it can produce scientific sound results, and if it will not be detrimental to the individual. This analysis should be made independently whether consent has been provided by the individual.

3. Consent in secondary use of electronic health data

European Doctors warn about the need to comply with medical confidentiality and professional secrecy obligations to which the processing activity for secondary use must not overrule.

[4] In medical research, the principles of the Declarations of Helsinki and Taipei have to be complied with. The General Data Protection Regulation (GDPR) is not sufficient to address the processing of health data for secondary purposes. The Declarations are more exhaustive in relation to the right to information, the right to access the information about one's health data, and requirements for consent and respective withdrawal limitations. Feedback of findings to the data subject is also desirable for transparency reasons and it may help promote the research by the community at large. See in this sense the WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects, adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964 and as amended by the 64th WMA General Assembly, Fortaleza, Brazil, October 2013; and the WMA Declaration of Taipei on Ethical Considerations Regarding Health Databases and Biobanks, adopted by the 53rd WMA General Assembly, Washington, DC, USA, October 2002 and revised by the 67th WMA General Assembly, Taipei, Taiwan, October 2016.

[5] See CPME leaflet on 'Role of Ethics Committees in the European Health Data Space', 25 May 2022, CPDP Conference 2022, <https://www.cpme.eu/api/documents/adopted/2022/04/A4_CPDP_Flyer_220427.pdf>.

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Pursuant to Article 9(2)(h) read together with paragraph (3) and Article 9(2)(i) of the GDPR, the respect of professional secrecy is a core element to safeguard the rights and freedoms of data subjects (natural persons). Removing the requirement to obtain informed consent from natural persons (Article 33(5) of the Proposal) implies a breach of confidentiality and professional secrecy, and compromises the principles of medical ethics.[6] The EHDS needs to respect individual consent according to national law and the principles of medical ethics.

4. Re-identification risks in secondary use

Several scholars have shown that with little information (e.g. weight-size ratio, age and sex), the re-identification of natural persons is possible and remains a risk to protect patient's privacy.[7] CPME welcomes the principle of anonymisation as a rule for processing health data for secondary use (Articles 44(2) and 47(1) of the Proposal) and the prohibition to re-identify electronic health data in a pseudonymised format (Article 44(3) of the proposal). Sanctions should be high in case of re-identification and disclosure of de-identified personal data, and Member States should consider criminalising such conduct to serve as a deterrent measure.

5. Data quality in the clinical file

The Proposal allows for the possibility of patients or their representatives to insert their electronic health data in their EHR and that information should be marked as inserted by the patient or representative (Article 3(6) of the Proposal). European Doctors warn that this possibility could lead to the EHR becoming less suitable as a clinical tool. The file might be easily saturated with data (due to future interactions of the EHR with medical devices, wellness apps and other software, or result from patient's medical condition which require continuous care), rendering it difficult to find the relevant and useful information.

The Proposal lacks clarification on what doctors and other HCPs, limited by time constraints, need to consult in the EHR, how 'personal notes' will be considered in the EHR and possible liability questions.

6. Costs and impact on small medical practices

Doctors and other healthcare professionals will be required to systematically register the relevant health data in the electronic format in an EHR system (Article 7(1) of the Proposal). This implies that

[6] In this sense, see the WMA Declaration of Taipei on Ethical Considerations Regarding Health Databases and Biobanks, which specifies that consent is only valid if the concerned individuals have been adequately informed about the research.

[7] Sweeney L, Abu A, and Winn J. Identifying Participants in the Personal Genome Project by Name. Harvard University. Data Privacy Lab. White Paper 1021-1. April 24, 2013. (PDF), <https://dataprivacylab.org/projects/pgp/1021-1.pdf>; Gutmann, A. (2013). Data re-identification: prioritize privacy. Science, 339(6123), 1032-1032, <https://www.science.org/doi/10.1126/science.339.6123.1032-b>; El Emam, K., Jonker, E., Arbuckle, L., & Malin, B. (2011). A systematic review of re-identification attacks on health data. PloS one, 6(12), e28071, < https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0028071>; Y. Sei, H. Okumura and A. Ohsuga, "Re-Identification in Differentially Private Incomplete Datasets," in IEEE Open Journal of the Computer Society, vol. 3, pp. 62-72, 2022, doi: 10.1109/OJCS.2022.3175999, < https://ieeexplore.ieee.org/abstract/document/9779455>.

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these professionals are connected to the national electronic health system and/or to the European Health Data Space (EHDS), and that they adapt to the European electronic health record exchange format (EEHRxF).

Member States need to plan in advance and foresee at national level specific budget lines for direct financial support for doctors and other healthcare professionals willing to digitalise and connect their medical practice, with all that it implies (e.g. new infrastructure and cybersecurity maintenance, capacity building and other preparatory actions). The Commission should ensure that Member States distribute evenly and fairly among those affected by the proposal the EU financial incentives available.

Micro-enterprises[8] are excluded from the obligation to make their data available for secondary use in the framework of EHDS. For CPME, this threshold should be higher to also exclude small enterprises[9] or, at least, adherence should be made voluntary.

The time spent by a doctor and other healthcare professionals reviewing and analysing the electronic file may vary considerably, depending not only on the purpose of the consultation (diagnosis, treatment, referral) but also on the patient-doctor relationship (new patient, chronic patient, or regular patient). This time needs to be accounted for by Member States, as well as the time spent in updating or rectifying the electronic file.

7. Conclusion

For the Proposal to be successful, great efforts will be required. Member States are at different digitisation speeds and individuals have different attitudes towards health data sharing. Medical confidentiality, privacy and personal data protection and individuals' consent need to be at the centre of secondary use of electronic health data. In addition, the new way of working will demand investments and continuous development of technical solutions. It is necessary to ensure that the tasks which will have to be performed by doctors do not create a disproportionate administrative burden or cost on professionals. European doctors remain committed to finding workable solutions to achieve a EHDS which will benefit patients.

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[8] Article 2(3) of the Annex to the Commission Recommendation 2003/361/EC of 6 May 2003 concerning the definition of micro, small and medium sized enterprises (OJ L 124, 20.5.2003, p. 36): *"(…), a microenterprise is defined as an enterprise which employs fewer than 10 persons and whose annual turnover and/or annual balance sheet total does not exceed EUR 2 million."*

[9] Article 2(2) Commission Recommendation 2003/361/EC: "(…) a small enterprise is defined as an enterprise which employs fewer than 50 persons and whose annual turnover and/or annual balance sheet total does not exceed EUR 10 million."

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