

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.

European Health Data Space

Reaction to Council's Mandate and European Parliament's Amendments

European Doctors welcome the progress of the legislative file and the impetus to continue building a European Health Union with this key pillar. CPME believes that the proposal for a Regulation on the European Health Data Space (EHDS) has been improved by the co-legislators, addressing Member States' specific situations and historical experiences.

CPME strongly welcomes the recognition of the **principles of professional secrecy and patient confidentiality** in the recitals of the Regulation. European Doctors call for more ambition from co-legislators and expressly devote a paragraph article on these "patient-doctor" relationship key principles.¹ We support the European Parliament's approach on medical liability (AM 122) and on prohibited purposes (AM 333). CPME further recommends a thorough analysis of recitals to ensure coherence with the respective article.²

As co-legislators engage in trilogue negotiations, CPME highlights key aspects for a successful compromise and with positive impact for European Doctors:

1. CPME supports the Council's **flexible approach to the secondary use of data** (Recital 37a and Article 35F of the Council's mandate).
2. European Doctors support **electronic registration** of health data by healthcare professionals in primary use and the right for natural persons to **object to the access to their personal electronic health data registered** in an electronic health record system in primary use. To prevent any misconception, CPME stresses that a right to object to the registration of personal health data in an EHR system, as proposed by the European Parliament (AM 555), should not result in an obligation for doctors to register health data

¹ Please see CPME [Proposed amendments on the European Health Data Space](#), January 2023.

² For example, Recital 19 in relation to new Article 6(2) of the Council's mandate; Recital 20 with Article 7A of the Council's mandate; and Recital 21 with Article 8 of the Council's mandate.

in paper records. Member States should also establish the rules and specific safeguards regarding such objection mechanism.

3. On the **right to restrict access and information on access**, CPME strongly supports the Council's approach where *"the healthcare provider or health professional shall be informed exclusively about the existence of restricted electronic health data"* (Article 7A (3) of the Council's mandate). This is a paramount requirement to provide safe healthcare without hindering the private life of patients.
4. European Doctors further support the European Parliament's amendment which safeguards the **integrity of health professionals**, including from violent patients, *"(... where there are factual indications that disclosure would endanger the vital interests or rights of the health professional or the care of the natural person"* (AM 123). Member States should be able to set out additional safeguards and/or restrictions to the right to restrict access and information on access.
5. CPME supports the Council's approach to delete the provision on **telemedicine** (Article 8) and other related articles. This provision implies regulating over Member States' responsibilities for the organisation and delivery of health services and medical care, including the management of health services.
6. CPME regrets that **small enterprises** have not been exempted from providing data for secondary use. We believe that this additional digital burden can deeply aggravate the administrative burnout. 40% of a doctor's time is spent on administrative work (15h–20h per week). CPME sees positively the solution proposed by the Council of **"health data intermediation entities"** to relieve healthcare professionals of this task (Article 32A (4) of the Council's mandate). However, the relationship between healthcare professionals and "health data intermediation entities" needs to be clarified.
