



Proposal of the Council of European Dentists with partners

Joint statement on the European Health Data Space

In a joint statement, five healthcare professions to include doctors, dentists, community pharmacists, hospitals and nurses support amendments to the European Health Data Space (EHDS), which safeguard confidentiality and ethical duties, propose clarity on medical liability, reduce administrative burdens and offer appropriate compensation for the high costs of digitalisation.

As co-legislators continue their negotiations on the European Commission's Proposal for a Regulation on the European Health Data Space (EHDS), healthcare professions appeal for wise provisions that ensure a smooth transition for the workforce and feasible implementation for professional practice. For the EHDS to be truly workable for healthcare professions longer implementation timelines will be required.

The Council of European Dentists (CED), the Standing Committee of European Doctors (CPME), the European Federation

of Nurses Association (EFN), the European Hospital and Healthcare Federation (HOPE) and the Pharmaceutical Group of the European Union (PGEU) call upon the co-legislators of the European Health Data Space to respect higher ethical principles of patient confidentiality and professional secrecy, to exclude healthcare professionals from providing data again for secondary use, to bring clarity and certainty for liability of healthcare professionals in the electronic health record (EHR), to provide financial compensation for digitisation costs.

limited to the primary use of data, meaning prevention, diagnosis, treatment, and care, avoiding duplication of work. CED, CPME, EFN, HOPE and PGEU support amendments 1217, 1218, 1219 and 1220, which partly reflect these concerns by excluding small enterprises in the context of healthcare professionals practice and pharmacies.

- **To bring clarity and certainty for liability of healthcare professionals in the electronic health record.**

The draft regulation needs to specify what healthcare professionals are required to see in the EHR in a short time frame without fear of being prosecuted for negligence. Depending on the medical history, an EHR can reach thousands of electronic pages. Similarly, the draft regulation needs to provide answers for cases when patients block certain information from healthcare professionals, on the legal value of “patient provided data” in the file, and on who is competent to rectify a clinical fact in the file and how.

CED, CPME, EFN, HOPE and PGEU support amendments 232, 655, 679, 680, 683 and 684, which address liability of healthcare professionals. It should be clear that healthcare professionals cannot be responsible for the quality of the data in the EHR when these data are originally stored by another healthcare professional. Healthcare professionals can only be responsible for the data they have collected and inserted themselves. CED, CPME, EFN, HOPE and PGEU support amendments 216, 220, 221, 654, 656, 660 and 662 on the rectification of clinical facts. It should be further clarified that healthcare professionals are only required to review the “patient summary”. “Patient provided data” should be a separate electronic health data category in Annex I pursuant to amendment 2137.

- **To provide financial compensation for digitisation costs.**

The costs of digitalisation should not be passed on to healthcare professionals, hospitals and healthcare services. Member States should foresee specific budget lines for direct financial support to healthcare professionals, hospitals and healthcare services willing to connect to MyHealth@EU and/or adapt to new specifications of registering electronic health data. Digitalisation should not increase administrative work for healthcare professionals, hospitals and healthcare services, and should be voluntary.

CED, CPME, EFN, HOPE and PGEU support amendments 3, 8, 22, 200, which recognise the need for additional funding. It needs to be further ensured that Member States directly apply the funding for healthcare professionals, hospitals and healthcare services who are to be connected to MyHealth@EU.

Source: CED

- **To respect ethical principles of patient confidentiality and professional secrecy.**

Providing data for secondary use must never breach patient confidentiality and professional secrecy. The data sharing obligations in secondary use must not endanger the patient–healthcare professional relationship. The unique and irreplaceable asset of communicating in confidence will be rendered trivial, and the fundamental right of access to healthcare will be in jeopardy if these principles are not respected. Patients may become reluctant to seek treatment for fear that their condition will be disclosed to others. There must be no risk of exposing patients’ most sensitive data to unknown third parties, including for commercial purposes. CED, CPME, EFN, HOPE and PGEU support an explicit reference to the ethical principle of respecting patient confidentiality and professional secrecy in the draft regulation.

- **To exclude healthcare professionals from providing data again for secondary use.**

With the scarcity of healthcare professionals, they should not be burdened with administrative tasks that take away patient time and experience. This is especially relevant since the burden of compliance with the EHDS would require serious efforts, in particular from smaller healthcare practices. In some instances, this may even lead to closing of some practices and early retirement. Healthcare providers’ obligations should be