

WG eHealth

Peter Kukolik, Chair
CED General Meeting

May 2026



TEHDAS2 Public Consultation

Public consultations

TEHDAS2 is developing guidelines and technical specifications to enable seamless use of health data across Europe under the upcoming European Health Data Space (EHDS). Each document is released for a public consultation to ensure that the final outputs meet the needs of citizens, health professionals and regulators.



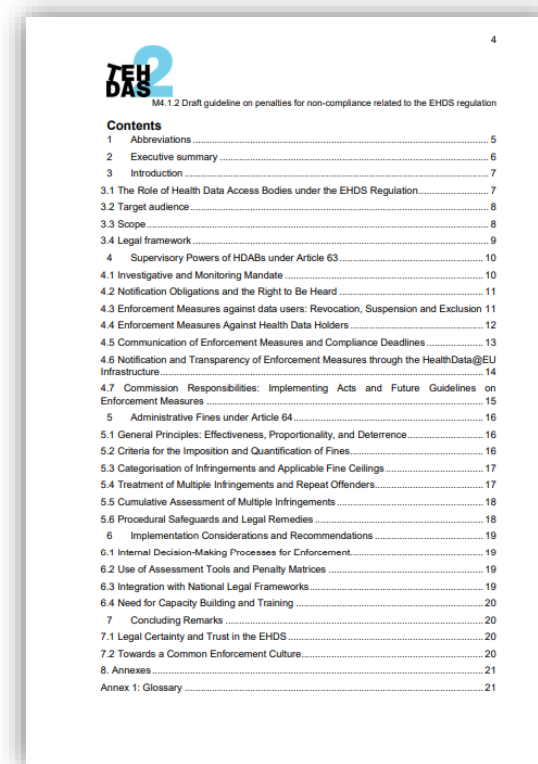
M4.1 Draft guideline on fees and penalties for non-compliance related to the EHDS regulation

Second section: 4.1.2 Draft guideline on penalties for non-compliance related to the EHDS regulation

TEHDAS2 – Second Joint Action Towards the European Health Data Space

17 September 2025

Co-funded by the European Union 



M4.1.2 Draft guideline on penalties for non-compliance related to the EHDS regulation

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Digital Omnibus Proposal

Simplification – digital package and omnibus

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- **Definition of Personal Data:** Shift from an ‘objective’ to a ‘contextual’ approach.
- **AI Training & Deletion:** Companies can retain sensitive data (including health data) in AI models if deletion is deemed a “disproportionate effort”.
- **CED Position:** Digital progress must not come at the expense of robust patient data protection.



EHDS & MyHealth@EU Consultation



European Health Data Space – requirements for cross-border exchange of personal health data (MyHealth@EU)

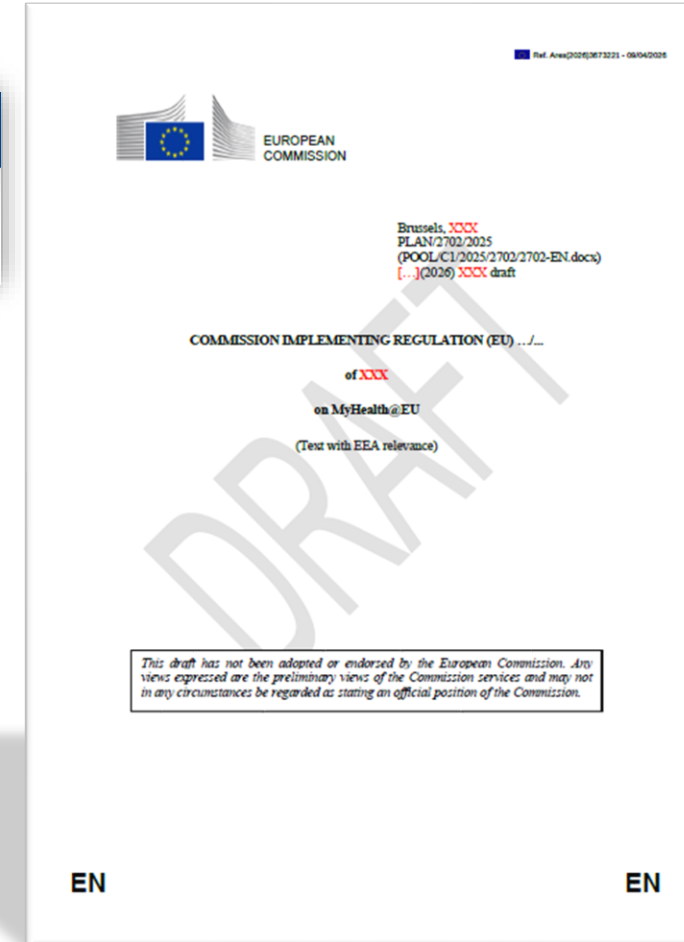
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European Health Data Space – requirements for cross-border exchange of personal health data (MyHealth@EU)

Clinical Accuracy: Preventing loss of detail in specialized dental terminology through clinical validation.

Legal liability: Clarifying responsibility between original data entry and automated mis-mapping.

Support for Small & Micro Dental Practices: Ensuring financial and technical aid for small/micro dental practises.



EHDS & Identity Management Consultation



European Health Data Space – identity management

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Professional Privacy: Disclosing only the minimum necessary information to protect the safety of healthcare professionals.

Delegated Access: Clear rules for staff/ assistant access to ensure accountability.

Security Balance: Protecting both patient rights and professional safety.



Updated CED Resolution



CED RESOLUTION

UPDATED CED Resolution on Data Sharing as part of eHealth: *Workflow, Prescription, Protection and EHDS*



I. Introduction: Dentistry and e-Health

The Council of European Dentists (CED) is a European not-for-profit association which represents over 340,000 dental practitioners across Europe through 32 national dental associations and chambers in 30 European countries. Established in 1951 to advise the European Commission on matters relating to the dental profession, the CED's key objectives are to promote high standards of oral healthcare and dentistry and effective patient-safety centered professional practice. While the cornerstone of the dentist-patient relationship is face-to-face contact, we recognize that digital health services have become an essential element of modern healthcare infrastructure.

The regulatory landscape has shifted significantly with the European Health Data Space (EHDS), which introduces a mandatory framework for the exchange of primary and secondary health data across the Union. While the CED supports the overarching goals of patient empowerment and seamless cross-border care, it is imperative that this transition remains operationally feasible and financially sustainable for the dental profession by EU level funding.

II. CED areas of concern

1. Digital Workflow

Digital workflow in dentistry has transitioned from being a voluntary tool for patient empowerment into a mandatory interoperability requirement under the EHDS. While these tools continue to facilitate the immediate flow of information between dentists, patients, and other health professionals, this transition must now move beyond simple data sharing toward a structured, legally compliant digital ecosystem.

The CED's primary concern is to ensure that the mandated digital workflow remains clinically feasible in daily practice. For the majority of dental practices, which operate as micro and small enterprises, the transition brings a heavy administrative and financial burden. The implementation must prioritize "future-only" data registration to avoid the unmanageable task of retrospective digitization. The digital workflow must build upon standards, for both format and semantics, that are relevant and suitable for the dental profession to facilitate reuse of clinical documentation. The digital workflow should support the "only-once" principle, ensuring that dentists spend their time on patient treatment rather than data entry.

2. e-Prescriptions

Under the EHDS regulatory environment, discrepancies in prescription validity and digital formats are addressed through common EU standards to ensure that patients can access their medication in any Member State. However, the CED emphasizes that this technical harmonization must not undermine the prescribing dentist's clinical oversight. Common

standards must include robust protocols for professional authentication and liability clarity, ensuring that a dentist's clinical decision remains the primary authority, even when the prescription is dispensed in a different jurisdiction.

3. Data protection

A critical concern arises from the EHDS transparency requirements regarding access logs. While the CED supports the patient's right to monitor data access, it is imperative that this information is limited to professional identification (such as clinical function or institutional affiliation). To uphold the EHDS principle of accountability without endangering the safety or private life of the practitioner, access logs must be managed via proportionate and secure systems. This approach ensures that transparency objectives are met while preventing even unintended misuse of administrative data, thereby protecting the integrity of the patient-practitioner relationship and maintaining a secure professional environment.

III. CED recommendations

The development of eHealth solutions should be based on a user-friendly and user-centred approach, adjusting them to the needs of dentists instead of creating an additional burden or increasing the costs of dental practice. The involvement of healthcare professionals in every decision-making on digital technologies in healthcare is a prerequisite for making the system support efficient care.

A guiding vision of CED regarding the future of dentistry is to ensure that every European has access to quality oral health care provided by qualified, skilled and fully competent dental practitioners, in a comfortable and cost-effective manner, using the most appropriate technology.

In light of this and the points above, the CED highlights the following recommendations:

- EHDS obligations must apply prospectively only. Dentists should not be burdened with the retrospective digitization of legacy records.
- To ensure the timely implementation of the EHDS, the CED urges action to define an EU standard for the format and semantics of dental health data exchange, while supporting the "once-only" principle.
- The CED strictly opposes the commercialization of health data. Secondary use must respect the right to opt-out and ensure that data is only processed via Health Data Access Bodies to guarantee the public good.
- There must be absolute legal clarity on how EHDS overlaps with the Medical Device Regulation (MDR) and GDPR to avoid a compliance burden where dentists face

conflicting regulatory requirements.

- The introduction of EHDS must be accompanied by the principle of financial compensation for implementation costs. Since dentists are the providers of these data, EU-level funding must cover the additional costs of hardware, software upgrades, and mandatory cybersecurity training.

The CED believes that digitization can be useful in transferring knowledge for education and research purposes, as long as patient confidentiality is ensured.

- Therefore, increased investment and promotion of digital literacy is required (at national, regional and local levels), through financing models and reimbursement schemes. This should cover appropriate education, identification of barriers to digital tools access, training and support of dentists and the dental team.
- Priority should be given to the implementation of digital skills education into the dental studies curriculum.
- The CED supports initiatives that increase transparency regarding data access. Patients must be informed as to who accessed their medical records and when, ensuring that personal health data is used in a manner that is scientifically sound and ethically acceptable.

Vote Time!



- **Does the GM agree to the adoption of the CED Resolution on Data Sharing as Part of the eHealth?**



THANK YOU!

