CED Position

European Health Data Space

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Council of European Dentists

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I – INTRODUCTION

The Council of European Dentists (CED) is a European not-for-profit association which represents over 340,000 dentists across Europe. The association was established in 1961 and is now composed of 33 national dental associations from 31 European countries. The CED's core mission is to promote the interests of the dental profession in the EU.

On 3 May 2022, the European Commission presented the proposal for a Regulation to create a European Health Data Space (EHDS)[1]. The aim of the EHDS, so far envisioned to be operational by 2025, is to connect national health systems based on interoperable digital exchange formats to enable secure and efficient cross-border transfer of health data. It is envisioned as a '*health-specific data sharing framework establishing clear rules, common standards and practices, infrastructures and a governance framework for the use of electronic health data by patients and for research, innovation, policy making, patient safety, statistics or regulatory purposes.*'[2] As such, the EHDS is intended to regulate aspects of both primary and secondary use of health data[3].

The CED welcomed the proposal on the EHDS, in light of its overall objective of '*empowering individuals across the EU to fully exercise their rights over their health data*'[4] and enabling health professionals to '*access a patient's medical history across borders, thus increasing the evidence base for decisions on treatment and diagnosis (…)*'[5]. Nevertheless, it is important to ensure that the proposal and its future implementation are truly workable and beneficial for healthcare professionals (HCPs), dentists included. This is especially relevant considering the progress on the file at the European Parliament and Council level. In light of the recent European Parliament Draft Report on EHDS[6], the CED welcomed the proposed inclusion of more robust measures focusing on 1) ensuring that health professionals and their representatives are involved in the activities of the digital health authority of each Member State (MS), guaranteeing that their interests are taken into account, 2) the importance of ensuring that sufficient EU level funding is provided for the timely and successful implementation of the EHDS across all MS, 3) additional provisions for lessening the burdens of EHDS implementation for healthcare professionals.

Nevertheless, a year into the launch of the EHDS proposal, the dental profession remains concerned about its practical implementation. These concerns are driven by a plethora of factors. There are many discrepancies and variations in progress among MS when it comes to use of electronic health records and dental data specifically. Furthermore, implementing and maintaining participation in the EHDS architecture brings numerous burdens to a dental practice. These include financial costs for software and hardware but also many hours dedicated to training and compliance – a time that dentists and their teams would devote to patient treatment and care. As such, a longer implementation period is essential. This is especially relevant for many smaller dental practices – for them, the increased financial and regulatory EHDS burdens could represent a significant challenge. In some cases, this could

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[1] European Commission, COM(2022) 197/2, Proposal for a regulation - The European Health Data Space, https://health.ec.europa.eu/publications/proposal-regulation-european-health-data-space_en

[2] European Commission, Questions and answers - EU Health: European Health Data Space (EHDS), https://ec.europa.eu/commission/presscorner/detail/en/qanda_22_2712

[3] European Parliament, The European Health Data Space, Section 'Primary use versus secondary use': '*The EHDS defines primary use of health data as use to support or provide direct individual healthcare delivery to the data subject. (…) Secondary use is defined as the use of individual-level (personal or non-personal) health data, or aggregated datasets, for the purpose of supporting research, innovation, policy making, regulatory activities and other uses.',* https://www.europarl.europa.eu/RegData/etudes/STUD/2022/740054/IPOL_STU(2022)740054_EN.pdf

[4] European Commission, Questions and answers - EU Health: European Health Data Space (EHDS), https://ec.europa.eu/commission/presscorner/detail/en/qanda_22_2712

[5] Ibid.

[6] European Parliament, Draft Report on the proposal for a regulation of the European Parliament and of the Council on the European Health Data Space, (COM(2022)0197 - C9-0167/2022 - 2022/0140(COD)), Committee on the Environment, Public Health and Food Safety, Committee on Civil Liberties, Justice and Home Affairs, https://www.europarl.europa.eu/doceo/document/CJ43-PR-742387_EN.html

even lead to closing of dental practices, opting for early retirement, or joining bigger dental chains.

II - CED POSITION

The CED would like to underline that the recommendations below are significant for the dental profession and for ensuring that the EHDS is truly workable. They were developed through the activities of the CED Working Group eHealth and were also updated to take into account the most recent developments on the proposal at the EU institutional level. In light of the EHDS proposal and its focus on secondary and primary data use, the CED recommendations are also structured accordingly, focusing on the overall proposal and then on the types of data use.

General

- From a medical perspective, it is essential that there are no additional costs and administrative burden associated with the introduction of the EHDS for dentists, especially since they will not be the primary beneficiaries. The requirements of dental practices that are categorised as micro and small enterprises[7] must be taken into particular account. Furthermore, considering the envisioned goal of having a functioning health data system, it is important to clarify how the costs for any additional hardware, software, cybersecurity trainings and administrative efforts for registering data and any related activities will be covered, and by which stakeholders (those should be the main beneficiaries of the EHDS). As part of the EHDS implementation, supranational (EU) financial support and supplementing actions should be provided to alleviate the abovementioned costs.

- A longer and workable implementation period is needed as much of the data mentioned in the EHDS proposal are not yet available electronically or only in rudimentary form, and there are discrepancies among MS on how such data are processed and stored. A longer implementation period, offering exclusion from the EHDS obligations for a timeframe based on individual MS needs and circumstances, is also crucial due to the significant administrative burden that many dental practices might face in order to participate in a structure such as the EHDS.

- It is essential to ensure that all healthcare professionals who deem it necessary are enabled to attend digital literacy courses. Since attending such courses brings additional costs for healthcare professionals but also time commitment that is normally dedicated to patients, Member States must take into account these burdens, including through envisioned financial support and subsidies.

- Since EHDS touches on various existing and developed legislations, it is important to have clarity on their interplay. For example, in the case of dentistry, the Medical Device Regulation (MDR) has a continuous impact – as such, it needs to be clarified what type (if any) additional compliance will be required in the case of a medical device that is providing health data. Further clarifications are also needed in relation to the provisions of EHDS and the existing General Data Protection Regulation (GDPR).

- Furthermore, in accordance with the subsidiarity principle, the individual healthcare systems of EU Member States (MS) must be respected. Despite all the advantages, care

[7] European Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises, section Annex, Article 2): *'(…) 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., (…) 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.'* https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:124:0036:0041:en:PDF#:~:text=The%20category%20of%20micro%2C%20small,not%20exceeding%20EUR%2043%20million.

must be taken when designing the EHDS to ensure a high level of data protection for both primary and secondary use of health data. It must be ensured that the secondary use of data is carried out according to public good principles. Health data are not and must not become a commodity.

- A clearly defined opt-out process should be in place for patients, enabling them to decide if and how they want their medical data (especially dental data) to be added as part of the EHDS and distributed within it.

- Data used in dentistry contain many variables and are therefore not shareable in a straightforward manner. They should therefore be excluded or kept as low as possible when it comes to sharing, especially considering that dentists are not the primary beneficiaries of the EHDS. From a dental perspective, radiographs, and clinical photos as well as 3D data are the only appropriate data to share at a European level.

- It must be ensured that the EHDS does not create silos within different levels of protection for health data (data protection vs data security). Data protection ensures that data are restorable in cases of loss and corruption; data security ‘shields’ data from unauthorised access and distribution. Both principles should exist hand in hand when implementing the EHDS.

- The overarching principles of common good, non-discrimination, data economy must be respected.

- It must be ensured that only "usable data sets" are transmitted. This means data sets that are consistent in terms of format, content, structure.

- The goal of the EHDS is to contribute to an efficient cross-border transfer of health data. As such, for a health record to be truly accessible and usable by HCPs across borders, it is crucial to ensure the use of consistent and coordinated medical terminology, but also the incorporation of recognised medical codes and all the necessary additional translations.

- A functioning patient education must be ensured, allowing for patients to be empowered and knowledgeable on the EHDS and the use of their data. Medical practices must not be burdened with additional costs and obligations for raising awareness and educating on this issue.

- There is a need to clarify the role dentists should assume according to the EHDS (data owner, data holder, etc.), since each of these roles bears a different set of rights and responsibilities. Furthermore, as work on EHDS progresses, it is also crucial to clearly outline the responsibilities of dentists in terms of registering health data, categories of data to be registered, data quality requirements (Art.7.3 EHDS). The CED has also continuously underlined that the data to be registered should be limited only to the degree appropriate for the specific medical field and treatment.

Primary use

- Dentists should be obliged to provide treatment data only once for the electronic patient record. All processing beyond this should subsequently be carried out via the electronic patient record or file platform (including consent).

- The obligation to provide data should apply only "per future" and in each case from the time when structured data formats / standards are available. There must be no obligation to register data retrospectively.

- There must be a low-effort procedure for obtaining and documenting patient consent regarding the electronic processing of their data.

- The CED highlights that data protection, both for the patient and the dentist, are crucially important. A fine balance should be ensured between the provisions in Art.3.9 and Art.3.10 of EHDS alike. Natural persons should have full control over restricting access to their health data without impeding dentists from providing diagnosis and treatment of importance. By having full access to a broad overview of the relevant patient health records, the dentist would also have an overview of all necessary health information (e.g. medical history, risk factors, comorbidities). Access to such data is to be treated with respect to all relevant data protection legislation and guidelines.

- As per the EHDS provisions, natural persons will also be empowered to know whether their electronic health data have been accessed by HCPs. As such, it is imperative that only necessary information that does not endanger the current or future safety, and privacy of the HCP, is made available to the patient.

Secondary use

- The provision of data for secondary purposes must not present an additional administrative burden on medical practices, already tasked with registering primary data. As such, a dental practice should not be expected or obliged to submit data on several occasions, a time that can be dedicated to patient treatment and care. This should be taken into account by the health data access bodies that MS should designate to deal with secondary data use (Art. 36, 37 EHDS).

- The group of persons/entities entitled to apply for obtaining secondary data must be limited (‘public service obligation’) and must be the subject of consistent checks and reviews including after approval of an application.

- Applications for data use must be assessed against a clearly defined criteria; such criteria should be developed in a holistic manner, based on input from relevant stakeholders involved in the process of data registering and use. This input must also include dentists.

- Applications for secondary data use must be explicitly approved (no automated or implicit approval) on a case-by-case basis, and in accordance with the abovementioned public service obligation and set of criteria.

- Dental and other medical practices that use data exclusively for health care should not be obliged to actively make these data available for secondary use.

- The CED welcomes the fact that entities with up to 10 employees and a turnover of up to 2 MLN EUR per year are exempt from the obligation to provide data for secondary use (‘micro enterprises’[8]) However, this threshold should be extended to small enterprises as well – comprised of up to 50 employees and 10 MLN EUR turnover per year[9].

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[8] European Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises, section Annex, Article 2)
[9] Ibid.