

## **BRUSSELS OFFICE UPDATE**

### **CED WORKING GROUPS AND BOARD TASK FORCES**

### **CED BOARD MEETING SEPTEMBER 2025**

#### **WG Education and Professional Qualifications (EPQ)**

- **WG meetings:**
  - ➔ Latest meeting: 1 September
  - ➔ Upcoming meeting: TBC

#### **Implementation Report on the Professional Qualifications Directive**

Due to shifting of units within the European Commission, the publication of the PQD Implementation report has undergone several delays and is now foreseen for the last quarter of 2025.

According to the latest minutes of the Group of Coordinators (GoC) meeting from March, the plan to improve and simplify the recognition of qualifications, announced by the Union of Skills, will depend on the outcome of the published Implementation report. The WG therefore stands ready for any needed reaction on the upcoming publication.

#### **Quality of the dental workforce and standards of foreign dental diplomas**

The latest WG meeting was dedicated to discussing the quality of dental workforce and standards of foreign dental diplomas, based on the memo shared by the KNMT to the Board meeting in May.

As agreed at the latest Board meeting in May, the discussion raised by KNMT was taken up by WG EPQ and ideas of actions to be taken to address these issues were exchanged during the September meeting.

The discussion gravitated around three main outlined topics:

- the introduction of language on mandatory continuing professional development under the PQD
- the inclusion of additional supporting clinical training modules and language testing as mandatory requirements for registering under the national competent authority.
- The strengthening of wording on clinical experience under the PQD and the reiteration of the CED position, outlined in the consultation response submitted in September 2024

However, the WG was reminded that, according to an EU court ruling, Member States are authorised to integrate mandatory additional year(s) of clinical training after the completion of undergraduate studies, applying only to graduates from the national state taking the decision (as a Member State competence). This mandatory clinical year cannot apply to incoming dentists having graduated from other EU Member States.

This also applies to the mandatory nature and content of CPD schemes.

The WG agreed to develop a policy or guidance paper on strengthening clinical training and CPD. This paper would include clear rules or guidance on the need to integrate additional clinical training following the completion of undergraduate studies, as well as life-long CPD.

The nature and content of such a document is yet to be determined.

Members also discussed of the possibility to request a meeting with the relevant European Commission representative on PQD issues, to put forward CED positions.

### **External Relations**

CED President and WG Chair attended the ADEE Meeting and ADEE 50th anniversary in August in Dublin.

### **Functioning of WG EPQ and ideas for optimisation**

The WG briefly discussed the functioning of WG EPQ and relevant ideas for improving its work.

## **WG eHealth**

- **WG meetings:**
  - ➔ Latest meeting: 27 February, in-person
  - ➔ Upcoming meeting: 16 October, in-person

### **Cybersecurity Task Force:**

Back in February, the WG eHealth provided a reply to the Polish Office for Registration of Medicinal Products, Medical Devices and Biocidal Products in relation to cybersecurity and medical devices questionnaire. In the questionnaire, they also asked if CED would be interested in joining a possible Task Force (TF) on the topic. While CED indicated its interest, no further information on the TF, its envisioned activities etc. was shared until we were invited to the first launch meeting which took place on 1 August. The meeting was attended by Chair Kukolik and Senior Policy Officer Nikoleta Arnaudova. The impressions from the meeting were disseminated to the WG.

According to the information we got during this first meeting:

- **Purpose of the Task Force:** producing a report, to be ready in December and to be presented to the Medical Device Coordination Group (*Medical Device Coordination Group (MDCG) deals with key issues from the medical devices*

*sector, from Notified Body oversight or standardisation to market surveillance, passing by international matters, new technologies and clinical investigation, the European Commission acts as its Chair and it is composed of Member State representatives and other stakeholders such as European associations), on cybersecurity topics that should be addressed - by the Commission- afterwards, maybe by legal acts, changes to existing legal acts or modified or improved guidance documents. The focus of the report will cover legal aspects (e.g. the interaction and discrepancies between the MDR and the EU Cyber Resilience Act) and also cover both pre and post market cybersecurity of medical devices.*

- The reason for the December deadline is that (so far), it is expected that this is when the Commission may launch its proposal for revision of the MDR, so they want this report to match the timeline.

#### Positives:

- Interesting group of stakeholders – competent authorities and ministries from member states, notified bodies, health, cyber and medical devices organisations. The European Commission attends as observer. The main lead is the Polish Office for Registration of Medicinal Products, Medical Devices and Biocidal Products.
- Relates to a legislative priority - the revision of the MDR, *however*, CED already plans to be involved in this in any case (especially via its WG Dental Materials and Medical Devices), we are already part of several MDCG configurations and in touch with the Commission responding to their consultations on the MDR etc. We are also part of the big MDCG group to which the report of this TF will be submitted to for consultation.
- Pre market/post market focus could be interesting (namely the post part when devices are utilized at user level)

#### Negatives:

- It is unclear whether AI in relation to cybersecurity as a topic will be included (so far, the organisers did not seem too keen to incorporate it, according to our understanding)
- Important initial documents for the TF (such as its scope of work) were discussed and prepared beforehand and the rest of us were presented with already drafted texts
- Very short timeline of producing something by December
- It touches on other pieces of legislation that has not been the focus of CED so far (e.g. the Cyber Resilience Act)
- In general, the meetings every 2-3 weeks might pose a problem in terms of how fast they want participants to vote, give input, make decisions – from CED perspective, this barely gives enough time, considering our necessary decision making process at WG and Board level
- The whole process and first meeting appear to be quite rushed, considering that this is a technical and complex topic
- The WG eHealth Chair also noted the friction among some of the state (national ministries of health for example) participants on basic issues, e.g.

what the scope of work should be, which ended up dominating the discussion during this first meeting.

- So far, information and supporting documents were sent very last minute, including the day before the first meeting itself. Again, this would be problematic for more robust and concrete texts that would require input.

The WG was asked whether CED should remain as observer, have more active role or stop its participation. Unfortunately, the member with specific cybersecurity expertise (who was asked to join the Task Force) stated that this is not possible for him at the moment. Overall, there was some preference for potentially keeping observer status but some members were also against that.

WG Member Vasileios Stathopoulos volunteered to attend meetings. He attended the second meeting which took place on 3 September together with CED Senior Policy Officer Nikoleta Arnaudova and Policy Officer Elif Dincher. He stated that he found the second meeting too administrative due to its focus on planning - and as such will need to attend another meeting to give better feedback. At the time of writing this document, a third meeting is envisioned for sometime in start of October but exact timing is yet to be communicated.

**Board guidance required: should CED remain in this configuration and in what capacity?**

**Reply to consultation on European Commission Cybersecurity Action Plan for Hospitals and Healthcare providers:**

In July 2025, the WG provided a reply to the Consultation, highlighting the priorities and concerns of the dental profession in relation to cybersecurity. As a reminder, the WG discussed the Plan during its last meeting and was overall supportive of it. The Plan is part of the Political Guidelines of the 2024-2029 Commission mandate, and focuses on improving threat detection, preparedness, and crisis response in the healthcare sector in relation to cybersecurity. It aims to provide tailored guidance, tools, services, and training to hospitals and healthcare providers. As a further reminder, since this is an Action Plan, it is not 'hard law' like a directive or regulation but rather offers guidance and pathways to improving cybersecurity.

**AI and liability:**

At its upcoming in-person meeting, the WG plans to continue discussing the topic of AI and liability of healthcare professionals and practices. The discussion may lead to the creation of a specific statement/position on the topic.

**Updates of older eHealth WG positions:**

During its upcoming in-person meeting, the WG plans to discuss previous positions from the last few years. The goal is to identify which positions would need to be updated considering that the topic of eHealth progresses and evolves very quickly.

**WG Dental Materials and Medical Devices (DMMD)**

- **WG meetings:**
  - ➔ Latest meeting: 17 March online
  - ➔ Upcoming meeting: 16 September online

### **Medical Device Coordination Group (MDCG) Guidance on the health institution exemption'**

The guidance was opened for initial round of feedback by MDCG members (this includes CED) by 5 September. One of the key references in this specific MDCG Guidance document is in relation to what constitutes as a health institution (and therefore is covered by certain exemptions under the MDR, e.g. in relation to in-house use of devices). The new version contains examples of such health institutions – CED included a proposal for the inclusion of additional wording that includes other healthcare practices (such as dental ones). The proposal was sent to the relevant contacts, next steps are yet to be communicated.

### **Meeting with MDCG Working Group on Market Surveillance on CAD/CAM:**

As per previous information shared with the Board, on 26 June, the CED President, the WG DMMD Chair, Nicola Paolucci and Nikoleta Arnaudova attended an online meeting on CAD/CAM (organised by the European Commission in light of its role as the secretariat for the MDCG WG on Market Surveillance) where CED and the dental technicians representative organisation (FEPPD) presented their positions on the matter. In August, CED contacted the Market Surveillance Working Group Chairs to check on any additional next steps and results from the discussion on the topic, so far no reply has been received.

**Board decision required: guidance as needed.**

### **CED draft reply to the recently launched call by the European Commission on Medical devices and in vitro diagnostics – targeted revision of EU rules**

At its upcoming meeting, the WG DMMD will discuss the call for evidence that was recently launched on this topic. A CED draft reply was shared with them.

The call is coming ahead of the envisioned proposal for review of the MDR that is expected in Q4 2025 or Q1 2026. According to the Commission, the initiative will aim to simplify and streamline the regulatory framework, and make it more cost-efficient and proportionate, while preserving a high level of public health and patient safety and maintaining the overall structure of the current regulatory framework. More specifically, the initiative aims to:

- reduce the administrative burden including reporting obligations;
- enhance the predictability and cost-efficiency of the certification processes of notified bodies;
- make the conformity assessment requirements more proportionate, especially for low- and medium- risk devices and those that cater to special patient needs;
- enable further digitalisation;
- streamline procedures including those on governance;
- enable the EU medical device sector to benefit from international cooperation including reliance, where appropriate;
- better align the regulatory framework with other relevant legislation.

### **WG Oral Health (OH)**

- **WG meetings:**

- ➔ Latest meetings: 30 June
- ➔ Upcoming meeting: TBC, end of September/beginning of October

### **Prevention and accessibility of oral healthcare**

At the latest meeting on 30 June, the WG discussed the drafting of a new policy document on prevention, following the decision to merge two of the workstreams. This paper will simultaneously update two outdated CED policy papers: the 2019 CED White Paper on Oral Care: “Prevention is better than cure” and the 2011 CED Resolution “For Better oral health of all EU citizens: Mutual Integration of Oral and General Health”.

In line with the target audience and objectives of this paper, as well as the scope of action following its adoption, the WG also received an update on the recent launch of the MEP Interest Group on Health Inequalities, Prevention and Risk Factors at the European Parliament. The WG discussed the possibilities of using such policy material for advocacy activities with this MEP interest group.

The WG therefore agreed to initiate the drafting of this paper, firstly within the remaining members of the merged workstream. Further issues on the key issues and direction of the paper will be discussed at a future group meeting.

Additionally, the WG was informed of the on-going global WHO negotiations around the UN Zero Draft Political Declaration on the prevention and control of NCDs and the promotion of mental health and well-being, and the current efforts being deployed for the inclusion of oral health promotion under the scope of the paper. According to latest reports, oral health is now mentioned among the scope of NCDs included in the document.

### ***Amalgam***

Alongside the drafting of the Prevention paper, the draft survey on alternative amalgam composites was shortened and revised. The results of this survey would be used to include data on the accessibility and availability of certain oral treatments in the prevention paper.

An initial version of this survey was shared with the Board at the November Board Meeting, date at which the Board took the decision to temporarily postpone the survey. The Board had also invited the WG to further reflect on the direction and objectives of the survey. An updated and shortened version of the survey has been added as part of the working documents for this meeting.

### **Sugar**

The WG has been discussing the future development a lobby package on sugar, for supporting NDAs in lobbying activities on sugar at a national level. This lobby package is still foreseen to be developed.

Written exchanges have been carried out between the CED and the Standing Committee of European Doctors (CPME) regarding current and past activities on the topic of sugar or any relating topics, as well as possibilities for collaborating on future advocacy activities with the goal of strengthening sugar control legislation. This includes involvement and activities touching upon the EU Cardiovascular Health Plan,

the EU School Fruit, Vegetables and Milk Scheme, the Tobacco Tax Directive. The possibility of a future collaboration has however not yet been determined.

## **Tobacco**

The GM adopted in May the updated CED Resolution on Tobacco, Alternative Tobacco and Tobacco-Free Nicotine Products.

The CED is currently preparing a response to the European Commission consultation on the Proposal for a revised Council Directive on the structure and rates of excise duty applied to tobacco and tobacco related products (or the revision of the Tobacco Taxation Directive). The deadline for submission of input is 29 October. The WG will be presented with a draft CED reply for feedback in the upcoming weeks.

This consultation stems from the announcement by the European Commission, on 16 July 2025, of the revision of the EU Tobacco legislation.

This announcement unveiled two major proposals, including the long-awaited revision of the Tobacco Taxation Directive (previously Council Directive 2011/64/EU on the structure and rates of excise duty applied to manufactured tobacco), and the additional revision of the Excise Duty Directive and the creation of a new Tobacco Excise Duty Own Resource, with 15% of minimum excise rates of each country for manufactured tobacco and related products going towards the EU budget.

The revision of the Tobacco Taxation Directive expands the scope of the Directive to include new alternative tobacco products, including heated tobacco, e-cigarettes, nicotine pouches and other nicotine products, as well as an increase in minimum taxation rates for targeted products.

## **Antimicrobial Resistance**

No new activities have been started on AMR by the WG. The WG was however informed of the recent publication by the European Medicines Agency (EMA) of recommendations to limit prescription and change the authorisation of the use of antibiotic azithromycin in the EU (as it is shown to carry a higher risk of AMR, with the consumption of this antibiotic on the rise in recent years). According to the recommendations, this would apply to antibiotics given in the case of dental infections (including periodontal abscesses and periodontitis).

## **Ageing**

The paper on Ageing and Oral Health will be presented for adoption at the November GM. At the latest WG meeting, it was agreed to present this document as a White Paper. The number of scientific references was reduced in an effort to put forward a paper to be used for policy purposes. The latest amendments included the addition of commercial determinants of health.

The WG was informed of the latest institutional activities in the area of ageing, including the adoption by the ECOSOC Council of Council Conclusions supporting older people in reaching their full potential in the labour market and society, as well as the Danish Presidency priority of supporting the future of ageing and long-term care.

## **Obstructive Sleep Apnea (OSA)**

The WG held a discussion on the introduction of a new topic of work around obstructive sleep apnea. The WG Chair presented the relevance of this interdisciplinary topic and the idea of drafting a paper addressing the interdisciplinary management of OSA by dentists. Following discussions around the key issues surrounding the topic, the WG agreed to draft an Action Proposal Form to be presented to the Board at the September meeting.

Needed clarification remains on the scope of the topic, including its possible extension to cover dental sleep medicine in general and a wider group of sleep disorders.

### **EU Cardiovascular Health Plan**

The WG prepared and submitted on the 15 September a CED response to the European Commission call for evidence on the EU Cardiovascular Health Plan.

This response highlighted the mutual interaction between oral and cardiovascular health and called upon the European Commission to embed oral health across all aspects of the EU Cardiovascular Health Plan. This includes acknowledging the role of dentists in the screening, prevention, and detection of oral and cardiovascular diseases, as well as the importance of treating oral diseases for the effective management and treatment of cardiovascular diseases.

### **External meetings:**

The CED will keep participating in the European Medicines Agency's (EMA) online HCPs POG meetings (meeting of eligible Healthcare Professionals Learned Societies Policy Officers' Group (POG)). The next meeting will take place on 20 October.

## **WG Patient Safety, Infection Control and Waste Management (PSICWM)**

- **WG meetings:**
  - ➔ Latest meeting: 13 February
  - ➔ Upcoming meeting: 15 September 25

### **Paper on mouthguards:**

At its upcoming meeting on 15 September, the WG will discuss a draft position on mouthguards. The text is envisioned for adoption at the November 2025 General Meeting.

In this recommendation paper, the CED will focus on preventive measures against orofacial injuries that athletes may encounter during sports activities. As is well known, whether recreational or competitive, sports and athletic activities provide substantial benefits for physical, mental, and psychological well-being. However, athletes are at an elevated risk of sustaining traumatic dentofacial injuries (TDIs), particularly in high-contact sports. The growing awareness of these risks has led to the development of preventive oral care programs and the recommendation of protective appliances, particularly custom-made mouthguards (CMSs). These devices are proven to minimize the risk of traumatic dental injuries by absorbing and redistributing the force of impacts, stabilizing the jaw, and separating oral structures to prevent soft tissue damage. For

this reason, their adoption should be considered a shared responsibility among athletes, coaches, parents, sports organizations, and dental professionals.

**Board decision required: guidance as necessary on the draft paper (CED-DOC-2025-040-E)**

### **Paper on vaccination policy**

The paper on vaccination policies for dentists and other dental professionals (supported through the responses of CED members to the 2023 survey on the same topics) has been published in the Expert Review of Vaccines, A MEDLINE-indexed peer-reviewed journal providing expert commentary on the development, application, and clinical effectiveness of new vaccines.

### **BTF Internal Market (IM)**

- **BTF meetings:**
  - ➔ Latest meeting: 13 March
  - ➔ Upcoming meeting: TBC

### **Corporate dentistry:**

The Task Force on corporate dentistry of ERO and CED continues working on this topic. The survey on corporate dentistry continued being open and was reshared with members who have not provided replies yet, and at the time of writing of this document, has 42 replies.

Thomas Wolf, as member of the Task Force, has already proceed with the preparation of a first scientific article using data from previous surveys conducted by CED. The first article is titled *Corporate dentistry in European Union: A cross-national survey of legal frameworks and market dynamics*, and uses data from the 2022 CED survey. The goal was to submit the manuscript to an international peer-reviewed journal (potentially the International Dental Journal).

### **CED Statement on Quality of Dentistry across borders:**

Based on input from several BTF members, the BTF prepared a statement to reflect on some of the challenges and concerns of European dentistry specifically in relation to third country (foreign educated) dentists in relation to matters such as linguistic knowledge, professional ethics, familiarity with the healthcare system of their country of work. The document was adopted at the May GM.

### **Hellenic Dental Association application to the BTF IM:**

The HDA has applied to be members to the BTF IM. Two members are proposed, Vasileios Stathopoulos and Sofia Papadima (lawyer for the HDA).

**Board decision required: decision on the membership of HDA to the BTF IM**

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