// BRUSSELS OFFICE UPDATE

CED BOARD WORKING GROUP DENTAL MATERIALS AND MEDICAL DEVICES

NOVEMBER 2018 GENERAL MEETING

Last Meeting: 15 October 2018

Medical Devices Update

- Following feedback from WG Dental Materials and Medical Devices, a Draft CED Statement on MDR CAD-CAM (CED-DOC-2018-074-E) was developed and shared with the WG Members for feedback in early September. The finalised text was presented briefly during the WG Dental Materials and Medical Devices in-person meeting on 15 October and is ready for voting at the November General Meeting.
- The WG was contacted with regards to two different European Commission Consultations:
  - The Commission's Joint Research Center (JRC), together with DG GROW is running a public consultation on the expert groups according to Article 106 of the Medical Devices Regulation. Following feedback from WG Members, the CED provided replies to the relevant points of the Consultation.
  - EUnetHTA Joint Action 3, WP4 Joint Production has developed draft recommendations for Horizon Scanning, including a workflow for Topic Identification, Selection and Prioritisation to support European Health Technology Assessment (HTA) cooperation.
- Three meetings of relevance to medical devices, organised by the European Commission, took place in September – the meetings focused on 1) the International Medical Device Regulators Forum and its activities, 2) Unique Device Identification (UDI), and 3) the work of the European Commission Medical Device Coordination Group. Relevant points were communicated briefly during the last WG meeting on 15 October.

Health Technology Assessment (HTA)

- The last WG meeting was attended by a representative of the European Commission who provided information and overview on HTA; the Council of European Dentists does not have an official position on this topic and has therefore predominantly taken an observing role. In addition to that, it is important to note that HTA is restricted in scope and may not touch on health technologies that are of relevance to the dental profession.
- Since the European Commission would like to encourage further cooperation on HTA among Member States, it announced at end of 2017 that it will push for an initiative on this; the initiative was adopted on 31 January 2018. The main goals of this initiative were

highlighted as allowing for new health technologies to reach patients faster, while at the same time boosting Europe's competitiveness in the health sector.

- The proposal from the European Commission has been voted at the European Parliament and is now going to the Council. It is unlikely that finalisation takes place before the EP elections. The CED will continue monitoring the situation and will communicate any relevant updates to its members.

Mercury Regulation – Next Steps

Feasibility Study

- WG Chair Jane Renehan, Susie Sanderson and Lea Pfefferle met with the Commission on 27 September to discuss the feasibility study that will investigate the possible dental amalgam phase-out by 2030.
- Timeline:
    - Start: September 2018
    - Stakeholder workshop and presentation of final first draft: Autumn 2019
    - Final report: January 2020
- Main contractors: Wood plc (Caspar Cordon) and Deloitte France (Andreas Mitsios – who was involved in the 2012 BIO IS study on dental amalgam).
- The CED representatives explained that it is crucial that prevention is phased up for the phase down or even a phase out of dental amalgam to be successful. The Commission delegates were interested to hear about the aspect of prevention and said they would take this into account.
- The CED offered that we could provide contact information for experts on various issues related to dental amalgam (provided they agree to work on this) and put the contractors in touch with them.
- The CED discussed that there needs to be more funding for research and development into new materials and into the environmental impact of alternative materials. The Commission suggested they could speak to their colleagues to place hooks in the high-level wording of Horizon Europe that could later on make it possible to have specific projects on this.
- The Commission explained that the phrasing of 'business as usual' in the tender refers to the implementation of the Mercury Regulation.

National Action Plans

- The Commission is planning to call a meeting of national experts in December to discuss the progress on the National Action Plans (NAPs) that have to be published by July 2019. The objective of the NAPs is to identify national actions that will help to phase down the use of dental amalgam.
- The NAPs and their impact should also be discussed in the feasibility study, yet the timing presents an issue since the NAPs will only be published in July 2019 but the first final draft of the feasibility study has to be ready by autumn 2019.
- The CED encourages all members to be engaged in the set-up of their national action plans.
- The CED is preparing a document outlining important issues that the Commission should discuss with the member states in light of the meeting in December.

Tooth Whitening

- The WG has created an advocacy document that should be send to members to lobby their national contacts to reverse the ban on the use of tooth whitening in persons under 18.
- The document includes speaking points, a summary of previous activities, a bibliography and some suggestions for action.

ISO Declaration of Dental Materials

- The CED sent a letter to the TC 106 Dentistry in advance of their September meeting to reiterate the need to include the declaration of dental materials in the updated ISO 4049.
- The ISO delegates in the relevant TC have approved the wording and it is now up to the national standardisation bodies to approve the updated ISO 4049.
- The CED encourages member organisations to be aware of the position the respective national standardisation bodies are taking and to get in contact in case they are contradictory to the CED efforts.

Titanium Dioxide

- In 2017 a report from the European Chemicals Agency (ECHA) risk assessment committee recommended that Titanium Dioxide (TiO2) should be classified as category 2 carcinogen meaning it's a suspected carcinogen, not a known one — when inhaled.
- The European Commission is currently working on a proposal that has to be accepted by Member States. The current proposal foresees to classify the chemical as carcinogenic only in its powder form. This only applies to mixtures containing 1% or more of particles with the diameter <10ɲm containing TiO2. If that happens, every product containing the chemical in powder form, such as paper and powdery makeup, would need to have a warning label saying it is "suspected of causing cancer."
- Products in liquid and solid form, such as sunscreens and paints, would need to carry a label warning that "dangerous" droplets or dust may form when the product is used.
- Some countries, led by France, are pushing for stricter labelling for liquids and solids.
- Given that TiO2 is used in some composite resins, the CED will continue to monitor the issue.

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