

## **CED GUIDANCE DOCUMENT**

### **NATIONAL ACTION PLAN FOR THE REDUCTION OF THE USE OF DENTAL AMALGAM**

*February 2018*

#### **1. Context and Timeline**

- In order to implement the [UN Minamata Convention on Mercury](#), the EU adopted the so-called [Mercury Regulation](#) (2017/852/EU) in May 2017. This Regulation introduces provisions on dental amalgam (Article 10), including the requirement for each member state to publish a **national action plan by 1 July 2019** indicating how the phase-down of the use of dental amalgam will be achieved.
- At the same time, the European Commission is tasked to conduct a study to assess the feasibility of a phase-out of dental amalgam by 2030. This study has to be finalised by 30 June 2020 and will take into account the national action plans.
- Therefore it is of crucial importance that the national action plans are a) well-designed and b) that dentists are leading on or are at least involved in the development of their country's plan.
- It is evident that each country will create a unique plan and that these plans should not be used to compare countries against each other. The aim, however, is the same; namely to present feasible options for a phase-down of dental amalgam.

#### **2. Suggested Action Items**

1. Investigate which government body deals with the implementation of the Mercury Regulation and specifically Article 10. In some countries the responsibility may lie with either or both the Ministry for Health and Ministry for the Environment and it will be important to know who has been given the leadership role.
2. Identify who is in charge of developing the national action plan - in some countries the development will be the responsibility of the self-regulating bodies like the chambers, in others it will be the ministries;
  - a. Explore if the ministry has already initiated the work on the national action plan, if applicable

3. Put together your suggestions for the national action plan as per the below proposal and inform the CED if you have any issues;
4. Work with the appropriate bodies to come to an agreement on the plan if agreement is needed;
5. The national action plan must be finalised by 1 July 2019.

### **3. Involvement of the dental community**

- Relevant members of the dental community (including practitioners, those in dental public health, academic and teaching establishments etc.) need to be involved in the consideration of the national action plan to ensure that it includes measures that are realistic and practical.

### **4. Suggested Content of the National Action Plan**

We suggest you might find it useful to include the following items in your national action plan. If you identify additional areas that you believe are valuable for other CED members, please share them with the CED Office. This is a possible framework and the content of each of the points depends on your national context:

- **Investment Need:**
  - Identify where investment is required (e.g. in prevention, R&D, upskilling, etc.) as per your points below and who needs to make the investment. Estimate the value of the investment that will be required if possible.
- **Data collection on use of amalgam**
  - Present all available data on the current use of dental amalgam in your national context.
  - If no data are available, state the reasons and, if there is a possibility to collect these data in the future, refer to that.
- **Prevention and public education**
  - The Minamata Convention argues that one measure to reduce the use of dental amalgam is to set out national objectives aiming at dental caries prevention and health promotion to minimise the need for dental restoration
  - Consider if data are available to measure the success of existing prevention and dental public health programmes and demonstrate where levels of dental disease have been reduced. Which cohorts of the population are demonstrating improvements? Is this success likely to continue? Are the currently successful programmes sustainable and adequately funded in the long term?
  - Describe how prevention and public education on oral health can be improved in your country and what investments are needed to achieve this.

- **Funding and health insurance systems**
  - Discuss whether insurance systems and/or state funded dental services are assisting in or currently counter-productive to the aims of phasing down the use of dental amalgam.
  - If amalgam is the reference product for reimbursement, suggest the changes will be required in the future.
  - Use data that you already have on future projections of reimbursement and what this would mean for the dental profession.
  
- **Undergraduate and postgraduate training and CPD**
  - The Minamata Convention suggests that representative professional organisations and dental schools ensure that all dental professionals are educated and trained in the use of mercury-free dental restoration alternatives and promote best management practices.
  - Indicate whether training in the use of alternative materials is already included in the undergraduate curriculum in all dental schools in your country.
  - Indicate whether postgraduate training is readily available and accessible in the use of alternative materials and the knowledge and experience of restorative techniques that may not have been acquired during undergraduate education.
  - Where these arrangements are not already in place, properly funded and accessible, indicate where the responsibilities lie, practical solutions to achieving the changes and an estimate of the funding requirements.
  
- **R&D into alternative materials**
  - The Minamata Convention sees promoting research and development of quality mercury-free materials for dental restoration as one of the measures to reduce the use of dental amalgam.
  - Discuss involvement of research teams (academic and industry) in restorative materials, techniques and environmental impacts in your country.
  - Elaborate what has to be done to encourage more research and development of alternative materials, including their environmental impact.
  - Suggest who should finance this R&D, e.g. the government, industry, etc.
  
- **Amalgam waste management**
  - Discuss the situation in your country, e.g. how widely are amalgam separators already used, the recycling of waste amalgam, availability of licensed waste companies.
  - Quantify the investment needed to outfit all practices with amalgam separators.
  - Evaluate whether financial support is needed to fulfil the mandatory outfitting with amalgam separators. Estimate the costs.

- **Regulatory compliance**
  - Elaborate on how and who will ensure compliance with the national action plan and the Mercury Regulation. This could, for example, refer to practice inspections and audits, and action taken by regulatory authorities in case of non-compliance.
  
- **Patient consent and record keeping**
  - There should be clear guidance for dentists in the two way communication required to achieve valid consent of patients or their guardians regarding the choice of dental filling materials. Guidance will also be valuable in relation to the detailed records that should be kept of the conversations leading to these decisions. We suggest that the dental body takes the lead on providing detailed advice to dental professionals.
  - It is likely that some patients may misunderstand the rationale behind the environmental drivers of the phasing down of dental amalgam and ask that their existing sound dental amalgam restorations are removed. Expert opinion ([SCENIHR](#)) is that such treatment will usually be unnecessary and not be in the patient's best interest. Careful and valid consent will be needed for such elective treatment. Dental Associations may have a role in advising dentists about how to respond to such requests so that they manage the risk of any adverse results from unnecessary treatment. Please see the section below on public messaging.
  
- **Public relations messaging**
  - The moves to restrictions of the use of dental amalgam, particularly in under 15s, are likely to raise some unwarranted concerns amongst the public and patients in relation the health risks of dental amalgam. It will be important to prepare and agree consistent communications messages, emphasising the environmental origin of the restrictions and bearing in mind the lack of an evidence base on health grounds.
  - Consider who is responsible for developing the communications/public relations plan and ensuring that urgent work takes place on this.
  - Decide whether the communications actions within the plan should be proactive to try to prevent anxiety or reactive in the event of public concern.
  
- **Commentary on the regulation in relation to the restriction on the use of amalgam in the treatment of deciduous teeth, children under 15 years and pregnant or breastfeeding women, except when strictly deemed necessary by the practitioner on the ground of specific medical needs of the patient**
  - The Regulation introduces the above mentioned language on the restriction of use of amalgam from 1 June 2018. We suggest you consider whether practitioners require guidance on what is strictly deemed necessary on the ground of specific medical needs. We recommend that you do not stay

entirely silent on the issue. At the same time our advice is that it will be counterproductive to provide an exhaustive list of medical indications.

- Instead we suggest that dentists are likely to make an assessment of the medical need by focusing on the following aspects:
  - Caries experience
  - Overall medical condition
  - Cooperation of the patient
  
- **Goals and timeframe - taking all the above factors into consideration :**
  - **Goals:** Provide realistic aims for the phase-down of dental amalgam that can be achieved in the given timeframes.
  - **Timeframe:** Estimate the short- and long-term aspects of each of your objectives.
  - **Reduction Targets:** We recommend that you consider whether to set explicit reduction targets:
    - On the one hand, you may not want to set or agree explicit reduction targets unless you are sure that they can be achieved without disadvantaging patients or destabilising dental businesses. On the other hand, setting or agreeing explicit reduction targets may assist you in securing funding and investment where it is needed to achieve the targets.
    - You may find that you are pushed to agree reduction targets that are prescribed by the government. Such targets will always have to be dependent on the national context (for example - oral health levels, prevention programmes, funding systems and the previous/current use of dental amalgam). Keep in mind that, just because one country has either already achieved minimal use of dental amalgam or declares its intention to set bold targets, the reality is that individual countries will have unique challenges that must be taken into account.
    - It is likely that zero usage of dental amalgam cannot be achieved because some patients will satisfy the exceptions included in Article 10.

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