

The Secretary, Expert Committee on the Selection and Use of Essential Medicines

Medicines Selection, IP and Affordability, Department of Health Products Policy and Standards
20 Avenue Appia
1211 Geneva 27
Switzerland

Geneva, 19 May 2021

Subject: FDI World Dental Federation comments to application ‘C.7 Proposed new section: Section 30 – dental preparations – EML and EMLc’

Dear Dr Huttner,

Ahead of the meeting of the 23rd WHO Expert Committee on the Selection and Use of Essential Medicines to update the WHO Model List of Essential Medicines (EML) and the WHO Model List of Essential Medicines for Children (EMLc), FDI World Dental Federation (FDI) would like to congratulate the Expert Committee on its efforts to increase access to a comprehensive list of essential medicines, medical devices, and products for all worldwide. We take this opportunity to share our comments on the application C.7 which suggests the following:

- Establishment of a new section 30 within the EML and EMLc entitled “Dental Preparations”;
- Addition within this new section of a sub-section 30.1 entitled “Medicines for dental caries”;
- Moving the existing entry “sodium fluoride” (currently listed under section 27 “Vitamins and Minerals”) to sub-section 30.1 (without any changes to the current specifications);
- Addition of a new entry under sub-section 30.1 for fluoride toothpaste;
- Addition of a new entry under sub-section 30.1 for silver-diamine fluoride (SDF);
- Addition of a new entry under sub-section 30.1 for glass-ionomer cementum (GIC).

This new application is of paramount importance given that oral diseases affect almost half of the world’s population. In addition to the physiological and psychosocial impact they have on individuals resulting in a significant number of lost work and school days, they impose a huge financial burden on families and health systems. More specifically, tooth decay (dental caries) affects both children and adults, leads to preventable pain and health expenditure, increases the risk of some systemic diseases, and disproportionately impacts those from low- and middle-income countries and marginalized groups. Therefore, increasing access to basic oral healthcare is crucial to improve people’s overall health outcomes and well-being.

For this reason, FDI welcomes the recognition for the need to create a section under the EML and EMLc on “Dental preparations” with a focus on increasing access to fluoride-containing (or fluoride-releasing) products to reduce the burden of dental caries, the most prevalent disease globally, affecting more than 1 in 4 people in the world.^[1] Fluoride has a proven efficacy, cost-effectiveness, and safety for reducing the



prevalence and severity of dental caries and delaying its onset. Moreover, through topical action, fluoride can also play a therapeutic role in the treatment of non-cavitated enamel carious lesions as well as in cavitated caries (e.g., root carious lesions).^[2] The use of toothpaste, a self-care product, with a fluoride concentration between 1,000 and 1,500 ppm has also proved to be effective in preventing, arresting and treating dental caries with a negligible risk of fluorosis,^[3] and it should be made available widely as an over-the-counter product at an affordable price and subject to reduced taxation.^[4]

FDI believes that the inclusion of these products (fluoride toothpaste, SDF and GIC) in essential packages of care, medicines, and supplies, such as the WHO-endorsed Basic Package of Oral Care,^[5] is crucial to increase access to oral healthcare for all. Also, increasing access to fluoride toothpaste can decrease the misuse of non-fluoride or homemade toothpastes, which do not have a caries-preventive effect. However, we are concerned that the inclusion of fluoride toothpaste, SDF and GIC in the EML and EMLc might be misleading for countries who do not process these products as medicines but rather as cosmetic products (i.e., fluoride toothpaste) or medical devices or products (i.e., SDF and GIC), easing their commercialization and therefore access in those countries. Thus, **we would like to stress the relevance for fluoride toothpaste, SDF and GIC to be considered under the EML and EMLc as “Device” under medicine type, and include under Expert Committee recommendations, that these products should be considered a cosmetic product, medicinal device or product, or medicine depending on national regulatory frameworks and classification systems** with the finality of increasing their access while ensuring their quality. To avoid any misinterpretations and for accuracy, **we would also recommend that the new sub-section 30.1 is entitled “Preparations against dental caries”** instead of “Medicines for dental caries”, in line with the new section 30 entitled “Dental preparations”.

Furthermore, we recognize the need to increase access to alternatives to dental amalgam in accordance with the Minamata Convention on Mercury, and also the role that GIC can have in increasing access to restorative treatment in remote settings, including in places with no electricity nor running water.^[5] That said, more research needs to be done to find full alternatives to dental amalgam that are as durable, accessible and affordable, while being environmentally sound, and **we therefore encourage that the new section “Dental preparations” of the EML and EMLc is revised regularly in the future** to be updated with other medicines, medical devices, and restorative materials for oral health as they become available and cost-effective.

We are grateful for this opportunity to comment on the EML and EMLc review process. For any questions, please contact Dr. Charanjit Jagait, FDI’s Communications and Advocacy Director, at: cjagait@fdiworldldental.org.

Best regards,

Dr Gerhard K. Seeberger
President

Mr Enzo Bondioni
Executive Director



References:

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- [4] FDI World Dental Federation. Promoting oral health through fluoride toothpaste: Adopted by the FDI General Assembly: 7 September 2018, Buenos Aires, Argentina. Original version adopted by the FDI General Assembly: November 2000, Paris, France. *International Dental Journal*. 69(1):17-8, 2019. <https://doi.org/10.1111/idj.12469>.
- [5] FDI World Dental Federation. The Challenge of Oral Disease – A call for global action. Oral Health Atlas, 2nd edition (eds. Benzian H, Williams D). Geneva: FDI World Dental Federation, 2015. <https://www.fdiworldddental.org/oral-health-atlas>.