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Re: IADR Comments on 2021 proposed revisions to WHO List of Essential Medicines.

- **Support: C.7 Proposed new Section: Section 30 – dental preparations – EML and EMLc**
- **Support: A.14 Fluoride toothpaste – dental caries – EML EMLc**
 - **But maintain “sodium fluoride” in Group 27 “vitamins and minerals”**

via email: emlsecretariat@who.int

The International Association for Dental Research (IADR), which represents over 10,000 researchers around the world with a mission to drive dental, oral and craniofacial research for health and well-being worldwide, appreciates the opportunity to share our thoughts on the Model List of Essential Medicines (EML) being developed by the World Health Organization (WHO). IADR applauds the WHO on their continuous effort to ensure the efficacy, safety, and cost-effectiveness of medicines for the updating of both the WHO EML and WHO EML for Children (EMLc). The use of the EML by over 150 countries as a guide to create individual country specific lists that define the medicines that are funded and provided bolster the importance of critically selecting the essential applications that are added to the EML.

IADR supports the establishment of a new section within the EML and EMLc for “Dental Preparations” with a subsection to include “Medicine for dental caries”. Oral diseases affect ~3.5 billion people globally and pose a major health burden for many countries and affect people throughout their lifetime, causing pain, discomfort, disfigurement and even death¹. According to the Global Burden of Disease Study in 2017, untreated dental caries in permanent teeth is the most common health condition. Globally, ~2.3 billion people suffer from caries of permanent teeth and more than 530 million children suffer from caries of primary teeth^{2,3}. Unequal distribution of oral health professionals, lack of appropriate health facilities and high cost for dental treatment in most countries translates to low access to primary oral health services. These factors often contribute to the high burden of oral health diseases in low- and middle-income countries⁴.

The inclusion of a Dental Preparations section (30) and a Medicines for dental caries subsection (30.1) within the EML defines dental preparation resources as medicines that are considered necessary for all health systems. This provides the foundation for individual countries to have increased access and

provide funding for these essential resources to facilitate sustainable, equitable access and promote appropriate use. Due to the caries burden being notably unequal across populations, with a clear socioeconomic gradient showing higher disease burden in deprived and disadvantaged populations, the addition of this section can be utilized as a key tool for achieving universal health coverage by providing guidance to governments, health facilities and procurers. IADR supports the further refinement of the EML and EMLc at the national level based on national needs, criteria, and legislation, to define the process for each included material or product.

IADR supports adding fluoride toothpaste to the subsection 30.I Sodium fluoride and other fluoride salts are ingredients of various dental preparations used to prevent dental caries and promote the remineralization of carious tooth substance⁵. Therefore, the inclusion in subsection 30.I will allow for increased access to essential resource that may be utilized in preventative dental health measures as discussed earlier.

Regular toothbrushing with fluoride toothpaste is a principal non-professional intervention to prevent caries across all age groups. Extensive clinical trials over the last 60 years have shown that fluoride toothpaste delivers fluoride safely and is effective in preventing caries⁹. The use of fluoride toothpaste has been shown to be a systemic intervention for the prevention of caries in older adults⁹. Up to 24% of caries lesions are prevented by using over the counter fluoride toothpaste when compared to non-fluoride toothpaste⁸. Over the counter fluoride toothpastes at a concentration of 1000-1500 ppm have been shown to be effective at disease-level prevention in primary and permanent tooth with a negligible risk of fluorosis⁶. Although ~1.5 billion people are estimated to use fluoride toothpastes regularly, it is not universally accessible and affordable to populations in middle and low-income countries⁷. Considering its cost effectiveness, safety, and efficacy, toothbrushing with fluoride toothpaste is the best approach to address the high burden of preventable caries across populations worldwide⁸. Therefore, inclusion in the WHO EML and EMLc will be critical to increasing the accessibility of fluoride toothpastes on national levels in countries that are of middle or lower income.

To ensure that the inclusion of fluoride toothpaste does not result in a reduction in access in countries that do not typically process fluoride toothpaste as a medicine, IADR supports the classification of fluoride toothpaste under subsection 30.I as a cosmetic product, medicinal device or product, or medicine dependent upon national regulatory frameworks and classification systems. This may reduce any misinterpretations and reduce the possibility of a circumvention in access.

However, fluoride is a mineral that is essential for our body to develop and function normally and therefore should **not** be removed from Section 27 Vitamins and Minerals. In addition to its use in dental preparations, the mineral fluoride, prevents tooth decay by making the enamel more resistant to the action of acids¹⁰. They and accelerate the buildup of healthy minerals in the enamel, further slowing the occurrence of decay¹⁰. Therefore, it is appropriate that sodium fluoride be also retained in section 27. Although technically, “fluoride” is the mineral and “sodium fluoride” the salt. The WHO may consider altering Section 27 to simply stating “fluoride”.

IADR appreciates the opportunity to provide comments on the Model List of Essential Medicines currently being reviewed. IADR stands ready to work with the WHO and the Expert Committee on the Selection and Use of Essential Medicines to further define the classification of the fluoride toothpaste subsection. If you have any further questions, please contact Dr. Makyba Charles-Ayinde, Director of Science Policy, at mcayinde@iadr.org.

Sincerely,



Christopher H. Fox, DMD, DMSc
Chief Executive Officer

¹World Health Organization. (2020). Oral Health. [accessed 05/14/2021]: <https://www.who.int/news-room/fact-sheets/detail/oral-health>.

²Global Burden of Disease and Injury Incidence and Prevalence Collaborators. (2020). Global, regional, and national incidence, prevalence, and years lived with disability for 354 diseases and injuries for 195 countries and territories, 1990-2017: a systematic analysis for the Global Burden of Disease Study 2017. *Lancet*. 10;392(10159):1789-1858.

³Global Burden of Disease 2017 Oral Disorders Collaborators. (2020). Global, regional, and national levels and trends in burden of oral conditions from 1990 to 2017: A systematic analysis for the Global Burden of Disease 2017 study. *J Dent Res*. 99(4):362-373.

⁴World Health Organization. (2021). What is Burden of Oral Diseases. [accessed 05/14/2021]. https://www.who.int/oral_health/disease_burden/global/en/

⁵Chu CH, Lo E. (2008). Uses of Sodium Fluoride Varnish in Dental Practice. *Ann R Australas Coll Dent Surg*. 19:58-61

⁶Wong MCM, Clarkson J, Glenny AM, Lo ECM, Marinho VCC, Tsang BWK, Walsh T, and Worthington HV. (2011). Cochrane Reviews on the Benefits/Risks of Fluoride Toothpastes. *J Dent Res*. 90(5):573-9.

⁷FDI World Dental Federation. (2015). The Challenge of Oral Disease - A Call For Global Action. Oral Health Atlas 2nd edition (eds Benzian, H & Williams, D). Geneva & Brighton: FDI & Myriad Edition.

⁸Horst JA, Tanzer JM, and Milgrom PM. (2018). Fluorides and Other Preventative Strategies for Tooth Decay. *Dent Clin North Am*. 62(2): 207-234.

⁹Paris S, Banerjee A, Bottenberg P, Breschi L, Campus G, Doméjean S, Ekstrand K, Giacaman RA, Haak R, Hannig M, Hickel R, Juric H, Lussi A, Machiulskiene V, Manton D, Jablonski-Momeni A, Santamaria R, Schwendicke F, Splieth CH, Tassery H, Zandona A, Zero D, Zimmer S, Opdam N. (2020). How to Intervene in the Caries Process in Older Adults: A Joint ORCA and EFCD Expert Delphi Consensus Statement. *Caries Res*. 54(5-6):1-7.

¹⁰Medjedovic E, Medjedovic S, Deljo D, and Sukalo A. (2015). Impact of Fluoride on Dental Health Quality. *Mater Sociomed*. 6:395-8.