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Secretary of the Expert Committee on the Selection and Use of Essential Medicines
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Via email to emlsecretariat@who.int

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EML Application A.14 - Joint comment of all ten WHO Collaborating Centers related to Oral Health

Dear Dr Huttner

We are pleased to jointly submit our comments related to the application

A.14 Fluoride Toothpaste – Dental Caries - EML and EMLc

As WHO Collaborating Centers for oral health (WHO CCs), we are dedicated to supporting WHO in its efforts to improve oral health globally. The initiative to expand the WHO List of Essential Medicines (EML) for adults and children (EMLc) by including several dental preparations is very pertinent and timely. The addition of fluoride toothpaste (A.14), glass ionomer cement (A.16) and silver diamine fluoride (A.28) to the EML would represent a significant milestone in addressing the significant burden of dental caries worldwide.

Application A.14 highlights in detail both the public health needs of populations suffering from dental caries, and the proven benefits of using fluoride toothpaste for its prevention. The scientific evidence for the health benefits of fluoride toothpaste is very strong. The regular use of fluoride toothpaste results in significant reductions in the incidence and severity of dental caries across different age groups, populations and settings, independently of their respective risk profiles. At the same time, possible toxicity and side-effects are well documented and pose no public health concern. The provisions of ISO 11609 (2017) give authoritative and sufficient guidance on quality, abrasiveness, as well as prevention of misuse and labelling transparency of fluoride toothpaste for consumer protection.

Fluoride toothpaste is therefore a key element in public health and population-wide strategies to address and reduce the burden of dental caries and related inequalities. On the one hand, regular exposure to appropriate and effective low-level doses of fluoride from toothpaste reduces the incidence and severity of dental caries. On the other hand, regular toothbrushing and enhancing of oral hygiene contributes to the prevention of periodontal diseases and dental caries. This twofold impact gives fluoride toothpaste a unique role in the public health toolkit for oral diseases. Since using fluoride toothpaste does not require professional support or intervention, it is a pivotal measure of self-care for people across the lifespan in the context of basic hygiene habits. In view of the persisting lack of universal primary oral health care, the only available option for large parts of the global population is effective self-care and prevention.

However, access to and affordability of fluoride toothpaste is of concern, as well as efficacy of products within their expiration period. In order to improve compliance with the recommendation of twice-daily brushing with effective fluoride toothpaste, the product should be universally available and affordable, and its quality be controlled. The inclusion of fluoride toothpaste as requested in *Application A.14* would strengthen the role of fluoride toothpaste in the context of essential public health interventions.

Moreover, governments and regulatory bodies such as national agencies for food and drug control, would be encouraged to step up their efforts to ensure quality, availability and affordability of fluoride toothpaste. Mechanisms that have been successfully used in the context of quality assurance, of improving availability and affordability of other essential medicines include capacity building for laboratory control and regulatory oversight, fiscal measures, approaches to differential pricing or bulk procurement for community programmes. The inclusion of fluoride toothpaste in the EML/EMLC provides governments with an expanded range of policy options to positively impact oral health of their populations.

Lastly, the resolution of the WHO Executive Board adopted in January 2021 (Resolution EB148/1), the related decisions of the upcoming 74th World Health Assembly (Agenda item 13.2; Documents A74/10 Rev.1) recognize the important role of fluorides for the prevention of dental caries. The report of the Director-General (document EB148/8) states that “Prevention of oral diseases is frequently not prioritized. Opportunities for oral health promotion in key settings – such as schools, communities and workplaces – are not systematically used. The use of fluorides for prevention of dental caries is limited, and essential prevention methods, such as use of fluoridated toothpaste, are often not affordable for many people” (paragraph 11). The report therefore recommends “promoting legislation to increase the affordability and accessibility of high-quality fluoride toothpaste and advocating for its recognition as an essential health product” (paragraph 23).

We could not agree more with this approach and encourage the Expert Committee on the Selection and Use of Essential Medicines during its 23rd meeting in June 2021 to consider the *Application A.14* favourably for the betterment of oral health worldwide.

The WHO CCs related to oral health remain at the Committee’s and WHO’s disposal for additional information, data and other support.

Signed by the directors of all WHO CCs listed below (in alphabetical country order)

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