Dr Benedikt Huttner Secretary of the Expert Committee on the Selection and Use of Essential Medicines World Health Organization, Geneva, Switzerland Via email to emlsecretariat@who.int

21 May 2021

EML Application A.16 - 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.16 Glass Ionomer Cement – 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 glass ionomer cement (A.16), fluoride toothpaste (A.14) 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.16 highlights in detail both the public health needs of populations suffering from dental caries, as well as the double role of glass ionomer cement (GIC) as a fissure sealant and a filling material. The material's public health relevance is building on its unique properties— the continued low-dose release of fluoride for enhanced prevention of dental caries and the adhesive capacity even under adverse conditions of humidity or wetness in a cavity that is to be filled. This makes the material particularly suitable for low-resource settings with simple infrastructure and clinical conditions. The treatment guidelines of the American Dental Association recommending sealants for non-cavitated coronal and approximal carious lesions recognize this aspect and state that "if maintaining a dry field is not possible, a hydrophilic sealant material such as glass ionomer cement may be preferred over resin-based material."¹

The application document describes the evidence related to using GIC as a fissure sealant material in comparison with resin-based materials. In this context we would like to point out that a comparison only looking at retention rates of both materials is somewhat limited since retention on the tooth surface is not the principal outcome measure when using GIC. In fact, the caries-protective effect of the continued low-dose release of fluoride from GIC is the main advantage, and this effect remains measurable even with only partial retention of the GIC fissure sealant. The outcome measurements should therefore also take into account caries prevention.

With regard to using GIC as a filling material we would like to bring your attention a new publication that was published after the application was filed.² The authors of the systematic review and meta-analysis conclude (among other findings) that "there is evidence that Atraumatic restorative treatment/High-

¹ Slayton RL, Urquhart O, Araujo MWB et al. Evidence-based clinical practice guideline on nonrestorative treatments for carious lesions: A report from the American Dental Association. J Am Dent Assoc. 2018;149(10):837-849.e19.

² Frencken JE, Liang S, Zhang Q (2021) Survival estimates of atraumatic restorative treatment versus traditional restorative treatment: a systematic review with meta-analyses. Br Dent J (online first 27.4.2021) https://doi.org/10.1038/s41415-021-2701-

viscosity glass ionomer cement (ART/HVGIC) can replace traditional amalgam restorations in primary molars and in single-surface cavities in posterior permanent teeth". This re-confirms the public health relevance of GIC as an alternative, highly cost-effective dental filling material in view of the phase-down of dental amalgam in the context of the Minamata Convention.

Primary oral healthcare in low-resource settings is oftentimes limited by a lack of essential supplies such as filling material, which leads to an unnecessary focus of treatment on tooth extraction even in situations where a tooth-saving filling would still be an option. Including GIC in the EML and EMLc as requested in *Application A.16* would strengthen the availability of GIC in the context of essential oral healthcare interventions. Governments and regulatory and policy-making 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 GIC as an essential material for oral healthcare. The inclusion of GIC 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), recognizes the need to phase-down the use of mercury containing dental filling materials and states that "a viable replacement material should be developed through focused research". We believe that GIC is such a material 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.16* 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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