May 21, 2021
The Benedikt Huttner
Secretary
Expert Committee on the Selection and Use of Essential Medicines
Medicines Selection, IP and Affordability (MIA)
Department of Health Products Policy and Standards (HPS)
20 Avenue Appia
CH-1211 Geneva 27

Dear Dr Huttner,

RE: Application to add **GLASS IONOMER CEMENTS *"GIC"* AND HIGH VISCOSITY GLASS-IONOMER CEMENTS *"Hv-GIC"*** to the WHO Model List of Essential Medicines

I would appreciate the attention of the Expert Committee to the following comments on the inclusion of GLASS IONOMER CEMENTS on the WHO Essential Medicines List. I am submitting this comment as a practicing dentist. There are several reasons why I believe this proposal should be supported at this time:

1) *"GIC"* are able to produce an ions exchange with hard dental tissue after their setting.
First of all *"GIC"* are able to release fluoride from the restorative's bulk because fluoride is not involved in the setting reaction between powder (glass particles rich in Calcium and Aluminum and other ions) and liquid (aqueous solution of polyacrylic acid and other polyalkenoic acids).
Fluoride has typically carious lesion preventive features because is able to bind hydroxiapatite of enamel of dentin (soluble in the saliva at pH: 5.5) to form fluoroapatite that are less soluble in the saliva during caries bacteria attack (soluble at pH: 4.5).
"GIC" are also able to recharge fluoride if restoration's bulk is exposed to fluoride source as fluoride toothpaste, mouthwash, etc.
An update of conventional *"GIC"* after their market introduction (Wilson and Mc Lean 1977) has been the *" resin modified glass-ionomer cement Rm-GIC "*that are enriched with resin particles and so with better mechanical properties to bite forces and reduced solubility to saliva".

2) *"GICs"* are able to produce ions exchange (calcium, phosphate and other ions) with carious affected dentine (tissue damaged but not completely destroyed by acid and collagenolytic enzyme produced during carious process.

This ion's exchange between affected dentin and *"GIC"* is able to produce a new interface zone between affected dentin and *"GIC"* called interdiffusion zone. This interdiffusion zone is more acid resistant than natural dentine and allows the remineralization of affected dentine.
This features means that is possible not to remove all carious tissue from the cavity – for example in developing countries where removing of carious tissue is managed by only hand instrument – and moreover arrests the progression of carious lesions and remineralizers the carious dentine left in the deep of the cavity.
This concept of remineralization of carious dentine by *"GIC"* interdiffusion zone is nowadays really emphasized also in Europe, USA and Japan and called *"Selective Carious Tissue removal SCTR". "SCTR"* is mini-invasive approach towards carious lesions and many literature publications and clinical trial supports the effectiveness of *"SCTR".*

3) One of the negative features of *"GIC"* – and in part also of *"Rm-GIC"* is their saliva solubility during the time and the low mechanical properties to resist to bite forces and wear.
This problem seems solved by the new generation of *"GIC"* called *" high viscosity glass-ionomer cement Hv-GIC"* that are more rich in resin particles (methacrylate particles) and other features that make this material capable to have high mechanical properties able to resist to bite force and saliva solubility.

4) Fluoride release, ions exchange with affected carious dentine make *"GICs"* and in particular *"HvGICs"* the best restorative choice in high caries risk patients in both developed and developing countries.

Here below there are some high-quality literature references not provided in the original application that suggest the good properties of *"GICs"* and *"HvGICs"* as restorative material.

•Van Dijken JW., Kieri C. et al.
"Longevity of extensive class II open-sandwich restorations with a resin – modified glass – ionomer cement"
J. Dent. Res: 1999;78:1319-25

•Andersson-Wenchert IE., Van Dijken JW. et al.
"Durability of extensive class II open – sandwich restorations with a resin – modified glass ionomer cement after 6 years"
Am. J. Dent. 2004; 17: 43-50

•Vilkinis V. Horsted-Bindslev P. et al.

"Two-year evaluation of class II resin – modified glass ionomer cement / composite open sandwich and composite restorations"
Clin. Oral Investig. 2000; 4: 133-9

•Chadwick BL., Evans DJP.
"Restoration of class II cavities in primary molar teeth with conventional and resin modified glass ionomer cements: a systematic review of the literature"
Eur. Arch. Paediatr. Dent. 2007; 8: 14-21

•Molina GF., Faulks D. et al.
"High-viscosity glass-ionomer vs. composite resin restorations in person with disability: five year follow up of clinical trial"
Braz. Oral Res. 2019; 33: e099.
doi: 10.1590/1807-3107bor-2019.vol33.0099.eCollection 2019

•Salinovic I., Stunja M. et al.
"Mechanical properties of high viscosity glass ionomer and glass hybrid restorative materials"
Acta. Stomatol. Croat. 2019; 53: 125-131

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