

MEMORANDUM

From:	Director, NCD	To:	Director, HPS	Date:	18 January 2021
Our ref:		Attention:	Secretary of the Expert Committee on Selection and Use of Essential Medicines		
Your ref:		Through:	ADG/UCN		
Originator:	BV/ss	Subject:	PROPOSAL TO ESTABLISH A NEW SECTION IN THE WHO MODEL LISTS OF ESSENTIAL MEDICINES FOR DENTAL PREPARATIONS		

The Department of Noncommunicable Diseases requests the Expert Committee on Selection and Use of Essential Medicines to consider the establishment of a new section for dental preparations in the WHO Model List of Essential Medicines (EML) and Model List of Essential Medicines for Children (EMLc).

The request

1. Establish a new section within the EML and EMLc: “30. Dental Preparations”
2. Add within this section a new sub-section “30.1 Medicines for dental caries”
3. Move the existing entry for “sodium fluoride” (currently listed in Section 27: Vitamins and Minerals) to the new category 30.1, without changes to the current specifications
4. Add an entry in new group 30.1 for fluoride toothpaste (FT; see separate application details)
5. Add an entry in new group 30.1 for silver-diamine fluoride (SDF; see separate application details)
6. Add an entry in new group 30.1 for glass-ionomer cementum (GIC; see separate application details)

Rationale - Burden of oral disease

The rationale for the modification and addition of a new category for dental medicines is grounded in the significant burden of oral diseases, particularly untreated dental caries. Oral diseases, similar to the other non-communicable diseases, are major public health problems in all countries worldwide. The Global Burden of Disease Study 2017 estimated that oral diseases affect close to 3.5 billion people worldwide, with caries of permanent teeth being the most common condition (1). Like other noncommunicable diseases, inequalities are found throughout the life course and across populations in low-, middle- and high-income countries. With limited resources for prevention and control, low- and middle-income countries face the highest burden of oral diseases. Globally, it is estimated that 2.3 billion people suffer from caries of permanent teeth and more than 530 million children suffer from caries of primary teeth (1, 2). The majority of caries remains untreated. The caries burden is hugely unequal across populations within and between countries, with a clear socio-economic gradient showing higher disease burden in deprived and disadvantaged populations that at the same time have less access to care, including prevention (3). Caries is a disease of all age groups with an onset in early childhood and continued increase over the life-course. Most significant incidence increases are observed in adolescent age groups. Other oral diseases of public health significance include severe periodontal (gum) disease, severe tooth loss, oral cancer and other diseases and disorders that affect the oral cavity. Worldwide, oral diseases accounted in 2015 for US\$ 357 billion in direct costs and US\$ 188 billion in indirect costs (4). €90 billion were spent on treatment of oral diseases in the European Union, the third-highest expenditure among NCDs after diabetes and cardiovascular diseases (3).

Oral healthcare is often not covered in primary health care, leading to considerable expense for individuals. High out-of-pocket expenditures particularly affect disadvantaged populations.

Rationale – public health relevance of fluorides

Adequate intake of fluoride has a beneficial effect on oral health in both children and adults. Fluoride prevents caries by several different actions and is one of the pillars of caries prevention. However, access and usage of fluorides is insufficient and unequally distributed, with populations at higher risk of caries having generally lower access to fluorides (5). Main barriers for access to fluorides are related to cost and affordability (for fluoride toothpaste), unavailability of piped water (for water fluoridation) or lack of access to dental care (for professionally applied fluoride solutions) (6). FT is the most common and cost-effective way of fluoride use with an estimated 1.5 billion daily users. SDF is the most effective caries preventive fluoride agent and can be applied in a simple way by health professionals or community health workers. It arrests the progression of caries and prevents the development of new cavities. GIC is a cost-effective filling material, its high-viscosity formulations are cost-effective for therapeutic sealants of teeth with or without caries, as well as a caries protective effect (7). With the Minamata Convention's commitment to eliminate mercury-containing products, such as dental amalgam (8) - currently one of the most frequent filling materials, GIC will be of increasing public health relevance. Strengthening availability and affordability is therefore a public health priority.

Conclusion

In view of the burden of oral disease, and dental caries in particular, the establishment of a new category of medicines for oral diseases is highly pertinent. The availability of efficient and cost-effective fluoride formulations for different indications and delivery modes of fluoride makes them highly relevant public health medicines for to address the global burden of caries. Increasing the usage of fluorides for caries prevention through their inclusion in the EML has the potential for significant reductions in caries incidence and severity, as well as reduced economic burden for health systems, improvements in quality of life and economic productivity. The inclusion of a new category "dental medicines" in the EML should accelerate the implementation of an UHC's oral health benefit package in primary health care and improve affordability of essential dental medicines, generic drugs and other supplies for the prevention and control of oral diseases. Further medicines for oral diseases may be added to EML in the future.

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