

A.14	Fluoride toothpaste
<p>Does the application adequately address the issue of the public health need for the medicine?</p>	<p> <input checked="" type="checkbox"/> Yes  <input type="checkbox"/> No  <input type="checkbox"/> Not applicable         </p> <p>Comments:</p>
<p>Briefly summarize the role of the proposed medicine(s) relative to other therapeutic agents currently included in the Model List, or available in the market.</p>	<p><b>The request in the application is to reclassify entry of sodium fluoride in the EDL from the current group of “Dental medicines” ( category 30) to the sub-group of “medicines for dental caries” (category 30.1)</b></p>
<p>Have all important studies and all relevant evidence been included in the application?</p>	<p> <input checked="" type="checkbox"/> Yes  <input type="checkbox"/> No  <input type="checkbox"/> Not applicable         </p> <p>If no, please provide brief comments on any relevant studies or evidence that have not been included:</p>
<p>Does the application provide adequate evidence of efficacy/effectiveness of the medicine for the proposed indication?</p>	<p> <input type="checkbox"/> Yes  <input type="checkbox"/> No  <input checked="" type="checkbox"/> Not applicable         </p> <p>Briefly summarize the reported benefits (e.g. hard clinical versus surrogate outcomes) and comment, where possible on the actual magnitude and clinical relevance of benefit associated with use of the medicine(s).</p> <ol style="list-style-type: none"> <li>1. Primary and permanent teeth: “The are benefits of using fluoride toothpaste at certain strengths to prevent tooth decay when compared with non-fluoride toothpaste. The stronger the fluoride concentration, the more decay is prevented”</li> <li>2. The preventive fraction in the permanent dentition using a 1500ppm fluoride toothpaste was 24% in 70 studies summing observations from 42,300 children over three years (preventive fraction is the difference in mean caries increments between the treatment and control groups expressed as a percentage of the mean increment in the control group).</li> <li>3. The effect increased with higher baseline caries levels, higher fluoride concentration in the toothpaste, higher frequency of use and supervised toothbrushing (higher compliance).</li> <li>4. When compared with mouthrinse and gels, fluoride toothpastes have similar effectiveness for the prevention of dental caries in children. Acceptance is likely to be greater for fluoride toothpaste</li> </ol> <p>Is there evidence of efficacy in diverse settings (e.g. low-resource settings) and/or populations (e.g. children, the elderly, pregnant patients)? <b>There is evidence of use in</b></p>

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	<b>diverse settings. However, assessment of efficacy, especially in resource-poor settings is challenging</b>
Does the application provide adequate evidence of the safety and adverse effects associated with the medicine?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable Comments: <b>Dental fluorosis is the major risk factor based on amount dispensed, amount ingested, age and frequency of use. This is mitigated by size of toothpaste dispensed.</b>
Are there any adverse effects of concern, or that may require special monitoring?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Not applicable Comments:
Briefly summarize your assessment of the overall benefit to risk ratio of the medicine (e.g. favourable, uncertain, etc.)	<b>The benefits to risk ratio is favourable</b>
Briefly summarize your assessment of the overall quality of the evidence for the medicine(s) (e.g. high, moderate, low etc.)	<b>Quality of evidence is high</b>
Are there any special requirements for the safe, effective and appropriate use of the medicine(s)? (e.g. laboratory diagnostic and/or monitoring tests, specialized training for health providers, etc)	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Not applicable Comments: <b>The requirements to avoid dental fluorosis have been taken care of in the size of the toothpaste to be dispensed.</b>
Are you aware of any issues regarding the registration of the medicine by national regulatory authorities? (e.g. accelerated approval, lack of regulatory approval, off-label indication)	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Not applicable Comments: <b>The product is already in the EDL</b>
Is the proposed medicine recommended for use in a current WHO Guideline approved by the Guidelines Review Committee? (refer to: <a href="https://www.who.int/publications/who-guidelines">https://www.who.int/publications/who-guidelines</a> )	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable Comments:
Briefly summarize your assessment of any issues regarding access, cost and affordability of the medicine in different settings.	<b>While fluoride toothpaste is highly cost effective, it is not universally accessible or affordable in most low and middle-income countries.</b>
Any additional comments	<b>None</b>

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Based on your assessment of the application, and any additional evidence / relevant information identified during the review process, briefly summarize your proposed recommendation to the Expert Committee, including the supporting rationale for your conclusions, and any doubts/concerns in relation to the listing proposal.	The request in the application is to reclassify entry of sodium fluoride in the EDL from the current group of “Dental medicines” ( category 30) to the sub-group of “medicines for dental caries” (category 30.1). Based on the evidence provided I recommend that the committee accepts this application
References (if required)	