

R.1 Review of age-appropriateness of formulations on the EMLc

Reviewer summary	<input checked="" type="checkbox"/> Supportive of the proposal <input type="checkbox"/> Not supportive of the proposal <p>Justification (based on considerations of the dimensions described below):</p> <p>The aim of this application is only to change formulations to be more suitable for children for medications that were already in the EMLc.</p> <p>The review for the formulation change follows a rigorous process utilizing a standardized tool.</p> <p>Issues regarding price, cost-effectiveness and budget implications in different setting have been consulted and deemed as still acceptable.</p> <p>For some age-appropriate formulations that might still not widely available, recommendations have been made so it could be promoted for development to fill priority unmet needs for the paediatric population.</p>
<p>Does the EML and/or EMLc currently recommend alternative medicines for the proposed indication that can be considered therapeutic alternatives?</p> <p>(https://list.essentialmeds.org/)</p> <p>The aim of this application is only to change formulations to be more suitable for children for medications that were already in the EMLc.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Not applicable
<p>Does adequate evidence exist for the efficacy/effectiveness of the medicine for the proposed indication?</p> <p>(e.g., evidence originating from multiple high-quality studies with sufficient follow up. This may be evidence included in the application, and/or additional evidence identified during the review process;)</p> <p>All medicines included in the formulation change have been through rigorous process previously to review its efficacy/effectiveness.</p> <p>The review for the formulation change follows a rigorous process utilizing a standardized tool.</p>	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable
<p>Does adequate evidence exist for the safety/harms associated with the proposed medicine?</p> <p>(e.g., evidence originating from multiple high-quality studies with sufficient follow up. This may be evidence included in the application, and/or additional evidence identified during the review process;)</p> <p>All medicines included in the formulation change have been through rigorous process previously to review its safety and harm.</p>	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable
<p>Overall, does the proposed medicine have a favourable and meaningful balance of benefits to harms?</p> <p>The balance between benefits and harms have been considered for all the medicines included in the EMLc.</p>	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable
<p>Are there any special requirements for the safe, effective and appropriate use of the medicines?</p> <p>(e.g. laboratory diagnostic and/or monitoring tests, specialized training for health providers, etc)</p> <p>Depends on the medication; some of them have specific requirements for their administration. However, all medications included have been deemed as suitable to be included in the EMLc.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Not applicable

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<p>Are there any issues regarding price, cost-effectiveness and budget implications in different settings?</p> <p>Issues regarding price, cost-effectiveness and budget implications in different setting have been reviewed during the experts committee meeting and all medications included have been deemed as suitable to be included in the EMLc.</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Not applicable</p>
<p>Is the medicine available and accessible across countries?</p> <p>(e.g. shortages, generics and biosimilars, pooled procurement programmes, access programmes)</p> <p>Some medications or formulations might still not widely available, however some recommendations have been made for identified gaps in terms of age-appropriate formulations that are not currently available so it could be promoted for development to fill priority unmet needs for the paediatric population.</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Not applicable</p> <p>Some medications or formulations might still not widely available, however some recommendations have been made for identified gaps in terms of age-appropriate formulations that are not currently available so it could be promoted for development to fill priority unmet needs for the paediatric population.</p>
<p>Does the medicine have wide regulatory approval?</p>	<p><input type="checkbox"/> Yes, for the proposed indication</p> <p><input type="checkbox"/> Yes, but only for other indications (off-label for proposed indication)</p> <p><input type="checkbox"/> No <input checked="" type="checkbox"/> Not applicable</p>