

## A.7 Ciclopirox HPCP – EML

<b>Reviewer summary</b>	<input type="checkbox"/> Supportive of the proposal <input checked="" type="checkbox"/> Not supportive of the proposal  Justification (based on considerations of the dimensions described below): <ul style="list-style-type: none"> <li>- There is demonstrated efficacy in mild-moderate onychomycosis, moderate quality evidence of superior efficacy over other topical antifungals, even then complete cure rates remain low (about 15% or less)</li> <li>- No head to head trials with oral only or oral + topical antifungal treatment</li> <li>- Optimal duration of treatment not clear, the very long durations in the data presented (48-60 weeks) would be associated with low adherence</li> <li>- Not available in most LMICs</li> <li>- No studies on cost-effectiveness</li> </ul>
Does the EML and/or EMLc currently recommend alternative medicines for the proposed indication that can be considered therapeutic alternatives?  ( <a href="https://list.essentialmeds.org/">https://list.essentialmeds.org/</a> )	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Not applicable
Does adequate evidence exist for the efficacy/effectiveness of the medicine for the proposed indication?  (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;)  No clear evidence presented, one Cochrane systematic literature review but no clear comparators  Some pictures presented that were not very clear	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Not applicable
Does adequate evidence exist for the safety/harms associated with the proposed medicine?  (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;)  Generally safe, may cause nail discolouration	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable
Overall, does the proposed medicine have a favourable and meaningful balance of benefits to harms?  Use limited to mild to moderate disease and where systemic therapy may be contraindicated	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Not applicable
Are there any special requirements for the safe, effective and appropriate use of the medicines?  (e.g. laboratory diagnostic and/or monitoring tests, specialized training for health providers, etc)  Regular nail trimming	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable

25<sup>th</sup> WHO Expert Committee on Selection and Use of Essential Medicines  
Expert review

<p>Are there any issues regarding price, cost-effectiveness and budget implications in different settings?</p> <p>No data on cost-effectiveness of ciclopirox HPCH. Some data presented on ciclopirox 8% water insoluble lacquer</p>	<p><input type="checkbox"/> Yes      <input checked="" type="checkbox"/> No      <input 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>Only available in a few countries globally, not available in low-resource countries</p>	<p><input type="checkbox"/> Yes      <input checked="" type="checkbox"/> No      <input type="checkbox"/> Not applicable</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 checked="" type="checkbox"/> No      <input type="checkbox"/> Not applicable</p>