

D.1 Iodine capsules 190 mg – EML and EMLc

Reviewer summary	<input type="checkbox"/> Supportive of the proposal <input checked="" type="checkbox"/> Not supportive of the proposal <p>Justification (based on considerations of the dimensions described below):</p> <p>The application is for the deletion of Iodine from the WHO EML and the WHO EMLc due to decrease medical needs over years and the absence of demands. The application is come from the manufacturer. However iodized oil provides effective, safe, and economically sound prophylaxis against endemic goiter and related disabilities in situations in which salt iodination is not feasible for economic or political reasons. Currently, about 88% of households worldwide use iodized salt, but iodine insufficiency is still prevalent in certain regions, particularly Southeast Asia, sub-Saharan Africa, and Eastern Europe. Alternative supplier needs to be found to fill the needs of the medicine in the area where it is mostly needed.</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>	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input 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>The proposal is for deletion of the medicine. However, iodine oil has a long history in the treatment of iodine deficiency. Its greatest use has been for women and young children with moderate to severe deficiency, to buy time while awaiting the implementation of effectively iodized salt.</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>The medicine is already in the EML/EMLc, safety/harms is not the issue.</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>For people with iodine deficiency, the benefits outweigh the harms.</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>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Not applicable <p>The medicine is already in the EML/EMLc</p>
<p>Are there any issues regarding price, cost-effectiveness and budget implications in different settings?</p> <p>Iodized oil is much more expensive than iodized salt but is used especially for severe iodine deficiency in remote areas. It provides instant correction of the deficiency and the consequent prevention of brain damage.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Not applicable

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<p>Is the medicine available and accessible across countries?</p> <p>(e.g. shortages, generics and biosimilars, pooled procurement programmes, access programmes)</p> <p>Cease production according to the manufacturer.</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>Since 2022, all the marketing authorization in export countries was withdrawn and he manufacturer has applied the withdrawal of the last marketing authorization, which is in France.</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>