

M.2/M.2a Halothane – EML and 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>Considering</p> <ul style="list-style-type: none"> - The recommendation by the 2023 Expert Committee to delete halothane from the Model Lists without further discussion, given the limited role among anaesthetic gases and the availability of safer alternative and agents leading to lower greenhouse gas emissions. - The request from the World Federation of Societies of Anaesthesiologists (WFSA) to discontinue halothane from the 2027 EML, to allow sufficient time for Member States where halothane is still used to implement this change at the clinical, operational and budgetary levels <p>This Reviewer would be in favor of supporting the deletion in 2025 as planned, acknowledging that some member states still use halothane and may need more time to phase out its use completely. The Committee may consider the promotion of the actions suggested by WFSA to implement the discontinuation of halothane from clinical practice.</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>General anaesthetics and oxygen > Inhalational medicines</p> <p>Halothane</p> <p>Isoflurane</p> <p>Ketamine</p> <p>Nitrous oxide</p> <p>Oxygen</p> <p>Propofol</p> <p>Sevoflurane</p> <p>Thiopental</p>	<input checked="" type="checkbox"/> Yes <input 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>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" 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>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Not applicable
<p>Overall, does the proposed medicine have a favourable and meaningful balance of benefits to harms?</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" 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>Are there any issues regarding price, cost-effectiveness and budget implications in different settings?</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Not applicable

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Expert review

Is the medicine available and accessible across countries? (e.g. shortages, generics and biosimilars, pooled procurement programmes, access programmes)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Not applicable
Does the medicine have wide regulatory approval?	<input type="checkbox"/> Yes, for the proposed indication <input type="checkbox"/> Yes, but only for other indications (off-label for proposed indication) <input type="checkbox"/> No <input checked="" type="checkbox"/> Not applicable