

I.3	Ethionamide – drug-susceptible tuberculosis meningitis – EML and EMLc
Draft recommendation	<input checked="" type="checkbox"/> Recommended <input type="checkbox"/> Not recommended <p>Justification:</p> <p>TB meningitis if not diagnosed or treated early can cause irreversible neurological sequelae or even death. It is more common in children and people living with HIV. Ethionamide is already in the complementary list in the anti-TB medicine list and as an alternative regimen to the 12 month regimen.</p> <p>Systematic review and meta-analysis has proven favourable outcomes and no relapse after 2 years of completing the treatment when the 6 month (6HRZEto) was compared to the 12 month (2HRZE/10HR) replacing the ethambutol with ethionamide</p>
Does the proposed medicine address a relevant public health need?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable <p>Comments:</p> <p>TB meningitis common in children and people living with HIV</p>
Does adequate evidence exist for the efficacy/effectiveness of the medicine for the proposed indication? (this may be evidence included in the application, and/or additional evidence identified during the review process)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable <p>Comments:</p> <p>Systematic review and meta-analysis proven</p>
Does adequate evidence exist for the safety/harms associated with the proposed medicine? (this may be evidence included in the application, and/or additional evidence identified during the review process)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable <p>Comments:</p> <p>Already included in the complementary list for anti-TB medicines</p>
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 <p>Comments:</p>

24th WHO Expert Committee on Selection and Use of Essential Medicines
Expert review

<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><input type="checkbox"/> Yes</p> <p><input checked="" type="checkbox"/> No</p> <p><input type="checkbox"/> Not applicable</p> <p>Comments:</p>
<p>Are there any issues regarding cost, cost-effectiveness, affordability and/or access for the medicine in different settings?</p>	<p><input type="checkbox"/> Yes</p> <p><input checked="" type="checkbox"/> No</p> <p><input type="checkbox"/> Not applicable</p> <p>Comments:</p>
<p>Are there any issues regarding the registration of the medicine by national regulatory authorities?</p> <p>(e.g. accelerated approval, lack of regulatory approval, off-label indication)</p>	<p><input type="checkbox"/> Yes</p> <p><input checked="" type="checkbox"/> No</p> <p><input type="checkbox"/> Not applicable</p> <p>Comments:</p>
<p>Is the proposed medicine recommended for use in a current WHO guideline?</p> <p>(refer to: https://www.who.int/publications/who-guidelines)</p>	<p><input checked="" type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Not applicable</p> <p>Comments:</p> <p>6 months regimen</p>