

C.3	<b>Chlorpromazine, fluphenazine decanoate/enantate and haloperidol – review of square box alternatives – EML</b>	
<b>Draft recommendation</b>	<input checked="" type="checkbox"/> Recommended <input type="checkbox"/> Not recommended Justification: The submitted application contains several proposals for changes of Chlorpromazine, fluphenazine decanoate/enantate and haloperidol status in EML. <ol style="list-style-type: none"> <li>1. Since haloperidol is the first line therapy, remove chlorpromazine from the main list and add it as therapeutic alternative to haloperidol.</li> <li>2. Add haloperidol decanoate and zuclopenthixol decanoate (if included in new version of WHO guideline) as therapeutic alternatives to fluphenazine.</li> </ol>	
Does the proposed medicine address a relevant public health need?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable Comments:	
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 Comments:	
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 Comments:	
Are there any adverse effects of concern, or that may require special monitoring?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable Comments:	

24<sup>th</sup> 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 checked="" type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Not applicable</p> <p>Comments: Parental dosage forms require close observation of the patients by qualified medical staff.</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: <a href="https://www.who.int/publications/who-guidelines">https://www.who.int/publications/who-guidelines</a>)</p>	<p><input type="checkbox"/> Yes</p> <p><input checked="" type="checkbox"/> No</p> <p><input type="checkbox"/> Not applicable</p> <p>Comments: It is expected that the recommendations made by this proposal on changing the current status of chlorpromazine, fluphenazine decanoate/enantate and haloperidol on the EML will be approved by the WHO Guidelines Review Committee.</p>