

I.3	Antibiotics for bronchitis and bronchiolitis
Does the application adequately address the issue of the public health need for the medicine?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable Comments: while bronchitis and bronchiolitis are not life threatening compared to ARIs, they pose significant concerns due to clinical practices surrounding their management. Clinicians tend to irrationally prescribe antibiotics and injections for these conditions. These practices could potentially lead to medication complications, drug resistance.
Briefly summarize the role of the proposed medicine(s) relative to other therapeutic agents currently included in the Model List, or available in the market.	Antibiotics have no role in the treatment of bronchitis and bronchiolitis. They are indicated for other respiratory infections some of which are already covered in the appropriate sections of the EML.
Have all important studies and all relevant evidence been included in the application?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable If no, please provide brief comments on any relevant studies or evidence that have not been included:
Does the application provide adequate evidence of efficacy/effectiveness of the medicine for the proposed indication?	<input checked="" type="checkbox"/> Yes, partially <input type="checkbox"/> No <input type="checkbox"/> Not applicable Briefly summarize the reported benefits (e.g. hard clinical versus surrogate outcomes) and comment, where possible on the actual magnitude and clinical relevance of benefit associated with use of the medicine(s). <ol style="list-style-type: none"> Efficacy: Bronchitis: A Cochrane SR reviewed 7 antibiotics for bronchitis and reported no clinical difference with placebo. Bronchiolitis: 2 cochrane reviews did not find any clinical difference with placebo. Tolerability and safety: Cost: prescribing unnecessary medicines is an an unnecessary increase household expenditure. Complications resulting from these could also be huge. Is there evidence of efficacy in diverse settings (e.g. low-resource settings) and/or populations (e.g. children, the elderly, pregnant patients)? Yes

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Does the application provide adequate evidence of the safety and adverse effects associated with the medicine?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Not applicable Comments: I was still unclear about safety in pregnancy and breastfeeding.
Are there any adverse effects of concern, or that may require special monitoring?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Not applicable Comments:
Briefly summarize your assessment of the overall benefit to risk ratio of the medicine (e.g. favourable, uncertain, etc.)	Favourable. Recommend removal of antibiotics for bronchitis and bronchiolitis.
Briefly summarize your assessment of the overall quality of the evidence for the medicine(s) (e.g. high, moderate, low etc.)	Moderate
Are there any special requirements for the safe, effective and appropriate use of the medicine(s)? (e.g. laboratory diagnostic and/or monitoring tests, specialized training for health providers, etc)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Not applicable Comments: however, clinician training on differential diagnosis is imperative to ensure cases of ARIs are not missed.
Are you aware of any issues regarding the registration of the medicine by national regulatory authorities? (e.g. accelerated approval, lack of regulatory approval, off-label indication)	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Not applicable Comments:
Is the proposed medicine recommended for use in a current WHO Guideline approved by the Guidelines Review Committee? (refer to: https://www.who.int/publications/who-guidelines)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable Comments: several guidelines already mention the use of the agent in their recommendations:
Briefly summarize your assessment of any issues regarding access, cost and affordability of the medicine in different settings.	

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Any additional comments	
Based on your assessment of the application, and any additional evidence / relevant information identified during the review process, briefly summarize your proposed recommendation to the Expert Committee, including the supporting rationale for your conclusions, and any doubts/concerns in relation to the listing proposal.	I recommend the removal of antibiotics for treatment of bronchitis and bronchiolytixs.
References (if required)	