

<b>1.7</b>	<b>Antibiotics for complicated intra-abdominal infections – neonates and children</b>
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: Intra-abdominal infections in neonates and children are relatively rare (compared for example to pneumonia) but cause significant morbidity and mortality globally.
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.	This application focusses on the addition of the indication of mild and severe complicated intra-abdominal infection (cIAI) to the already listed medicines ampicillin, gentamicin and metronidazole. The recommended dosing of these medicines in the EMLc would be unchanged.
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:  There is a very limited evidence base comparing different antibiotic regimens in cIAI in neonates and children.  However, the application would align the EMLc with the WHO Pocket Book 2013.
Does the application provide adequate evidence of efficacy/effectiveness of the medicine for the proposed indication?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" 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).  See above, direct evidence of clinical efficacy compared to other antibiotic regimens in this population is not available.  Is there evidence of efficacy in diverse settings (e.g. low-resource settings) and/or populations (e.g. children, the elderly, pregnant patients)?  No

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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: Ampicillin, gentamicin and metronidazole have been listed on the EMLc since its earliest editions. The toxicity profile of these agents is well established.
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: See above
Briefly summarize your assessment of the overall benefit to risk ratio of the medicine (e.g. favourable, uncertain, etc.)	Although direct evidence of efficacy is randomised clinical trials is lacking, there is decades of clinical experience of treatment globally with this combination of antibiotics in this condition in this population.  The IDSA recommendations for cIAI also include, ampicillin, gentamicin and metronidazole.
Briefly summarize your assessment of the overall quality of the evidence for the medicine(s) (e.g. high, moderate, low etc.)	low
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 checked="" type="checkbox"/> No <input type="checkbox"/> Not applicable Comments:
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: <a href="https://www.who.int/publications/who-guidelines">https://www.who.int/publications/who-guidelines</a> )	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable Comments: WHO Pocket Book 2013 WHO 2017 recommendations on newborn health.
Briefly summarize your assessment of any issues regarding access, cost and affordability of the medicine in different settings.	Widely available low cost generic antibiotics.

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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.	The recommendation is to add the indication of cIAI to the antibiotics ampicillin, gentamicin and vancomycin already listed on the EMLc.
References (if required)	