F.3	Antibiotics-new strengths/formulations
Does the application adequately address the issue of the public health need for the medicine?	☒ Yes ☐ No ☐ Not applicable Comments: The application adds new formulations of commonly used generic antibiotics to the EML. The aim of the application is to focus the EML on the most commonly used oral and intravenous formulations that are appropriate for the range of indications on the EML.
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.	For amoxicillin, the 500 mg tablet is already included on the EML with the indication of CAP and sinusitis. The proposal is to add the 1 gram tablet for adults and adolescents. This would reduce the number of tablets that patients take each day, likely enhancing adherence. The same principles are applied to the other oral medications discussed below. For intravenous antibiotics, higher strength vials increases the simplicity and safety of administration, when the available formulation is closely aligned to the recommended dose. For cefalexin the proposal is to add a 500 mg tablet formulation to the currently listed 250 mg tablet for the indications of COPD, pharyngitis and skin and soft tissue infections. For ceftriaxone, the proposal is to add the 2 gram vial to the already listed 1gm vial (and child 250 mg) for the indications of severe infections CAP/HAP, IAI enteric fever and meningitis. For ciprofloxacin the proposal is to add the oral 500 mg formulation to the current 250 mg for a range of infections, including bacterial diarrhoea, cholera, enteric fever febrile neutropenia, UTI, mild IAI. For clindamycin the proposal is to add the 600mg and 900 mg injection formulations in addition to the 150 mg, for the indication of bone and joint infection. For phenoxymethylpenicillin (Pen V) the proposal is to add the oral 500 mg formulation to the currently listed 250 mg formulation for pharyngitis and CAP. For vancomycin the proposal is to add the 500 mg and 1 gram powder for injection in addition to the listed 250 mg for the treatment of MRSA.
Have all important studies and all relevant evidence been included in the application?	☒ Yes ☐ No ☒ Not applicable If no, please provide brief comments on any relevant studies or evidence that have not been included: This application focusses on the addition of higher strength formulations aimed at enhancing adherence and simplifying ease of administration. There is a considerable literature – not summarised here – demonstrating the reducing pill burden enhances adherence to medication and that appropriate formulations can reduce drug errors.

Does the application provide adequate evidence of efficacy/effectiveness of the medicine for the proposed indication?	☐ Yes ☐ No ☒ 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 Is there evidence of efficacy in diverse settings (e.g. low-resource settings) and/or populations (e.g. children, the elderly, pregnant patients)? See above. There is no summary of the availability of all these formulations at a national level, although they are very standard doses in adult HIC and LMIC settings with multiple generic manufacturers.
Does the application provide adequate evidence of the safety and adverse effects associated with the medicine?	☐ Yes ☐ No ☒ Not applicable Comments: All of the medicines are already on the EML and there is no evidence that these different formulations would be expected to have different safety profiles.
Are there any adverse effects of concern, or that may require special monitoring?	☐ Yes ☒ No ☒ Not applicable Comments:
Briefly summarize your assessment of the overall benefit to risk ratio of the medicine (e.g. favourable, uncertain, etc.)	See above.
Briefly summarize your assessment of the overall quality of the evidence for the medicine(s) (e.g. high, moderate, low etc.)	See above.
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)	☐ Yes ☒ No ☐ 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)	☐ Yes ☒ No ☐ 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)	☐ Yes ☒ No ☐ Not applicable Comments:
Briefly summarize your assessment of any issues regarding access, cost and affordability of the medicine in different settings.	No detailed data is provided, but in general the cost is related to the quantity of the antibiotic.
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 for the Committee to approve the addition of these formulations for the proposed indications. The formulations correspond most closely with the recommended doses for adults of these medications in the forthcoming WHO Antibiotic Handbook. Where possible it is appropriate that the key formulations of the core antibiotics on the EML are closely aligned to WHO prescribing guidance.
References (if required)	