Does the application adequately address the issue of the public health need for the medicine?

Yes ☒ No ☐

Please provide brief details:
It is estimated that 558,000 new MDR/RR-TB cases emerged in the world in 2017 and 230,000 patients died of this form of TB. Between 25,000 and 32,000 children are estimated to develop MDR-TB each year.

Have all important studies/evidence of which you are aware been included in the application?

Yes ☒ No ☐

Please provide brief comments on any relevant studies that have not been included: None

Does the application provide adequate evidence of efficacy/effectiveness of the medicine for the proposed use?

Yes ☒ No ☐

(a) Briefly summarise the reported benefits (e.g. clinical versus surrogate) and comment, where possible, on the actual magnitude of benefit associated with use of the medicine:

The relative risk of treatment failure versus treatment success with regimen containing imipenem or meropenem for MDR TB was 0.4 (0.2 -0.7). Similarly, relative risk of death versus survival with regimen containing imipenem or meropenem for MDR TB was 0.2 (0.1 -0.5)¹.

(b) Is there evidence of efficacy in diverse settings and/or populations? Please provide brief details:

Although, there is limited evidence in diverse settings, the lack of effective medications to treat drug-resistant TB makes a case for wider use of these drugs.

Has the application adequately considered the safety and adverse effects of the medicine? Are there any adverse effects of concern, or that may require special monitoring?
Yes ☒ No ☐

Please provide brief details: The authors have summarized well in the application.

Bullet 11- Summary of comparative evidence on safety.

(5) Please comment on the overall benefit to risk ratio of the medicine (e.g., favourable, uncertain etc).

Imipenem/cilastatin and meropenem combined with clavulanic acid should be added to the EML. Given the limited therapeutic options for MDR TB, all efforts must be made to ensure that effective medications to treat drug-resistant TB become more widely available to the patients who need them, particularly in low resource settings which carry the largest burden of MDR/RR-TB.

References:

ADDITIONAL CONSIDERATIONS:

(6) Are there special requirements or training needed for the safe, effective and/or appropriate use of the medicine?
   Yes □ No □

Please provide brief details:

(7) Are there any issues regarding the registration of the medicine by regulatory authorities? (e.g., recent registration, new indications, off-label use)
   Yes □ No □

Please provide brief details:

(8) Is the medicine recommended for use in a current WHO GRC-approved Guideline (i.e., post 2008)?
   Yes □ No □

Please provide brief details:

(9) Please comment briefly on issues regarding cost and affordability of this medicine.

(10) Any additional comments?

(11) Please frame the decisions and recommendations that the Expert Committee could make.

(12) References (if required)