| A.34 | Pretomanid – multidrug-resistant or rifampicin-resistant tuberculosis – EML |
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| **Draft recommendation** | ☒ Recommended<br>☐ Not recommended<br>Justification:<br>TB is a public health crisis and a health security threat with increasing MDR/RR TB globally. Pretomanid in combination with bedaquiline and linezolid for MDR/RR TB has proven both cost and cost effective and safe and in fluoroquinoline resistant with BPaLM which is the regimen with moxifloxacin has proven efficacious and safe.<br>Due to its shorter and less pill regimen, it improved the patient compliances with better patient experience and thus preventing further resistance. |
| Does the proposed medicine address a relevant public health need? | ☒ Yes<br>☐ No<br>☐ Not applicable<br>Comments: |
| Does adequate evidence exist for the efficacy/effectiveness of the medicine for the proposed indication?<br>(this may be evidence included in the application, and/or additional evidence identified during the review process) | ☒ Yes<br>☐ No<br>☐ Not applicable<br>Comments: |
| Does adequate evidence exist for the safety/harms associated with the proposed medicine?<br>(this may be evidence included in the application, and/or additional evidence identified during the review process) | ☒ Yes<br>☐ No<br>☐ Not applicable<br>Comments:<br>Hepatotoxicity for which liver enzymes and clinicl sigsn and symptoms has to be watched |
| Are there any adverse effects of concern, or that may require special monitoring? | ☐ Yes<br>☒ No<br>☐ Not applicable<br>Comments: |

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| Are there any special requirements for the safe, effective and appropriate use of the medicines?<br><br>(e.g. laboratory diagnostic and/or monitoring tests, specialized training for health providers, etc) | ☒ Yes<br>☐ No<br>☐ Not applicable<br>Comments:<br>DST but this is a WHO essential list for diagnostics |
| Are there any issues regarding cost, cost-effectiveness, affordability and/or access for the medicine in different settings? | ☐ Yes<br>☒ No<br>☐ Not applicable<br>Comments: |
| Are there any issues regarding the registration of the medicine by national regulatory authorities?<br><br>(e.g. accelerated approval, lack of regulatory approval, off-label indication) | ☐ Yes<br>☒ No<br>☐ Not applicable<br>Comments: |
| Is the proposed medicine recommended for use in a current WHO guideline?<br><br>(refer to: https://www.who.int/publications/who-guidelines) | ☒ Yes<br>☐ No<br>☐ Not applicable<br>Comments: |