F.13	Fixed Dose Combination of rifapentine (300mg) and isoniazid (300mg)
Does the application adequately address the issue of the public health need for the medicine?	☐ Yes ☐ No ☒ Not applicable Comments:
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 proposes a formulation amendment to the core list in section 6.2.5 Antituberculosis medicines as per the latest edition of the core EML (21st edition). This application requests the inclusion a fixed-dose combination of two existing medicines. Both rifapentine and isoniazid have featured as antituberculosis medicines on the core list of the EML for several years (2015 and 1977 respectively).
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:
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). The applicant requests the new formulation as the availability of rifapentine and isoniazid as a single, fixed-dose combination tablet would reduce pill-burden significantly to the benefit of adherence to treatment Is there evidence of efficacy in diverse settings (e.g. low-resource settings) and/or populations (e.g. children, the elderly, pregnant patients)? n/a
Does the application provide adequate evidence of the safety and adverse effects associated with the medicine?	☐ Yes ☐ No ☒ Not applicable Comments:
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.)	Not applicable

Briefly summarize your assessment of the overall quality of the evidence for the medicine(s) (e.g. high, moderate, low etc.)	Not applicable
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: Different formulations are already listed in the current WHO EML and WHO EMLc.
Briefly summarize your assessment of any issues regarding access, cost and affordability of the medicine in different settings.	Different formulations and strengths are available and affordable across different countries.
Any additional comments	None
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 reviewer recommends the inclusion of rifapentine (300mg) and Isoniazid (300mg) FDC formulation for the indication of TB on the WHO EML. Different countries have access to different formulations (in terms of registration, affordability, and supply) and adding options may increase-availability and the pool of suppliers.
References (if required)	