

**Recommendations of the SEC (Antimicrobial & Antiparasitic) made in its 01<sup>st</sup>/26 meeting held on 08.01.2026 at CDSCO HQ New Delhi:**

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>SND Division</b>			
1.	SND/CT/25/000146  Pretomanide Tablets 200 mg	M/s. Macleods Pharmaceuticals Ltd.	<p>Firm presented their proposal for grant of permission to conduct Phase IV Clinical Trial in Multidrug-resistant Tuberculosis (MDR-TB) Patients before the committee.</p> <p>The committee noted that the drug is approved as conditional access under National TB Elimination Programme (NTEP).</p> <p>After detailed deliberation, the committee opined to submit the revised protocol with the following changes.</p> <ul style="list-style-type: none"> <li>• Number of subjects should be statistically justified and increased.</li> </ul> <p>Accordingly, firm should submit the revised Phase IV Clinical Trial protocol to CDSCO within 15 days for further review</p>