

**Recommendations of the SEC (Antimicrobial & Antiviral) made in its 02<sup>nd</sup>/25 meeting held on 13.02.2025 at CDSCO (HQ), New Delhi:**

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>SND Division</b>			
1.	SND/MA/23/000153 Linezolid Dispersible Tablets 150 mg	M/s Macleods Pharmaceuticals Ltd	<p>In light of earlier SEC recommendation dated 10.04.2024, firm presented BE study report, justification for Phase III clinical trial waiver and regulatory status of Proposed formulation before the committee in presence of expert from Central TB Division, MoHFW.</p> <p>The committee noted that Linezolid dispersible Tablets 150mg formulation as an Anti-TB drug is not approved in the country.</p> <p>After detailed deliberation, the committee recommended for grant of permission to manufacture &amp; market of Linezolid Dispersible Tablets 150 mg subject to condition that the firm for usage in India should adhere with National TB elimination Program guidelines and same are to be included in Dosage and administration section of packaging insert as a Note.</p>
2.	SND/MA/24/000200 Linezolid Dispersible Tablets 150 mg	M/s Micro Labs Limited	<p>The firm presented the proposal along with BE study report and justification for Phase III clinical trial waiver before the committee in presence of expert from Central TB Division, MoHFW.</p> <p>The committee noted that Linezolid dispersible Tablets 150mg formulation as an Anti-TB drug is not approved in the country.</p> <p>After detailed deliberation, the committee recommended for grant of permission to manufacture &amp; market of Linezolid Dispersible Tablets 150 mg for WHO TB Programme along with usage in India should adhere with National TB elimination Program guidelines and same are to be included in Dosage and administration section of packaging insert as a Note.</p>

