

Recommendations of the SEC (Investigational New Drugs) made in its 04th/26 meeting held on 10.03.2026 at CDSCO (HQ), New Delhi:

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
IND Division			
1.	<p>IND/CT18/FF/2025/4 8700 and E-receipt no. 130870/2026/CRU</p> <p>ZAYNICH™[Zidebactam- cefepime (also known as WCK-5222)] for injection, 3 g/vial</p>	M/s. Wockhardt Limited	<p>Firm presented nonclinical and clinical study data in continuation to the earlier 11th/25 SEC (IND) meeting held on 19.12.2025.</p> <p>After detailed deliberation, the committee recommended for grant of import and marketing permission of drug ZAYNICH™ [Zidebactam-cefepime] for injection, 3 g/vial for the indication 'Adult (18 years of age or older) patients with complicated urinary tract infections, or pyelonephritis, including concurrent bacteremia, caused by carbapenem-sensitive designated Gram-negative bacteria, with a condition to submit a Phase-IV protocol within 3 months of grant of Marketing Authorization.</p> <p>Accordingly, the firm is requested to submit a revised package insert for deliberation by the SEC.</p> <p>For the other indications applied for, the firm is required to conduct a Phase-III clinical trial with sample size having sufficient statistical power to detect clinical efficacy, and with a comparator group. Accordingly, the firm is required to submit a protocol to CDSCO for further review by the committee.</p>
2.	<p>E-receipt no. 134445</p> <p>LNP8701</p>	M/s Lupin Limited	<p>In light of earlier SEC recommendation dated 14.02.2024, firm has presented safety data of first four cohort of phase I study, before the committee.</p> <p>After detailed deliberation, the committee recommended to proceed for the next cohort dose as per the approved protocol.</p>