Recommendations of the SEC (IND) made in its 11th/25 meeting held on 19.12.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
IND Division			
1.	IND/CT04/FF/2024/51305 Utreglutide solution for injection 0.75/1.5/3.0/6.0 mg/ml (GL0034)	M/s Sun Pharmaceutical Industries Limited	In light of earlier SEC recommendation dated 08.10.2025, firm has presented revised Phase-II study protocol No. ICR/25/014, Version No. 2.0 dated 31.10.2025 before the committee. After detailed deliberation, the committee recommended for conduct of study as per protocol presented by the firm.
2.	IND-11012(17)/2/2025-eoffice Nafithromycin tablet 400mg	M/s. Wockhardt Limited	In continuation to SEC deliberations dated 30.04.2025 & 08.10.2025, matter was placed before the committee having ICMR – AMR division expert as special invitee. Firm presented following data before the committee ;- (a) patient distribution data for community-acquired bacterial pneumonia in country. (b) plan to ensure appropriate use of Nafithromycin Tablets by track & trace mechanism and complete batch reconciliation through digital portal. (c) copy of agreement with ICMR for surveillance of AMR and its inclusion in ICMR Annual Surveillance report 2024. (d) promotional material related to training to medical specialist (i.e, pulmonologist) & pharmacist. Firm also presented the tele-caller system to train and monitor the stockist and pharmacist to update the real-time supply details on digital portal. After detailed deliberation the committee opined that the drug is approved for the treatment of adults (> 18 years of age) with community-acquired bacterial pneumonia (CABP). It should be available to patients in need. Restricting access to newer, effective options like Nafithromycin, results in continued use of ineffective antibiotics such as Azithromycin and Clarithromycin which not only worsens patient outcomes but

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			also accelerates the rise of resistant pathogens. It is also opined that the sale & distribution of drug may be restricted through Schedule H1 warning on the label. Committee noted the measures taken by the firm in order to combat AMR & prevent its inappropriate use. After detailed deliberation, the committee recommended for the withdrawal of the stipulated condition i.e, "For supply only to Medical Colleges/ Tertiary care Hospitals/ District Hospital", from permission i.e, Form CT-23 & on label with the following condition ; – (1) Strict monitoring of distribution to be done by the firm & all proactive measures to be taken for prescription by Medical Specialist (pulmonologist) only and restrict distribution beyond permitted sales outlet. (2) Firm shall submit the drug distribution data with complete batch reconciliation on half-yearly basis to CDSCO, from the digital portal. Accordingly, firm is required to submit the revised package insert, primary, secondary labels, artwork etc., to CDSCO for review.
3.	IND/CT04/FF/2025/53378 Nor-Ursodeoxycholic Acid tablet 500mg	M/s. Shilpa Medicare Limited	Firm presented Phase-IV study protocol no. 019/N-UDCA/SML/2025, Version 1.0, dated 26.11.2025 before the committee. After detailed deliberation, committee recommended for conduct of the study provided following changes be made in the study protocol: 1. The title of the study protocol shall be revised to include NAFLD indication as approved by CDSCO instead of MASLD. 2. Sample size should be increased to 300 subjects.

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			3. Liver biopsy test should be removed from the study protocol. Accordingly, firm should submit revised protocol to CDSCO.
4.	IND/CT18/FF/2025/48700 ZAYNICH™ (Zidebactam+ Cefepime for injection, 3g/ vial) (WCK 5222)	M/s. Wockhardt Limited	Firm presented preclinical and clinical study report for Phase-I (conducted in US), Phase-II clinical report (conducted in India) and Phase-III GCT study report (conducted in US, Europe, China, India etc.) before the committee. The committee opined that firm has not mentioned subset of cUTI and in which group of patients the drug is indicated. Further in Phase-II and Phase-III study, patients with osteomyelitis were not included. However, firm has applied for approval of Osteomyelitis as well. In view of above, and after detailed deliberation committee has recommended as follows: - 1. Firm should present specific and precise comparative data of Phase-I, Phase-II and Phase-III study including specific indication for which study has been conducted. 2. Firm should present the specific indication proposed for approval. 3. Firm should present proposed package insert, labels. Accordingly, firm should submit above mentioned data to CDSCO for further deliberation before the committee.