Recommendations of the SEC (Investigational New Drugs) made in its 08th /25 meeting held on 04.09.2025 at CDSCO (HQ), New Delhi:

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
IND Division			
1.	IND-12011(13)/23/2025-eoffice Levormeloxifene fumarate tablets 15 mg	M/s. Cipla Ltd.	The firm presented the amendment in phase I study vide protocol no. 0116-01-23, Version 05 dated 19.02.2025, before the committee. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm, subject to the condition that firm should include transvaginal sonography test for uterus and both ovaries at end of study period. Accordingly, firm should submit revised protocol to CDSCO for further evaluation.
2.	IND/CT04/FF/2025/49677 Nafithromycin 400 mg Tablet	M/s. Wockhardt Ltd.	The firm presented the proposal for grant of permission to conduct Phase III study vides protocol no. W-4873-302, version 1.0, dated 23.04.2025, for the indication Acute Bacterial Rhinosinusitis (ARBS) before the committee. The committee has noted that the drug is already approved in the country for the treatment of adults with community acquired bacterial pneumonia (CABP). After detailed deliberation, the committee recommended for following changes in the presented protocol ; - 1. Dose of Amoxicillin - Clavulanic acid 625 mg tablet orally in control arm should be revise from twice daily to thrice a day daily as per IDSA and National guideline. 2. Protocol design should be revised to include administration of Azithromycin 500 mg tablet OD along with Amoxicillin - Clavulanic acid 625 mg tablet orally to all patients in control arm. 3. Treatment should be started on first visit of the patients. 4. Sample size should be inflated by

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			10% to account for lost to follow-up. Accordingly, firm should submit revised protocol to CDSCO for further evaluation by the SEC.
3.	IND/CT04/FF/2025/47801 ZY-19489 tablet 900 mg	M/s Zydus Lifesciences Limited	Firm has presented the proposal to conduct Bioavailability study vides Protocol no. ZY19489 1003, version 01 dated 17.06.2025 as per the recommendations of 04th/25th SEC (IND) meeting dated 29.05.2025. After the detailed deliberation, the committee recommended for the conduct of Bioavailability study as per protocol presented by the firm
4.	IND/CT04/2025/48419 Usnoflast (ZYIL 1) 25 mg, 50 mg & 75 mg capsule	M/s. Zydus Lifesciences Limited	Firm has presented the Phase II Clinical study report (ZYIL1.23.003 version no. 01, dated 24.10.2024) and Drug-Drug Interaction phase I study Protocol No.: C1B05514, Version 01 dated: 12.03.2025 as per the recommendations of 06th/25th SEC (IND) meeting dated 08.07.2025. After detailed deliberation the committee noted the results of the Phase II Clinical study report as presented by the firm and recommended to conduct Drug-Drug Interaction phase I study as per protocol presented by the firm.