Recommendations of the SEC (Investigational New Drugs) made in its 8th/26 meeting held on 06.05.2026 at CDSCO (HQ), New Delhi:

S. No.	File Number, name of drug, strength and dosage form	Name of firm	Recommendations
IND Division			
1.	E-143967 AUR -112 Tablets 100 mg/ 300 mg	M/s Aurigene Oncology Limited	Firm had been issued Phase-I clinical trial permission under Form CT-06 titled as "A Phase I, Open label, Dose Escalation, Multicenter, First-in-Human (FIH) Study Evaluating the Safety, Pharmacokinetics and Pharmacodynamics of Oral AUR112 in Patients with Relapsed Advanced Lymphoma (ADITI-1) vide Protocol No. AUR 112-101 version 2.0 dated 28.03.2024." The firm presented amendment in Phase-I clinical study protocol (AUR112-101, Version 3.0 dated 19.11.2025) due to increase in sample size of subjects in dose expansion cohort , backfill cohort of part - 1 study, fresh tumour biopsy at baseline for biomarker evaluation, specific response evaluation criteria for the Waldenstrom Macroglobulinemia etc, was deliberated before the Committee. After detailed deliberation, the committee recommended the proposed protocol amendment as presented by the firm with following conditions:- 1) ICF should clearly mention no benefit to patient for fresh tumor biopsy and is purely for research purpose and should have no cost to the patient for the biopsy or its complication. 2) An independent DSMB should be constituted for review of safety data. 3) At the end of part – 1 study, the criteria for deciding dose for Part–2 study should be defined.

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2.	IND/CT04/FF/2026/56016 SN-38 Lipid suspension for injection & diluent for SN-38 Lipid suspension for injection, 10ml vial	M/s. Intas Pharmaceuticals Limited	Firm has presented Phase-I Clinical Study Report and Phase IIa study protocol (0024-26 version 1.1 dated 26.03.2026) before the Committee. After detailed deliberation the committee considered the Phase-I Clinical trial results and recommended to conduct Phase-IIa clinical trial as per protocol presented by the firm before the committee with suggestion to increase the number of CT sites. (Dr. Rajeev Sood didn't participate in the discussion)
3.	IND/CT18/FF/2025/48700 ZYANICH™ (Zidebactam & cefepime for injection, 3g/vial)	M/s Wockhardt Limited	In light of earlier SEC recommendation dated 10.03.2026, firm has presented the revised package insert before the committee. After detailed deliberation, the committee opined that: 1) The recommendation given in SEC meeting dated 10.03.2026 w.r.t. indication has been discussed in detail and committee recommended that indication should be 'Adult (18 years of age or older) patients with complicated urinary tract infections, or pyelonephritis, including concurrent gram negative bacteremia for grant of import and marketing permission of drug ZAYNICH™ [Zidebactam-cefepime] for injection, 3 g/vial with other conditions remaining the same as per the recommendation of earlier SEC dated 10.03.2026. 2) The package insert has been deliberated and committee recommended that it should be revised inline with the revised indication as recommended above. 3) The drug should be sold on the prescription of a "Medical

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			Specialist" only. Accordingly, firm should submit revised package insert to CDSCO.
4.	IND-12013 (13) /1/ 2026-eoffice MKP11093 Powder for oral suspension	M/s Mankind Pharma Limited.	In light of earlier SEC recommendation dated 30.01.2025, firm presented first cohort study data before the committee. After detailed deliberation committee recommended as follows:- i. Interim safety data for 50 mg and 100 mg dose should be submitted to CDSCO before proceeding for dose of 150 mg cohort for further review by the committee.