Recommendations of the SEC (Investigational New Drugs) made in its 7th/26 meeting held on 16.04.2026 at CDSCO (HQ), New Delhi:

S. No.	File Number, name of drug, strength and dosage form	Name of firm	Recommendations
IND Division			
1.	E-139111 AUR -107 Tablets 5 mg/ 20 mg	M/s Aurigene Oncology Limited	Firm has obtained Phase I CT permission no. CT/ND/15/2023 dated 13.04.2023 for AUR 107-101 Protocol Version 2.0., and subsequently amendment permission dated 02.02.2024 for protocol no. AUR 107-101 Version 3.0 Dated 20.10.2023 to enrol the patients with multiple myeloma in backfill cohorts. The firm presented the amendment protocol no. AUR107-101 Version 4.0 to increase in sample size of subjects in dose escalation cohorts and backfill cohort which has been deliberated in details before the committee. The committee does not recommended the escalation of the dose up to 150 mg at present & an extension of 100 mg cohort may be done with addition of 3 more patients. A clear plan with in-silico models, Drug-drug interaction studies may be submitted. The following suggestions for inclusion/exclusion as well as sampling criteria in addition to previously approved protocol should be incorporated in the study protocol. 1. Plasma concentration of the drug to be measured uniformly at routine intervals for all newly recruited subjects. 2. Blood Sugar monitoring & Platelet levels monitoring criteria must be included. Accordingly, firm should submit above mentioned data & revised protocol for further evaluation & deliberation by the committee.
2.	IND/CT04/FF/2025/49494 Ranpirnase 0.3000 mg/ml + Oxymetazoline Hydrochloride1.0 mg/ml U.S.P.+ Tobramycin	M/s CBCC Global research LLP	The proposal of the firm for grant of permission to Phase II Clinical Trial study of drug OKG-0303 was deliberated by New Drug Division of CDSCO in the SEC (Ophthalmology) on 16.07.2025 and committee recommended that the firm should submit data/preclinical study showing:

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	3.0000 mg/ml U.S.P. Eye Drop (OKG-0303)		• Potential therapeutic benefits for proposed indication • Adequate justification/rational for the combination of the product • Firm may come up with Phase-I CT protocol or justification for waiver of Phase I CT. The firm has submitted Phase I /II clinical trial protocol titled "A Phase I Open Label, Multicenter Study to Evaluate the Safety and Efficacy of OKG-0303 in Healthy subjects and in Patients with Adenoviral Conjunctivitis: Expanding to A Phase 2, Randomized, Multicenter, Double Blind, Vehicle Controlled Trial in Patients with Adenoviral Conjunctivitis" in the Investigational New Drugs division as one of the drugs of proposed FDC is Ranpirnase, which is not approved globally. After detailed deliberation, the committee recommended to incorporate following changes and submit revised study protocol to CDSCO for further deliberation by the SEC committee: 1. The clinical trial must be a multi-arm Phase I study with a fixed-dose combination (FDC) of Ranpirnase + Tobramycin only. Another arm should be a lubricant and in case the patients do not respond SOC to be provided. 2. The clinical trial must be Multi-centric including both the Government & the Private Clinical trial sites & clinical trial design (i.e. RCT) should be adaptive and dynamic. 3. Justification for sample size. 4. The viral as well as the bacterial load pre and post treatment must be determined. Also, since administering an anti-viral and anti-bacterial together, the impact on resistance of the virus and bacteria to be determined in in-vitro setting. 5. Firm should submit Animal study data with proposed fixed dose combination.