Recommendations of the SEC (Investigational New Drugs) made in its 6th/26 meeting held on 08.04.2026 at CDSCO (HQ), New Delhi:

S. No.	File Number & Drug Name, Strength	Name of firm	Recommendations
IND Division			
1.	E-134639 AUR-104 5 mg/ 20 mg Tablets	M/s Aurigene Oncology Limited	The firm presented the proposal for discontinuation of Phase-I clinical trial before the committee. The firm has enrolled total 09 subjects in the said trial and due to dose limiting toxicities, risk-benefit analysis does not allow to continue the trial. After detailed deliberation, the committee agreed for the discontinuation of the study
2.	IND-12013 (17) / 1/ 2026-eoffice AUR-103 Calcium 100 mg Capsule	M/s Aurigene Oncology Limited	The firm presented the proposal for discontinuation of Phase Ib/II clinical trial before the committee. The firm has enrolled total 02 subjects in the said trial and facing practical challenges in recruitment of subjects with HER2-positive gastric/ gastroesophageal junction adenocarcinoma. After detailed deliberation, the committee agreed for the discontinuation of the study.
3.	E-137832 AUR-106 25 mg and 100 mg Tablet	M/s Aurigene Oncology Limited	The firm presented the proposal for discontinuation of Phase I clinical trial before the committee. The firm has enrolled total 21 subjects and none of the subjects achieve complete or partial response during the study. After detailed deliberation, the committee agreed for the discontinuation of the study.
4.	E-139111 AUR-107	M/s Aurigene Oncology Limited	Firm did not present the proposal.
5.	IND/CT04/FF/2025/52715 E-14309/2026/CRU AUR103 100 mg Capsule	M/s Aurigene Oncology Limited	Firm presented Clinical Trial Protocol entitled “A Phase-II Proof of Concept study of AUR103 Calcium in combination with Nintedanib in patients with Idiopathic Pulmonary Fibrosis (BHARAT-4)’’ before the committee. After detailed deliberation, committee opined that the presented protocol should be revised w.r.t. Part-2 of study protocol to include following: 1) Standard of care i.e. Pirfenidone and

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			Nintedanib. 2) Duration of the study should be 52 weeks instead of 6 months, a 26-week blinded interim analysis is recommended with a constituted DSMB to ensure that the participants of the trial are NOT being exposed to additional risk for a prolonged period owing to lack of efficacy or increased treatment emergent adverse events of the Investigational New Drug. 3) An interim analysis and DSMB review is recommended after the similar number of doses as given in the oncology trials since patient populations are different and drug combination are different. 4) An interim analysis/ circuit breaker for futility analysis should be built into protocol design for Phase 2 part. 5) For the Idiopathic Pulmonary Fibrosis, it is recommended to use an add-on placebo in the control group to ensure full blinding of the study. 6) The primary endpoints should include FVC, FEV-1 along with the quantitative assessment of the HRCT. 7) “Subset of patient should be assessed for histopathological changes preferably with cryo-biopsy” as exploratory objective. 8) Firm should submit the statistical justification for sample size to be used for Part-2 of the study protocol. The committee recommended to accept Part 1 and agreed to Part 2 of study protocol after all suggested revisions are made in the protocol as above. Accordingly, firm should submit revised protocol to CDSCO for further deliberation by the Committee.

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			The firm is also requested to submit Risk Assessment Report on the possibility of Drug-Drug Interaction of AUR103, Standard therapy i.e. Pirfenidone and Nintedanib for further deliberation by the committee.