Recommendations of the SEC (Investigational New Drugs) made in its 13th/26 meeting held on 08.07.2026 at CDSCO (HQ), New Delhi:

S. No.	File Number, name of drug, strength and dosage form	Name of firm	Recommendations
IND Division			
1.	IND/CT04/FF/2024/44989 0.1% Saturated Anacardic Acid (SAA) Lotion	M/s Avinia Therapeutics Private Limited	In light with earlier SEC recommendation dated 29.05.2025, firm has presented non-clinical data along with the Phase I clinical trial protocol. After detailed deliberation, the committee opined that the Phase I CT protocol presented should be revised to incorporate the following points: - 1) Evaluation in healthy subjects' (1 or more doses) safety and PK data to be made in comparison to the vehicle (Placebo). First dose should be administered at the site and subjects to be remain under observation for at least 6 hrs. The subjects should be advised to report at site immediately upon any Adverse Events. 2) Sentinel cohort must be made in healthy volunteers. 3) Submit justification for selecting the dose. 4) The duration of drug administration and follow up should be as planned for the subsequent patient study. 5) The firm should submit Risk management plan and compliance management plan of Investigational New Drug at home. 6) Study in patients should be proceeded only after submission of healthy volunteer's data which to be presented before the committee. Accordingly, the firm should submit revised protocol along with justification for dose, Risk Management Plan, Compliance Management Plan to CDSCO for further deliberation by the committee.

S. No.	File Number, name of drug, strength and dosage form	Name of firm	Recommendations
FDC Division			
2.	FDC/MA/24/000072 Pioglitazone Hydrochloride IP eq. to Pioglitazone 15 mg/15 mg + Ezetimibe IP 10 mg/5 mg Tablets	M/s Mankind Pharma Ltd.	Firm did not participate in the meeting.