Recommendations of the SEC (IND) made in its 01st/25 meeting held on 30.01.2025 at CDSCO (HQ), New Delhi:

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
IND Division			
1.	IND/CT/24/000083 MKP-11093	M/s Mankind Pharma	Firm has presented clinical trial protocol titled, "Phase I, Double-blind, Randomized, Placebo Controlled Study, to Assess the Safety, Tolerability and Pharmacokinetics of Single and Multiple Ascending Dose of MKP 11093 Suspension Administered Orally in Healthy Subjects vide Protocol Number: 0233-24 Version No. 1, Date 24-SEP-2024." After detailed deliberation, the committee has recommended for conduct of Phase I study as per protocol presented with following condition : 1. The firm should submit first cohort study data to CDSCO for further review by the committee. 2. The firm should incorporate test for hypercoagulability, mechanism to monitor platelet function (Qualitatively and quantitatively) pre and post dosing in the clinical trial protocol. Accordingly, firm should revise and submit the protocol to CDSCO.
2.	IND/CT/23/000088 PNB-001	M/s Biosphere Clinical Research Private Limited	The firm has presented Study rationale for proposed indication (T2DM) and amendment in Protocol titled "A Phase II, Multicenter, Randomized, Double-blind, Placebo controlled clinical study to evaluate the efficacy and safety of PNB-001 in subjects with Type 2 Diabetes Mellitus" Protocol Number: BCR-PNB-004, Version: 3.0 dated: 08.08.2024", for inclusion of female subject with non-child bearing potential. After detailed deliberation, the committee has opined that the rationale for conducting the study for

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			T2DM indication is not upto the satisfaction level as the justification presented has not been substantiated with documents, study reports (preclinical) etc. Committee has further opined that once the rationale for T2DM study has been justified, the protocol will be deliberated and revised accordingly.
3.	IND/CT/24/000016 ZYAT1	M/s Zydus Lifesciences	Firm has presented interim CSR (2 Dose cohort Data) (ZYAT1 1001.CSR.INT-01) as per the condition (XVIII) mentioned in ZYAT1 Phase I CT permission and revised protocol ZYAT1 1001, Version: 03 Dated: 12.11.2024 for the study titled, "A Phase 1, Prospective, Open label Study of ZYAT 1 administered via oral route to determine the safety, tolerability and pharmacokinetics in healthy adult human participants Protocol Number: ZYAT1 1001, Version: 03 Dated: 12.11.2024" After detailed deliberation, the committee has recommended to continue the study as MAD with following condition: 1. Firm shall submit study data of first 3 doses (25 mg, 50 mg and 75 mg) in healthy subject along with DSMB recommendation before initiation of next dose in patient for further evaluation by the committee. 2. The firm shall initiate segment -I & II reproductive or developmental toxicity study to submit it before Phase II trial.
4.	IND/MA/24/000033 Nor-Ursodeoxycholic acid Tablets 500 mg	M/s Shilpa Medicare Limited	Firm has presented the Phase III clinical trial study report titled "A phase-III, Randomized, Double-Blind, placebo controlled, multicentre, Parallel group study to evaluate the safety and efficacy of Nor-Ursodeoxycholic Acid 1500 mg (500 mg x 3 tablet) in patients suffering from Non-alcoholic Fatty Liver Disease (NAFLD)" vide protocol

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			no. 001/Nor-UDCA/SML/2023 Version No. 2.0 , Date 18th May 2023. After detailed deliberation, the committee has noted the result as presented by the firm and recommended for grant of approval to manufacture and market of Nor-Ursodeoxycholic acid Tablets 500 mg indicated for the treatment of patients with Non-alcoholic fatty liver disease. Firm has also presented the Package Insert of the above drug before the committee. After detailed deliberation, the committee has approved the Package Insert with condition to incorporate warning statement, “To be prescribed by gastroenterologist/ hepatologist”. Further, firm is required to submit the Phase IV clinical trial protocol within 03 months of granting of MA for review by the committee.
5.	IND/CT/23/000021 AUR-108	M/s Aurigene Oncology Ltd	The firm did not turn up for the presentation