Recommendations of the SEC (IND) made in its 02nd/26 meeting held on 05.02.2026 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
IND Division			
1)	IND-12011(13)/23/2025-e-office Levormeloxifene Fumarate Tablet 15 mg	M/s Cipla Limited	In light of earlier SEC recommendation dated 04.09.2025, firm has presented revised phase I Protocol No. 0116-01-23, version no. 6.0 dated 15 Sep 2025 with certain additional changes before the committee. After detailed deliberation, the committee noted the changes and recommended for conduct of study. Accordingly, firm needs to submit the revised Phase I study protocol with changes presented before SEC to CDSCO
2)	IND-12013(19)/3/2025-eoffice LNP3693 solution for injection	M/s Lupin Limited	Firm presented amended protocol no. LRP/LNP3693/2023/001 version 3.0 dated 23.07.2025 before the committee. After detailed deliberation, the committee recommended for following changes in the presented protocol: - 1. Firm required to constitute DSMB for the said study. 2. Results of tolerability of the clinical trial medications in 8 patients of each cohort must be evaluated by DSMB before deciding to enroll the remaining 12 patients of each cohort. 3. Inclusion criteria should be revised to include, Biomarker strategy for patient selection of each cohort in dosing of drug LNP3693 in combination with Pembrolizumab. 4. Minimum level of PD-L1/ MSI for each indication shall be determined & mentioned in inclusion criteria. 5. In the exclusion criteria patients already exposed to immunotherapy shall be mentioned. Accordingly, firm should submit revised protocol to CDSCO for further deliberation in the SEC.

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3)	IND-12013(13)/9/2025-eoffice ZRC-3306 (Anti-PCSK9 Product)	M/s Zydus Lifesciences Ltd.	Firm presented that due to lack of desired pharmacodynamic effect, firm is discontinuing the Phase I clinical study (Protocol No. ZYPCSK9 1001, Version: 01, dated 29.05.2023) granted vide permission number IND/CT/23/000051 dated 19 Sep, 2023. After detailed deliberation, the committee agreed for discontinuation of the said study.
4)	IND/CT04/FF/2025/52081 HRF -10071 (40 mg, 80 mg,120 mg)	M/s Hetero Labs Limited	Firm presented protocol of Phase II study, Protocol No. HCR/II/HERF10071HIV/05/2025; Version-1.0; Dated 25/07/2025, before the committee. After detailed deliberation, the committee recommended for conduct of above-mentioned phase II study, as presented by the firm. 1. The firm should abide by all applicable rules of the HIV/AIDS Prevention & Control Act 2017 and relevant Guidelines of NACO.
5)	IND/CT04/FF/2026/54083 HRF -10071 (40 mg, 80 mg,120 mg)	M/s Hetero Labs Limited	Firm presented Phase IIb/III study, protocol number HCR/II/III/HRF10071 HIVHTE/09/2025; Version-1.0; Dated 10/09/2025 before the committee. After detailed deliberation, committee recommended for conduct of above-mentioned phase IIb/III study, as presented by the firm with following condition. 1. In case of opportunistic infection TB, the patient must be withdrawn from the study. In case of any other opportunistic infection, DSMB need to take decision for continuation of the patient in the study. 2. The firm should abide by all applicable rules of the HIV/AIDS Prevention & Control Act 2017 and relevant Guidelines of

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			NACO. Accordingly, firm should submit revised protocol to CDSCO mentioning the condition no.01.