Recommendations of the SEC (Investigational New Drugs) made in its 02nd/24 meeting held on 14.02.2024 at CDSCO (HQ), New Delhi:

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT04/FF/2023/40890 ZRC-NB-3224	M/s. Zydus Lifesciences Ltd.	The firm presented their proposal of Phase I/II clinical trial protocol before the committee. After detailed deliberation, the committee recommended for approval of the proposed study of the firm with the condition that firm should submit the results of Phase I study (Single ascending dose study) of the proposed trial to CDSCO for further evaluation by the committee before proceeding to Phase II study (Multiple ascending dose study) of the proposed trial.
IND Division			
2.	F.No. IND/CT/ 24/ 000002 Ferroquine Capsules 300mg and ZY-19489 Capsules 300mg	M/s. Zydus Lifesciences Limited	The firm presented their proposal to conduct Phase I clinical trial before the committee. After detailed deliberation, the committee recommended that the firm should submit justification for proposed combination of drugs in terms of safety and efficacy and to submit the preclinical toxicity studies of proposed combination.
3.	F.No.IND/CT/24/ 000008 HRF-10071 Tablet 120 MG + Ethinyl Estradiol 0.03 mg and Levonorgestrel 0.15mg Tablet	M/s. Lambda Therapeutic Research Limited	The firm presented their proposal to conduct Phase I clinical trial before the committee. After detailed deliberation, the committee recommended for the conduct of clinical trial as per the protocol presented by the firm.
4.	F.No.IND/CT/23/ 000057 SCD-153 Topical Solution	M/s. Sun Pharma Advanced Research Company Limited	The firm presented the safety data of first two dose cohorts in the Phase I study before the committee for proceeding to higher dose cohorts. After detailed deliberation, the committee noted the safety data and recommended to proceed for dosing of next three cohorts as per the approved Protocol.
5.	F.No.IND/CT/24/ 000005	M/s. Aurigene Oncology Limited.	The firm presented their proposal to conduct Phase I clinical trial before the committee.

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
	AUR 104 tablets 5mg and 20 mg		After detailed deliberation, the committee recommended that the firm should present the detailed safety data for the proposed dose and pharmacokinetic–pharmacodynamics data of the study drug for further review by the committee.
6.	F.No.IND/CT/24/ 000006 LNP8701 Tablets 10 mg, 50 mg	M/s. Lupin Limited	The firm presented their proposal to conduct Phase I clinical trial before the committee. After detailed deliberation, the committee recommended that the firm should conduct the study only in subjects with metastatic cancer and should submit the data of first four cohorts to CDSCO for review by the committee before further proceeding. Accordingly, the firm should submit the revised protocol to CDSCO for further review by the committee.
7.	F.No.IND/CT/23/ 000101 Halofuginone Hydrobromide Oral Gel 0.01, 0.03 and 0.06% w/w	M/s. Yenepoya Foundation For Technology Incubation, C/o Yenepoya University	The firm presented their proposal to conduct Phase I/II clinical trial before the committee. After detailed deliberation, the committee recommended the firm should submit the detailed information on the study drug including use of standardized dose of the phytopharmaceutical content that induces the disease in animal model.