Recommendations of the SEC meeting to examine IND proposals, made in its 31st meeting held on 13.01.2023, 02:00 PM at CDSCO, HQ New Delhi, through Webex (Video Conference):

Sr.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
1.	F. No. IND/CT/23/000001 LNP7457 1.5 mg Tablet	M/s Lupin Limited	The firm presented its proposal to conduct Phase I clinical trial alongwith in-vitro and in-vivo preclinical data before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the study as per the presented protocol with the following conditions: 1. The starting dose should be 1 mg/day. 2. As part of PK, the metabolites should also be estimated. 3. Drug concentration in CSF at T_{max} should be estimated in a sub group of patients. 4. More Govt. Clinical trial sites should be included in the study.
2.	F. No. IND/CT/22/000020 Nor-ursodeoxycholic acid tablets 500 mg	M/s Shilpa Medicare Limited	The firm presented the Phase I protocol amendment before the committee. After detailed deliberation, the committee recommended for approval of the amendment in Phase I clinical trial protocol vide Protocol No. C1B01758, Protocol version: 02, dated May 23, 2022.
3.	F. No. IND/CT/22/000019 HRF-10071 and Tenofovir alafenamide and Emtricitabine	M/s Veeda Clinical Research Ltd.	The firm presented the Phase I Clinical study report to evaluate the Pharmacokinetic interactions between HRF-10071 and Tenofovir Alafenamide and Emtricitabine before the committee. The committee noted the results.