Recommendations of the SEC meeting to examine IND proposals, made in its 34th meeting held on 17.04.2023, 12:00 Noon 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/23/000021 AUR108 Capsules	M/s Aurigene Discovery Technologies Limited	The firm presented its proposal to conduct Phase I clinical trial along with in-vitro and in-vivo preclinical data before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase I Clinical trial as per the presented protocol with the condition that the firm should conduct the study with the lower dose and fewer subjects i.e 50 mg in 03 subjects and present the data before the committee for further consideration.
2.	F. No. IND/CT/22/000013 GRC 54276	M/s Glenmark Pharmaceutical Ltd	The firm presented results of Phase 1a clinical study and requested for amendment in the protocol for Phase Ib before the committee. After detailed deliberation, the committee noted the results of Phase 1a clinical study & agreed to the firm's request. Further, the committee recommended for grant of approval for the amendment in Phase Ib clinical trial protocol vide protocol No. GRC 54276-101, version 05 dated 24.03.2023.
3.	F. No. 12-11/17-DC Arimoclomol	M/s Covance India Pharmaceutical Services Pvt. Ltd	The firm presented its proposal for discontinuation of the Phase II study entitled "Multicenter Double-Blinded, Randomized Placebo-controlled study of Arimoclomol in patients diagnosed with Gaucher Disease Type 1 or 3". The firm presented following justification for premature termination of the study. 1. There was no statistically significant improvement in patient's medical condition was

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			observed after more than 1 year of open-label arimoclomol treatment. 2. The Clinical trial conducted under COVID-19 restrictions was no longer able to provide meaningful data. 3. It was not possible to assess the main clinical outcome endpoints required for the trial objectives for more than 12 months for many of the participants. Without the Gaucher Disease specific clinical scores (GD1-DS3 and mSST), ultrasound, or biomarkers of interest, the trial was no longer able to test its hypothesis or meet its long-term evaluation objectives. After detailed deliberation, the committee noted the results & agreed to the firm's request.