Recommendations of the SEC meeting to examine IND proposals, made in its 30th meeting held on 19.12.2022, 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/22/000082 AUR106 Tablets	M/s Aurigene Discovery Technologies Limited	The firm presented their proposal to conduct Phase I clinical trial alongwith preclinical data before the committee. After detailed deliberation, the committee recommended that the trial should be Phase I/II as add on therapy. Accordingly, the firm should submit revised clinical trial protocol to CDSCO for further review by the committee.
2.	F. No. IND/MA/19/000009 Remogliflozin and Remogliflozin + Metformin	M/s Glenmark Pharmaceuticals Ltd.	In light of SEC committee recommendation dated 23.09.2022, the firm presented the proposed amendment in approved patient enrolment number from 10,000 to 5000 subjects and to stop further enrolment of active post marketing surveillance (PMS) study before the Committee. After detailed deliberation, the committee recommended that the firm's request should be considered subject to the condition that the firm should submit the PSUR data up to 02 years.
3.	F. No. IND/CT/22/000020 Nor-ursodeoxycholic acid tablets 500 mg	M/s Shilpa Medicare Limited	The firm did not turn up for the meeting.
4.	F. No. ND/CT/22/000064 AKP-11 Ointment	M/s ICBio Clinical Research Pvt. Ltd.	In light of SEC committee recommendation dated 09.11.2022, the firm presented their proposal to conduct Phase II clinical trial along with the preclinical and clinical study data before the committee. After detailed deliberation, the committee recommended that the firm should submit following details: 1. Complete details of proposed product, proof of concept etc. 2. Proposed indication based on the peer reviewed published

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			literature, evidence and Phase I clinical trial data. 3. Justification for need of the product for the proposed indication. 4. The firm should include a gold standard comparator or placebo in the protocol and study should be two/three arm. Accordingly, the firm should submit revised clinical trial protocol, preclinical, clinical data and other supportive data to CDSCO for further review by the committee.