Recommendations of the SEC meeting to examine IND proposals, made in its 6th meeting held on 30.09.2020 at CDSCO - HQ, New Delhi through Webex (Videoconference).

Agenda No	File No. & Drug Name, Strength	Firm Name	Recommendation
New Drug Division			
1.	AB1001 Topical Gel	M/s Ahammune Biosciences Private Limited	The firm presented their proposal along with non clinical data and protocol for first in human (FIH) Phase I Clinical Trial in patients with 90 days duration of treatment. In light of its mechanism of action, the committee observed that the investigational drug has potential for immunomodulatory effect. After detailed deliberation the committee recommended that: 1. The firm should conduct a Phase I Clinical Trial Safety, Tolerability & PK study in healthy volunteers with two weak duration of treatment and accordingly the firm should submit revised protocol for further consideration by the committee. 2. Committee also opined that before conduct of Clinical Trial with long term duration of treatment (90 days) animal data assessing impact of the investigational drug for its potential immunomodulatory effect will be required.
2.	Bioplatin	M/s Rasayani Biologics Pvt. Ltd.	The firm presented their Phase-I Clinical Trial report. The committee observed the following: 1. The pharmacokinetics results are inconclusive. 2. In the safety data generated, the data on maximum tolerated dose (MTD), frequency of dosing etc., are not conclusive. Accordingly the firm may submit appropriate clinical development protocol to CDSCO for further review by the

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			committee.
3.	Centhaquine Citrate Injection 1.0 mg/vial	M/s Pharmazz India Private Limited	Firm presented their proposal along with the Package Insert, Label & Carton & Phase IV Clinical Trial protocol before the committee. After detailed deliberation, the committee recommended for approval of the package insert and also grant of permission to conduct the Phase IV Clinical Trial as per protocol presented.
Biologicals Division			
4.	Chikungunya vaccine	M/s Bharat Biotech International Limited	The firm presented Phase II/III clinical trial protocol along with safety and immunogenicity data from Phase I Clinical Trial After detailed deliberation the committee recommended for grant of permission to conduct the Phase II clinical trial part of the protocol and submit the results for consideration of Phase III clinical trial.
5.	Chikungunya Virus Vaccine.	M/s Indian Immunologicals	The firm presented Phase I clinical trial protocol along with non-clinical data. After detailed deliberation the committee recommended for grant of permission to conduct the Phase I clinical trial subject to following conditions: 1. Normal saline to be used as placebo 2. The interval between the doses should be 28 days rather than 30 days.