Recommendations of the SEC meeting to examine COVID-19 related proposal under accelerated approval process made in its 127th meeting held on 26.11.2020 at CDSCO, HQ New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Division			
1.	F. No. ND/CT/20/000061 Colchicine + Umifenovir Hydrochloride	M/s Laxai Life Sciences Ltd	In light of earlier recommendation dated 08.09.2020, the firm presented their justification/clarification along with revised protocol before the committee. The committee noted that Umifenovir is not approved in the country as antiviral drug. After detailed deliberation, committee recommended that the firm should conduct Phase II pilot study with Colchicine only and protocol for same should be submitted for further review by the committee.
GCT Division			
2.	CT/101/20 Online submission (22207) Enoxaparin/Clexane	M/s Tech Observer India	In light of earlier SEC recommendation dated 10.11.2020, the firm presented their justification/clarification before the committee. After detailed deliberation, the committee recommended for the grant of permission to conduct the Phase IIIb clinical trial subject to the following conditions: a. Current COVID-19 standard of care should be provided to the trial subjects at all the trial centre. b. Self-subcutaneous injection training should be provided to the trial subjects before initiating the trial. c. During the trial PI/Co-PI should monitor/interact with the patients initially for 28 days atleast once daily and it should be recorded. The heparin administration should be supervised by PI/Co-PI by audio &video. d. In addition to the routine monitoring the trial subjects should be specifically monitored for CNS symptoms such as Confusion, Headache, Drowsiness, loss of consciousness, neurological deficit and in such cases CT scan should be

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			performed immediately.
Biological Division			
3.	BIO/CT/04/FF/2020/22708 Pegylated interferon alfa-2b	M/s Cadila Healthcare Limited	The firm presented their proposal to conduct Phase III CT along with CT protocol. After detailed deliberation, the committee recommended for grant of permission to conduct Phase III CT subject to the condition that, the primary objective should be revised as two-point improvement in the WHO 7-point ordinal scale. Accordingly, the firm should submit the revised protocol to CDSCO for approval.
4.	BIO/CT/20/000093 Itolizumab injection	M/s Biocon Biologics India Limited	The firm presented the proposal for amendment to already approved Phase IV Clinical trial before the committee. After detailed deliberation committee recommended that the firm should amend the primary objective to include clinical outcome efficacy assessment in addition to safety assessment as primary endpoint. Firm should submit justification for the proposed amendments. Accordingly, the firm should submit the revised proposal for further consideration of the committee. The firm informed the committee that approximately 2000 COVID-19 patients that has been used under the emergency use authorization. The firm should submit safety data including the mortality data generated till date. Dr. Sushant H. Meshram did not participate in the deliberation.
5.	BIO/CT18/FF/2020/22772 Bamlanivimab	M/s Eli Lilly and Company (India) Pvt. Ltd.	Firm presented their proposal for grant of permission to Import and Market 700mg dose of the drug under Restricted Emergency Use for treatment of mild to moderate COVID-19 with waiver of local clinical trial in the country.

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			Firm presented the Phase II data in the out-patient data which was conducted in mild to moderate cases (all the cases in this trial are mild cases according to Indian guidelines). The committee noted that 700 mg dose was not showing efficacy in the primary end point and any significant change in any other endpoint including hospitalization. After detailed deliberation, with the available data, the committee is of the opinion that emergency use authorization cannot be recommended.
6.	X.11026/219/2020-BD COVID-19 Hyper-Immune globulin (Human) solution (Version 2.0, 09.11.2020)	M/s Virchow Biotech Pvt. Ltd, Hyderabad	The firm presented the revised clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct phase II clinical trial subject to the following conditions: a. One more arm with dose of 75mg/kg should be included for conduct of study. b. Sample size should be 20:20:20 in each arm with no more than two drop out in each arm. c. Adverse effect should be monitored and recorded during the conduct of the study.