Recommendation of the SEC meeting to examine COVID-19 related proposal under accelerated approval process made in its 131st meeting held on 17.12.2020& 18.12.2020at CDSCO, HQ New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
NewDrug Division			
1.	ND/MA/20/000166 Aviptadil for injection 1000 mcg/ml	M/s MSN	Firm presented their proposal for approval of manufacture and marketing the drug for emergency with waiver of Phase III clinical trial. After detailed deliberation, committee noted the data presented is not sufficient for marketing authorization. Therefore committee did not recommend for grant of approval of emergency use authorization.
2.	ND/CT21/BO/2020/23164Aviptadil (API) &Aviptadil injection 150ug/10 ML (Formulation) for emergency use	M/s Zuventus Healthcare Ltd	Firm presented their proposal for conduct of Phase III clinical trial before the committee. After detailed deliberation committee recommended that the protocol should be revised to include the following: 1. Primary and secondary objective shall be in line with the international trial, which is ongoing. 2. Withdrawal criteria should be clearly defined in the protocol 3. Criteria for organ failure shall be clearly defined in the protocol 4. WHO ordinal scale should be used for assessment instead of NIAID. Accordingly, revised clinical trial protocol shall be submitted for further review.
3.	ND/MA/20/000149 Purified aqueous extract of Cocculushirsutus Tablets 400 mg	M/s Sun pharmaceuticals Ltd	In light of earlier SEC recommendation, the firm presented their reanalysed results with the request for grant of emergency use authorization. After the presentation of reanalysed data committee observed that the results of the study did not meet the efficacy criteria of primary end point.

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			Therefore committee has not recommended for grant of approval of emergency use authorization at this stage.
4.	ND/CT/04/FF/21597 Import of CHC-Fulvic Acid	M/s Sphaera Pharma Pvt Ltd	Firm presented their proposal before the committee. After detailed deliberation, committee recommended that firm should present the mechanism of action, with regard to its selectivity in suppressing type I cytokine by passing type II or the other way, animal, PK/PD, safety, efficacy data as well as clinical data along with the justification for dose selection for the proposed clinical trial for further consideration.
SND Division			
5.	SND/MA/20/000344 Baricitinib Tablets 1mg, 2mg & 4mg	M/s Natco	Firm presented the proposal for Emergency Use Approval for Baricitinib Tablets 1mg, 2mg & 4mg indicated in combination with Remdesivir, for the treatment of suspected or laboratory confirmed COVID-19 in hospitalized adults and paediatric patients two years of age or older requiring supplemental oxygen, invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO). Firm presented the published clinical data in support of drug use in COVID-19. After detailed deliberation, committee did not recommend Baricitinib Tablets indicated in combination with Remdesivir, for the treatment of suspected or laboratory confirmed COVID-19 in hospitalized adults and paediatric patients two years of age or older requiring supplemental oxygen, invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO) for Emergency Use Approval.
6.	SND/MA/20/000339 Remdesivir injection (without Cyclodextrin) 100/20ml (5mg/ml)	M/s Cipla	Firm presented the proposal before the committee. Committee noted that, in the proposed formulation SBECD is replaced with

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			Polysorbate 80 and PEG 300 with the intention to reduce the renal toxicity. After detailed deliberation the committee recommended that the firm should conduct Bioequivalence study and also clinical trial to assess the renal toxicity of the new formulation. Accordingly, firm should submit Bioequivalence study protocol and Clinical trial protocol to CDCSO for further review by the committee.
7.	SND/MA/20/000356 Ivermectin 12 mg Tablets	M/s Zuventus	The firm presented their proposal for manufacturing and marketing of Ivermectin 12 mg Tablets for treatment in Covid -19 before the committee. Committee noted that the data presented by the firm were not adequate for consideration for approval of Ivermectin 12 mg Tablets for use in treatment of COVID-19. After detailed deliberation, committee recommended that formulation of Ivermectin 12 mg tablets may be considered for the already approved indication for approval by CDSCO as per the regulatory provisions.
8.	12-01/2020/DC(Pt-NSRT-SND) Eflornithine granules 2.5 gm & 5.0 gm	M/s Naveen Saxena Research & Technology	In light of the earlier recommendation of the SEC held on 04-11-2020 firm presented the revised Phase II clinical trial. After detailed deliberation committee recommended for grant of permission to conduct of Phase II Clinical Trial subject to the condition that 7 point WHO ordinal scale should be used and sample size should be increased to 208.
Biologicals Division			
9.	BIO/CT/000178 Equine COVID-19 Antiserum [F(ab)2] (BSVEQAb)	M/s Bharat Serum and Vaccine Limited	The firm presented their proposal for conduct of Phase I/II clinical trial of Equine COVID-19 Antiserum [F(ab)2] (BSVEQAb) along with non clinical studies before the committee. After detailed deliberation, the committee

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			recommended for grant of permission to conduct the clinical trial subject to the following amendments to the protocol: 1. In inclusion criteria, the definitions of moderate patient should include SpO2 between 90 to 93 %. The respiratory rate should be >24 per minute, heart rate should be upto 120 per minute. 2. The WHO progression scale mentioned in the exclusion criteria should be deleted. 3. The viral clearance should be secondary endpoint. 4. The sample size in Phase I should not be less than 30 patients. 5. The firm should present the results of Phase I study before proceeding to Phase II study. 6. The safety data should be evaluated by DSMB constituted for the study. Accordingly, the firm should submit revised clinical trial protocol to CDSCO for approval.
10.	BIO/CT/20/000186 Product: SARS-CoV-2 rS Protein Nanoparticle Vaccine] with Matrix-M1 Adjuvant CT Phase III	M/s Serum Institute of India Pvt. Ltd. (SIIPL), Pune	Firm presented their proposal to conduct Phase III clinical trial of SARS-CoV-2 rS Protein Nanoparticle Vaccine] which is a bridging trial to the ongoing Phase III clinical trial in UK before the committee. After detailed deliberation, the committee recommended that the protocol should be revised as mentioned below: 1. The design of the clinical trial should be revised to adaptive Phase II/III clinical trial. 2. Placebo arm should be included in the study. 3. Interim Safety data from Phase II clinical trial should be submitted to CDSCO along with the recommendations of DSMB before proceeding to Phase III clinical trial. 4. In the exclusion criteria, specify the maximum dose of antiplatelet dugs permitted. 5. The firm should clarify the use of antiplatelet agents apart from Aspirin 325 mg and dual antiplatelet therapy to be used during the trial. Further, the firm should submit the following information/data for consideration: • Submit the safety data of M1

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			adjuvant along with published literature • Justify the non-inferiority margin proposed for statistical analysis Accordingly, firm shall submit revised clinical trial protocol before the committee for further consideration.
11.	BIO/CT/20/000093, Itolizumab	Biocon Biologics India Limited	In-light of the earlier recommendations of the SEC meeting dated 26.11.2020, firm presented the Phase IV protocol. After detailed deliberation, the committee recommended for grant of approval for the amended clinical trial protocol version 4.0, dated 30.11.2020.