Recommendations of the SECmeeting to examine COVID-19 related proposals under accelerated approval process made in its 140th meeting held on 18.01.2021 & 19.01.2021 at CDSCO, HQ New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/IMP/19/000077 Colchicine	M/s Laxai Life Sciences Pvt. Ltd	In light of earlier SEC recommendation dated 08.12.2020, firm presented the revised Phase II CT Protocol before the committee. After detailed deliberation the committee recommended for grant of permission to conduct of Phase II CT with the drug subject to following condition: 1. ITT analysis should be included **2.** Discharge criteria should be specified **3.** BP for both diastolic and systolic should be measured for inclusion of patients.
2.	ND/CT-21/21/20/23164 Aviptadil Injection 150ig/10ml (FF)	M/s Zuventus Healthcare limited	In light of earlier SEC recommendation dated 17.12.2020, firm presented the revised Phase III CT Protocol before the committee. After detailed deliberation the committee recommended for grant of permission to conduct of Phase III CT with the drug subject to condition that criteria for discharge of patients from ICU should be defined clearly in the protocol.
3.	ND/CT/21/000001 Aviptadil I.V infusion 140 mcg/ml	M/s Dr. Reddy	The firm presented their Phase II/III Clinical Trial protocol before the committee. The committee after detailed deliberation recommended for grant of permission to conduct the Phase III Clinical Trial with the drug subject to conditions that: 1. The trial should be termed as Phase III Clinical Trial instead of Phase II/III trial and accordingly proposed interim analysis should be deleted from the protocol. 2. Criteria for discharge of patients from ICU should be defined clearly in the protocol.

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4.	F. No. ND/MA/20/000040 Collidal Silver 50 ppm hand sanitizer	M/s Nanz med Pvt. Ltd.	In light of SEC dated 08.12.2020, the firm presented their clinical study protocol before the committee. The committee after detailed deliberation committee recommended that the firm should submit the in-vitro efficacy data as already recommended by the committee along with safety protocol for further consideration.
Biological Division			
5.	BIO/CT/20/000186 SARS-CoV-2 rS Protein Nanoparticle Vaccine] with Matrix-M1 Adjuvant (COVOVAX)	M/s Serum Institute of India Pvt. Ltd, Pune	In light of SEC recommendations dated 13.01.2021, the firm presented its proposal along with various comparator options. After detailed deliberation, the committee recommended that firm should conduct the proposed study with placebo or other vaccine as the comparator for which justification is required. Accordingly, the firm should submit revised clinical trial protocol before the committee for further deliberation.
6.	BIO/CT/21/000001 Chimpanzee Adenovirus Vectored COVID-19 Vaccine (BBV154)	M/s Bharat Biotech International Ltd., Hyderabad	The firm presented animal toxicity and immunogenicity, CMC data along with the protocol to conduct Phase I/II clinical trial of Chimpanzee Adenovirus Vectored COVID-19 Intranasal Vaccine (BBV154) After detailed deliberation the committee recommended that, the firm should generate Safety and Immunogenicity data in Phase-I clinical trial (75 subjects) in the proposed doses as per the protocol and submit the data for the consideration of the committee to proceed to Phase II clinical trial. Accordingly, firm should submit revised clinical trial protocol for consideration of the committee.
7.	BIO/CT/21/000004 Equine Anti-Covid antibody fragments f(ab')2	M/s JSS medical research India Pvt Ltd	The firm presented its proposal for conduct of Phase I & II clinical trial of Equine Anti-Covid antibody fragments

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			f(ab')2. After detailed deliberation, the committee recommended that, the firm should generate pharmacokinetic data in animals & also provide justification for human dose & dosing schedule for further consideration.
8.	BIO/CT04/FF/2020/23436 Etanercept	M/s Lupin	Firm presented their proposal for conduct of Phase II/III study in COVID-19 patients. After detailed deliberation, the committee recommended that, firm should revise the design of the protocol to two arm study wherein first arm shall be Etanercept +SOC and the other arm shall be SOC. Further, the primary objective should be revised to 2 point reduction in 7 point WHO 'Ordinal Scale'. Accordingly firm shall submit revised protocol for evaluation by the committee.
9.	BIO/CT18/FF/2020/23014 Olokizumab	M/s Dr. Reddy's Laboratories Limited	Firm presented the proposal for marketing the drug in COVID-19 indication with waiver of clinical trial. The committee noted that the drug is not approved in India for any indication. Further based on presentation, for COVID 19, it is not approved by regulatory authority of Russia. After detailed deliberation, the committee did not recommend for approval of the drug for restricted emergency use.
SND Division			
10.	SND/MA/20/000344 Baricitinib Tablets 1/2/4 mg	M/s Natco	In light of earlier recommendation of SEC meeting held on 17.12.2020, the firm has submitted their justification requesting local clinical trial waiver of Baricitinib Tablets for use in COVID-19 as restricted emergency use. After detailed deliberation the committee recommended that the firm

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			should conduct the Phase III clinical trial. Accordingly, firm should submit the Phase III clinical trial protocol for further review.
11.	SND/MA/20/000339 Remedesivir Injection 100 mg/20ml (5mg/ml) (Without Cyclodextrin)	M/s Cipla	In light of earlier recommendation of SEC meeting held on 17.12.2020, the firm presented their justification, rationale and protocol for in-vitro studies in-lieu of Bioequivalence and clinical studies. After detailed deliberation the committee reiterated its earlier recommendation.
GCT Division			
12.	CT/113/20 Online submission (10488) Baricitinib	M/s Eli Lilly	The firm presented the proposed clinical study protocol amendment no. 14V-MC-KHAA(e) dated 25.11.2020 and protocol addendum 14V-MC-KHAA (5.0) dated 01.12.2020 before the committee. The committee after detailed deliberation recommended for the approval of proposed clinical study protocol amendment no. 14V-MC-KHAA (e) dated 25.11.2020 and protocol addendum 14V-MC-KHAA (5.0) dated 01.12.2020.
13.	CT/112/20 Online Submission (GCT/PostAppr/2020/10495) JS016	M/s Parexel	Firm has presented their justification before the committee. After detailed deliberation Committee opined that justification submitted by firm for inclusion of asymptomatic and mild COVID patients is not adequate. The Clinical trial should be conducted accordingly as per protocol approved.
14.	CT/04/2021 Online submission (23229) Immunoglobulin	ICMR	The applicant presented clinical study protocol as part of Global study before the committee. The committee after detailed deliberation recommended for grant of permission to conduct the trial as per the

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			protocol. Preferably same product should be used at both the proposed study centres in India.
15.	CT/67/20 Online Submission (10567) Dapagliflozin	M/s. George Clinical	Firm presented the proposal for Protocol amendment version-4,Dated 20 November before the committee. After detailed deliberation committee opined that justification for additional primary efficacy endpoint as proposed should be provided by the firm for further consideration of the committee.