Recommendations of the SECmeeting to examine COVID-19 related proposalunder accelerated approval process made in its 78th meeting held on 28.05.2020 at CDSCO, HQ New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/MA/20/000072 Favipiravir Tablets 200 mg & 600 mg	M/s. BDR Pharma,	The firm presented their proposal along with protocol for Phase III trial with Favipiravir Tablets 600 mg and its t.i.d dose administration before the committee. After detailed deliberation, the Committee recommended that the clinical trial should be conducted with Favipiravir Tablets 200 mg with its b.i.d dose administration as already approved for clinical trial for other applicants. The inclusion and exclusion criteria, primary and secondary end-points etc. are also not clearly defined in the protocol presented. Accordingly, the clinical trial protocol should be re-written clearly defining the inclusion and exclusion criteria, primary and secondary end-points etc. and submitted for further review by the committee.
2.	ND/MA/20/000040 Colloidal Silver BP 50 ppm, dosage form Gels, hand sanitizer	M/s Nanz Med Sciences Pharma Pvt. Ltd.	In light of recommendation of the committee dated 24.04.2020, the firm presented the protocol for clinical trial before the committee. After detailed deliberation, the Committee recommended for grant of permission to conduct the clinical trial subject to condition that "seven days pre-test conditioning period" mentioned in exclusion criteria should be revised to "over-night pre-test conditioning period".
3.	IND/MA/FF/20/00001 Lyfaquin™ (lyophilized centhaquine citrate injection 1.0 mg)	M/s Pharmazz India Private Ltd	The firm presented their proposal along with protocol for Phase III trial before the committee. The Committee noted that the drug is approved as add on resuscitative agent for hypovolemic shock. It is not approved as standalone therapy. The firm has proposed for clinical trial to assess the efficacy and safety of Centhaquine in critically ill COVID -19 patients with acute respiratory distress syndrome (ARDS). The committee after detailed

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			deliberation opined that the justification presented is not adequate for conduct of the clinical trial in the proposed condition and did not recommend for approval of the trial.
4.	ND/CT+/04/FF/2020/19862 Pirfenidone 267 Mg Tablets	M/s. Shilpa Medicare Raichur	The firm presented their proposal along with the protocol for clinical trial. The committee opined that the applicant should make comprehensive presentation including the data of Pirfenidone in ARDS in the next meeting for consideration.
5.	12-01/20-DC (Pt-116) WHO – Solidarity Trial (Remdesivir; Lopinavir (given with Ritonavir); Interferon β1a (with Lopinavir& Ritonavir); Hydroxychloroquine or Chloroquine	ICMR-National AIDS Research Institute, Pune	The matter was deferred
Subsequent New drug			
6.	SND/CT/20/0000021 NICLOSAMIDE IM Depot 900/3.75 mg/ml	M/s Daewoong Pharma	In light of earlier SEC recommendation firm presented results of toxicity studies along with Phase I trial protocol in COVID-19 patients. After detailed deliberation, the committee recommended that the firm should submit revised Phase I protocol for conduct of Phase I trial PK, PD & Safety study in healthy volunteers parallelly in South Korea and India. Accordingly, the revised protocol along with status of Phase I study in South Korea should be submitted for further consideration.
Blood and Blood Product Division			
7.	Fx.11026/74/2020-Bd Convalescent Plasma for Covid-19 Infected Patients	M/s. Institute of Liver & Biliary Sciences, New Delhi	The applicant presented the results of the pilot clinical trial along with protocol for the larger clinical trial. After detailed deliberation the Committee recommended for grant of permission to conduct the clinical trial subject to following conditions: 1. The subject should be randomised in 1: 1ratio. 2. The inclusion criteria should be revised to mention the Oxygen saturation level in resting state as less than 90% or as per the latest WHO guidelines. 3. "In case compatible plasma is not

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			available, reduction of titre will be done using an ABO antibody immune absorption column" mentioned under infusion of Convalescent plasma should be deleted.
8.	.X.11026/67/2020-Bd Platelet Derived Growth Factor Concentrate	M/s.Seragen Bio-Therapeutics Pvt. Ltd	Applicant presented their revised proposal along with study protocol for Phase I trial before the committee. After detailed deliberation the committee recommend that the firm should submit the revised protocol with all the criteria like, title of protocol, primary objective, secondary objective, primary outcome, secondary outcome, randomisation etc and submit the same for deliberation by the committee.
GCT Division			
9.	CT/45/2020 BDB-001 injection STS-BDB001-04: Version/DateV2.0/May 7, 2020	M/s. George Clinical India Pvt Ltd, Bangalore Sponsor:- Staidson (Beijing) Biopharmaceuticals co. ltd., Beijing, China	Applicant presented their proposal along with study protocol for Phase II trial before the committee. **Assessment of risk versus benefit to the patients-** The safety profile of the study drug from various preclinical toxicology studies and clinical studies justify the conduct of the trial. **Innovation vis-a-vis existing therapeutic**: To evaluate efficacy and safety of BDB-001 injection in the treatment of progressive severe COVID-19. **Unmet medical need in the country-** To develop safe and efficacious treatment in progressive severe COVID-19. After detailed deliberation the committee recommended for grant of permission to conduct the study subject to following conditions: 1. 28 days all cause mortality should be an additional primary endpoint instead of being secondary endpoint. 2. The investigator in each site should be either Pulmonologist or at least M.D. (Internal Medicine). 3. The copy of regulatory approval for the study from Spain should be submitted to CDSCO before initiation of the study

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10.	Ayurvedic Formulation Ashwagandha	Dr. Arvind Chopra, Centre for Rheumatic Disease (CRD), Pune	The clinical study protocol of Ashwagandha for the prophylaxis against SARS-CoV-2 infection in High Risk Population was presented for inputs from the committee. During the presentation the committee discussed various aspects like methodology for randomization, classification and definition of high risk contacts, Mobile App based data capturing on the basis of five questions etc, and suggested that the randomization should be proper and Classification & Definition of Contacts as per the ICMR guidelines for testing of COVID-19 patients should be followed for high risk contacts.The data to be captured should be based on various parameters as specified in said guidelines of ICMR. However, the committee did not discuss the product and the details of its scientific basis, as only advice was sought by the applicant.
11.	Ayurvedic Formulation: i. AYUSH-64: 500mg Tablets ii. Yashtimadhu : 300mg tablet iii. SanshamaniVati Plus	Dr. Arvind Chopra, Center for Rheumatic Disease (CRD), Pune	The clinical study protocol of Ayurvedic formulations in mild to moderate COVID-19 patients was presented for inputs from the committee. During the presentation, the committee discussed various aspects like criteria for mild and moderate COVID-19 patients, stratified sampling and analysis for mild and moderate cases, etc and suggested accordingly on these aspects. However, the committee did not discuss the product and the details of its scientific basis, as only advice was sought by the applicant.
Biologicals Division			
12.	X-11026/135/2020-BDItolizumab Solution for infusion vial 5 mg/mL	M/s. Biocon	The firm presented their proposal along with interim results of the on-going clinical trial before the committee. After detailed deliberation the committee opined as under: 1. Interim analysis was not part of the protocol. 2. Randomization was not proper. 3. The data presented is inadequate. Analysis of patients from control arm was not done. In view of above, the committee did not

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			consider the proposal for approval of emergency use of the drug. Further the committee opined that such interim analysis of the RCT is not scientifically justifiable for intended purpose as per the protocol and therefore clarification on the randomisation being followed in the study need to be submitted.