Recommendations of the SEC meeting to examine COVID-19 related proposal under accelerated approval process made in its 178th meeting held on 26.08.2021 & 27.08.2021 at CDSCO, HQ New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
New Drug Division			
1.	12-01/2021-DC (Pt-248) Pentoxifylline	Max Hospital Saket New Delhi	The applicant presented their proposal of the academic study before the committee. After detailed deliberation, the committee recommended that the applicant should submit protocol of Phase II proof of concept, study with statistically significant sample size, study objective and endpoints should be as per WHO ordinal scale. Accordingly, revised protocol should be submitted for review by the committee.
2.	ND/CT/20/00046 Umifenovir	CSIR	In light of earlier recommendation of the SEC (COVID) meeting held on 29.07.2021, the applicant requested for reconsideration of the recommendation and presented the clarification before the committee. After detailed deliberation the committee reiterated its earlier recommendation dated 29.07.2021 Accordingly, applicant should conduct large Phase III clinical Trial in statistically significant number of mild Covid -19 patients and accordingly, submit the protocol for further consideration by the committee.
Biological Division			
3.	BIO/CT/21/000021 Whole Virion, Inactivated Corona Virus Vaccine (BBV152)	M/s. Bharat Biotech International limited	The firm presented interim safety data 4 weeks after second dose in the age group 12-18 years & 6-12 years and 4 weeks after first dose in the age group 2-6 years of Phase II part of the Phase II/III clinical trial of Whole Virion, Inactivated Corona Virus Vaccine (BBV152) in the age group of 2 to 18 years, as per the recommendations of the SEC & clinical trial permission. The committee noted the interim safety results presented. Further, the committee recommended that the firm should present the complete safety and immunogenicity data for evaluation.

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4.	BIO/CT/21/000089 Covid-19 vaccine containing SAR-CoV-2 receptor Binding Domain of SARS-CoV-2	M/s. Biological E Limited	In light of the recommendations of SEC meeting dated 29.07.2021, the firm presented revised clinical trial protocol for conduct of the Phase II/III clinical trial of Covid-19 vaccine containing SAR-CoV-2 receptor Binding Domain of SARS-CoV-2 in the age group of 5 years to 18 years. After detailed deliberation, the committee recommended for grant of permission for conduct of the Phase II/III clinical trial in the age group of 5 years to 18 years.
5.	BIO/CT/21/000051 Covid-19 vaccine containing SAR-CoV-2 receptor Binding Domain of SARS-CoV-2	M/s. Biological E Limited	In light of the recommendations of SEC meeting dated 19.08.2021, the firm presented revised clinical trial protocol for conduct of Phase II/III clinical trial of Covid-19 vaccine containing SAR-CoV-2 receptor Binding Domain of SARS-CoV-2 in age group of 18 to 80 years. After detailed deliberation, the committee recommended for approval of the amendment in approved Phase II/III clinical trial protocol.
6.	BIO/MA/21/000068 Tocilizumab	M/s. Hetero Biopharma Limited	In-light of the SEC meeting dated 22.07.2021, the firm presented the proposal for marketing authorization of Tocilizumab (formulated drug substance & single use vials in 3 strengths) (a). 80mg/4mL (b). 200mg/10mL (c). 400mg/20mL based on the Phase III clinical trial in the country. The firm presented efficacy and safety data of the drug in comparison to the innovator. After detailed deliberation, the committee recommended for grant of permission for manufacture for restricted use of the drug under emergency situation in adult patients with Cytokine Storm of severe COVID-19 Pneumonia subject to following conditions - 1. The firm should conduct Phase IV clinical trial. 2. The firm should submit Risk Management Plan to address the safety issues in post marketing scenario. 3. The drug should be supplied only on the prescription of medical specialist for use

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			in hospital/ institutional set up only. 4. The Package Insert containing all details including the safety information should be provided along with the drug product for use in hospital/ institution. 5. Product labels should be as per the New Drugs and Clinical Trials Rules, 2019
7.	BIO/IMP/21/000045 Regdanvimab	M/s. Abbott Healthcare Pvt. Ltd.	In-light of the SEC meeting dated 14.06.2021, the firm presented the proposal for marketing authorization of Regdanvimab Concentrate for solution for infusion vial 960 mg/16 ml (strength 60 mg/ml) based on waiver of local (Phase III & Phase IV) trial in the country. The committee noted that the drug is approved only in South Korea and there is no efficacy data of the drug on the COVID variants prevalent in India. Further, there is no safety and efficacy data in Indian population. After detailed deliberation, the committee did not recommend for the grant of Emergency approval of the drug.
8.	BIO/CT/21/000108 Protein subunit vaccine against SARS-CoV-2 Virus	M/s. Reliance Life Sciences Pvt. Ltd., Mumbai	The firm presented its proposal for conduct of Dose escalation Phase I clinical trial of Protein subunit vaccine against SARS-CoV-2 Virus along with clinical trial protocol and pre-clinical (animal) toxicity data. The firm mentioned that it has inadvertently mentioned the volume of blood to be withdrawn for Immunogenicity assessment as 20 ml in the protocol & requested to consider it as 80 ml, the committee agreed for the same. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase I clinical trial subject to the condition that immunogenicity to be assessed at day 42 instead of day 14.
9.	CT10/BIO/20/000030 (CT) Anti-COVID19 Serum	M/s Premium Serums and Vaccines Limited, Pune	The firm presented its proposal for use of Anti-COVID-19 Serum manufactured using own bulk along with animal toxicity data and requested for use of the batches in clinical trial.

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			After detailed deliberation, the committee noted that Phase I clinical trial is ongoing and therefore recommended for submission of Phase I clinical trial data for consideration of the proposal..
SND Division			
10.	SND/IMP/21/000048 Low Residue Quat Metered Dose concentrate containing, Didecyl Dimethyl ammonium chloride (DDAC) 2.0% (3.6% w/w) in 100 ml (Hard surface disinfectant)	M/s. ECO Labs	The firm did not turn up for deliberation
11.	SND/IMP/21/000056 Klercide Sporicidal Active chloride (0.5%), chloride-based disinfectant of floor, wall and other hard surfaces, specifically effective against COVID-19 Causing Coronavirus (Hard surface disinfectant)	M/s. ECO Labs	The firm did not turn up for deliberation

GCT Division			
12.	CT/83/21 Online submission (27175) Ampion	M/s. QED Clinical Services	The firm presented the proposal for Phase II clinical trial no. AP-019 Ver. 1.2 Dated 25May2021 with IP-Ampion (5% Human Serum Albumin) before the committee. **Risk-Benefit:** Patients with respiratory distress due to COVID-19 may be at a high risk of progressing to life-threatening, critical disease. Ampion may provide a safe and effective treatment option for these patients **Innovation vis-a-vis existing therapeutic:** Ampion may be effective in interrupting the inflammation associated with COVID-19 and improving the clinical course and outcome of patients. **Unmed Medical need:** This study aims to evaluate the effects of Ampion on mortality and clinical outcomes in patients with respiratory distress due to COVID-19. The data from this study will inform decisions for the clinical development of Ampion. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed Phase II study.
13.	CT/91/21 Online submission (27236) PF-07321332/ Ritonavir (150 mg/100mg)	M/s. Pfizer	The firm presented the proposal of Phase II/III clinical study protocol no. **C4671002, Amendment 2, dated 19 July 2021** before the committee. After detailed deliberation, the committee opined that the proposal can be reviewed only after receiving complete pre-clinical toxicity data and clinical Phase I data with proposed IP.
14.	CT/84/21 Online submission (27228) Itolizumab	M/s. Biocon Limited	The firm presented the proposal of Phase III trial protocol no. BIO-ITOLIZ-304 Version: 1.0 dated 21Jul2021. After detailed deliberation, the committee recommended that the firm should revise the protocol with followings changes- 1) The "Adaptive" word should be removed from the proposed study protocol title. 2) Age group should be 18 to 65 years under the inclusion criteria. 3) For exclusion of TB subjects, three times

			TB gold (IGRA) test and one time TB PCR test with uniform lab method to be carried out. 4) Criteria for hospital discharge should be defined in the protocol. 5) There should be no re-dosing of the IMP, accordingly re-dosing of 0.8mg/kg should be removed from the proposed study protocol. 6) The interim analysis should be done once after 50% of total proposed subjects recruitment with 28days of treatment. 7) Clinical trial sites should be geographically distributed across the Country. 8) SoC should be uniform as per ICMR/GoI guideline at all participating sites and it should be recorded in CRF. 9) HRCT should be done for diagnosis of pulmonary fibrosis at screening/baseline and end of the treatment for the patients enrolled with chronic lung disease. Accordingly, the firm should submit revised study protocol for further review by the Committee.
15.	CT/99/21 Online Submission (27626) Ad26.COV2.S Vaccine	M/s Johnson and Johnson	The firm presented the proposal for Phase II/III clinical study protocol no. VAC31518COV3006, Amendment 1, dated 13 July2021 before the committee. **Risk versus benefit:** The safety profile from the pre-clinical and clinical trials in adults, may justify the conduct of the trial. **Innovations Vs existing therapeutic option:** The objective of the study is to evaluate the Safety, Reactogenicity, and Immunogenicity of Different Dose Levels of Ad26.COV2.S Administered as a One- or Twodose Regimen in Healthy Adolescents from 12 to 17 Years Inclusive **Unmet medical need:** As on date there is no approved treatment for the COVID-19. The trial drug may be an alternative treatment/prevention option for COVID-19 infection. After detailed deliberation, the committee recommended for grant of permission to conduct the study with the following

			conditions: 1) The firm should submit the interim safety and efficacy data from Part I of the study before the Committee (along with IDMC report) and only after its review the Part II study should be initiated. 2) The firm should actively monitor the AEs including MIS-C, post vaccine dose 1 and 2 for 42 day to 3 months under the primary endpoint. 3) The firm should use only the ICMR approved kits for rapid serological test for antiSARS-CoV-2 antibody. 4) The firm should enrol a separate cohort for sero-positive in Part II of study.