Recommendations of the SEC meeting to examine COVID-19 related proposal under accelerated approval process made in its 148th meeting held on 23.03.2021 & 24.03.2021 at CDSCO, HQ New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
Biological Division			
1.	BIO/CT/20/000077 Whole Virion Inactivated Corona Virus Vaccine (BBV152) (Phase II Clinical Trial protocol amendment)	M/s Bharat Biotech International limited, Hyderabad	The firm presented amendments in the approved Phase II clinical trial protocol for administration of booster dose after 6 months after second dose. After detailed deliberation, the committee recommended that the firm should conduct the booster dose study only in 6 mcg cohort and also should follow up the subjects at least for 6 months after the third dose. Further, the firm should present the details of the primary and secondary objectives and various assessments to be carried out in the subjects. Accordingly, firm should submit the revised clinical trial protocol for evaluation.
2.	BIO/CT/20/000077 Whole Virion Inactivated Corona Virus Vaccine (BBV152) (Phase III Clinical Trial protocol amendment)	M/s Bharat Biotech International limited, Hyderabad	The Firm presented amendments in the approved Phase III clinical trial protocol for unblinding of subjects on placebo and addition of another cohort in Brazil. The committee noted that vaccines are available under the immunization program & therefore all the eligible age groups under the immunization program should be permitted for unblinding for vaccination. After detailed deliberation, the committee recommended that the firm may unblind the participants of age group of more than 45 years and offer to administer the vaccine free of cost as and when they become eligible for the vaccine in the national program. Further, the committee recommended that the firm should submit detailed revised clinical trial protocol for inclusion of cohort from Brazil along with the revised statistical calculation for assessing the efficacy of the vaccine. Accordingly the firm should submit the

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			revised clinical trial protocol for evaluation.
3.	BIO/CT/21/000001 Adenoviral vector COVID-19 vaccine (BBV154) (Intranasal) (Phase I Clinical Trial protocol amendment)	M/s Bharat Biotech International Limited, Hyderabad	The Firm presented amendments in the approved Phase I clinical trial protocol for collection of additional nasopharyngeal swab for IgA assay. After detailed deliberation, the committee noted that there is no change in the primary or secondary objectives or the design of the study except for taking an additional sample. Therefore the committee recommended for approval of the proposed amendments.
SND Division			
4.	SND/MA/21/000028 Remdesivir Oral Solution 100 mg/5ml	M/s Lupin Limited	The firm presented the proposal along with the animal study data of pharmacokinetics of the proposed Remdesivir formulation and Absolute bioavailability study protocol. After detailed deliberation the committee recommended for grant of permission to conduct of the bioavailability study, as per the protocol presented, subject to the condition the study should be conducted in male human subjects in fasting condition only. Accordingly the firm should submit the revised protocol to CDSCO for approval.
5.	SND/CT/000021 Niclosamide IM depot injection 960 mg/4 ml	M/s Daewoong Pharmaceutical	In light of recommendation of 143rd SEC dated 11.02.2021, firm presented Phase I, Part B Clinical Trial Protocol for Niclosamide IM depot injection 960 mg/4 ml. After detail deliberation, the Committee recommended for grant of permission to conduct the PK Study initially with group 3 (480mg in 2 dose, day 1 & day 2) in atleast 16 subjects. Accordingly, the firm should submit revised Phase I, Part B Clinical Trial protocol to CDSCO for approval & present the result of the above PK study before the committee for

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			further consideration.
6.	SND/CT/21/0000002 Niclosamide for the treatment of hospitalized Covid-19 patients	M/s Laxai Life	The firm presented the proposal along with Phase II Clinical trial protocol. After detailed deliberation the committee recommended for grant of permission to conduct the Phase II Clinical trial subject to condition that the protocol should be revised as below:- 1. Time to clinical improvement should be stated as 2 point improvement in the WHO 8 point ordinal scale. 2. Dose of the drug should be stated as 2g (500mg x 4 tablets) throughout the protocol. 3. To include the patients with 90 – 93% of SpO2 and the patients with less than 90% SpO2 are to be excluded in the study. 4.Patiant with Systolic blood pressure <100 mm Hg are to be excluded in the study 5. Number of sites are to be increased to expedite the recruitment of patients. 6. Vaccination status of patients enrolled in the study are to recorded. Accordingly, the firm should submit the revised protocol to CDSCO
7.	SND/CT/20/000018 Nitazoanide Tablets 500 mg	M/s JSS Medical	The firm presented the revised Phase III clinical study protocol before the committee. After detailed deliberation, the committee approved the discontinuation of the HCQ from the test arm. Further, recommended that in primary and secondary objectives the time to clinical improvement should be stated as 2 point improvement in the WHO 8 point ordinal scale. Accordingly, the firm should submit the revised study protocol to CDSCO for

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GCT Division			
8.	CT/09/2021 online submission (23712) BRII-196 and BRII-198	M/s PPD	In light of recommendation dated 11.02.2021, the firm presented their justification for phase 2/3 clinical trial before the committee. After detailed deliberation the committee recommended that firm should submit following data for further review by the committee. 1. Procedure explained by the firm for blinding is not feasible in Indian context; Hence the firm should supply identical vials of active and placebo. 2. In the efficacy endpoint as regards to hospitalization the words "severe Covid" should be removed. 3. The firm should submit phase II efficacy data.
9.	CT/22/2021 online submission (24108) Nafamostat mesilate	M/s George Institute	The applicant presented their proposal along with study protocol for phase III clinical trial before the committee. After detailed deliberation, the committee noted that- 1. The proposed study drug is not approved for any other indication in India. 2. Safety data is not available for test drug. 3. Robust data for phase I, II, III clinical trial with antiviral activity is not available for Nafamostat. Hence, the committee didn't recommend for approval of the proposed protocol for phase III clinical study.
10.	CT/67/2020 online submission (10567)	M/s George Clinical	The firm presented their proposed protocol amendment version 4.0 dated 20-Nov-2020 before the committee.

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	Dapagliflozin		After detailed deliberation, the committee opined that- 1. The firm should not change the secondary endpoint to co-primary endpoint. 2. If there is amendment in the Global Clinical Trial then the Indian data should be analysed separately according to the original protocol.
11.	CT/14/21 Online submission (23828) SNG001	M/s Paraxel	In light of earlier recommendation dated 11.02.2021, the firm presented their justification for phase III clinical trial before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the study.