Recommendations of the SEC meeting to examine COVID-19 related proposal under accelerated approval process made in its 191st meeting held on 02-11-2021 at CDSCO, HQ New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
New Drugs Division			
1.	ND/MA/20/000149 Purified aqueous extract of Cocculus hirsutus (AQCH) tablets 400mg	M/s. Sun pharmaceutical Industries Limited	In light of recommendations of the earlier meetings dated 29.10.2020 and 17.12.2020 & 18.12.2020, the firm presented their proposal with reanalysed data w.r.t clinical improvement, viral clearance hospital discharge etc. and requested for approval of the drug for Emergency use. As per the approved clinical trial protocol, the primary efficacy endpoint was assessment of the proportion of patients showing clinical improvement (Time frame: Day 14) and secondary efficacy endpoint was assessment of the proportion of patients showing clinical improvement (Time frame: Day 7, Day 28); Time to clinical improvement (Time frame: upto 28 days), etc. Accordingly, based on the clinical trial data submitted by the firm, the committee in its earlier meetings dated 29.10.2020 and 17.12.2020 & 18.12.2020 did not recommend for grant of approval of emergency use authorisation at that stage as the study did not meet the efficacy criteria of primary efficacy endpoint. However, the firm presented again the reanalysed data of assessment w.r.t clinical improvement, etc. at Day 4 through Day 14. Considering the present control on the pandemic in India, the committee after detailed deliberation recommended that the firm should submit and present complete background data/information regarding capturing of the data and reanalysis of the same on Day 4 through Day 14 in respect of various parameters, viz, clinical improvement, viral clearance, hospital discharge etc before the committee for further consideration in this regard.

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Biological Division			
2.	BIO/CT04/FF/2021/26247 Tocilizumab	M/s. Reliance Life Sciences Pvt. Ltd	In-light of the SEC meeting dated 14.06.2021 the firm presented the revised Phase II protocol for Tocilizumab in COVID-19 indication. After detailed deliberation, the committee recommended for grant of approval to conduct the Phase II clinical trial with following minor amendments – (a) The firm shall use rate of cumulative mortality as one of the primary endpoint. (b) Rescue therapy by day 28 may be co-primary end-point Accordingly, firm should submit revised clinical trial protocol with necessary amendments to CDSCO for approval.
3.	BIO/CT/21/000145 Olokizumab	Dr. Reddy's	The firm presented its proposal for conduct of Phase III clinical trial with Olokizumab in Covid-19 patients. After detailed deliberation, the committee recommended for the following changes in the clinical trial protocol: • Tocilizumab should be part of the Standard of care (SOC) in the comparator arm of the study. • TNF-α should be in one of the inflammatory marker in the secondary end point. Accordingly, the firm should submit the revised protocol before the committee.
4.	BIO/CT/21/000143 Recombinant adeno vector SARS-CoV-2 Vaccine SPUTNIK-Light (Phase III (Heterologous Booster dose trial)	M/s. Dr. Reddy's Laboratories, Ltd, Hyderabad	The firm presented its proposal for conduct of Phase III (Heterologous Booster dose trial) of Recombinant adeno vector SARS-CoV-2 Vaccine SPUTNIK-Light before the committee. After detailed deliberation, the committee recommended that the firm should submit the following information along with supporting data: 1. The safety and immunogenicity data of all the vaccines under study after the primary

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			vaccination. 2. Justification for the need of the booster dose, full dose and administration of the booster dose six months after the second dose. 3. Study endpoint should have objective criteria. 4. Justification for conducting the study in all adult population instead of high risk population. 5. The design of the study should be revised to include placebo as comparator. Accordingly, firm should submit the revised clinical trial protocol for further review by the committee.
5.	BIO/CT/21/000102 Recombinant adeno vector SARS-CoV-2 Vaccine SPUTNIK-Light (Phase III Amendment)	M/s. Dr. Reddy's Laboratories, Ltd, Hyderabad	The firm presented its proposal for amendment in Phase III clinical trial protocol of Recombinant adeno vector SARS-CoV-2 Vaccine SPUTNIK-Light before the committee. After detailed deliberation, the committee recommended for approval of the amendment in the Phase III clinical trial protocol.
6.	BIO/CT/21/000142 COVID-19 vaccine containing SARS-CoV-2 Receptor Binding Domain of SARS-CoV-2 (Heterologous Booster dose trial)	M/s. Biological E Limited Hyderabad	The firm presented its proposal for conduct of Phase III clinical trial of COVID-19 vaccine containing SARS-CoV-2 Receptor Binding Domain of SARS-CoV-2(Heterologous Booster dose trial) before the committee. After detailed deliberation, the committee recommended that the firm should submit the following information along with supporting data: 1. The safety and immunogenicity data of all the vaccines under study after the primary vaccination. 2. The rationality and desirability for administration of booster dose, full dose and administration of the booster dose six months after the second dose.

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			3. Study endpoint i.e., number of fold rise of titres should be justified. 4. Justification for conducting the study in all adult population instead of high risk population. 5. The design of the study should be revised to include placebo as comparator. Accordingly, firm should submit the revised clinical trial protocol for further review by the committee.
7.	BIO/CT/20/000186 SARS-CoV-2rS Protein Nanoparticle Vaccine [COVOVAX]	M/s. Serum Institute of India Pvt. Ltd. Pune	The firm presented interim safety data of Phase II/III clinical trial of SARS-CoV-2rS Protein Nanoparticle Vaccine [COVOVAX] for 12-17 years and 07 to 11years age group before the committee. After detailed deliberation, the committee noted the results of the study and recommended for continuation of clinical trial as per the approved protocol.