Recommendations of the SEC meeting to examine COVID-19 related proposal under accelerated approval process made in its 141st meeting held on 03.02.2021 at CDSCO, HQ New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/IMP/20/000110 COVID-19 mRNA Vaccine BNT162b (EUA)	M/s Pfizer Limited, Mumbai	The firm presented its proposal for emergency use authorization of COVID-19 mRNA Vaccine BNT162b before the committee. The committee noted that incidents of palsy, anaphylaxis and other SAE's have been reported during post marketing and the causality of the events with the vaccine is being investigated. Further, the firm has not proposed any plan to generate safety and immunogenicity data in Indian population. After detailed deliberation, the committee has not recommended for grant of permission for emergency use in the country at this stage.
2.	BIO/CT/20/000186 SARS-CoV-2 rS Protein Nanoparticle Vaccine with Matrix-M1 Adjuvant (Phase II/III)	M/s Serum Institute of India Pvt. Ltd. (SIIPL), Pune	In light of recommendations of SEC committee dated 18.12.2020 and 13.01.2021, the firm presented its proposal along with revised protocol for conducting phase II/III clinical trial of SARS-CoV-2 rS Protein Nanoparticle Vaccine with Matrix-M1 Adjuvant before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct Phase II/III clinical trial subject to the condition that the participants randomized to the placebo arm may be unblinded 60 days after the second dose upon request of the clinical trial participant only. Such participant may be offered investigational vaccine as per the dose and schedule prescribed in the protocol.

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3.	BIO/CT/20/000095 ChAdOx1 nCoV-19 Corona Virus Vaccine (Recombinant) (Phase II/III trial protocol amendment)	M/s Serum Institute of India Pvt. Ltd. (SIIPL), Pune	Firm presented its unbinding plan for safety cohort in the light of marketing authorisation of ChAdOx1 nCoV-19 Corona Virus Vaccine (Recombinant) for restricted use in emergency situation. After detailed deliberation, the committee recommended that the participants randomized to the placebo arm may be unblinded 60 days after the second dose upon request of the clinical trial participant only. Such participant may be offered investigational vaccine as per the dose and schedule prescribed in the protocol.
4.	BIO/CT/21/000001 Chimpanzee Adenovirus Vectored COVID-19 Vaccine (BBV154) (Intranasal) (Phase I)	M/s Bharat Biotech, Hyderabad	In light of recommendations of SEC committee dated 19.01.2021, the firm presented its proposal along with revised phase I clinical trial protocol of Chimpanzee Adenovirus Vectored COVID-19 Vaccine (BBV154) (Intranasal) before the committee. After detailed deliberation, the committee recommended for conduct of proposed Phase I clinical trial.
5.	BIO/MA/20/000103 Whole Virion, Inactivated Corona Virus Vaccine (BBV152) (Amendment in Factsheet)	M/s Bharat Biotech, Hyderabad	The firm presented the proposed amendments in factsheet of Whole Virion, Inactivated Corona Virus Vaccine (BBV152) approved for restricted use in emergency use in clinical trial mode before the committee. After detailed deliberation, the committee recommended that the firm should prepare a supporting guidance for factsheet clarifying the use of vaccine in humans with allergies, immunocompromised/ using immunosuppressants and patients on blood thinners/anti-coagulants and present before the committee for further consideration.

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6.	BIO/CT/20/000159 Whole Virion, Inactivated Corona Virus Vaccine (BBV152) (Amendment in Informed Consent Form)	M/s Bharat Biotech, Hyderabad	The firm presented the amendment in Informed Consent Form for Phase III clinical trial of Whole Virion, Inactivated Corona Virus Vaccine (BBV152). After detailed deliberation, the committee recommended for grant of permission to collect nasopharyngeal swab and blood sample subject to obtaining informed consent from the clinical trial participants.
7.	BIO/CT/21/000019 UB-612 vaccine for COVID-19 (Phase II/III)	M/s Aurobindo Pharma Ltd., Hyderabad	The firm presented its proposal for conduct of Phase II/III clinical trial of UB-612 vaccine for COVID-19 along with protocol, animal studies and Phase I clinical trial report conducted in Taiwan. After detailed deliberation, the committee recommended that the firm should submit the Phase II/III clinical trial protocol approved by the regulatory authority of Brazil. Further, the proposed Phase II/III clinical trial protocol should be revised with respect to the following: 1. The sample size should be justified. 2. Specify the Phase II & Phase III parts in the clinical trial. 3. Clinical trial sites should be geographically distributed. 4. The clinical trial shall be double blind and the clinical parameters under study with respect to immunogenicity cohort shall be in line with the proposed clinical trial in Brazil. Accordingly, firm should submit revised clinical trial protocol for further deliberation before the committee.

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8.	BIO/CT/21/000009 Novel Corona Virus 2019-nCoV Vaccine (Phase I/II)	M/s Cadila Healthcare Ltd., Ahmedabad	The firm presented its proposal for conduct of Phase I/II clinical trial of Novel Corona Virus 2019-nCoV Vaccine 3mg (two dose schedule) before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase I/II clinical trial subject to the condition that the study should be double blind and safety should be the primary objective. Accordingly, firm should submit revised clinical trial protocol for approval .
9.	BIO/CT/21/000085 Novel Corona Virus 2019-nCoV Vaccine (Amendment for extension of Phase I part of Phase I/II clinical trial)	M/s Cadila Healthcare Ltd., Ahmedabad	Firm presented its proposal for extension of Phase I part of the ongoing Phase I/II clinical trial for assessment of persistence of neutralizing antibodies. After detailed deliberation, the committee recommended for grant of permission to the proposed Phase I extension study.