Recommendations of the SEC meeting to examine COVID-19 related proposal under accelerated approval process made in its 194nd meeting held on 24.11.2021 at CDSCO, HQ New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
Biological Division			
1.	BIO/CT/21/000149 M/s Bharat Biotech International Limited	Whole-Virion Inactivated SARS-CoV-2 Vaccine (COVAXIN)	The firm presented its proposal for conduct of Phase II/III clinical trial of Whole-Virion Inactivated SARS-CoV-2 Vaccine (COVAXIN) in pregnant women along with the clinical trial protocol. After detailed deliberation, the committee recommended that firm should submit the following information before the committee for further review: 1. Safety data of pregnant women vaccinated in the immunization program 2. Data of developmental toxicity studies in animal. 3. The safety follow up should be increased to 6 months from the date of birth.
2.	BIO/MA/21/000056 M/s Serum Institute of India Pvt. Limited	SARS-COV-2 Recombinant Spike Protein Nanoparticle Vaccine (SARS-COV-2 rS) With Matrix-M1™ Adjuvant	The firm presented its proposal for grant of market authorization of SARS-COV-2 Recombinant Spike Protein Nanoparticle Vaccine (SARS-COV-2 rS) with Matrix-M1™ Adjuvant for restricted use in emergency situation in the age group of 18 years and above along with the interim safety and immunogenicity data of Phase II/III bridging clinical trial conducted in the country. The firm has submitted interim clinical trial data of safety and efficacy from Phase III clinical trials conducted in UK & US. The committee noted that the vaccine is technology transfer of NOVAVAX vaccine and is not yet approved in the country of origin. After detailed deliberation, the committee recommended that firm should submit the following data/clarifications for further consideration: 1. The correct status of the Phase-III clinical trials in USA & UK along with up to date data on the safety, efficacy and

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			immunogenicity. Further, as informed by the firm they should communicate whether the study for efficacy endpoint is continuing or is there any amendment in clinical trial protocol in country of origin. 2. Comparative statement of immunogenicity parameters of the subjects from the USA, UK and other overseas Phase-III studies with data from phase-III study in India. 3. Review status of the application with regulatory authorities of USA & UK.
3.	BIO/CT/21/000150 M/s PGIMS, Chandigarh	[Covishield, Covaxin and Sputnik-V]	The institute presented its proposal for conduct of Academic clinical trial with Covishield, Covaxin and Sputnik-V]. After detailed deliberation, the committee recommended that the Institute should submit revised clinical trial protocol for further review before the committee with the following changes: 1. Efficacy objectives should be omitted. 2. Interchangeability should be defined 3.The sponsor's role should be clearly defined in protocol including compensation and medical management. 4. The immunogenicity parameters should be same as those assessed in the efficacy studies of the vaccine. 5. Since the Sputnik V have two different components therefore its inclusion shall be reviewed. 6. DSMB to be constituted and to be defined in the study protocol.
4.	BIO/CT/21/000194 Cadila Healthcare Limited	Novel Corona Virus - 2019-nCov vaccine (**ZyCovD vaccine)**	The firm presented amendment in Phase III efficacy trial in Novel Corona Virus 2019-nCoV vaccine for modification in number of target COVID-19 RT-PCR cases in primary objective. The committee noted that, the target COVID-19 cases as per approved clinical

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			trial protocol are 158, however, till date about 105 COVID-19 cases have been reported. During the deliberation, the firm proposed to seek permission for undertaking of second interim analysis and present the data. After detailed deliberation, the committee agreed to the request of the firm for presenting the data as above.
5.	BIO/CT/20/000182 M/s Gennova Biopharmaceuticals Limited	mRNA Vaccine for Injection (COVID-19)	In light of the SEC meeting dated 11.10.2021, the firm has submitted revised clinical trial protocol for the discontinuation of recruitment of subjects in Phase II part of the Phase I/II clinical trial of mRNA Vaccine for Injection (COVID-19) [HGCO19]. The firm presented amended clinical trial protocol as Phase I clinical trial. After detailed deliberation, the committee recommended for grant of approval for the revised protocol.