Recommendations of the SEC meeting to examine COVID-19 related proposal under accelerated approval process made in its 197th meeting held on 10.12.2021 at CDSCO, HQ New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
Biological Division			
1.	BIO/MA/21/000144 SARS-CoV-2 (Covid-19) Vaccine containing RBD antigen of SARS-CoV-2	M/s. Biological E Ltd.	The firm presented their proposal for grant of marketing authorization to SARS-CoV-2 (Covid-19) Vaccine containing RBD antigen of SARS-CoV-2 for restricted use in emergency situation along with the interim safety and immunogenicity data of Phase II/III clinical trial and interim safety & immunogenicity data of Phase III active comparator trial. The firm also presented interim report for animal challenge study conducted in monkey, PI, factsheet. The committee noted that the studies are ongoing and the firm has submitted immunogenicity data of 498 subjects in the Phase III active superiority trial. During the deliberation the committee asked following data: • Complete neutralising antibodies data & safety data for all subjects from the Phase III trial as per clinical trial protocol. • Histopatholgy data for animal challenge study. • Revised SmPC, PI & factsheet incorporating the updated safety & immunogenicity data. In response the firm has stated that it will submit the above data before the committee and requested for time. Accordingly, the committee recommended to deliberate the proposal after submission of said data.

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2.	BIO/CT/21/000142 SARS-CoV-2 (Covid-19) Vaccine containing RBD antigen of SARS-CoV-2	M/s. Biological E Ltd.	In light of the recommendations of the SEC meeting dated 02.11.2021, the firm presented its revised clinical trial protocol for conduct of Phase III clinical trial for administration of booster dose of SARS-CoV-2 (Covid-19) Vaccine containing RBD antigen of SARS-CoV-2. The committee noted that the safety & efficacy data of SARS-CoV-2 (Covid-19) Vaccine containing RBD antigen of SARS-CoV-2 is yet to be evaluated from the Phase III trials. After detailed deliberation, the committee recommended that firm should submit complete safety & immunogenicity data of the vaccine and justification for the proposed age group, timing for booster, sample size and increase the frequency of safety monitoring after second dose. Accordingly, the firm should submit revised clinical trial protocol for further review by the committee.
3.	BIO/MA/20/000102 ChAdOx1 nCoV-19 Corona Virus Vaccine (Recombinant) [COVISHIELD]	M/s. Serum Institute of India Pvt. Ltd	The firm presented the proposal for amendments in prescribing information (PI) of ChAdOx1 nCoV-19 Corona Virus Vaccine (Recombinant) [COVISHIELD] as below: 1. To administer booster (third) dose, six months after second dose based on the results of Phase I/II clinical trial of Oxford/AstraZeneca vaccine conducted in UK & approval of administration of booster dose by UK-MHRA. 2. Safety update regarding events of cerebrovascular venous and sinus thrombosis without thrombocytopenia given under heading "Special warnings and special precautions for use". The committee noted that the firm has presented immunogenicity data of only 75 subjects from UK study. Further, the firm has not presented any data from Indian population for the requirement of booster dose based on demographical profile and waning immunogenicity, the interval between the first & second dose etc. Further the firm also not

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			presented the proposal for generation of local clinical trial data for booster (third) dose. After detailed deliberation, the committee recommended for the amendment in PI with respect to safety information and with regard to the booster dose, the firm may submit the above data and proposal along with justification for further consideration.