Recommendations of the SEC meeting to examine (COVID-19) related proposal under accelerated approval process made in its 246th meeting held on 06.04.2023at CDSCO (HQ), New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendations
1.	BIO/MA/23/000022 Lyophilized mRNA Vaccine for Injection (COVID-19) [10 μg/dose [10 μg/0.1 mL] [Omicron variant -sub lineage BA.1]	M/s. Gennova Biopharmaceuticals Limited.	The firm presented its proposal for grant of permission to manufacture and market Lyophilized mRNA Vaccine for Injection (COVID-19) [10 μg/dose [10 μg/0.1 mL] [Omicron variant -sub lineage BA.1] indicated as a single booster dose in individuals aged ≥18 years administered at least 4 months after completion of ®primary vaccination with either COVISHIELD™ or COVAXIN along with the interim data of Phase II followed by Phase III clinical trial conducted in the country. The firm presented Phase II clinical trial data for all (140) subjects which includes safety data (up to 90 days follow up) & immunogenicity data up to 29 days by measuring GMT by IgG-ELISA against SARS-CoV-2 Spike protein, neutralizing antibody titers against SARS-CoV-2 (omicron variant) using surrogate virus assay(cPASS™) and cellular responses. Further, the firm presented interim Phase III clinical trial data for approx. 3000 subjects including safety data up to 29 days & immunogenicity data for 420 subjects up to 29 days measuring GMT by IgG-ELISA against SARS-CoV-2 Spike protein, neutralizing antibody titers against SARS-CoV-2 (omicron variant) using PRNT assay & surrogate virus assay (cPASS™) and cellular responses. The firm presented the interim clinical trial data of Phase II/III heterologous booster dose and requested for submission of Phase III safety data up to 90 days for all the subjects at the earliest. Accordingly, after detailed deliberation, the committee recommended that the firm should submit the 90 days safety data of Phase III clinical trial along with proposed summary of product characteristics (SmPC), Package Insert (PI) and fact sheet to CDSCO for further deliberation.

2.	BIO/CT/22/000090 SARS-CoV-2 rS Protein (COVID-19) Nanoparticle Vaccine[COVOVAX]	M/s. Serum Institute of INDIA Pvt. Ltd.	In light of the earlier SEC (Covid-19) meeting recommendation dated 11.01.2023, the firm presented its proposal for grant of permission to conduct Phase III clinical trial of SARS-CoV-2 Recombinant spike protein Nanoparticle vaccine (SARS-COV-2-Rs) with Matrix-M1 Adjuvant (COVOVAX) for administration of heterologous booster (third) dose to individuals of age ≥12 to <18 years who have received primary vaccination against Covid-19. After detailed deliberation, the committee recommended that the sample size in the proposed age group should be recalculated and increased along with justification. Accordingly, the firm should submit revised protocol for deliberation.
3.	12-03/BBIL/2023-BD ChAd36-SARS-CoV-S COVID-19 Vaccine (recombinant) (iNCoVACC)	Ms. Bharat Biotech International Limited.	The firm presented its proposal for conducting an active post marketing surveillance study of ChAd36-SARS-CoV-S COVID-19 Vaccine (recombinant) COVID-19 vaccine as per the condition of manufacturing and marketing permission. After detailed deliberation, the committee recommended to conduct the PMS study as per the protocol presented.