Recommendations of the SEC meeting to examine COVID-19 related proposal under accelerated approval process made in its 211th meeting held on 14.02.2022 at CDSCO, HQ New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
Biological Division			
1.	BIO/MA/22/000010 SARS-CoV-2 (Covid-19) Vaccine containing RBD antigen of SARS-CoV-2	M/s. Biological E Ltd. Hyderabad.	The firm presented its proposal for grant of permission to manufacture SARS-CoV-2 (Covid-19) Vaccine containing RBD antigen of SARS-CoV-2 for restricted use in emergency situation in the age group of ≥ 12 years to <18 years along with the interim safety & immunogenicity data of Phase II/III clinical trial conducted in subjects ≥ 5 years to <18 years before the committee. The firm presented interim safety data in 200 subjects & interim immunogenicity data of day 42 (14 day's post dose 2) in 170 subjects including Neutralising Antibody titres in 139 subjects for the age group of ≥ 12 years to <18 years along with comparison with adult age group of earlier phase II/III and III trials. The committee noted that the interim immunogenicity and safety data in the age group of ≥12 years to <18 years including T-cell response, Th1 and Th2 ratio is comparable with the adult age group. The neutralizing antibody titres was non-inferior to the titres of adult population and vaccine was found to be safe in the aforementioned age group. After detailed deliberation, in the light of pandemic situation the committee recommended for grant of permission to manufacture SARS-CoV-2 (Covid-19) Vaccine containing RBD antigen of SARS-CoV-2 for age group of ≥12 to <18 years for restricted use in emergency situation with the condition to submit ongoing clinical trial data.