Recommendations of the SEC meeting to examine COVID-19 related proposal under accelerated approval process made in its 228th meeting held on 30.05.2022 at CDSCO (HQ), New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
Biological Division			
1.	BIO/MA/22/000054 SARS-CoV-2 (Covid-19) Vaccine containing RBD antigen of SARS-CoV-2 CORBEVAX vaccine	M/s Biological E Ltd., Hyderabad	In light of the SEC meeting dated 25.05.2022, the firm presented updated interim safety data up to 25.05.2022 (follow up of 3 months) of Phase III clinical trial data conducted in the country for its proposal for grant of market authorization permission for restricted use in emergency situation to administer heterologus booster (third) dose of SARS-CoV-2 (COVID-19) Vaccine containing RBD antigen of SARS-CoV-2 to individuals of age >18 years after 6 months of administration of primary vaccination (two doses) of COVAXIN & COVISHIELD vaccines. The firm also presented the immunogenicity data including neutralising antibodies against variants of concern (VOC) including Omicron. The committee also reviewed Summary of product Characteristics (SmPC), Prescribing Information (PI) & Factsheet presented before the committee. After detailed deliberation, the committee recommended for grant of marketing authorization permission for additional indication of the SARS-CoV-2 (Covid-19) Vaccine containing RBD antigen of SARS-CoV-2 for administration of heterologous booster (third) dose to individuals aged ≥18 years to 80 years after 6 months of administration of primary vaccination (two doses) of COVAXIN or COVISHIELD vaccines for restricted use in emergency situation with condition that the firm should continue to review & submit the safety follow up data after heterologous boost. Further, the conditions of the original Market Authorization permission of the said vaccine should remain unchanged.