

Recommendations of the SEC meeting to examine COVID-19 related proposals under accelerated approval process made in its 138th meeting held on 13.01.2021 CDSCO, HQ New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/MA/20/000103 Chimpanzee Adenovirus vector vaccine (Intranasal) (BBV154) (CT Phase I/II)	M/s Bharat Biotech International limited, Hyderabad	Firm has requested more time for presentation.
2.	BIO/CT/20/000186 SARS-CoV-2 rS (COVID-19) Nanoparticle Vaccine (Liquid) with Matrix M1 Adjuvant (CT Phase II/III)	M/s Serum Institute of India Pvt. Ltd. (SIPL), Pune	In light of the recommendations of the SEC meeting dated 18.12.2020, the firm presented revised Phase II/III clinical trial protocol before committee. The committee noted that COVID-19 vaccine is now approved in the country. After detailed deliberation, the committee recommended that the firm should replace the placebo with comparator vaccine and revise the protocol accordingly for consideration of the committee.
3.	BIO/CT/20/000162 Gam-COVID-Vac Combined vector vaccine (Sputnik – V vaccine) (CT Phase II/III)	M/s Dr Reddy's Laboratories Limited, Hyderabad	Firm presented the safety data from Phase II part of Phase II/III clinical trial of Gam-COVID-Vac Combined vector vaccine (Sputnik – V vaccine). The committee noted the interim safety and immunogenicity results from the ongoing phase II of the Phase II/III clinical trial. After detailed deliberation, the committee recommended for continuation of the clinical trial as per approved protocol.