

Recommendations of the SEC meeting to examine COVID-19 related proposal under accelerated approval process made in its 146th meeting held on 10.03.2021 at CDSCO, HQ New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
Biological Division			
1.	BIO/MA/20/000103 Whole Virion, Inactivated Corona Virus Vaccine (BBV152) (Phase III interim report)	M/s Bharat Biotech, International Limited, Hyderabad	In continuation to the SEC meeting dated 08.03.2021, firm presented updated interim safety and efficacy data of its phase III clinical trial of Whole Virion, Inactivated Corona Virus Vaccine (BBV152) in the country. The committee noted that the firm has carried out interim analysis after 43 cases of symptomatic RT-PCR positive COVID-19 have been reported out of which 36 were in the placebo arm and 7 in the vaccine arm. After detailed deliberation, the committee recommended for omission of the condition of the use of the vaccine in clinical trial mode. However, the vaccine should be continued to be used under restricted use in emergency situation condition. Further, the ongoing phase III clinical trial should be continued as per the approved protocol. The firm should update the prescribing information and factsheet accordingly (under restricted use in emergency situation condition). All other conditions of the marketing authorisation shall continue to remain effective.