

Recommendations of the SEC meeting to examine COVID-19 related proposal under accelerated approval process made in its 222nd meeting held on 22.04.2022 at CDSCO, HQ New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
Biological Division			
1.	BIO/MA/21/000124 Whole-Virion Inactivated SARS-CoV-2 vaccine (BBV152)	Bharat Biotech International Limited	<p>In furtherance of review of recommendations of SEC dated 11.10.2021 and in light of the recommendations of SEC meeting dated 21.04.2022, firm presented the long term safety data 180 days post second dose of Phase III clinical trial conducted in paediatric population along with the AEFI data of the immunized population in age group of >15-17 years and adults and the Post marketing Surveillance study data in age group >15-17 years before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of approval of the vaccine for restricted use in emergency situation in the present circumstances of pandemic situation in >6 years to <12 years of age with the condition that to submit SmPC, PI, factsheet accordingly and ongoing clinical trial data. Further, other terms and conditions applicable for >12 to 18 years age group shall remain unchanged.</p>