Recommendations of the SEC meeting to examine COVID-19 related proposals under accelerated approval process made in its 134th meeting held on 01.01.2021 CDSCO, HQ New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/MA/20/000102 ChAdOx1 nCoV-19 Corona Virus Vaccine (Recombinant) (COVISHIELD)	M/s Serum Institute of India Pvt Ltd.	In light of the recommendations of the committee in its earlier meeting dated 30.12.2020, the firm presented the details of the conditions & restrictions under which AstraZeneca was granted Emergency Use Authorization in UK and the revised factsheet & prescribing information in Indian context as required by the committee for further consideration. Further, the firm also presented the proposed Summary of Product Characteristics (SmPC) and risk management plan including Pharmacovigilance plan. The committee deliberated on various critical areas for consideration including safety, immunogenicity, efficacy data, indication, age group, dosing schedule, precautions, storage, warnings, adverse effects of special interest, risk benefit evaluation, proposed factsheet, PI, SmPC, Risk management plan etc. The committee reviewed the proposal of restricted emergency use along with above details in its meetings dated 09.12.2020, 30.12.2020 and 01.01.2021 as well as reviewed continuously the data as and when received. The MHRA approval dated 30.12.2020 along with its conditions/restrictions was also reviewed by the committee. The committee noted that the safety & immunogenicity data presented by the firm from the Indian study is comparable with that of the overseas clinical trial data. Considering the serious nature of the COVID-19 pandemic, emergency situation, there is an urgent need of vaccine in the country. After detailed deliberation, the committee recommended for grant of permission for restricted emergency use of the vaccine subject to various regulatory provisions including following: **1.** The vaccine is indicated for active immunization to prevent COVID-19 disease in individuals of ≥ 18 years of age. **2.** The vaccine should be administered intramuscularly in two doses of 0.5 ml each (containing $5x10^{10}$ vp per dose) with interval of 4 to 6 weeks. **3.** The vaccine should be supplied along with factsheet & separate leaflet for the guidance of the healthcare provider. **4.** The firm should submit the updated PI,

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			SmPC & factsheet incorporating the changes as discussed during the meeting. **5.** The firm should ensure that factsheet for the vaccine recipient/his attendant is provided prior to administration of the vaccine. **6.** The firm should disseminate the instructions & educational material including factsheet, PI, SmPC, storage instructions etc. in their website. **7.** The firm should submit safety, efficacy & immunogenicity data from the ongoing clinical trials nationally and internationally for review at the earliest. **8.** The firm should submit safety data including the data on AEFI and AESI with due analysis every 15 days for the first two months & monthly thereafter till the completion of the ongoing clinical trial in the country. Thereafter, the firm should submit the safety data as per the provisions and standard procedures. **9.** The firm should submit India specific Risk management plan. Dr. Sushant H Meshram didn't participate in this deliberation.
2.	BIO/MA/20/000103 Whole Virion, Inactivated Corona Virus Vaccine (BBV152) (EUA)	M/s Bharat Biotech International limited, Hyderabad	In light of the earlier recommendations of the committee dated 30.12.2020, the firm presented safety & immunogenicity data, GMT, GMFR including SAE data from the Phase I & Phase II clinical trial along with the data from the ongoing Phase III clinical trial in the country. The committee noted that this vaccine is Inactivated Whole Virion, Corona Virus Vaccine having potential to target mutated corona virus strains. The data generated so far demonstrates a strong immune response (both antibody as well as T cell) and in-vitro viral neutralization. The ongoing clinical trial is a large trial on 25800 Indian subjects in which already 22000 subjects have been enrolled including subjects with comorbid conditions as well which has demonstrated safety till date. However, efficacy is yet to be demonstrated. After detailed deliberation, the committee recommended that the firm should try to expedite the recruitment and may perform interim efficacy analysis for further consideration of restricted emergency use approval.
3.	BIO/IMP/20/000110 COVID-19 mRNA	M/s Pfizer Ltd., Mumbai	The firm did not turn up for the deliberation.

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	Vaccine BNT162b2		