Recommendations of the SEC meeting to examine COVID-19 related proposal under accelerated approval process made in its 133rd meeting held on 30.12.2020 at CDSCO, HQ New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendations
Vaccine Division			
1.	BIO/MA/20/000102 ChAdOx1 nCoV-19 Corona Virus Vaccine (Recombinant) (EUA)	M/s Serum Institute of India Pvt. Ltd. (SIIPL), Pune	In light of the earlier recommendations the firm presented safety immunogenicity & efficacy data of phase II/III clinical trials of AstraZeneca vaccine carried out in UK & Brazil & South Africa along with the safety & immunogenicity data from the ongoing Phase II/III clinical trial of COVISHIELD vaccine manufactured by SIIPL in the country. The firm also presented the draft factsheet & prescribing information of the vaccine. The firm also mentioned that AstraZeneca had received Emergency Use Authorization for the vaccine in UK subject to various conditions & restrictions. The committee discussed the safety, efficacy & immunogenicity data, draft factsheet & prescribing information as provided by the firm & decided that clarification/justification on various aspects are still needed. After detailed deliberation, the committee recommended that the firm should submit complete details of the conditions & restrictions under which AstraZeneca was granted Emergency Use Authorization in UK and also present the revised factsheet & prescribing information in Indian context as required by the committee for further consideration. Also the firm was informed during the meeting regarding other requirements including clarification/justification on factsheet & prescribing information.
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, the firm presented updated recruitment status & safety data including SAE data of the ongoing Phase III clinical trial in the country. After detailed deliberation, the committee recommended that firm should update & present Immunogenicity, Safety & Efficacy data for further consideration.
3.	BIO/IMP/20/000110 COVID-19 mRNA Vaccine BNT162b2	M/s Pfizer Ltd., Mumbai	The firm did not turn up for the presentation