Recommendations of the SEC meeting to examine COVID-19 related proposal under accelerated approval process made in its 183rd meeting held on 16.09.2021 at CDSCO, HQ New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
Biological Division			
1.	BIO/MA/21/000036 Sputnik V vaccine	M/s Hetero Biopharma, Telangana	The firm presented its proposal for grant of Permission to Manufacture Gam COVID Vector vaccine (Sputnik V) along with interim safety and immunogenicity results from the Phase III clinical trial. After detailed deliberation, the committee recommended for grant of permission to manufacture Sputnik V vaccine for restricted use in emergency situations subject to various regulatory provisions including following: 1. The vaccine is indicated for active immunization to prevent COVID-19 disease in individuals of $\geq$ 18 years of age. 2. The vaccine should be administered intramuscularly in two doses of 0.5 ml each with interval of 21 days. (Day 0: Component I & Day 21: Component II). The vaccine has to be stored at -18°C. 3. The firm should submit PI, SmPC & Factsheet to CDSCO after incorporating the latest safety & immunogenicity data. 4. The vaccine should be supplied along with factsheet & separate leaflet for guidance of the healthcare provider 5. The firm should ensure that factsheet for the vaccine recipient/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 & immunogenicity data from the ongoing clinical trial in the country for review as and when available. 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

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			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.
2.	(BIO/CT/21/000079) Inactivated Rabies Vector Platform Corona virus vaccine (rDNA-BBV151)	M/s. Bharat Biotech International Limited, Hyderabad	The firm presented proposal for amendments in the approved clinical trial protocol for conduct of Phase I clinical trial of Inactivated Rabies Vector Platform Corona virus vaccine (rDNA) (BBV151). After detailed deliberation, the committee recommended for approval of the amendment of Phase I clinical trial protocol for administration of COVAXIN vaccine to study participants at day 42±7. However, the firm should continue further follow up as per the earlier approved clinical trial protocol.
3.	(BIO/CT/20/000159) Whole-virion Inactivated SARS-CoV-2 Vaccine (BBV152)	M/s Bharat Biotech International Ltd.	The firm presented proposal for amendments in the approved clinical trial protocol for Phase III clinical trial of Whole-virion Inactivated SARS-CoV-2 Vaccine (BBV152). The committee noted that the primary endpoint of the trial has been achieved. After detailed deliberation, the committee recommended for approval of the amendment of Phase III clinical trial protocol for withdrawal of cohort from Brazil.
4.	4-37/Roche/PAC-R-Casirivimab & Imdevimab /2021-BD Casirivimab and Imdevimab	M/s Roche Products (India) Pvt Ltd	The firm presented the proposal for approval of additional indication for use of the drug in post-exposure prophylaxis of COVID-19 based on clinical data generated overseas. The committee noted that the additional indication is approved in US, UK and France. After detailed deliberation, the committee recommended for grant of additional indication for post-exposure prophylaxis in-line with US-FDA for adults ≥ 18 years of the age. Further, the committee recommended that the firm should submit the safety data from the PMS study in India in

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			children for consideration of the extension of indication to children.
5.	BIO/CT/21/000108 Protein subunit vaccine against SARS-CoV-2 Virus	M/s Reliance Life Sciences Pvt., Ltd.,	The firm presented amendments in the approved clinical trial protocol for conduct of Phase I clinical trial of Protein subunit vaccine against SARS-CoV-2 Virus. During the deliberation the firm proposed for inclusion of additional 2.5mcg dose arm in the phase I clinical trial protocol. After detailed deliberation, the committee recommended for the approval of the proposed amendments as proposed by the firm. Accordingly firm should submit revised Phase I Clinical trial protocol for approval to CDSCO.
6.	BIO/CT/21/000134 Novel Corona Virus - 2019-nCov vaccine [3mg-two dose]	M/s Cadila Healthcare ltd.,	The firm wanted time to present the details of the protocol. As desired by the firm , the proposal was deferred for further discussion whenever they are ready.
GCT Division			
7.	CT/91/21 PF-07321332/ Ritonavir	M/s Pfizer	In light of the earlier recommendation of SEC dated 26-08-2021 and 27-08-2021 , the firm presented the proposed amended-study protocol no. C4671002, Amendment 3 dated 03Aug2021 with justification. After detailed deliberation, the Committee recommended for grant of permission to conduct the proposed clinical trial with the following conditions: 1) Up to 100 subjects should be recruited in the study from India. 2) The firm should submit the final study data from the clinical Phase I study (FIH Study) to the CDSCO for review. 3) The firm should submit the completed non-clinical toxicological study data.