Recommendations of the SEC meeting to examine COVID-19 related proposal under accelerated approval process made in its 181rd meeting held on 09.09.2021 at CDSCO, HQ New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
New Drug Division			
1.	ND/CT-21/FF/21/26235 Aviptadil Solution for Inhalation 67 mcg/ml.	M//s Biophore Pvt Ltd.	In light of earlier recommendation of the SEC dated 22.06.2021, the firm presented their proposal for seeking approval of the product for restricted use under emergency situation. After detailed deliberation, the committee opined that the presented safety & efficacy data of the product Aviptadil inhalation route is not adequate. In view of above, the committee recommended that the firm should conduct initially a Phase-II study as proof of concept and accordingly the firm should submit the protocol for review by the committee.
2.	ND/MA/21/000050 Molnupiravir 200mg Capsule	M/s Hetero Labs Limited	The firm presented the interim Clinical Trial data in moderate COVID-19 patients. After detailed deliberation, the committee opined that presented results from part-I of the study on 100 patients do not indicate the trends towards meeting the primary end point of clinical 2 point improvement at 8 point WHO ordinal scale at day 14. Accordingly, the firm should revise the protocol appropriately for conducting the part II of the study for moderate COVID-19 patients and submit the same for further review by the committee.
SND Division			
3.	SND/CT/21/000036 Urosodiol Injection 625mg/25ml	M/s Shilpa Medicare	In light of recommendation of earlier committee meeting held on 14.06.2021, the firm presented the report of in-vivo anti-inflammatory activity and in-vitro antiviral activity of Ursodiol injection 625mg/25ml in COVID 19 animal model to support the proposed Phase II clinical trial. After detailed deliberation, the committee recommended that the firm should revise the Phase II CT study protocol, as follows: 1. Title of the study should be revised

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			by mentioning the dosage and route of administration. 2. Primary objective should be clearly defined as 2point improvement at the 8 point WHO ordinal scale at day 14 3. Moderate infection should be defined as per ICMR/MoHFW guidelines. Accordingly, the firm should submit the revised Phase II clinical trial protocol for review by the committee.
4.	SND/MA/20/000215 Remdesivir Sublingual Tablet 20mg	M/s Jubilant Generics	In light of earlier recommendation of SEC meeting dated 20/05/2021 and the opinion of the innovator firm M/s. Gilead, the firm presented the justification and Phase III Clinical trial protocol. After detailed deliberation, the committee opined that the firm should revise the protocol and Clinical study design to make it a Phase II/III trial. Accordingly, the firm should submit the revised clinical trial protocol for review by the committee
Biological Division			
5.	12-05/SIIPL/PAC-Covishield/21-BD ChAdOx1 nCoV-19 Corona Virus Vaccine (recombinant) Covishield	M/s Serum Institute of India Pvt. Ltd.	In light of the earlier recommendation of the SEC dated 24.06.2021, the firm presented updates in SmPC, Package Insert and Factsheet of Covishield Vaccine (ChAdOx1-nCoV-19 Corona virus vaccine), (Recombinant). After detailed deliberation, the committee recommended for approval of the revised SmPC, Package Insert and Factsheet of Covishield Vaccine (ChAdOx1-nCoV-19 Corona virus vaccine), (Recombinant).
6.	BIO/CT21/FF/2021/27788 Etanercept	M/s Lupin Limited	The firm presented the proposal for approval for restricted use under emergency situation for Moderate COVID 19 indication along with Phase II clinical study report before the committee. After detailed deliberation, the committee opined that the presented Phase II clinical study report did not meet the primary efficacy end point as proposed in the Phase II Clinical Trial Protocol. Accordingly, the firm should submit the revised Clinical Trial Protocol which may also include the test for

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			screening of TB for review by the committee.