Recommendations of the SEC meeting to examine COVID-19 related proposal under accelerated approval process made in its 209th meeting held on 09.02.2022 at CDSCO, HQ New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
Biological Division			
1.	BIO/CT/21/000070 Anti-COVID 19mAbs cocktail(ZRC-3308)	M/s Cadila Healthcare Ltd.	The firm presented their proposal for amendment in already approved Phase I/II clinical trial protocol. After detailed deliberation the committee recommended that the firm should submit strong evidence of enrolment of post vaccinated subjects in the clinical trials of similar products along with justification for further deliberation before the committee.
New Drug Division			
2.	ND/CT/21/000079 101-PGC-005 (‘005)	M/s Laxai Pharmaceuticals	In light of the recommendation dated 01.10.2021, the firm presented their proposal alongwith justification before the committee. The committee recommended that the firm should first conduct Phase I study in healthy human volunteers to assess the Pharmacokinetics (ADME) of the parent drug including demonstration of release of dexamethasone only in macrophages and not in systemic circulation. Accordingly, the firm should submit the Phase-I protocol for further deliberation by the committee.
3.	ND/CT/22/000013 Co-Pack of Nirmatrelvir Tablets 150/300 mg and Ritonavir Tablets 100/100 mg	M/s Hetero Lab Ltd.	In light of the earlier recommendation dated 21.01.2022, the firm presented data alongwith bioequivalence study protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the bioequivalence study as per the protocol presented.
4.	ND/CT21/FF/2022/30230 Co-Pack of Nirmatrelvir Tablets 150mg and Ritonavir Tablets 100mg	M/s Zenara Pharma Pvt. Ltd.	The firm presented their proposal of local clinical trial waiver along with the Bioequivalence Study protocol for grant of permission to manufacture and market the drug Combi pack of Nirmatrelvir Tablets 150 mg + Ritonavir Tablets 100 mg in India. After detailed deliberation, the committee

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			recommended for grant of permission to conduct the bioequivalence study as per the protocol presented with the condition that the sample size should be 48 subjects.
5.	ND/CT/22/000008 Co-Pack of Nirmatrelvir Tablets 150 mg and Ritonavir Tablets 100 mg	M/s Optimus.	In light of the earlier recommendation dated 21.01.2022, the firm presented data alongwith bioequivalence study protocol before the committee. After detailed deliberation, committee recommended for grant of permission to the conduct bioequivalence study as per the protocol presented.
SND Division			
6.	SND/IMP/22/0000003 Azelastine Hydrochloride 1mg/ml Nasal Spray	M/sUrsapharm India	The firm presented their proposal for additional indication along with Phase III clinical trial protocol. After detailed deliberation, the committee recommended that the firm should conduct phase II clinical trial in India in mild COVID patients including patients with comorbidity with prevention of hospitalization as primary efficacy end point. Accordingly, the firm should submit the phase II clinical trial protocol to CDSCO for review by the committee.
7.	SND/CT/21/000029 Remdesivir Injection 100mg/20ml (5mg/mL) (Solution Form)	M/s Dr. Reddy ‘s Labs	The firm has presented the Phase IV clinical trial protocol of Remdesivir Injection 100mg/20ml (5mg/mL) (Solution form) for approval. After detailed deliberation the committee recommended for grant of permission to conduct the study subject to regulatory provisions & condition that:- 1. The firm should assess the safety as the co- primary objective. 2. The samples size should be increased to 200 patients, out of which atleast 25% of the patients should be from sever disease category.
GCT Division			

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8.	CT/92/21 Proxalutamide (GT0918)	M/s. IQVIA	The firm did not turn up for presentation.
9.	CT/155/21 Alteplase	M/s. Parexel	The firm presented their proposal for phase IIb/III clinical trial before the committee. **Assessment of risk vs. Benefit to the** patients: The safety profile of the study drugs from preclinical toxicology, Phase I & II studies including repeat dose toxicity study justify the conduct of the trial. **Innovation vis-à-vis Existing Therapeutic option:** Main objective is to evaluate the efficacy and safety of two(Part 1) different dosing regimen and of one dosing regimen (Part 2) of intravenous alteplase given for up to 5 days on top of standard of care (SOC) compared with SOC alone in ARDS associated with COVID-19. **Unmet Medical need in the country:** The test drug may potentially provide treatment in Patients with ARDS associated with COVID-19. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed study.
10.	CT/161/21 AZD1222 vaccine	M/s. IQVIA	The firm has presented their proposal for phase IV clinical trial before the committee. After detailed deliberation the committee noted that the test product is AZD1222 vaccine U K and not the covishield. Hence as proposed by the firm during the presentation the committee opined that the applicant should submit phase II clinical trial protocol to CDSCO for further review by the committee.
11.	CT/100/21 Anti-COVID-19-AKS-452	M/s. Veeda	The firm presented their proposal for protocol amendment version 2.0 and presented data of 100 patients before the committee. After detailed deliberation committee recommended for grant of approval of

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			proposed protocol amendment.
12.	CT/173/21 Sample Collection Observational Study	M/s.Pharm-Olam	The firm presented their proposal for the observational study before the committee. The committee opined that proposed study does not involve administration of vaccine but involves only collection of sample from already vaccinated subjects, hence does not fall under the definition of clinical trial under ND & CT rule. The firm may follow the procedure as applicable for such studies.
New Drug Division			
13.	SND/MA/21/000577 Molnupiravir Tablets 800mg	Various application	Various application for Permission to Manufacture & Market Molnupiravir 200 mg, 400 mg, 800 mg Capsules /Tablets was discussed in the meeting. After detailed deliberation, the committee opined that Molnupiravir 800 mg Capsules /Tablets can be considered, for which the firms should conduct BE study of Molnupiravir 800 mg Capsules /Tablets with 4 capsules of Molnupiravir 200 mg of the innovator. Accordingly, the firms should submit BE study protocol for review by the committee.