Recommendations of the SEC meeting to examine COVID-19 related proposal under accelerated approval process made in its 200th meeting held on 05.01.2022 at CDSCO, HQ New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
New Drugs Division			
1.	ND/CT/21/000079101-PGC-005	M/s. Laxai Life Sciences Pvt. Ltd.	The firm did not turn up for presentation.
2.	ND/MA/20/000149 Purified aqueous extract of Cocculus hirsutus (AQCH) tablets 400mg	M/s. Sun Pharmaceutical Industries Limited	In light of earlier recommendations of SEC meeting dated 02.11.2021, the firm presented the background data/information and reanalysis data before the committee. The committee observed that there is no difference in terms of clinical improvement at day 14 between the AQCH group and SOC group, although there are clinical improvement at day 8, 9,…….13. After detailed deliberation, the committee recommended that further data is required to assess the potential efficacy of the drug in moderate COVID-19 patients. Accordingly, the firm may submit their plan/ proposal.
3.	12-01/2021-DC(Pt248) Pentoxifylline	M/s. Max Hospital, Saket New Delhi	In light of earlier recommendation of the SEC (COVID) meeting held on 27.08.2021, the applicant presented their revised proposal before the committee. After detailed deliberation the committee recommended for grant of permission to conduct the proposed proof of concept clinical trial with condition that the applicant needs to present data on interim analysis of 50 patients in each group for review by the committee for consideration of continuation of the study in remaining patients.
GCT Division			
4.	CT/144/21 Proxalutamide (GT0918)	M/s. SIRO	The firm presented their Phase III clinical trial proposal before the committee. After detailed deliberation committee opined that firm needs to revised and submit Phase II proof of concept study for further review by the committee.

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
5.	CT/40/21 Ensovibep (MP0420)	M/s. IQVIA	The firm presented their proposed protocol amendment before the committee. After detailed deliberation the committee recommended for approval of the proposed protocol amendment MP0420-CP302(CSKO136A12201J) version 1.0 dated 19-Oct-2021.
6.	CT/145/21 Niclosamide Nasal Spray 1%	M/s. George Institute	The firm presented their Phase III clinical trial proposal before the committee. **Assessment of risk versus benefit to the patients-**The safety profile of the study drug from preclinical and clinical studies justify the conduct of the trial. **Innovation vis-a-vis existing therapeutic**- To determine if nasal Niclosamide reduces the risk of confirmed symptomatic COVID-19 infection in vulnerable renal and immunosuppressed patients participating in the study. **Unmet medical need in the country**- The test drug to be used as prophylaxis for patient at risk of COVID-19 infection. After detailed deliberation, the committee recommended for grant of permission to conduct the phase III clinical trial.
7.	CT/155/21 Alteplase	M/s. Parexel	The firm didn't turn up for presentation.
8.	CT/161/21 AZD1222 vaccine	M/s. IQVIA	The firm didn't turn up for presentation.