Recommendations of the COVID-19 SEC made in its 91th meeting held on 10.07.2020 under accelerated approval process at CDSCO HQ New Delhi:

Agenda No	File Name &Drug Name, Strength	Firm Name	Recommendation
New Drug Division			
1.	F. No. 12-01/20 (Pt-240) Phase II Clinical Trial on nCovid-19 patients by using Life Viro Treat (Chlorine water) 1 mg/m^3 solution	M/s Supreme Industries	In light of earlier presentation dated 18.06.2020, firm presented information and justification from the available published literature data and interim results of toxicity study being conducted in mice by the firm. It was also mentioned during the presentation that they have plan to conduct toxicity study in rabbits & pharmacodyanamic studies in rodent and non rodents species. After detailed deliberation, the committee recommended as under: 1) The firm should submit animal toxicity studies and pharmacodyanamic studies data generated with their product. 2) Along with the animal data the firm may submit protocol for a phase-I trial in healthy volunteers for further consideration.
2.	ND/IMP/20/000058 Inosine Pranobex 500 mg Tablets	M/s Themis Medicare Limited	The firm presented their proposal for import and marketing of the drug with local clinical trial waiver for 9 different indications including influenza and other acute respiratory viral infections including Corona Virus

Agenda No	File Name &Drug Name, Strength	Firm Name	Recommendation
			infections. After detailed deliberation, the Committee recommended that the firm should present their proposal in respect of specific indication(s) along with supporting data including detailed clinical data for that indication(s) to consider the matter further.
3.	12-20/2020-DC(Pt-Misc-SND) Favipravir	Internal discussion	The committee was apprised about regulatory provision regarding the requirements of CMC data bioequivalence data, animal toxicity data etc for subsequent new drug. After detailed deliberation, the committee recommended that the subsequent applicant should submit the required data as per rules for SND. The committee also recommended that CDSCO should ask M/s Glenmark about the status of their clinical trial and its final report.
Biological Division			
4.	BIO/CT/20/00037 Itolizumab 25 mg/5 mL solution for intravenous infusion in vials	M/s Biocon Biologics India Limited	The firm presented the Phase II clinical trial results generated in COVID-19 patients. Details of Primary endpoint of mortality, other key endpoints of lung function such as improvement in PaO2 and O2 saturation were presented. Key inflammatory markers IL-6, TNFα etc were presented to have been reduced significantly with the drug

Agenda No	File Name &Drug Name, Strength	Firm Name	Recommendation
			thereby preventing hyper-inflammation. The committee also noted that the drug is already approved and marketed for other indications. After detailed deliberation, the committee recommended for grant of permission to market the drug for Restricted Emergency Use of the drug in the country for the treatment of CRS in moderate to severe ARDS patients due to COVID-19, subject to the following conditions- 1. The firm should conduct Phase IV clinical trial study of the subject drug. 2. The firm should submit Risk Management Plan to address the safety issues including infusion reactions and lymphopenia in post marketing scenario. 3. Written informed consent from each patient/ or his representative prior to administration of the drug shall be obtained. Informed consent form to be used should contain in a language understandable to the patient/ or his representative the factual detail about the drug, its restricted emergency use approval, alternative therapy available etc. The copy of the informed consent form should be submitted to CDSCO before launching the drug product for the indication. 4. The drug should be supplied

Agenda No	File Name &Drug Name, Strength	Firm Name	Recommendation
			only on the prescription of medical specialist for use in hospital/ institutional set up only. 5. The Package Insert containing all details including the safety information and Informed Consent Form should be provided along with the drug product for use in hospital/ institution.