Recommendations of the SEC (Antimicrobial & Antiviral) made in its 98th meeting held on 20.01.2021 at CDSCO HQ New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
1.	ND/IMP/20/000093 Letermovir Conc. Solution for Infusion (240 mg/12 ml), 480 mg/24 ml	M/s MSD Pharma	Firm didn't turn up for presenation
2.	ND/CT/20/000108 Pretomanid	M/s Mylan laboratories Ltd.	The firm presented the Phase IV CT protocol before the committee. After detailed deliberation the committee recommended for grant of permission to conduct the Phase IV clinical trial as per the protocol presented subject to following conditions: 1. Firm should constitute DSMB as per requirements. 2. Firm should submit the interim data analysis report after review by DSMB to CDSCO for review by the committee.
3.	12-01/20-DC (Pt-279) C-Tb with QUANTIFERON-TB Gold Plus and 2 T.U Tuberculin PPD	ICMR-Regional Medical Research Centre, Bhubaneshwar	In light of earlier recommendation dated 23.12.2020, the applicant presented the research project proposal with the drug before the committee. After detailed deliberation the committee noted that the study design, primary and secondary objective, comparability data etc was inadequate. Accordingly the committee opined the following. 1. Applicant should present specificity, sensitivity, standardization as well as comparatively data with gold standards. 2. Applicant should submit the revised research project proposal to CDSCO. Further, the matter should be discussed in upcoming SEC along with expert from TB program.
4.	12-03/19-DC Rifampsin, INH,	NITRD	The firm presented amendment in the protocol of clinical trial before the

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	Pyrazinamide, Ethambutol, Levofloxacin, Clofazamine, bedaquiline, Linezolid, Rifapentine, Pyridoxine		committee. After detailed deliberation, the committee recommended for approval of the amendment of protocol as proposed.
5.	SRP of Oseltamivir	12 SRP	The committee deliberated the recommendation of the NCC-PvPI. After detailed deliberation, the committee opined that further details on the ICSRs in respect of severity seriousness, outcome and other details should be obtained from PvPI for further consideration
6.	SRP of Piperacililin+Tazobactum	12 SRP	The committee deliberated the recommendation of the NCC-PvPI. After detailed deliberation, the committee opined that further details on the ICSRs in respect of severity seriousness, outcome and other details should be obtained from PvPI for further consideration
7.	SRP of Tinidazole	12 SRP	The committee deliberated the recommendation of the NCC-PvPI & recommended that CDSCO should request the State Drugs Controllers to direct the manufactures of the Tinidazole formulation to include Hyperpigmenation as an ADR of the drug Tinidazole.
SND Division			
8.	SND/MA/20/000357 Itraconazole capsule 130 mg	M/s Glenmark Pharma	Firm presented the proposal along with Bioequivalence study protocol. After deliberation the committee recommended for grant of permission to conduct the Bioequivalence study as per the protocol submitted.
9.	SND/MA/20/000338 Amikacin Injection 750 mg/3ml & 100mg/4ml	M/s Aristo	The firm presented the proposal along with the justification for Amikacin Injection 750 mg/ 3ml & 1000 mg/4ml (Additional pack size/ Additional Srength). Amikacin Injection 1000 mg/4 ml is already approved in US, UK & Europe and Amikacin Injection 750 mg/3ml is also approved in US. After detailed deliberation the committee recommended for grant of permission to manufacture and market Amikacin Injection 750 mg/

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			3ml & 1000 mg/4ml.
GCT Division			
10.	CT/103/20 Online Submission (22252) Rilematovir	M/s. J&J	The firm presented the proposal of clinical trial to be conducted with the infants and children (≥28 days to ≤5 years of age) and subsequently in neonates (< 28 days of age). **Assessment of Risk vs. benefit to the patients**: The safety profile of the study drug from preclinical and clinical studies justify the conduct of the trial. **Innovation vis-à-vis existing therapeutic option:** Respiratory syncytial virus (RSV) is considered the most important cause of acute lower respiratory tract infection (LRTI) in infants and young children. Rilematovir (RMV) is a specific small molecule that blocks entry of the RSV by inhibiting fusion of the viral envelope with the host cell membrane. It is developed for treatment of RSV A and B infection. **Unmet medical need in the country-** To evaluate the superiority of rilematovir compared to placebo treatment with respect to the clinical outcome on the RSV Recovery Scale. After detailed deliberation the committee recommended that the firm should provide the safety data generated so far with the IMP (Rilematovir) in support of the Clinical Trial in the proposed subjects and the proposal should be deliberated in presence of pediatrician.
11.	CT/40/19 Online Submission (10285) Baloxavire marboxil	M/s. Roche	Firm presented their proposal for protocol amendment before the committee. After detailed deliberation the committee recommend for approval of the protocol amendment version 3.0 dated 10-Aug-2020 with condition that PCR based diagnosis of influenza be done (with similar limit of detection).
FDC Division			
12.	FDC/CT/20/000057	M/s. GlaxosmithKline	In light of earlier recommendations

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	Potassium Clavulanate equivalent to Clavulanate Acid + Amoxycillin Trihydrate eq. to Amoxycillin free acid (42.90mg + 600mg) powder for reconstitution into suspension	Pharmaceuticals Ltd.	of SEC dated 22.10.2020, the firm presented their proposal before the committee. After detailed deliberation, committee recommended that the firm should submit revised Phase IV protocol covering all the approved indications for further review by the committee within 45 days.
13.	FDC/MA/20/000192 Zinc suphate Monohydrate 0.0110g/200ml + Sodium Citrate 0.5800g/200ml + Potassium Chloride 0.3000gm/200ml+Sodium Chloride 0.5200gm/200ml + Dextrose Anhydrous 2.7000gm/200ml Oral Solutions	M/s. Halewood Laboratories Pvt. Ltd.	Firm presented their proposal before the committee. After detailed deliberation, the committee recommended that the firm should conduct Phase III Clinical trial for proving the efficacy and safety in statistically significant number of subjects. Accordingly, the firm should submit Phase III Clinical Trial protocol for the indication "Acute Infectious Diarrhoea" for further review by the committee.
14.	FDC/IMP/20/000075 Avibactam 0.5gm + Ceftazidime 2gm Powder for concentrate for solution for infusion	M/s. Pfizer Ltd.	Firm presented their proposal before the committee. The firm submitted that the proposed indication is already approved in EU. After detailed deliberation, the committee recommended for grant of permission for the following additional indication: • Complicated Intra-abdominal infections (cIAI) • Complicated Urinary tract infections (cUTI), including pyelonephritis • Hospital-acquired pneumonia (HAP) including ventilator associated pneumonia (VAP) with susceptible gram negative microorganisms. Treatment of patients with bacteraemia that occurs in association with, or is suspected to be associated with, any of the infections listed above.