Recommendations of the SEC (Antimicrobial & Antiviral) made in its 102nd meeting held on 27.07.2021 at CDSCO HQ, New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
1.	ND/IMP/20/000092 Letermovir film coated tablet 240 mg and 480 mg	M/s. MSD	In light of earlier recommendations of SEC, the firm presented justification for the waiver of Phase IV clinical trial condition as part of post submission meeting. After detailed deliberation, the committee didn't recommend the waiver of Phase IV clinical trial condition and reiterated its earlier recommendation dated 23rd Dec 2020.
2.	ND/IMP/20/000093 Letermovir Concentrate for solution for infusion 240 mg/12 ml and 480 mg/24 ml	M/s. MSD	In light of earlier recommendations of SEC, the firm presented justification for the waiver of Phase IV clinical trial condition as part of post submission meeting. After detailed deliberation, the committee didn't recommend the waiver of Phase IV clinical trial condition and reiterated its earlier recommendation dated 24th Mar 2021.
SND Division			
3.	SND/MA/21/000307 Posaconazole Gastro Resistant Tablet 300 mg	M/s Aet Laboratories	The firm presented their proposal for additional indication of Posaconazole Gastro Resistant Tablet 300 mg. The committee noted that the proposed indication as mentioned below are already approved for Posaconazole 100 mg DR tablets: 1. For the treatment of oropharyngeal candidiasis, including oropharyngeal candidiasis refractory to Itraconazole and/or fluconazole. 2. For prophylaxis of invasive Aspergillus and Candida infections in patients, 13 years of age and older, who are at high risk of developing these infections due to being severely immunocompromised, such as hematopoietic stem cell transplant (HSCT) recipients with graft-versus-host disease (GVHD) or those with hematologic malignancies with prolonged neutropenia from chemotherapy. 3. Zygomycosis (Mucormycosis) in patients with diseases refractory to other therapy, or patients who are intolerant to other therapy. After detailed deliberation the committee recommended for grant of permission for approval of the proposed additional indication subject to condition that the firm should submit the BE study report to CDSCO as

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			stipulated by the committee during the approval of Posaconazole Gastro Resistant Tablet 300mg.
4.	SND/MA/21/000144 Tigecycline for injection 100mg/vial	M/s Protech Telelinks	The firm presented the proposal along with the justification for approval of Tigecycline for Injection 100mg/vial. After detailed deliberation the committee opined that the justification submitted by the firm is inadequate and committee did not recommend for approval of Tigecycline for Injection 100mg/vial.
5.	SND/MA/21/000309 Fosfomycin Sodium for Injection 4gm	M/s Indasi Lifesciences	The firm did not turn up for presentation.
6.	SND/MA/20/000357 Itraconazole 130 mg Capsule	M/s Glenmark Pharma	The firm presented the BE study report of Itraconazole Capsules 130mg before the committee. After detailed deliberation the committee recommended for grant of permission for manufacture and marketing of Itraconazole Capsules 130mg indicated for the treatment of the following fungal infections in immune-compromised and non-immunocompromised adult patients: • Blastomycosis, Pulmonary and extrapulmonary • Histoplasmosis, including chronic cavitary pulmonary disease and disseminated ,non-meningeal histoplasmosis, • Aspergillosis, pulmonary and extra-pulmonary, in patients who are intolerant to Amphotericin B therapy.
7.	SND/MA/21/000279 Itraconazole 130 mg Capsule	M/s Macleods Pharma	The firm presented the BE study protocol of Itraconazole 130mg capsules before the committee. After detailed deliberation the committee recommended for grant of permission for conduct of the BE study as per the protocol presented before the committee.
8.	SND/MA/21/000336 Liposomal Amphotericin B injection 50 mg/vial	M/s Biozenta Life Sciences	The firm presented their proposal for manufacturing and marketing of Liposomal Amphotericin B injection 50mg/ml (Lyophilized) before the committee. After detailed deliberation committee opined that firm has not presented the characterization data and PK data. Hence, firm needs to submit and present the details of characterization

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			including PK data in comparison with innovator for further review by the committee.
9.	SND/MA/21000100 Linezolid Sustained Release Tablets 1200 mg	M/s Zuventus Healthcare	In light of earlier recommendations of SEC meeting held on 23.06.2021 & 24.06.2021, the firm presented their proposal of manufacture and marketing permission of Linezolid Sustained Release Tablets 1200 mg. After detailed deliberation, the committee recommended for grant of manufacture and marketing permission of Linezolid Sustained Release Tablets 1200 mg for already approved indication, subject to condition that the firm should conduct active PMS study. Accordingly, firm should submit active PMS protocol for review by the committee.
GCT Division			
10.	CT/103/20 Online Submission (22252) Dated 16/10/20 Rilematovir	M/s. J&J	In view of the recommendation of SEC dated 20.01.2021, 25.02.2021, and 24.06.2021, the Firm presented the proposed phase III study protocol no. 53718678RSV3001 dt.17Aug2020 with data and justifications. After detailed deliberation, the Committee recommended for grant of permission to conduct the study with condition that the firm should submit the safety and efficacy interim trial data in infants and children (along with IDMC report) to the CDSCO/Committee for review and after review of the same, the study in neonate population should be initiated.
11.	CT/41/21 Online Submission (25211) Dated 27/04/21 Cipargamin (KAE609)	M/s. Novartis	The firm presented the proposed Phase II study protocol no: CKAE609B12201; Ver.:00, dated 14-Oct-2020 before the committee. **Risk-Benefit Assessment:** Severe malaria is a medical emergency in the malaria endemic countries. With currently one WHO recommended IV treatment, there is considerable medical need for an additional treatment option. **Innovation Vs Existing Therapy:** KAE609 is a novel spiroindolone class drug with potent and fast-acting schizonticidal activity, which acts by disrupting the malaria parasite Na+ homeostasis by inhibition of the ATPase PfATP4. **Unmet Need:** The proposed study is to investigate the efficacy (parasite reduction and clinical outcome), safety, tolerability and

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			pharmacokinetics of different injectable dose regimens of KAE609 in comparison to injectable Artesunate. After detailed deliberation, the committee recommended for grant of permission to conduct the study with following conditions: **1)** The age group for the Cohort-1 should be from 18≤ to 65 year of age. **2)** The age group for the Cohort-2 should be from 12 to ≤18 year of age. **3)** The firm should include the test of haemoglobin in plasma and haemoglobin in urine in its routine analysis. **4)** The firm should submit the safety and efficacy data (with DMC report) from the Cohort-1 and Cohort-2 before the Committee and after review of the same the Cohort 3-5 study should be initiated.
12.	CT/91/19 Online Submission (11540) Dated 15/05/21 Bedaquiline Tablets	M/s. Doctors Without Borders India	The firm presented the proposed amended study protocol no. NCT02754765, Version: 3.5.1 IN, dated: 01-Mar-2021 before the committee. After detailed deliberation, the committee recommended for approval of the protocol amendment to conduct the study.
FDC Division			
13.	FDC/MA/21/000142 Ivacaftor 125mg/125mg + Lumacaftor 100mg/200mg tablets	M/s. Laurus Labs Ltd.	The proposal was deferred.
14.	FDC/MA/20/000144 Lamivudine 300mg + Dolutegravir 50mg tablets	M/s. Emcure Pharmaceuticals Ltd.	The firm presented the BE Study report before the committee along with the request for Phase IV clinical trial waiver. After detailed deliberation, the committee recommended for grant of permission for manufacture and marketing of the proposed FDC with the condition that firm should conduct Phase IV Clinical Trial. The trial protocol shall be submitted within 3 months from the date of approval.
Medical Device Division			
15.	IMP/MD/2021/41387 Absorbable Antibacterial Envelope (Tyrx)	India Medtronic Private Limited	The firm didn't turn up for the presentation.