Recommendations of the SEC (Antimicrobial & Antiviral) made in its 117th meeting held on 26.08.2022 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	12-01/18-DC (Pt.337) Cephalosporin Class associated with Fixed Drug Eruption (FDE)	SRP, PvPI-IPC, Ghaziabad	The recommendation of the SRP was appraised before the committee. After detailed deliberation, the committee recommended that CDSCO should request the State Drugs Controllers to direct the manufacturers to include Cephalosporin Class associated with Fixed Drug Eruption (FDE) as ADR in the corresponding PIL of the drugs.
2.	12-01/18-DC (Pt.337) Tigecycline associated coagulopathy	SRP, PvPI-IPC, Ghaziabad	The recommendation of the SRP was appraised before the committee. After detailed deliberation, the committee recommended that CDSCO should request the State Drugs Controllers to direct the manufacturers to include Tigecycline associated coagulopathy as ADR in the corresponding PIL of the drugs.
3.	12-01/18-DC (Pt.337) Remdesivir associated sinus bradycardia	SRP, PvPI-IPC, Ghaziabad	The recommendation of the SRP was appraised before the committee. After detailed deliberation, the committee recommended that CDSCO should request the State Drugs Controllers to direct the manufacturers to include Remdesivir associated sinus bradycardia as ADR in the corresponding PIL of the drugs.
4.	12-01/18-DC (Pt.337) Oseltamivir associated sinus bradycardia/bradycardia	SRP, PvPI-IPC, Ghaziabad	The recommendation of the SRP was appraised before the committee. After detailed deliberation, the committee recommended that CDSCO should request the State Drugs Controllers to direct the manufacturers to include Oseltamivir associated sinus bradycardia/bradycardia as ADR in the corresponding PIL of the drugs.
5.	12-01/18-DC (Pt.337) Piperacillin + Tazobactuam associated acute generalized exanthematous pustulosis (AGEP)	SRP, PvPI-IPC, Ghaziabad	The recommendation of the SRP was appraised before the committee. After detailed deliberation, the committee recommended that CDSCO should request the State Drugs Controllers to direct the manufacturers to include

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			Tazobactuam associated acute generalized exanthematous pustulosis (AGEP) as ADR in the corresponding PIL of the drugs.
6.	12-01/19-DC/PU-032 Targocid (Teicoplanin Injection 200mg & 400mg	M/s. Sanofi	In light of earlier SEC recommendation dated 13.06.2019, the firm presented the proposal to update the package insert in respect of safety related changes like warning, precaution & adverse reaction etc. of approved indication before the committee. After detailed deliberation, the committee recommended for approval of the updated package insert in line with the company core sheet version 4 dated 25.02.2021 as presented by the firm.
7.	ND/IMP/22/000030 Ayers & Co Hand Sanitizer and Ayers & Co Surface Disinfectant	M/s. Adiro Labs Pvt.Ltd.	In light of earlier SEC recommendation dated 26.07.2022, the firm presented their justifications for additional short term and long term safety data before the committee. The product is already marketed in Australia. After detailed deliberation, the committee recommended for grant of permission to import and market the product of Ayers & Co. Hand Sanitizer and Ayers & Co. Hospital grade disinfectant subject to condition that the firm should provide a leaflet with every pack of the product for consumer highlighting do's and don'ts including advisory in case of accidental exposure.
SND Division			
8.	SND/MA/22/000216 Chlorhexidine gluconate 2% w/v wet wipes	M/s. Carenow Medical Pvt. Ltd.	The firm presented their proposal of manufacture and market of Chlorhexidine gluconate 2% w/v wet wipes for the indication as "Chlohexidine Gluconate Wet Wipes are disposable antibacterial towels that provide rinse-free bathing for patients at hospitals protecting them from nosocomial infection, the product is intended to be used on all exposed skin" alongwith manufacturing process, testing procedure, global uses and published data as well as data generated by the firm with their own product before the committee.

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			After detailed deliberation, the committee recommended for grant of permission to manufacture and market of Chlorhexidine gluconate 2% w/v wet wipes for proposed indication as mentioned above.
9.	SND/IMP/22/000056 DelamanidDispersible Tablets 25 mg (Additional strength for additional indication)	M/s. Mylan Laboratories	The firm presented the proposal for import and marketing of Delamanid Dispersible Tablets 25 mg for the indication "for use as part of an appropriate combination regimen for pulmonary multi-drug resistant tuberculosis (MDR-TB) in adults, adolescents, children and infants with a body weight of at least 10 kg when an effective treatment regimen cannot otherwise be composed for reasons of resistance or tolerability" before the committee. After detailed deliberation, the committee recommended that the proposal should be re-deliberated in next meeting along with the Pediatrician and TB expert.
10.	SND/MA/22/000210 Meropenem Injection 125 mg	M/s. Aristo Pharmaceuticals	The firm presented the proposal for manufacture and marketing of Meropenem Injection 125 mg per vial for the indication "Meropenem injection is indicated in children for treatment of the following infections caused by single or multiple bacteria sensitive to Meropenem- Pneumonia and Nosocomial Pneumonia, Urinary Tract Infections, Intra- abdominal Infections, Skin and Skin Structure Infections, Meningitis, Septicaemia. Meropenem has been proved efficacious alone or in combination with other antimicrobial agents in the treatment of polymicrobial infection" before the committee. After detailed deliberation, the committee recommended that the proposal should be redeliberated in next meeting along with the pediatrician.
FDC Division			
11.	FDC/MA/21/000232 Tinidazole 100mg +Norfloxacin 100mg suspension	M/s. Rivpra Formulation Pvt. Ltd	In light of earlier SEC recommendation dated 25.5.2022, the firm presented its proposal along with the justification before the committee. After detailed deliberation, the committee reiterated with earlier recommendation

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			and didn't recommend for approval of the proposed FDC.
12.	FDC/MA/20/000053 Potassium Clavulanate Diluted IP eq. to Clavulanic acid 50.41 mg + Amoxicillin Trihydrate IP 652.78mg Oral suspension	M/s. Alkem Health Science	The firm presented the proposal before the committee along with the justification for BE/CT study waiver. After detailed deliberation, the committee opined that 1. The product is already approved in different strength by CDSCO. 2. There is no unmet need for proposed strength. 3. The product in proposed strength (Potassium Clavulanate Diluted IP eq. to Clavulanic acid 50.41 mg + Amoxicillin Trihydrate IP 652.78mg) is not approved internationally. In view of above, the committee did not recommend for the approval of the FDC in proposed strength.
13.	FDC/MA/20/000150 Zinc Citrate Trihydrate eq. to Zinc 10mg + Ascorbic acid 1000 mg effervescent tablets	M/s. Kusum Healthcare Pvt. Ltd.	The firm presented their proposal before the committee along with justification for Phase IV CT study waiver. After detailed deliberation, the committee considered the justification for Phase IV CT study waiver and recommended for Active PMS study. Accordingly, the firm should present the Active PMS study protocol before the committee for review.