Recommendations of the SEC (Antimicrobial & Antiviral) made in its 11th/25 meeting held on 15.10.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
1.	ND/MA/25/000118 & ND/MA/25/000117 Delafloxacin Tablets 450 mg & Delafloxacin for Injection 300 mg/vial	M/s. Sun Pharma Laboratories Limited	Firm presented their proposed i.e. Phase III CT protocol Titled: 'A Prospective, Multicenter, Randomized, Open Label, Active-Controlled, Phase 3 Study to Evaluate the Efficacy and Safety of Delafloxacin (Injection and Tablets) in comparison to Linezolid (Injection and Tablets) and Aztreonam Injection in patients with Acute Bacterial Skin and Skin Structure Infections. (Protocol Number: ICR/25/015; Protocol Version 1.0 dated 28/JUL/2025)'along with BE study report, before the committee. The committee considered BE study result. Further, the committee noted that Delafloxacin is a broad spectrum antibiotic. Thus, it must be used only in case of severe ABSSSI with Multi Drug Resistance organisms. After detailed deliberation, the committee recommended that firm should submit revised Phase-III CT protocol to CDSCO for further review by committee, by incorporating following changes. **1.** Patients with severe ABSSSI with risk factors for the MDR organism to be included. **2.** In the comparator arm drug Meropenam should be used instead of Aztreonam. **3.** Only MRSA culture positive patients should be included in the study. Till the receipt of culture result, the patient must be treated with standard of care treatment. **4.** Subject monitoring should include QT prolongation and neuropathy assessment.
2.	ND/MA/25/000118 & ND/MA/25/000117	M/s. Sun Pharma Laboratories Limited	Firm presented their proposed i.e. Phase III CT protocol titled: 'A Prospective, Multicenter, Randomized, Open Label,

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	Delafloxacin Tablets 450 mg & Delafloxacin for Injection 300 mg/vial		Active-Controlled, Phase 3 Study to Evaluate the Efficacy and Safety of Delafloxacin (Injection and Tablets) in comparison to Levofloxacin (Injection and Tablets) in patients with Community Acquired Bacterial Pneumonia'. (Protocol Number: ICR/25/010; Protocol Version 1.0 dated 14/JUL/2025), before the committee. After detailed deliberation, the committee recommended that firm should submit revised Phase-III CT protocol to CDSCO, by incorporating following changes. **1.** Patients with severe Community Acquired Bacterial Pneumonia with risk factors for the Multi Drug Resistance organism, to be included. **2.** Subject monitoring should include QT prolongation and neuropathy assessment.
3.	ND/MA/25/000111 Lenacapavir Tablets 300mg	M/s. Hetero Labs Limited, Hetero Corporate	The firm presented their proposal for grant of permission for manufacture and Marketing of the drug Lenacapavir Tablets 300 mg along with justification for Phase III Clinical Trial waiver and BE study waiver, before the committee. The committee noted that firm has obtained permission for conduct of BE study for export purpose from BA/BE division of CDSCO. The said BA/ BE study is ongoing. The firm presented published clinical trial data of drug Lenacapavir. The committee noted that firm did not present any clinical study data on Indian subset to prove that there is no substantial ethnic variability. Thus, there is lack of sufficient efficacy and safety data to prove that the proposed dose requirement in Indian population is adequate. The Committee noted that the new drug Lenacapavir (both Tablet & Injectable formulations) is indicated for management of heavily treatment-

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			experienced adults with multi-drug resistance HIV-1 infection. After detailed deliberation, the committee did not recommend for BE waiver and local Phase-III CT waiver.
4.	ND/CT/25/000055 Colloidal Nano Silver Gel 32 ppm with lactic acid (vagigel)	M/s Biosphere Clinical research Private Limited.	In light of the earlier SEC recommendation dated 24.08.2025, firm presented toxicity data, phase I Clinical Trial report of drug product Colloidal Nano Silver Gel (Protocol No.: BCR-VIR-003, Version 1.0 dated 09.04.2024) and Phase II/III Protocol (Protocol No.: BCR-VIR-004, Version No 1.0 dated 15.05.2025) before the committee. The Committee noted that Colloidal Nano silver gel through vaginal route is not approved in any country. The committee reviewed the toxicity data and noticed that the firm has not presented the toxicity in intended route of administration, carcinogenicity, reproductive toxicity study in accordance with NDCT Rules, 2019. In view of above, committee recommended firm to present relevant toxicity data in order to consider firm's application for Phase II/III study
5.	ND-12011/7/2025-eoffice Moxifloxacin, Isoniazid, Rifampicin, Pyrazinamide and Ethambutol	CSIR-NIRT, Chennai	The Principal investigator presented protocol titled "Four-month moxifloxacin containing shorter regimen versus 6 months standard regimen for treatment of drug sensitive TB disease in children aged 1 year to 18 years - open labelled randomised controlled trial (4M kids trial)", before the committee. The committee noted that the use of quinolones for the treatment of TB may have risk of drug resistance and recurrence. After detailed deliberation, the committee recommended that more data/ evidence w.r.t. shortening of treatment regimen by using Moxifloxacin and advantages of the proposed trial need to be submitted to the CDSCO for further review by the

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			committee.
6.	ND/138/2025-eoffice Rifampicin, Isoniazid, Levofloxacin, Pyrazinamide, and Ethambutol	ICMR-NIRT, Chennai	The Principal investigator presented protocol titled "Multi-centric Parallel arm Randomized Clinical trial to improve treatment outcomes among persons with drug sensitive pulmonary TB treated with 4 or 6 months of High dose Rifampicin containing regimens with or without Levofloxacin (PRaCTISe-HR)", before the committee. The committee noted that comparator arm with the regimen of $2HR_{25}ZE$ L+ $2HR_{25}EL$ - {4M} may have risk of drug resistance and recurrence of tuberculosis, due to presence of Levofloxacin. After detailed deliberation, the committee recommended that the proposed protocol need to revised by excluding the comparator arm i.e. test regimen of $2HR_{25}ZE$ L+ $2HR_{25}EL$ - {4M}. Accordingly, applicant is required to submit revised study protocol to CDSCO for further review by the committee.
SND Division			
7.	SND/IMP/21/000058 Chlorine-baseddisinfectant concentrate53.000 %W/W tablet	M/s. Ecolab Food Safety And Hygiene Solutions Private Limited	The firm did not turn up for the presentation.
8.	SND/MA/24/000074 Amoxicillin Dispersible Tablets 500 mg and 1000 mg	M/s. Aurobindo Pharma Ltd.	The firm did not turn up for the presentation.
9.	SND/CT/25/000108 Povidone Iodine 0.5% w/v Nasal Spray	M/s. G.S. Pharmbutor Private Ltd.	The firm did not turn up for the presentation.
10.	SND/CT21/FF/2025/50234 Faropenem Sodium Dispersible Tablets 50 mg/100 mg	M/s. Akums Healthcare	Firm presented their proposal for the manufacturing and marketing of Faropenem Sodium Dispersible Tablets 50 mg/100 mg along with the clinical trial and BE waiver.

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			The SEC noted that proposed posology of the applied drug is in line with already approved posology/dosage schedule. After detailed deliberation, the committee recommend to grant permission for the manufacturing and marketing of Faropenem Sodium Dispersible Tablets 50 mg/100 mg along with the clinical trial and BE waiver.
FDC Division			
11.	FDC/MA/24/000245 A) Meropenem and Sulbactam for Injection 1.5 gm- Each bag contains: Meropenem (Sterile) IP eq. to Anhydrous Meropenem 1 gm + Sulbactam Sodium (Sterile) IP eq. to Sulbactam 500 mg + Sodium Carbonate IP (as buffer) (Sterile) eq. to Sodium 90.2 mg (B) Sodium Chloride Injection IP 0.9% w/v 100 ml- Each ml contains: Sodium Chloride IP 0.9% w/v + Water for Injection IP qs to 100ml sterile power for IV infusion in Dual Chamber Bag	M/s. Gufic Biosciences Limited	In light of earlier SEC recommendation dated 26.11.2024 & 27.11.2024, the firm presented the justification, published literature, animal toxicity data and in-vitro data before the committee. The committee noted that Meropenem 1000 mg + Sulbactam sodium 500 mg Injection is already approved by this office on 15.03.2011. Further, the firm presented the advantages of the modified container closure system with respect to already approved glass vial and various drugs approved in dual chamber bag in different countries like USFDA, EMA and Japan. After detailed deliberation, the committee recommended for grant of permission for manufacture and market the proposed FDC Meropenem (Sterile) IP eq. to Anhydrous Meropenem 1 gm + Sulbactam Sodium (Sterile) IP eq. to Sulbactam 500 mg + Sodium Carbonate IP (as buffer) (Sterile) eq. to Sodium 90.2 mg with Sodium Chloride IP 0.9% w/v in Dual Chamber Bag.
12.	FDC/MA/25/000182 Didecyl dimethyl ammonium chloride 4.96% + Copper(II) nitrate trihydrate 0.40% + N-carboxymethylpyridinium bromide 1.18% +	M/s. Cedrus Bio-Products Private Limited	The firm presented the proposal along with Acute Inhalation Toxicity study report and anti-microbial efficacy study report before the committee. After detailed deliberation, the committee opined that the firm should conduct vigorous inhalation toxicity studies on animals.

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	Inert ingredients (other) 94.64% Disinfectant Solution for Surface & Environment		In view of above, the firm should submit protocol to CDSCO for further review by the committee.