

Recommendations of the SEC (Antimicrobial & Antiviral) made in its 118th meeting held on 27.09.2022 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
1.	ND/MA/22/000123 Dalbavancin for injection 500 mg	M/s. BDR Pharmaceuticals International Ltd.	The firm did not turn up for presentation.
2.	12-1/20-DC (Pt-279) C-TB	ICMR, Bhubaneswar	In light of earlier SEC recommendation dated 05.05.2022, the applicant presented their request for inclusion of at least 400 nos. of children aged 1 month to < 18 years in the ongoing clinical trial before the committee. After detailed deliberation, the committee recommended for grant of permission for inclusion of atleast 400 nos. of children aged 1 month to < 18 years in the ongoing clinical trial.
3.	12-73/13-DC Bedaquiline Tablet 20 mg & 100 mg	M/s. Johnson & Johnson Pvt.Ltd.	The firm did not turn up for presentation.
SND Division			
4.	SND/IMP/22/000056 Delamanid Dispersible Tablets 25 mg	M/s. Mylan Laboratories	In light of earlier SEC recommendation meeting dated 26.08.2022, the firm presented the proposal for import and marketing of Delamanid Dispersible Tablets 25mg for the indication that “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 for grant of permission to import and marketing of Delamanid Dispersible Tablets 25mg for proposed indication as mentioned above.
FDC Division			
5.	FDC/MA/22/000148	M/s. FDC Ltd.	In light of earlier SEC recommendation dated 26.07.2022, the firm presented their

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	Sodium Chloride 2.6gm+Potassium Chloride 1.5gm+Dextrose Anhydrous 13.5gm+Sodium Citrate 2.9gm + Zinc Sulphate Monohydrate 0.0550gm sachets		proposal along with justification. The committee noted that FDC has already been approved by CDSCO. After detailed deliberation, the committee recommended for grant of permission for manufacture and marketing of the FDC.
6.	FDC/MA/20/000150 Zinc Citrate Trihydrate eq. to Zinc 10mg + Ascorbic acid 1000 mg effervescent tablets	M/s. Kusum Healthcare Pvt. Ltd.	In light of earlier recommendation dated 26.08.2022, the firm presented the active PMS study protocol before the committee. After detailed deliberation, the committee recommended for conducting the active PMS study with the condition that more Government sites should also be included in the study and accordingly, the details of the sites should be submitted to CDSCO. The result of the study should be presented before the committee for further review.
7.	FDC/MA/22/000159 Sodium Ascorbate eq. to Ascorbate acid IP 400mg 120mg + L-Lysine Hydrochloride USP 7.49mg eq. to L-Lysine USP +Ascorbic acid 50mg + Ascorbyl Palmitate 6mg Chewable tablet	M/s. Zuventus Healthcare Ltd.	The firm did not turn up for presentation.
8.	FDC/IMP/22/000025 Avibactam Sodium eq to Avibactam 0.5gm + Ceftazidime 2gm Powder for concentrate for solution for infusion	M/s. Pfizer Ltd.	In light of earlier recommendation dated 26.07.2022, the firm presented their proposal along with justification. The firm informed the committee that the product is already approved in EU countries. After detailed deliberation, the committee recommended for grant of permission for import and marketing of the proposed additional indication with condition to conduct the Phase IV CT study. The protocol should be presented before the committee for review.

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GCT Division			
9.	CT/40/19 Online Submission (19876) Baloxavir Marboxil	M/s. Roche	The firm presented protocol amendment version 4.0 dated 29 March 2022 Phase IIIB study protocol No. MV40618 for approval before the committee. After detailed deliberation, the committee recommended for approval of the protocol amendment as presented by the firm.
10.	CT/61/22 Online Fresh File (32932) Fosmanogepix	M/s. Pfizer	The firm did not turn up for presentation.
Medical Device Division			
11.	IMP/MD/2021/42818 High-level disinfectant for thermosensitive instruments and endoscopy equipment (ANIOXYDE 1000 LD)	M/s. Ecolab Food Safety and Hygiene Solutions Private Limited	The firm did not turn up for presentation.