Recommendations of the SEC (Antimicrobial & Antiviral) made in its 127th meeting held on 28.06.2023 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	12-73/13-DC Bedaquiline Tablets 20mg and 100mg	M/s. Johnson & Johnson Private Limited	The proposal of updating the PI of Bedaquiline Tablet was deliberated in the Subject Expert Committee (SEC) & it was found that sufficient data was not presented by the firm in support of changes in breast feeding section of the Package Insert. Further, the committee noted that firm's presentation at the time of SEC was different from that submitted to CDSCO in their application in the matter of Breast feeding PI update. It was also noted that the firm did not present their additional data w.r.t SEC recommendation dt. 31.01.2023 which was communicated to the firm vide letter dt. 28.02.2023. In view of above, the committee deferred the proposal till submission of latest version of package insert along with supportive data to update the Package Insert for further deliberation.
2.	12-43/14-DC (Pt-D) Dolutegravir tablet 50mg	M/s. Emcure Pharma Ltd.	The firm presented the Phase IV clinical trial study results of the drug Dolutagravir-50mg tablets before the committee. The committee opined that the product Dolutagravir-50mg tablets are found safe & efficacious. The committee noted that one death reported in 277 patients & opined that CDSCO should investigate the causality assessment of reported SAE as well the signal, if any, received by PVPI with this drug.
3.	ND/MA/23/000087 Tebipenem Pivoxil Dispersible tablets 50mg	M/s. Hetero Labs Ltd.	The firm presented the proposal for grant of permission to conduct bioequivalence study and justification for Phase III clinical trial waiver with the drug Tebipenem Pivoxil Dispersible tablets 50mg. After detailed deliberation, the committee recommended that the firm may conduct BE study as per the protocol presented and submit the BE study results. The decision to waive off the clinical trial will be taken after review of Bioequivalence study report, subject to regulatory

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
			compliance as per CDSCO guidelines.
4.	ND/MA/23/000093 Tedizolid Phosphate tablets 200mg	M/s. Exemed Pharma Ltd.	The firm presented the proposal for grant of permission to conduct bioequivalence study and Phase III clinical trial with the drug Tedizolid phosphate Tablet 200mg. The committee noted that Tedizolid phosphate Tablet 200mg is already approved in US, EU and Canada. After detailed deliberation, committee recommended for grant of permission to conduct the bioequivalence study as per protocol presented. The committee also opined that firm's phase III clinical trial proposal will be considered after review of the BE study results.
SND Division			
5.	SND/CT/22/000008 Fosfomycin (Trometamol) Powder 3gm	M/s Clinexel Life Sciences Pvt. Ltd.	The firm presented the proposal for grant of permission for amendment in phase III clinical trial permission issued in Form CT-06 for Fosfomycin (Trometamol) powder 3g due to change in clinical trial protocol alongwith summary of changes in present version of protocol (revised protocol No. Clinexel-SRS-001, version No. 2.0, date 28.03.2023), before the committee. After detailed deliberation, the committee recommended for approval of the protocol amendment in Phase III clinical trial as per the revised protocol presented by the firm.
FDC Division			
6.	FDC/MA/23/000143 Ferric Ammonium Citrate IP 160 mg + Cyanocobalamin IP 7.5mcg + Folic Acid IP 1.0mg Syrup	M/s. Biological E. Ltd.	The firm did not turn up for presentation.
7.	FDC/MA/22/000405 Rifapentine 150mg + Isoniazid 150mg tablets	M/s. J Duncan Healthcare Pvt. Ltd.	The firm has presented the proposal for BE/CT study waiver. The committee noted that the firm was conducting BE study for higher strength.

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
			After detailed deliberation, the committee accepted the rationality and recommended to submit the innovator product approval status for this FDC to CDSCO for further review.