Recommendations of the SEC (Antimicrobial & Antiviral)made in its 05th/24meeting held on 09.05.2024 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
BA/BE Division			
1.	File No. 12-09/2024/BA-BE/MISC-29/DC BABE/CT05/FF/2023 /41609 Bismuth Subcitrate Potassium + Metronidazole + Tetracycline Hydrochloride 140mg / 125mg /125mg Capsule	M/s. Veeda Clinical Research Limited, Ahmedabad - 380015	The firm presented the Bioequivalence study protocol of Bismuth Subcitrate Potassium + Metronidazole + Tetracycline Hydrochloride 140mg / 125mg /125mg capsule for export purposes. The committee observed that similar proposal of the said FDC was deliberated in the SEC (Antimicrobial & Antiviral) meeting dated 27.09.2023 and the committee noted the following observations: i. The fixed dose combination of metronidazole + tetracycline is banned in the country vide S.O No. 4447(E) dated 07.09.2018. ii. The contents of metronidazole and tetracycline in the proposed test and reference drug are below therapeutic levels. After detailed deliberation, the committee recommended that the permission to conduct proposed BE study in healthy volunteers should not be permitted in the country.
2.	File No. 12-09/ 2024/BA-BE/ MISC-15/DC BABE/CT05/FF/2023 /38905 Bismuth Subcitrate Potassium + Metronidazole + Tetracycline Hydrochloride 140mg /125mg /125mg Film Coated Tablets	M/s. Veeda Clinical Research Limited, Ahmedabad - 380015	The firm presented the Bioequivalence study protocol of Bismuth Subcitrate Potassium + Metronidazole + Tetracycline Hydrochloride 140mg /125mg /125mg film coated tablets for export purposes. The committee observed that similar proposal of the said FDC was deliberated in the SEC (Antimicrobial & Antiviral) meeting dated 27.09.2023 and the committee noted the following observations: i. The fixed dose combination of metronidazole + tetracycline is banned in

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SND Division			
3.	SND/MA/23/000315 Thymosin Alpha 1 for injection 1.6mg	M/s. Gufic Biosciences	The firm presented the proposal for manufacture and marketing of Thymosin Alpha 1 for injection 1.6mg (Additional Indication) along with Phase-III clinical trial report before the committee. The firm informed that the proposed drug Thymosin Alpha 1 for injection 1.6mg already approved by CDSCO on 16.01.2001 for the treatment of chronic hepatitis-B in patients 18 years of age or older with compensated liver diseases and Hepatitis-B viruses (HBV) replication and on 02.03.2022, for add on therapy for the treatment of moderate to severe COVID patients requiring ventilator support (NIV as well as Mechanical ventilation). After detailed deliberation, the committee recommended for grant of permission to manufacture and marketing of Thymosin Alpha 1 for injection 1.6mg (Additional Indication) for add on therapy for the treatment to existing standard of care (SoC) in sepsis patient. Subject to following conditions: 1. The firm should conduct Active PMS study. 2. To be sold under the prescription of RMP only. 3. In addition to above, firm should fulfill the requirement of CMC data.

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			Accordingly, the firm should submit Active PMS study protocol within 03 months from date of approval to CDSCO for further review by the committee.
4.	SND/MA/23/000123 Clarithromycin ER Tablets 1000mg	M/s. Abbott Healthcare Private Limited	In light of earlier SEC recommendation dated 31.05.2023, the firm presented BE report along with justification for waiver of Phase-III clinical trial before the committee. The committee noted that proposed drug Clarithromycin ER tablet 1000mg at presently not approved anywhere in the world. The Clarithromycin ER tablet 1000mg had been approved in the year 2005. However, later on the same was withdrawn from US market due to unknown reason. Further, there is no specific unmet medical need of proposedformulation. After detailed deliberation, the committee reiterated its earlier SEC recommendation to conduct Phase-III clinical trial. Accordingly, the firm should submit Phase-III clinical trial protocol to CDSCO for further review by the committee.
New Drugs Division			
5.	12-01/23-DC (Pt-202) Bedaquiline	PGIMER, Chandigarh	The applicant presented the proposal for grant of permission for conduct of academic trial; protocol title: A prospective, randomized study to evaluate the efficacy, safety and pharmacokinetic-pharmacodynamics of Bedaquiline based regimen in multibacillary leprosy not responding to WHO-MDT before the committee. After detailed deliberation, the committee recommended for conduct of academic trial as per protocol presented by the applicant.
6.	ND/MA/23/000093 Tedizolid Tablets 200 mg	M/s. Exemed Pharmaceuticals	M/s Exemed Pharmaceuticals has appraised to the committee that M/s Exemed and M/s Sun Pharmaceutical Industries Ltd entered into agreement and M/s Sun will own further commercial

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			activities of new drug Tedizolid tablets 200 mg. M/s Sun Pharma has already filled application for grant of permission to manufacture and market new drug Tedizolid tablets 200 mg based on the bio-equivalence data, Phase III clinical trial data, CMC data of M/s Exemed and Tedizolid tablet 200 mg will be manufactured at Exemed facility under loan license Accordingly, the firm deliberated Phase III clinical trial report of new drug Tedizolid tablets 200 mg before the committee. After detailed deliberation, the committee recommended for the grant permission to manufacture and market drug Tedizolid tablets 200 mg subject to the condition that the firm should conduct active surveillance study. Accordingly, the firm should submit active surveillance study protocol to CDSCO within three month of approval.
FDC Division			
7.	04-130/2009-DC (Pt. II) Cephalexin ER 375mg/750mg + Clavulanate Potassium 125mg/125mg Tablets	M/s. Sun Pharmaceuticals Industries	In light of earlier SEC recommendation dated 12.12.2019 and as per condition of Form CT-23 dated 14.08.2019, the firm presented Phase IV clinical trial report before the committee. After detailed deliberation, the committee noted and agreed to the result of the clinical trial report.