

Recommendations of the SEC (Antimicrobial & Antiviral) made in its 09th/24 meeting held on 19.09.2024 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/37/24 Online Submission (42311) Avibactam 0.5 g + Aztreonam 1.5 g Powder for Concentrate for Solution for Infusion	M/s. Pfizer Limited	The firm presented phase 2A clinical study protocol no. C3601010 dated 27 September 2023. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
Biological Division			
2.	BIO/CT04/FF/2024/4455 Dengue Monoclonal Antibody (Recombinant Dengue mAb) 25mg/mL	M/s. Serum Institute of India Pvt. Ltd.	The firm presented the proposal to conduct Phase III clinical trial titled "A Phase III, double-blind, randomized, placebo-controlled, multicentric study of dengue monoclonal antibody in children ≥ 5 years and adults with dengue" vide protocol number: Dengue-mAb-03 version 1.0, dated 04 Jul 2024 along with the results of the Phase II study. The committee reviewed the results of the Phase II study. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III clinical trial as per the protocol presented by the firm.
BA/BE Division			
3.	BABE/CT05/FF/2023/39060 FDC of Pretomaid and Bedaquiline Tablets 200 mg/100 mg	M/s. Macleods Pharmaceuticals Ltd.	The firm presented the Protocol No.: BEQ-3636-PrBe (F)-2023, Version No. 01, Protocol Date 28-JUL-2023, Protocol No. BEQ-3639-PrBe (F)-2023, version No. 01, date 28-JUL-2023 for BA/BE study for export purpose only. After detailed deliberation, the committee opined that the firm should provide the following data for further deliberation before the committee.- 1) More data on the toxicity for proposed FDC based on the real world experience. 2) Opinion of National Tuberculosis Elimination Programme on the safety and necessity for proposed FDC.

