Recommendations of the SEC (Antimicrobial & Antiviral) made in its 04th/24 meeting held on 10.04.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/37/24 Online Submission (42311) Aztreonam and Avibactam ± Metronidazole	M/s. Pfizer	The firm presented Phase IIa clinical trial study protocol No. C3601010 dated 27 September 2023. After detailed deliberation, the committee recommended that the proposal should be re-deliberated in presence of one pediatric infectious disease expert and one infectious disease expert.
BA/BE Division			
2.	File No.12-09/ 2024/BA-BE/ MISC-22/DC BABE/CT05/FF/2023 /40848 Dolutegravir, Emtricitabine and Tenofovir Alafenamide tablets for oral suspension 5 mg/15 mg/1.88 mg	M/s. Laurus Labs Limited, Telangana -500101	The firm presented bioavailability study protocol No. C1B03448 version No. 01 dated 01.12.2023 under fasting conditions and protocol No. C1B03449 version No. 01 dated 01.12.2023 under fed conditions. After detailed deliberation, the committee recommended to conduct the comparative Bioavailability study as presented by the firm.
SND Division			
3.	SND/MA/23/000153 Linezolid Dispersible Tablets 150mg	M/s. Macleods Pharmaceuticals Ltd.	The firm presented the proposal alongwith BE report and justification for Phase III clinical trial waiver. The committee noted that Linezolid dispersible tablets 150mg is not approved anywhere in the world as an Anti-TB drug. After detailed deliberation, the committee opined that the firm should submit regulatory status of proposed formulation as an Anti-TB drug in children. Further, the proposal is also required to be deliberated in presence of expert from Central TB Division, MoHFW for further review by the committee.
New Drugs Division			
4.	ND/CT/24/000004	M/s. GSK	The firm presented the proposal alongwith Phase III clinical trial protocol

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	Tafenoquine Tablets 50 mg /150 mg		of Tafenoquine tablets 50mg/150 mg before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III clinical trial as per protocol presented, with subject to the condition that the firm should submit IDMC recommendations along with interim analysis report of pediatric participants 12 to 18 year of age as per the protocol to CDSCO for further review by the committee for extension of the study.
5.	ND/MA/24/000031 RdESAT-6 and rCFP-10 (Cy-Tb) injection	M/s. Serum Institute of India Pvt. Ltd.	The firm presented the proposal for grant of permission for change in indication of rdESAT and rCFP-10 (Cy-Tb) injection for inclusion of infants and above along with clinical trial data of comparative study of testing the efficacy and safety of Cy-Tb with QuantiFERON-TB Gold Plus and 2 T.U. Tuberculin Purified Protein Derivative (PPD) RT23 SSI in tube for detection of TB infection in children aged<1 year to 18 years. The committee noted that M/s Serum Inst. of India has been granted permission to manufacture and market drugs rdESAT and rCFP-10 (Cy-Tb) injection for detection of Latent tuberculosis for population of 18 years and above with condition to generate more clinical data in population less than 18 years of age for approval of Cy-Tb in this age group. After detailed deliberation, the committee reviewed the recommendations of the ICMR as presented by the representative of ICMR and recommended for grant of permission for change in indication of rdESAT and rCFP-10 (Cy-Tb) injection for inclusion of age group 1 year and above. The committee also recommended that for population below 1 year the rdESAT and rCFP-10 (Cy-Tb) injection should be used for detection of latent TB in

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			implementation research mode under National programme only.
6.	12-01/23-DC (Pt-202) Bedaquiline	PGIMER, Chandigarh	The firm did not turn up for presentation.
7.	ND/MA/23/000160 Letermovir 240 mg and 480 mg Tablets	M/s. Zydus	The firm presented the proposal for grant of permission to manufacture and market of Letermovir tablets 240mg and 480 mg with Phase-III clinical trial waiver request along with BE study report. After detailed deliberation, the committee recommended for grant of permission to manufacture & market of Letermovir tablets 240mg and 480 mg in country with the conditions: i) The firm shall submit Phase-IV CT protocol to CDSCO within three months of grant of permission. ii) The drug product to be sold on prescription of specialists in organ transplant, infectious disease, hematologist etc.
8.	ND/IMP/23/000073 Baloxavir Marboxil Tablets (20mg, 40mg &80mg) (Xofluza)	M/s. Roche Products (India) Private Limited	The firm presented the proposal for grant of permission to Import and Market of Baloxavir Marboxil tablets (20mg, 40mg & 80mg) with Phase - III clinical trial waiver request. After detailed deliberation, the committee did not agree for Phase-III clinical trial waiver.
FDC Division			
9.	FDC/MA/21/000076 Amoxicillin Trihydrate IP eq. to Amoxicillin 600mg + Potassium Clavulanate IP eq. to Clavulanic acid 42.9 mg per 5 ml powder for reconstitution into suspension	M/s. Alkem Laboratories Ltd.	In light of earlier SEC recommendation dated 29.11.2023, the firm presented the revised Phase - IV CT protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase-IV CT as per presented protocol. Accordingly, the firm should submit Phase-IV CT report for further review by the committee.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
10.	FDC/MA/24/000083 Meropenem Trihydrate IP (Sterile) eq. to Anhydrous Meropenem 1000mg + Sodium Carbonate eq. to Sodium 90.2mg + Avibactam Sodium (Sterile) eq.to Avibactam 500mg injection	M/s. Akums Drugs and Pharmaceutical Limited	The firm presented the proposal before the committee. After detailed deliberation, the committee recommended as under: 1. The firm should present the justification on rationality for combining this FDC & its significant benefit along with recent supporting document/ literature. 2. Justification on dose titration with recent supporting document/ literature. 3. International approval status. 4. Recent scientific literature available from peer reviewed journal in support of combining proposed FDC. Accordingly, the firm should submit above data for further review by the committee.