Recommendations of the SEC (Antimicrobial & Antiviral) made in its 130th meeting held on 27.09.2023 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/MA/23/000093 Tedizolid Phosphate Tablet 200mg	M/s. Exemed Pharmaceuticals	In light with earlier SEC recommendation dated 28.06.2023, the firm presented BE Study results before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III Clinical trial as per the protocol presented.
2.	ND/MA/23/000039 Tedizolid Phosphate Tablet 200mg	M/s. Synokem	In light with earlier SEC recommendation dated 25.04.2023, the firm presented BE Study results before the committee. After detailed deliberation, the committee recommended for the grant of permission to conduct the Phase III Clinical trial as per the protocol presented.
3.	ND/MA/22/000100 Methenamine Hippurate 1gm Tablet	M/s. Lyrus Life Science	In light with earlier SEC recommendation dated 22.03.2023, the firm presented Cell line study-In-vitro Cytotoxicity study (MTT Assay) of Methenamine Hippurate before the committee. After detailed deliberation, the committee recommended that since the firm had asked for clinical trial wavier, the firm needs to further substantiate their claim with respect to safety of the drug. The firm should submit the safety data of the drug accordingly. Thereafter; the proposal may be re-deliberated along with at least two experts from the field of toxicology.
SND Division			
4.	SND/MA/20/000215 Povidine Iodine Throat Spray 0.465% w/v	M/s. G.S. Pharmbutor Pvt. Ltd.	In light of earlier SEC recommendation dated 23.12.2021, the firm presented Phase III clinical trial protocol (protocol No. CT-CE-TS-2022, Version: 1.0, Dated: 19.09.2022) before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III Clinical trial as per protocol presented by the firm.

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FDC Division			
5.	FDC/MA/23/000188 Abacavir Sulphate 60mg + Dolutegravir Sodium 5mg + Lamivudine 30 mg tablet for oral suspension	M/s. APL Health care Ltd.	In light of earlier SEC recommendation dated 23.08.2023, the firm presented their proposal before the committee along with justification for Phase III clinical trial waiver. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of the FDC subject to condition that the firm should conduct Phase IV clinical trial. Accordingly, the firm should submit Phase IV clinical trial protocol to CDSCO within 03 months of approval of the drug for review by the committee.
6.	FDC/MA/23/000186 Sodium chloride 0.9g/100ml + L-Alanyl/L-Glutamine 20g/100ml Injection 0.9 % W/V with double chamber bag	M/s. Rusoma Laboratories Pvt. Ltd	In light of earlier SEC recommendations dated 26.07.2023, the firm presented justification, & rationality for the proposed FDC. After detailed deliberation, the Committee recommended that the firm should conduct Animal toxicity study for proposed FDC in GLP certified laboratory. Accordingly, the firm should submit animal toxicity data before the SEC for further review.
GCT Division			
7.	CT/45/23 Online Submission (37306) Bemnifosbuvir & Ruzasvir	M/s. IQVIA	The firm presented Phase II clinical study protocol no. AT-01B-004 amendment 1.0, 09 Jan 2023 before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Study as per the protocol presented.
8.	CT/59/23 Online Submission (37768) Pretomanid	M/s. BJ Govt. Medical College	The firm presented Phase I clinical study protocol no. IMPAACT 2034, version 1.0, dated 15 July 2022, After detailed deliberation, the committee recommended to grant of permission to conduct the trial with the conditions that: 1. The study data of the earlier studies done on children should be submitted

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			2. The older subjects shall be recruited first and then the younger ones 3. Adequate sample size and geographically well distributed sites should be included in the study.
BA/BE Division			
9.	12-09/2023/BA-BE/Misc-12/DC (Application No. BABE/CT05/FF/2023/37467) Bismuth 140 mg + Tetracycline 125 mg + Metronidazole 125 mg Capsule	M/s. Torrent Pharmaceuticals Ltd.	The firm presented their Bioequivalence study protocol of Bismuth 140 mg + Tetracycline 125 mg + Metronidazole 125mg capsule for export purposes. The committee noted the following observations i. The fixed dose combination of metronidazole + tetracycline is banned in the country as per S.O No. 779(E) dated 10.03.2016. ii. The contents of metronidazole and tetracycline in the proposed test and reference drug are below therapeutic levels. In light of above, the committee recommended that, the permission to conduct proposed BE study in healthy volunteers should not be permitted in the country.