Recommendations of the SEC (Gastroenterology & Hepatology) made in its 62nd meeting held on 13.07.2023 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND/MA/19/0000712 Tacrolimus Hard Gelatin Capsules IP 0.75mg	M/s. Sandoz Pvt. Ltd	The firm didn`t turn up for presentation.
2.	SND/CT/22/000054 Ursodiol Injection 625mg/25ml (25mg/ml)	M/s Shilpa Medicare,	In light of earlier recommendation of the SEC dated 23.11.2022, the firm presented interim report of Cohort-I study (600mg dose) and Cohort-II study (900mg dose) of Ursodiol Injection 625mg/25ml (25mg/ml) of Phase-I clinical trial before the committee. The committee noted that there were no clinically significant vital sign changes, no serious or significant adverse events and death reported during the study. After detailed deliberation, the committee recommended for grant of permission to conduct the Cohort-III (1800mg dose) and Cohort IV (3500mg dose) of Phase-I clinical trial as per the protocol presented by the firm.
3.	12-69/2018-DC (Pt-Intas-SND) Tacrolimus Lipid Suspension	M/s Intas Pharmaceuticals Limited	The firm presented their proposal for manufacturing and marketing of Tacrolimus lipid suspension 4 mg/vial and diluent for Tacrolimus lipid suspension for enema along with the results of the Phase III clinical trial. After detailed deliberation, the committee recommended for manufacturing and marketing of Tacrolimus lipid suspension 4 mg/vial and diluent for Tacrolimus lipid suspension for enema with condition that the firm should perform active PMS study in minimum 400-600 patient after marketing the drug product. Accordingly, the firm should submit active PMS study protocol within 06 months of marketing of drug product to CDSCO for further review by the committee.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
FDC Division			
4.	FDC/MA/23/000140 Magaldrate 480mg I.P + Simethicone 20mg I.P. Suspension	M/s. Biological E. Ltd.	The firm has withdrawn the proposal.
GCT Division			
5.	CT/49/23 Online Submission (37494) PB016 (Vedolizumab)	M/s. Worldwide Clinical Trials	The firm presented Phase-III clinical trial protocol number- PB16-03-01 before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the study with condition that the primary endpoint should be demonstrated at week 10 instead of week 6.
6.	CT/43/19 Online Submission (23909) Mirikizumab	M/s. Eli Lilly	The proposal was deferred for next SEC meeting.
7.	CT/54/19 Online Submission (25667) Etrasimod	M/s. IQVIA	The proposal was deferred for next SEC meeting.
Medical Device Division			
8.	IMP/MD/2023/81256 Faciotens Abdomen, Fasiotens Hernia, Fasiotens Paediatric	M/s. Olivine International	The proposal was deferred for next SEC meeting.