Recommendations of the SEC (Gastroenterology & Hepatology) made in its 63rd meeting held on 23.08.2023 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
FDC Division			
1.	FDC/MA/22/000084 Combikit of Amoxycillin Tablets 1000mg + Clarithromycin Tablets 500mg + Esomeprazole 40mg Tablets	M/s. Malik Lifesciences	As per the condition mentioned in Form CT-23, the firm presented Phase IV clinical trial study protocol before the committee. After detailed deliberation, the committee noted that. 1. Protocol presented before SEC was inadequate. 2. Inclusion/Exclusion criteria to be specified. 3. All the tests for Duodenal ulcer should be repeated at the end of the study. 4. More Government sites should be included. After detailed deliberation, the committee recommended that the firm should submit revised Phase IV clinical trial study protocol for further review by the committee.
GCT Division			
2.	CT/43/19 Online Submission (23909) Mirikizumab	M/s. Eli-Lilly	The firm presented protocol addendum 17.2 dated 16 December 2022 for protocol no. 16T-MC-AMAP. After detailed deliberation, the committee recommended the approval of the protocol addendum 17.2 dated 16 December as presented by firm with condition that the patients who are willing to take medication should be included and accordingly consent shall be taken.
3.	CT/54/19 Online Submission (25667) Etrasimod	M/s. IQVIA	The firm presented protocol amendment version 4.0 dated 20 February 2023 for protocol no. APD334-303. After detailed deliberation, the committee recommended for approval of the protocol amendment as presented by firm
4.	CT/72/23 Online Submission (37575)	M/s. IQVIA	The firm presented Phase III clinical trial for protocol no. RNLC3132 protocol version 5.0 dated 14 December 2022.

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
	Rifaximin		After detailed deliberation, the committee recommended for grant of permission to conduct the study with condition that there should be at least 50% sites from Govt. Hospitals/Institutions.
5.	CT/158/21 Online submission (25412) Mirikizumab	M/s. Eli-Lilly	The firm presented major protocol amendment 16T-MC-AMAX (d), dated 06 Feb 2023. After detailed deliberation, the committee recommended for approval of the protocol amendment as presented by firm with condition that patients who are willing to take medication should be included and accordingly consent shall be taken.
Medical Device Division			
6.	IMP/MD/2023/81256 Faciotens Abdomen, Fasiotens Hernia, Fasiotens Paediatric	M/s. Olivine International	The proposal was deferred to next SEC meeting due to unavailability of general surgeon. The proposal should be presented in the next meeting in presence of general surgeon and pediatric surgeon.