Recommendations of the SEC (Gastroenterology & Hepatology) made in its 13th meeting held on 20.12.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/08/23 Online Submission (35298) ABX464 (Obefazimod)	M/s IQVIA	The firm has withdrawn the application.
2.	CT/139/24 Online Submission (46510) SAR441566	M/s Sanofi	The firm presented phase II clinical study protocol no. DRI18212 Amendment 01, Version 1 dated 23-Aug-2024. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with condition that more geographically distributed government sites shall be included in the study. (Dr. Gaurav Kumar Gupta didn't participate).
3.	CT/142/24 Online Submission (46507) RO7790121	M/s Roche	The firm didn't turn up for presentation.
4.	CT/141/24 Online Submission (46446) RO7790121	M/s Roche	The firm didn't turn up for presentation.
New Drug Division			
5.	ND/MA/24/000113 Elobixibat Tablets 5mg	M/s Exemed Pharmaceuticals	The firm presented the proposal for grant of permission to manufacture and market of Elobixibat Tablets 5mg along with bioequivalence study protocol before the committee. The committee noted that Elobixibat Tablets 5mg already approved for manufacture and market in India on 15-07-2024. After detailed deliberation, the committee recommended for grant of permission to conduct bio-equivalence study as per the protocol presented. Accordingly, the firm should submit the

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			bio-equivalence study report to CDSCO for further review by the committee.
FDC Division			
6.	FDC/MA/23/000079 Each Chewable Tablet Contains: Famotidine IP 10 mg + Calcium carbonate IP 800 mg + Magnesium hydroxide IP165 mg.	M/s PURE & CURE HEALTHCARE Pvt. Ltd	The firm presented the proposal along with Active PMS protocol before the committee. After detailed deliberation, the committee noted that the indication is not inline with CDSCO approved indication. Accordingly, the committee recommended that the firm should submit the revised Active PMS protocol with CDSCO approved indication for further deliberation by the committee.