Recommendations of the SEC (Gastroenterology & Hepatology) made in its 12th meeting held on 12.12.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/101/22 Online Submission (35074) SAR443122	M/s Sanofi	The firm presented the proposal for increase the number of subjects in the study from India 25 to 40 subjects in india Protocol no. DRI16804. After detailed deliberation, the committee recommended for approval of Increase the number of subjects in the study from 25 to 40 in India as presented by the firm with Condition that more government sites shall be included in the study and enrollment from government site shall be increased.
2.	CT/08/23 Online Submission (35297) ABX464	M/s IQVIA	The firm presented protocol amendment version 5.0 dated 10 April 2024 protocol no. ABX464-107. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
3.	CT/05/23 Online Submission (35242) ABX464 (Obefazimod)	M/s IQVIA	The firm presented protocol amendment version 5.1 dated 10 April 2024 protocol no. ABX464-106. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
4.	CT/158/21 Online Submission (35934) Mirikizumab	M/s Eli lily	The firm presented protocol amendment (e) dated 10 September 2024 protocol no. I6T-MC-AMAX. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
5.	CT/129/22 Online Submission (36162) Guselkumab	M/s J and J	The firm presented protocol amendment 3.0 dated 21 October 2024 protocol no. CNTO1959UCO3004. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
SND Division			
6.	SND/MA/23/000273 Ursodeoxycholic Acid (UDCA) tablet150mg/	M/s Abbott India Limited	In light of earlier SEC recommendation dated 12.09.2024, the firm presented revise Phase-III clinical trial protocol along with summary of changes before

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	300mg/450mg/600mg		the committee. After detailed deliberation, the committee recommended to conduct Phase-III clinical trial as per protocol presented by the firm.
New Drug Division			
7.	ND/MA/24/000073 Elobixibat Tablets 5mg	M/s BDR Pharmaceuticals International Pvt Ltd.	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. After detailed deliberation, the committee noted that drug Elobixibat Tablets 5mg already approved in the country to manufacture and market for sell. Accordingly, the committee recommended for grant of permission to conduct bio-equivalence study as per the protocol presented and the result of the bio-equivalence study should be presented before the committee for further consideration.
8.	ND/MA/24/000085 Fexuprazan Hydrochloride Tablets 40 mg	M/s Sun Pharma Laboratories Limited	The firm presented Phase III CT report (A Randomized, Multi-Centric, Two-Arm, Active-Controlled, Parallel, Double-Blind, Double-Dummy, Comparative Study to Evaluate Efficacy and Safety of Fexuprazan Tablets manufactured by M/s. Daewoong Pharmaceutical Co., Ltd., South Korea in Comparison to Esomeprazole Tablets manufactured by M/s. Sun Pharmaceutical Industries Ltd in Patients With Erosive Esophagitis) and BE Study report (An open label, balanced, randomized, single dose, two treatment, two sequence, two period, crossover, comparative bioavailability study of Fexuprazan Hydrochloride tablets 40 mg with Fexuclue (Fexuprazan Hydrochloride) Tablets 40 mg manufactured by M/s. Daewoong Pharmaceutical Co., Ltd., South Korea in healthy adult human subjects under fasting condition, before the committee. Firm also presented Prescribing

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			information of innovator product and India specific Prescribing information of applied product Fexuprazan Hydrochloride Tablets 40 mg before the committee. Committee noted that drugs Fexuprazan Hydrochloride Tablets 40 mg is approved in South Korea for Treatment of erosive esophagitis (EE). After detailed deliberation, the committee recommended for grant of permission to manufacture and market of drug Fexuprazan Hydrochloride Tablets 40 mg for the proposed indication subject to the condition that- (a)The firm should conduct Active PMS study for which protocol should be submitted to CDSCO within 3 months of approval for further evaluation by the committee. (b)The drug should be sold by retail under the prescription of Registered Medical practitioner only.