Recommendations of the SEC (Gastroenterology & Hepatology) made in its 59th meeting held on 18.04.2023 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/MA/20/000142 Pleacanatide 3 mg tablets	M/s. MSN Pvt. Ltd	Inlight of earlier SEC recommendation dated 23.11.2021, the firm presented the Phase III clinical trial results for manufacturing and marketing of Plecanatide 3mg tablets**.** The committee noted that the drug has been approved in USA since 2017. Also the clinical trial results demonstrate the efficacy and safety of Plecanatide 3mg tablets in Indian patients. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of the Plecanatide 3mg tablets for the proposed indications **"**Chronic Idiopathic Constipation (CIC) & Irritable bowel syndrome with constipation (IBS-C)", subject to the condition that- 1. The firm should conduct Phase IV clinical trial. Accordingly, Phase IV clinical trial protocol should be submitted within 3 months from the date of marketing approval. 2. The drug should be sold by retail only under the prescription of Gastroenterologist or Hepatologist only.
Biological Division			
2.	BIO/CT18/FF/2022/35021 Ustekinumab Pre-filled syringes 45 mg/0.5 ml, 90 mg/ml and Single use vial 130 mg/ 26 ml	M/s Johnson & Johnson Pvt. Ltd.	The firm presented its proposal for additional indication of Ustekinumab solution for injection for subcutaneous administration in prefilled syringes 45 mg/0.5ml, 90 mg/ml and Ustekinumab Solution for intravenous infusion in single use vial 130 mg/26 ml with local clinical trial waiver before the committee. After detailed deliberation, the committee recommended that the firm is required to submit additional safety data on Indian patients through Phase IV study for the approved indication (Crohn's disease) for

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			further consideration of present application for additional indication.
SND Division			
3.	SND/MA/22/000277 Amisulpride Injection 5mg/2ml	M/s. La Renon Healthcare Pvt. Ltd.	The firm presented its proposal for grant of manufacture and marketing permission of Amisulpride injection 5mg/2ml (additional dosage form) for the new indications as- (1) Prevention of postoperative nausea and vomiting (PONV), either alone or in combination with an antiemetic of a different class. (2) Treatment of PONV in patients who have received antiemetic prophylaxis with an agent of a different class or have not received prophylaxis, with local clinical trial and BA/BE study waiver before the committee. The committee noted that Amisulpride Injection 2.5mg/ml (5mg/2ml) (Brand Name: BARHEMSYS) was approved in USA on 26/02/2020 for the same indication. After detailed deliberation, the committee considered local Clinical Trial and BA/BE waiver and recommended for grant of permission to manufacture and market the Amisulpride Injection 5mg/2ml for proposed indications.
GCT Division			
4.	CT/131/21 Online Submission (21162) BI 685509	M/s. Parexel	The firm presented the proposal of protocol amendment version 4.0 dated 07-Jul-2022 and protocol amendment version 5.0 dated 16-Aug-2022 of Global Clinical Trial study protocol no. 1366-0021 before the committee. After detailed deliberation, the committee recommended the approval of the protocol amendment as presented by the firm.
5.	CT/05/23 Online Submission (35559) ABX464	M/s. IQVIA	The firm presented Phase-III clinical trial protocol number- ABX464-106, Version - 3.0, dated Oct. 06, 2022, before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the study.

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			(Note: Dr. Vineet Ahuja did not participate in the deliberation.)
Medical Device Division			
6.	CI/MD/2023/87869 Ligating Clips (Trutie)	M/s. Healthium Medtech Limited	The firm presented its proposal for post marketing clinical investigation of the proposed product in the country before the committee. After detailed deliberation, the committee recommended for grant of permission for conduct of the post marketing clinical investigation of the proposed product in the country on Indian population.
7.	CT/MD04/2017 Study Title- "Fully Covered Self Expanding Metal Stents (FCSEMS) for Pancreatic Duct Strictures in Patients with Chronic Pancreatitis"	M/s. Bostan Scientific India Pvt. Ltd.	The firm did not turn up for presentation.
GCT Division			
8.	CT/139/22 Online Submission (34735) Guselkumab & Golimumab	M/s. Parexel	The firm presented the data in line with the recommendations of the earlier SEC held on 16.03.2023. After detailed deliberation, the committee recommended for grant of permission to conduct the study.
9.	CT/140/22 Online Submission (34792) Guselkumab & Golimumab	M/s. Parexel	The firm presented the data in line with the recommendations of the earlier SEC held on 16.03.2023. After detailed deliberation, the committee recommended for grant of permission to conduct the study.
10.	CT/08/23 Online Submission (35680) ABX464 (Obertazimod)	M/s. IQUVIA	The firm presented Phase III clinical trial protocol number- ABX464-107, version - 3.0, dated Oct. 06, 2022, before the committee. After detailed deliberation, the committee

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
	Hard Gelatine Capsule		recommended for grant of permission to conduct the study. (Note: Dr. Vineet Ahuja did not participate in the deliberation.)