Recommendations of the SEC (Gastroenterology &Hepatology)made in its 47th meeting held on 13.04.2022 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/MA/22/000058 Linaclotide Capsule	M/s. Dr. Reddy's Laboratories Ltd.	The firm presented the Phase III clinical trial protocol and justification for BE study waiver before the committee. After detailed deliberation, the committee agreed with waiver of conduct of BE study and recommended for grant of permission to conduct the Phase III clinical trial as per the proposed protocol subject to the following conditions: 1. Patients requiring chronic diuretic treatment should be excluded from the study. 2. Serum electrolytes including bicarbonate should be monitored.
2.	ND/MA/22/000056 Elobixibat Tablets 5 mg	M/s. Dr. Reddy's Laboratories Ltd.	The firm presented their proposal along with BE study & Phase III clinical trial protocol. After detailed deliberation, the committee recommended for grant of permission to conduct the BE study & Phase III clinical trial as per the proposed protocol.
SND Division			
3.	SND/MA/22/000051 Rabeprazole Orally Disintegrating Tablets 10/20 mg	M/s. Dr. Reddy's Laboratories Ltd.	The firm presented the proposal along with BE study protocol. After detailed deliberation, the committee recommended for grant of permission for conduct of BE study as per the protocol presented subject to the following conditions: 1. The firm should include Hb% range cut off value for male and female subjects in inclusion criteria. Lower limit cut off for Hb% for female subjects should be 12G. 2. Female subjects with menstrual disorders should be excluded from the study.
FDC Division			
4.	FDC/MA/22/000065 Magnesium hydroxide + Calcium carbonate	M/s. Overseas Health Care Pvt. Ltd.	The firm presented their proposal along with BE study protocol with the request for Phase III clinical trial waiver.

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	+ Famotidine (165mg+800mg+10mg) chewable tablet		The committee noted that the subject FDC is approved in US (as an OTC product) and Ireland. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed BE study. The results of the BE study should be presented before the committee for further examination.
5.	FDC/MA/21/000281 Lactobacillus acidophilus LA 5 &Bifidobacterium BB12 1Billion /1gm Sachet	M/s. East India Pharmaceuticals Works Ltd.	Inlight of earlier SEC recommendation dated 19.01.2022, the firm presented their rationale before the committee. After detailed deliberation, the committee recommended that the firm should conduct Phase III clinical trial for each indication. Accordingly, the firm should submit Phase III clinical trial protocol for further review by the committee.
6.	FDC/MA/22/000084 Combikit of Amoxycillin Tablets 1000mg +Clarithromycin 500mg Tablets+ Esomeprazole 40mg Tablets	M/s. Malik Lifesciences	The firm presented their proposal before the committee along with request for Phase III clinical trial waiver. The committee noted that similar combipack is approved in Australia. However, the proposed combipack is not the same. After detailed deliberation, the committee recommended that the firm should conduct Phase III clinical trial. Accordingly, Phase III clinical trial protocol should be submitted by the firm for further review by the committee.
GCT Division			
7.	CT/18/20 Online Submission (13833) Hydrocortisone Acetate 90 mg Suppository	M/s. Novotech Clinical Research	The firm presented protocol amendment 1.6 dated 27-Sep-2021 before the committee. After detailed deliberation, the committee recommended for approval of the proposed clinical trial protocol amendment.
8.	CT/19 /21Online Submission (15273) LY3471851 (NKTR-358)	M/s. Eli Lilly	The firm presented protocol amendment J1P-MC-KFAH(b) dated 03-Jun-2021 before the committee. After detailed deliberation, the committee recommended for approval of the proposed protocol amendment. The

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			applicant also requested for waiver of the condition for regular inclusion of 50% Govt. sites, the committee opined that the applicant should submit proper justification with documentary proof for further consideration.
9.	CT/21/17 Online Submission (16204) Tenofovir	M/s. Klinera	The firm presented protocol amendment 5, dated 03-Sep-2021 before the committee. After detailed deliberation, the committee recommended for approval of the proposed protocol amendment.
Medical Device Division			
10.	CI/MD/2021/51275 Continent Ostomy Management System (SphinX)	M/s. Crimson Healthcare Pvt. Ltd	The firm presented their proposal for pilot clinical investigation of the proposed product before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct pilot clinical investigation of the proposed product on Indian population in the country.