Recommendations of the SEC (Gastroenterology & Hepatology) made in its 02nd/24 meeting held on 15.02.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/22/000101 Online Submission (30774) SAR443122	M/s. Sanofi	The firm presented protocol amendment 05, version 1 dated 25 September 2023 protocol No. DRI16804. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
2.	CT/23/000008 Online Submission (30765) ABX464 (Obefazimod)	M/s. IQVIA	The firm presented protocol amendment version 4.1 dated 03 November 2023 protocol No. ABX464-107. After detailed deliberation, the committee recommended for approval of protocol amendment and increase in number of subjects from 68 to 100 in India as presented by the firm. (Dr. Vineet Ahuja did not participate in this proposal)
SND Division			
3.	SND/CT/23/000068 Amisulpride Injection 2.5mg/ml (5mg/2ml)	M/s. La Ranon	As per the condition to manufacturing & marketing permission No MF/SND/23/000090 dated 06.06.23, the firm presented its Phase IV clinical trial proposal (protocol No. CT/2023/54 version No. 00 dated 09.Aug.2023) before the committee. After detailed deliberation, the committee recommended grant of permission to conduct the Phase IV clinical trial as per the protocol presented by the firm
4.	SND/MA/23/000268 Omeprazole Delayed release orally disintegrating tablets 10mg	M/s. Dr. Reddy's Laboratories Limited	The firm presented the proposal for manufacture and marketing of drug Omeprazole delayed release orally disintegrating tablet 10 mg before the committee along with bioequivalence study report of Omeprazole delayed release orally disintegrating tablet 20 mg and stated that this higher strength proposal was earlier deliberated and recommended in SEC (Gastroenterology & Hepatology) held on 21-Nov-2023.

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			After detailed deliberation, the committee recommended for grant of permission to manufacture & market the drug Omeprazole delayed release orally disintegrating tablet 10 mg. However, the firm is required to comply with the requirement of CMC data.
5.	SND/MA/23/000273 Ursodeoxycholic Acid Tablets IP 150mg/300mg/450mg /600mg (additional Indication)	M/s. Abbott Ltd	The firm presented its proposal of already marketed formulation Ursodeoxycholic Acid tablets IP 150mg/300mg/450mg/600mg for additional indication i.e. for the "treatment of Non-alcoholic fatty liver disease (NAFLD) with transaminitis" before the committee. It is informed that the applied indication is not approved anywhere in world After detailed deliberation, the committee opined for conducting the Phase III clinical trial for Ursodeoxycholic Acid tablets IP 150mg/300mg/450mg/600mg for applied indication. The firm is requested to submit the Phase III clinical trial protocol to CDSCO for further review by the committee.
6.	SND/MA/23/000189 Sodium Picosulfate Oral Solution BP 2.5mg/5ml	M/s. Pharma Force Lab	The firm presented their proposal for Sodium Picosulfate oral solution BP 2.5mg/5ml for the indication i.e. "for the short term relief of occasional constipation in adults and children over 12 years of age" with a request for BE study & clinical trial waiver. After detailed deliberation, the committee opined that firm should provide the clinical data on Indian population (adult& children of 12 age) or shall conduct Phase III clinical trial for the proposed formulation. Accordingly, firm is requested to submit the same to CDSCO for further review by the committee.
New Drugs Division			

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7.	ND/IMP/23/000054 Carbon-14 urea 37Kbq Capsules (PY test capsules)	M/s. 3BMS Diagnostics Pvt. Ltd.	The proposal of the firm was re-deliberated and the firm presented their proposal for grant of permission to import and market of new drug Carbon-14 Urea 37 Kbq capsules (PYtest capsules) with a request to local Phase III clinical trial waiver before committee. The firm presented the data w.r.t. Carbon-14 Urea 37 Kbq capsules (PYtest capsules) manufactured by other firms. Further, the H.pylori test does not fall under the category of unmet medical need and hence, the committee did not approve the local clinical trial waiver. After detailed deliberation, the committee recommended that the firm should conduct Phase III clinical trial with proposed drug. Accordingly, firm should submit Phase III clinical trial protocol for further consideration.
FDC Division			
8.	FDC/MA/19/000089 Sodium Alginate IP 250mg + Sodium Bicarbonate IP 133.5mg + Calcium Carbonate IP 80mg per 5mL Oral liquid	M/s. Naxpar Pharma Pvt. Ltd.	The firm did not turn up for presentation.