Recommendations of the SEC (Gastroenterology & Hepatology) made in its 65th meeting held on 17.10.2023 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/IMP/23/000054 (12-01/23-DC (Pt-80)) Carbon-14 urea 37 Kbq Capsules (PYtest capsules)	M/s. 3BMS Diagnostics Private Limited	The firm has presented their proposal for grant of permission to import and marketing of new drug Carbon-14 urea 37 Kbq capsules (PYtest capsules) along with local Phase III clinical trial waiver justification before committee. After detailed deliberation, the committee recommended that the firm should conduct Phase III clinical trial with proposed drug and accordingly firm should submit Phase III clinical trial protocol for further consideration of matter.
2.	ND/MA/22/000104 Vanoprazan Tablets 10mg & 20mg	M/s. BDR Pharmaceuticals Pvt. Ltd.	Due to the technical error at the firm's end, the proposal was deferred.
Biologics Division			
3.	BIO/CT21/FF/2023/37090 Adalimumab 100mg/ml	M/s. Enzene Biosciences Limited	The firm presented the proposal for approval of additional indications for Adalimumab injection. The Adalimumab injection is earlier approved for the indication "Ankylosing Spondylitis''. The firm intends to extrapolate the following additional indications: 1. Crohn's disease 2. Ulcerative colitis 3. Paediatric Crohn's disease 4. Paediatric ulcerative colitis. After detailed deliberation, the committee recommended that the firm should present the proposal indication wise along with proper justification.
4.	BIO/CT04/FF/2023/36848 Vedolizumab 300mg	M/s. Dr. Reddy's Laboratories Limited	The firm presented the PK study protocol titled "A Single Dose, Double-Blind, Parallel Arm, Comparative Pharmacokinetic Study of Dr. Reddy's Vedolizumab (DRL_VZ), US approved Reference Vedolizumab (Entyvio®) and EU approved Reference Vedolizumab (Entyvio®), Administered by the Intravenous Route to Normal Healthy Male Volunteers" vide protocol No VZ-01-001, version: 1.0 dated 10.03.2023.

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			After detailed deliberation, the committee recommended for approval to conduct the study as per the presented protocol.
SND Division			
5.	SND/MA/23/000163 Esomeprazole Magnesium Delayed Release Oral Suspension 10mg, 20mg & 40mg	M/s. Dr. Reddy's Laboratories Ltd.	The firm presented the proposal for grant of permission to manufacture and marketing of Esomeprazole Magnesium for delayed release oral suspension 20mg and 40mg (additional strength) along with Bioequivalence study report of Esomeprazole Magnesium for delayed release oral suspension 40mg and justification for clinical trial waiver before the committee. After detailed deliberation, the committee recommended that the firm should present the relevance of the proposed oral suspension in Indian population. In case no data is available, the firm should conduct Phase III clinical trial and accordingly, clinical trial protocol should be submitted.
FDC Division			
6.	FDC/MA/23/000279 Sodium Alginate IP 500mg + Potassium Bicarbonate BP 100mg uncoated Chewable Tablets	M/s. Akums Drugs & Pharmaceuticals Limited	The firm presented their proposal along with PMS protocol and requested for BE & Phase III CT waiver before the committee. The committee noted that the said FDC is already approved in UK, Switzerland, Singapore, UAE etc. After detailed deliberation, the committee considered the BE waiver & Phase III CT waiver and recommended for grant of permission for manufacturing and marketing of the FDC with the condition to conduct the PMS study as per the presented PMS protocol. The firm should submit PMS study report to CDSCO for review by the committee.
7.	4-111/2010-DC (Pt. TPL) (Pt. III) Esomeperazole Magnesium	M/s. Torrent Pharmaceuticals Ltd.	The proposal was deferred for next SEC meeting.

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	Trihydrate IP eq. To Esomeperazole 40mg (as delayed release pellets) + Levosulpiride (ER) 75mg hard gelatin capsule		
GCT Division			
8.	CT/106/22 Online Submission (27228) GSK3228836 Solution for Injection 150 mg/mL (Bepirovirsen)	M/s. GSK Pharma	The firm presented protocol amendment version 01 dated 20 March 2023 for protocol No. 202009. After detailed deliberation, the committee recommended to re-deliberate the proposal with the reason to be submitted by the for difference in the protocol in terms of quantification of HBsAg as primary endpoint (efficacy) and qualitative assay of HBsAg as end point in protocol, for further review by committee.
9.	CT/132/22 Online Submission (27312) NASH (HORIZON)	M/s. GSK Pharma	The firm presented protocol amendment 02 dated 15 June 2023 for protocol No. 218672. After detailed deliberation, the committee recommended for approval of the proposed protocol amendment as presented by the firm
10.	CT/138/22 Online Submission (27546) Tegoprazan	M/s. Dr. Reddy's	The firm presented protocol amendment version 04 dated 26 June 2023 for protocol No. DRL-IND-NDA08-TEG/2022. After detailed deliberation, the committee recommended for approval of the proposed protocol amendment as presented by the firm
11.	CT/75/23 Online Submission (37851) Efruxifermin	M/s. Klinera	The firm presented Phase III clinical study protocol No. AK-US-001-0105. After detailed deliberation, the committee recommended for grant of permission to conduct the study.
12.	CT/97/23 Online Submission (38932) Efruxifermin	M/s. Klinera	The firm presented Phase III clinical study protocol No. AK-US-001-0107. After detailed deliberation, the committee recommended for grant of permission to conduct the study.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
13.	SND/CT/23/00066 Ursodeoxycholic Acid (UDCA) 625mg & 100mg	M/s. Shilpa Medicare Limited	The proposal was deferred for next SEC meeting.