Recommendations of the SEC (Gastroenterology & Hepatology) made in its 61st meeting held on 14.06.2023 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
FDC Division			
1.	FDC/MA/23/000140 Magaldrate 480mg I.P + Simethicone 20mg I.P. Suspension	M/s. Biological E. Ltd.	The firm did not turn up for presentation.
GCT Division			
2.	CT/106/22 Online Submission (25668) Bepirovirsen	M/s. GSK Pharma	In light of condition No. 1 of clinical trial -"The study should be conducted initially in 20 subjects from India. The applicant should submit safety data of these 20 Indian subjects along with recommendations of independent data safety monitoring committee/board to CDSCO for further review by the committee. Once data is reviewed by SEC, trial might be conducted". The firm presented their alternate proposal before the committee. After detailed deliberation, the committee agreed with their proposal and recommended that the condition No. 1 of clinical trial permission should be read as – "The firm should submit safety data of initial 20 Indian subjects along with recommendations of independent data safety monitoring committee/board to CDSCO for further review by the committee and enrollment should be continued". (Dr. Praveen Rathi did not participate in deliberation).
3.	CT/107/22 Online Submission (25669) Bepirovirsen	M/s. GSK Pharma	In light of condition No. 1 of clinical trial -"The study should be conducted initially in 20 subjects from India. The applicant should submit safety data of these 20 Indian subjects along with recommendations of independent data safety monitoring committee/board to CDSCO for further review by the committee. Once data is reviewed by SEC, trial might be conducted". The firm presented their alternate proposal before the committee. After detailed deliberation, the committee agreed with their proposal and

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			recommended that the condition No. 1 of clinical trial permission should be read as – "The firm should submit safety data of initial 20 Indian subjects along with recommendations of independent data safety monitoring committee/board to CDSCO for further review by the committee and enrollment will be continued". (Dr. Praveen Rathi did not participate in deliberation).
4.	CT/101/22 Online Submission (25336) SAR443122	M/s. Sanofi	The firm presented protocol amendment 2, version 1, dated 28-09-2022 before the committee. After detailed deliberation, the committee recommended for approval of the protocol amendment 2, version 1, dated 28-09-2022 as presented by the firm.
Medical Device Division			
5.	CT/MD04/2017 Study Title- "Fully Covered Self Expanding Metal Stents (FCSEMS) for Pancreatic Duct Strictures in Patients with Chronic Pancreatitis"	M/s. Boston Scientific India Pvt. Ltd.	The firm presented the clinical investigation report for voluntary global post marketing study of the proposed product before the committee. The committee observed that the firm wanted to conduct more studies on larger population. After detailed deliberation, the committee agreed with the data presented by the firm before the committee.
6.	CI/MD/2021/50481 NOBIX System	M/s. CBCC Global Research LLP	The firm presented their proposal for amendment in clinical investigation plan to CIP No CL-011, Version 04 dated 27.03.2023, before the committee. The committee observed that the amendments in the clinical investigation plan are like updation of address of Clinical Research Organization and change in title of clinical investigation plan from single centre to multi centre. After detailed deliberation, the committee recommended for grant of permission to conduct the clinical investigation with amended clinical investigation plan.
7.	IMP/MD/2023/81256	M/s. Olivine International	The firm presented the proposal for permission to import and market the

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	Faciotens Abdomen, Fasiotens Hernia, FasiotensPaediatric		products in the country before the committee. After detailed deliberation, the committee recommended that the firm should present the proposal in the next meeting in presence of general surgeon and Pediatric surgeon.
8.	CI/MD/2023/88547 MANTIS Clip	M/s. Boston Scientific India Pvt. Ltd.	The firm presented the proposal for pivotal clinical investigation of the product in the country on Indian population before the committee. After detailed deliberation, the committee recommended for the grant of permission for conduct of the pivotal clinical investigation of the product on Indian population with the condition that the firm should include one more clinical study site from the government institutes for the study. Accordingly, the firm should submit amended clinical investigation protocol for further review by the committee.
9.	CI/MD/2023/87266 Spy Glass Discover Digital Catheter, Spyscope DS II Access and delivery catheter, SpyGlass DS Digital Controller, SpyGlass Discover Digital Controller	M/s. Boston Scientific India Pvt. Ltd.	The firm presented the proposal for voluntary global post marketing clinical investigation of the proposed products before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed study on Indian population with condition that the firm should include one more clinical study site from the government institutes for the study. Accordingly, the firm should submit amended clinical investigation protocol for further review.
SND Division			
10.	SND/MA/19/000071 Tacrolimus Hard Gelatin Capsules IP 75 mg	M/s Sandoz Pvt. Ltd.	The firm did not turn up for presentation.
GCT Division			
11.	CT/138/22 Tegoprazan 50mg tablets	M/s Dr. Reddy's	In light of recommendation of the earlier SEC dated 16.03.2023 & 17.03.2023, the firm presented revised protocol

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
			amendment version 3.0 dated 20-04-2023 before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as per the revised protocol amendment version 3.0 dated 20-04-2023.