Recommendations of the SEC (Gastroenterology & Hepatology) made in its 66th meeting held on 26.10.2023 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/MA/23/000141 Eluxadoline Tablets 100mg	M/s. Sun Pharmaceutical Industries Limited	The firm presented the proposal for grant of permission for manufacturing and marketing of the drug Eluxadoline tablets 75 mg & 100 mg along with Phase III clinical trial protocol and BE study report before the committee. After detailed deliberation, the committee recommended to conduct the trial subject to the following conditions: 1. Patients above 65 years of age should be excluded. 2. The clinical sites should be geographically distributed in the country.
2.	ND/MA/22/000104 Vanoprazan Tablets 10mg & 20mg	M/s. BDR Pharmaceuticals Pvt. Ltd.	The firm presented the proposal for grant of permission for manufacturing and marketing of the drug Vonoprazan tablets 10mg/20mg along with Phase III clinical trial protocol and BE study waiver before the committee. After detailed deliberation, the committee recommended for the grant of permission to conduct proposed Phase-III clinical trial along with the waiver of BE study subject to the following conditions: 1. The firm should reassess the calculation of sample size. 2. The clinical trial sites should be geographically distributed in the country. Accordingly, the firm should submit the revised protocol to CDSCO.
SND Division			
3.	SND/CT/23/00066 Ursodeoxycholic Acid (UDCA) 625mg & 100mg	M/s. Shilpa Medicare Limited	The firm presented the proposal for grant of permission to conduct Phase-III clinical trial of intravenous injection Ursodeoxycholic acid (UDCA) 625mg/25ml (25mg/ml) along with Phase-I study safety results and Phase-III clinical trial protocol before the committee.

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			The committee noted that the firm has conducted Phase-I study of intravenous injection Ursodeoxycholic acid (UDCA) 625mg/25ml (25mg/ml) on 6 healthy patients to find out MTD i.e. 600mg, 900mg, 1800mg & 3500mg. After detailed deliberation, the committee observed that as the firm has conducted Phase-I pharmacokinetic study on healthy volunteer and now proposed to conduct Phase-III clinical trial in Acute Liver Failure (ALF) patients for which dose ranging study is required before initiation of Phase-III clinical trial. Accordingly, the firm should submit Phase-II dose ranging study protocol to CDSCO for further review by the committee.
FDC Division			
4.	4-111/2010-DC (Pt. TPL) (Pt. III) Esomeperazole Magnesium Trihydrate IP eq. To Esomeperazole 40mg (as delayed release pellets) + Levosulpiride (ER) 75mg hard gelatin capsule	M/s. Torrent Pharmaceuticals Ltd.	In light of the condition mentioned in permission in Form CT-23 dated 13.02.2014, the firm presented the Phase IV clinical trial report along with request for removal of condition that FDC shall be supplied in a Monocarton of 10 tablets per strip and each pack, package insert and other promotional literature, since the firm propose to pack multiple strip in one carton. After detailed deliberation, the committee agreed and noted the result of Phase IV clinical trial report. Further, the committee also agreed for the removal of condition that FDC shall be supplied in a Monocarton of 10 tablets per strip and each pack, package insert and other promotional literature.
GCT Division			
5.	CT/14/17 Online Submission (27749) Filgotinib	M/s. KlinEra Corporation India	The firm informed the committee, they are withdrawing the application for protocol no. GS-US-419-3899
6.	CT/49/23 Online Submission	M/s. Worldwide Clinical Trials	The firm presented protocol amendment, protocol No. PB016-03-01

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
	(29000) PB016 (Vedolizumab) Powder for Concentrate for Solution for Infusion 300 mg	India Private Limited	After detailed deliberation, the committee recommended for approval for amendment as presented by firm.
Medical Device Division			
7.	CI/MD/2023/ 94424 EBDLR System	M/s. Ardent Clinical Research Services	In light of the earlier recommendation SEC meeting dated 14.09.2023, the firm presented their revised clinical investigation plan, protocol No. 001/EBDLR/YLSPLT/2023, version 2.0 dated 09.10.2023, before the committee. After detailed deliberation, the committee recommend for the grant of the permission to conduct the pilot clinical investigation of the applied product "Extracorporeal Bioengineered Dual-Cell Liver Regeneration System (EBDLR)" in the country with protocol No. 001/EBDLR/YLSPLT/2023, version 2.0 dated 09.10.2023.
8.	IMP/MD /2023/81256 Faciotens Abdomen, Fasiotens Hernia, Fasiotens Paediatric	M/s. Olivine International	In light of earlier SEC recommendations dated 14.09.2023, the firm presented their proposal for grant of permission to import Class A (sterile) medical devices which does not have predicate device i.e. Faciotens Abdomen, Fasiotens Hernia, Fasiotens Paediatric, before the committee. The firm has submitted regulatory approval for said products from countries like Australia and European Union Countries and presented the sales/marketing data of the products since the year 2021. After detailed deliberation, the committee recommended for grant of permission to import aforesaid Class A (sterile) medical devices which does not have predicate device in the country.