Recommendations of the SEC (Cardiovascular) made in its 13th/24 meeting held on 09.07.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/114/23 Online Submission (30882) Baxdrostat	M/s. AstraZeneca	The firm presented for waiver of condition (i and iii) and notification for acceptance of condition (ii), of CT for protocol No. D6970C00002. After detailed deliberation, the committee recommended for amendment as per conditions below:- (i) Atleast 50% trial sites should be Govt. sites and more subjects shall be enrolled from Govt. sites (ii) Investigators in the study should be cardiologist only. (iii) Standard of care along with study medication should be borne by the sponsor.
2.	CT/40/22 Online Submission (31413) KJX839	M/s. Novartis	In reference to earlier SEC recommendation dated 07.03.2024, the firm presented protocol amendment version 01 dated 16.08.2023 and protocol amendment version 02 dated 23.11.2023 for protocol No. CKJX839D12303. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
3.	CT/34/23 Online Submission (31565) LY3502970	M/s. Eli Lilly	The firm presented protocol amendment (c) dated 21 April 2023, (d) dated 17 January 2024 vide protocol No. J2A-MC-GZGS and waiver of CT NOC condition No. (ii) the applicant should include 50% Govt. sites and 50% subjects should be enrolled from Govt. sites. After detailed deliberation, the committee recommended for approval of protocol amendment and amendment in CT waiver conditions (ii) as follows:- (ii) Atleast 50% trial sites should be Govt. sites and more subjects shall be enrolled from Govt. sites

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4.	CT/39/24 Online Submission (42284) Retatrutide	M/s. Eli Lilly	In reference to SEC recommendation dated 04.04.2024, the firm presented Phase III clinical study protocol No. J1I-MC-GZBO dated 05.01.2024. After detailed deliberation, the committee recommended for grant of permission to conduct the trial with condition that the PI should be cardiologist and Co-PI should be nephrologist.
Medical Devices Division			
5.	F.No.29/Misc./03/2023-DC (287) (Part-1)or File No.: (MED-14/8/2024-eoffice) Symplicity Spyral	M/s. Medtronic Pvt. Ltd	The firm did not turn up for presentation.
BA/BE Division			
6.	BABE/CT05/FF/2024/42519 FDC of Rosuvastatin, Ezetimibe and Fenofibrate coated tablet 20 mg/10 mg/ 160 mg	M/s. Syngene International Limited	The firm presented the protocol No.: SYNCD-005-24 ver. 1.00 dated 15.03.2024 for BABE study for export purpose. After detail deliberation, the committee recommended for grant of permission to conduct the proposed BA/BE study for export purpose only.
SND Division			
7.	SND/MA/23/000221 Nifedipine Extended Release Tablets USP 90 mg (Additional Strength)	M/s. Unique Pharma Limited	The firm presented the proposal for manufacture and market of Nifedipine extended release tablets USP 90mg along with Bioequivalence study protocol and justification for waiver of Phase-III clinical trial before the committee. The firm informed that the proposed formulation Nifedipine extended release tablets USP 90mg is already approved by US FDA in year 2002. After detailed deliberation, the committee recommended for grant of permission to conduct bioequivalence study as per protocol presented by the firm and submit the BE study results along with clinical data to CDSCO for further consideration by the committee.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
8.	SND/MA/23/000226 Tolvaptan Tablets 7.5mg	M/s. MSN Labs Private Limited	The firm did not turn up for presentation
New Drugs Division			
9.	ND-11011(15)/10/ 2024-eoffice Vericiguat 2.5 mg, 5mg and 10mg film coated tablets	M/s. Bayer Pharmaceuticals Pvt. Ltd.	The firm presented the proposal for amendment in the warning statement of permission granted to import and market Vericiguat 2.5 mg, 5 mg and 10 mg film coated tablets before the committee. After detailed deliberation, the committee recommended that the firm should submit the scientific evidence/data to CDSCO for further deliberation before the committee.