Recommendations of the SEC (Cardiovascular & Renal)made in its 140th meeting held on 20.12.2023 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND/MA/23/000010 Bisoprolol Fumarate Tablets 1.25mg/3.75mg/7.5mg	M/s. Windlas Biotech limited	The firm presented their proposal for grant of permission to manufacture and marketing of Bisoprolol Fumarate Tablets 1.25mg/3.75mg/7.5mg along with justification for waiver of Phase-III clinical trial and Bioequivalence study before the Committee. The Committee noted that the Bisoprolol Fumarate Tablets 1.25mg, 5mg and 10mg already approved by CDSCO. Bisoprolol fumarate also fall under BCS Class-I drug. After detailed deliberation, the Committee recommended for grant of permission to manufacture and marketing of Bisoprolol Fumarate Tablets 1.25mg/3.75mg/7.5mg with waiver of Bioequivalence and Phase-III clinical trial study subject to condition that the firm should conduct Phase-IV trials. In addition to above firm should fulfil the requirement of CMC data. Accordingly, the firm should submit Phase-IV trial protocol to CDSCO within 03 months from date of approval of drug for further review by the committee.
FDC Division			
2.	FDC/MA/22/000406 Torsemide IP 10mg/20mg + Eplerenone IP 25mg/25mg film coated tablet	M/s. Synokem Pharmaceuticals Ltd.	The firm did not turn up for the presentation.
3.	FDC/MA/23/000195 Bisoprolol Fumarate IP 5mg/5mg + Perindopril Arginine 5mg/10mg film coated bilayer tablet	M/s. Servier India Pvt. Ltd.	In the light of earlier SEC recommendation dated 21.09.2023, the firm presented their proposal along with revised BE study protocol and justification for CT waiver before the committee.

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			The firm informed the committee that the product is already approved in countries like France, Italy, and Switzerland etc. After detailed deliberation, the committee considered the request for CT waiver and recommended for conducting the BE study. Accordingly, the firm should submit the BE study report to CDSCO for further review by the committee.
4.	FDC/MA/23/000247 Telmisartan IP + Amlodipine Besilate IP eq. to Amlodipine + Bisoprolol Fumarate IP(40mg+5mg+2.5mg)/(40mg+5mg+5mg)film coated tablet	M/s. Ravenbhel Healthcare Pvt. Ltd.	In the light of earlier SEC recommendation dated 21.09.2023, the firm presented their proposal along with revised BE study protocol before the committee. After detailed deliberation, the committee recommended for conducting the BE study. Accordingly, the firm should submit BE study report along with Phase III clinical trial protocol to CDSCO for further review by the committee.
GCT Division			
5.	CT/146/21 Online Submission (29795) Cefepime-zidebactam (FEP-ZID), also known as WCK 5222	M/s. Wockhardt Limited	The firm presented protocol amendment 1 version 2.0 dated 14 December 2021, protocol no. W-5222-301. After detailed deliberation, the committee recommended for approval of the protocol amendment as presented by the firm.
6.	CT/17/23 Online Submission (29195) Finerenone (Kerendia®)Empaglif lozin (Jardiance®	M/s. Fortrea	The firm presented the proposal for increase in number of subjects from 48 to 250 in India. After detailed deliberation, the committee recommended for approval for increase in number of subjects from 48 to 250 in India as presented by the firm.
7.	CT/47/21 Online Submission (29945) LIB003-007	M/s. Medpace	The firm did not turn up for the presentation.
8.	CT/43/21 Online Submission (29948) Atacicept	M/s. Medpace	The firm did not turn up for the presentation.
9.	CT/65/23 Online Submission (29991) Atacicept	M/s. Medpace	The firm did not turn up for the presentation.

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Medical Device Division			
10.	CI/MD/2023/97539 Hemodynamx System	M/s. Translumina Therapeutics LLP	The firm presented proposal for grant of permission for conduct of Pilot clinical investigation on proposed medical device Hemodynamx System in the country on Indian population before the committee. The said device Hemodynamx System is intended to increase the aortic valve EOA (Effective Orifice Area) and thus reduce the left ventricular pressure. The said study is Pilot Clinical investigation on 5 patients in India. The committee observed that there is not enough proven scientific evidence at present time to initiate first in human study (Pilot Clinical Investigstion). After detailed deliberation the committee did not recommend for grant of permission for proposed study as there is not enough scientific evidence in support of the proposal.