Recommendations of the SEC (Cardiovascular & Renal) made in its 117th meeting held on 11.01.2023 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	12-01/18-Dc (Pt-337)	Signal Review Panel	The committee was appraised the SRP recommendation. After detailed deliberation, the committee recommended that CDSCO should request the State Drugs Controller to instruct the manufacturers of the drug to include muscle spasm as an adverse drug reaction in the PIL of Losartan marketed in India.
SND Division			
2.	SND/MA/22/000083	M/s Pharose Remedies	The firm didn't turn up for the presentation.
FDC Division			
3.	FDC/MA/20/000151 Telmisartan 40mg +Azelnidipine 16mg tablets	M/s. Mascot Health Series	In light of earlier recommendations dated 07.09.2021 & 08.09.2021, the firm presented the proposal along with Phase III CT study report. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing the FDC of Telmisartan 40mg + Azelnidipine 16mg.
4.	FDC/MA/22/000302 Rosuvastatin + Bempedoic acid 5mg+180mg, 10mg + 180mg, 20mg + 180mg	M/s. Exemed	In light of earlier SEC recommendation dated 21.12.2022 firm presented revised Phase III CT study protocol. After detailed deliberation, the committee recommended that the firm should submit more data on multiple lower strengths of statins in combination with Bempedoic Acid.
5.	FDC/MA/22/000234 Bisoprolol Fumarate IP 5mg/2.5mg+ Cilnidipine IP 10mg/10mg tablets	M/s. Windlas Biotech	In light of earlier SEC recommendations dated 08.12.2022 & 09.12.2022, the firm presented revised Phase III CT protocol. After detailed deliberation, the committee recommended for grant of permission to conduct Phase III CT for the FDC of Bisoprolol 5mg + Cilnidipine 10mg tablets with the condition that the words under inclusion criteria "history of" should be deleted.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
6.	FDC/MA/22/000285 Carvedilol 6.25mg/12.5mg + Sacuibitril Valsartan100mg/100 mg tablets	M/s. Windlas Biotech Ltd.	In light of earlier SEC recommendation dated 11.10.2022, the firm presented its proposal alongwith justification. After detailed deliberation, the committee reiterated its earlier recommendation.
7.	FDC/MA/22/000344 Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5mg + Sacubitril/Valsartan as sodium 50mg/100mg/200mg tablets	M/s. Ravenbhel healthcare Pvt. Ltd	The firm did not turn up for presentation.
8.	FDC/MA/22/000363 Metoprolol Succinate SR 25mg/50mg + Dapagliflozin 5mg/10mg tablets	M/s. Eris	The firm presented its proposal along with BE and Phase III CT protocol. After detailed deliberation, the committee recommended for grant of permission to conduct proposed BE and Phase III CT with the condition that BE study results should be presented in the SEC before initiating the Phase III CT.
9.	FDC/MA/22/000406 Torsemide IP 10mg/20mg + Eplerenone 25mg/25mg film coated tablet	M/s. Synokem Pharmaceuticals Ltd.	The firm presented their proposal along with BE and Phase III CT study protocol. After detailed deliberation, the committee recommended for amendment of the indication as well as protocol for further review by the committee.
GCT Division			
10.	CT/133/22	M/s. AstraZeneca	The applicant presented Phase III study protocol no. D9488C00001 version: 2.0 dated 08 June 2022 before the SEC. After detailed deliberation, the SEC recommended for the grant of permission for conduct of the proposed study with the following conditions: 1. Potassium in diet during conduct of study should be defined. 2. Concomitant medicines causing hyperkalaemia during conduct of study should be clarified.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Medical Device Division			
11.	IMP/MD/2022/53336	M/s Renovate Biological LS private ltd.	The firm presented its proposal before the committee. After detailed deliberation, the committee observed that the data presented by the firm is inadequate in order to ensure the safety, effectiveness & performance of the device. The committee recommended that the firm should present adequate clinical investigation data, PMS study data to ensure the safety, effectiveness & performance of the device.
BA/BE Division			
12.	12-09/2022/BA-BE/Misc-19/DC	M/s. Ajanta Pharma Limited, Kandivli, India-400067	The applicant presented its BA/BE study for export purpose before the SEC. After detailed deliberation, the committee recommended that firm should submit and present more data regarding justification/ rationale and safety on healthy volunteers with the proposed formulation.