Recommendations of the SEC (Cardiovascular & Renal) made in its 111th meeting held on 11.10.2022 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND/MA/22/000083 Polystyrene Sulphonate Jelly 20% w/w	M/s. Pharose Remedies	The firm did not turn up for presentation.
2.	SND/MA/21/000482 Ticagrelor SR Tablets120/180mg	M/s. Theon Pharma	The firm presented BE study results of Ticagrelor SR Tablets 180mg/120mg along with Phase III CT protocol of Ticagrelor SR Tablets 180mg/120mg before the committee. On review of BE study results of Ticagrelor SR Tablets 180mg/120mg the committee noted the following: 1. Values of Cmax for Ticagrelor and its metabolite in test product is significantly higher than that of reference product in both the BE studies. 2. There are higher percentage of adverse events i.e drop in haemoglobin values in subjects. 3. There are significant number i.e (around 20%) lost to follow up subjects in BE study of Ticagrelor SR Tablets 120mg. After detailed deliberation, the committee opined that the firm should submit raw data of both BE studies along with the justification for above mentioned observations supported with scientific literature for further review by the committee.
3.	SND/MA/2200065 Dapagliflozin Film Coated Tablets 10 mg	M/s. Astrazenca Pharma	The firm presented the application for Import and marketing permission of Dapagliflozin film –coated tablets 10 mg for the additional indication "to reduce the risk of sustained e-GFR and kidney disease, cardiovascular death, and hospitalization for heart failure in adults with chronic kidney disease at risk of progression". After detailed deliberation, the committee recommended for grant of additional indication " to reduce the risk of sustained eGFR and kidney disease ,

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			cardiovascular death, and hospitalization for heart failure in adult with chronic kidney disease at risk of progression" with condition that: - It is indicated in adults for the treatment of patients of chronic Kidney disease (CKD) upto eGFR of greater than or equal to 25 ml/min/1.73m^2. Below this, initiation of the treatment is not recommended, however the patients may continue 10 mg orally once daily to reduce the risk of eGFR decline, ESKD, CV death and hHF.
FDC Division			
4.	FDC/MA/21/000007 Ivabradine HCl eq. to Ivabradine 5mg/5mg+Metoprolol Tartrate 50mg/25mg tablets	M/s. Pure & Cure	The firm did not turn up for presentation.
5.	FDC/MA/22/000241 Chlorthalidone IP 6.25mg/12.5mg + Cilnidipine 5mg/10mg + Bisoprolol Fumarate 5mg/10mg tablets	M/s. Windlas Biotech Ltd.	The firm presented their proposal alongwith CT Protocol as well as BE study protocol for the proposed FDC before the committee. After detailed deliberation, the committee recommended for grant of permission for conducting proposed BE Study. As regard to the Phase-III Clinical trial, committee mentioned that firm should justify and include heart rate cut-off in the protocol. Accordingly revised Phase III CT protocol should be submitted for review by the committee.
6.	FDC/MA/22/000259 Cilnidipine IP 20mg + Metoprolol Succinate IP 47.50mg eq. to Metoprolol Tartrate (As ER) 50mg Tablets	M/s. Ajanta Pharma Ltd.	The firm did not turn up for presentation.
7.	FDC/MA/22/000285 Carvedilol 6.25mg/12.5mg + Sacuibitril Valsartan 100mg/100mg tablets	M/s. Windlas Biotech Ltd.	The firm presented their proposal alongwith CT Protocol as well as BE study Protocol for the proposed FDC before the committee. After detailed deliberation, the committee recommended that firm should present adequate rationality, justification as well

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			as clinical proof of concept for the proposed FDC for further review by the committee.
8.	FDC/MA/22/000193 M/s. Bisoprolol 40mg/40mg + Telmisartan 2.5 mg 2.5 mg/5mg Tablets	M/s. Windlas Biotech Ltd.	In light of earlier SEC recommendation dated 07.09.2022, the firm presented the raw data as well as justification. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of the proposed FDC in the proposed strengths.
9.	FDC/MA/21/000134 Bisoprolol 2.5 mg + Telmisartan 40 mg	M/s. Micro Labs	The firm presented their proposal for grant of permission to manufacture and market the proposed FDC in lower strength, committee noted that firm has been granted permission to manufacture and market proposed FDC in higher strength based on Phase III CT data. After detailed deliberation, the committee recommended for grant of permission to manufacture and market the proposed FDC in lower strength.
Medical Device Division			
10.	CI/MD/2022/66765 Navitor™ Transcatheter Heart Valve	M/s. St. Jude Medical India Pvt. Ltd.	The firm presented the proposed protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct post market clinical investigation with the proposed device in India.
11.	CI/MD/2022/67700 Mitral Valve	M/s. Foldax India Pvt. Ltd	The firm presented their proposal protocol before the committee. After detailed deliberation, the committee opined that the clinical trial data from first human trial of USA need to be submitted for examination by the committee. Further, committee opined that atleast two expert cardiac surgeons need to be present in next meeting for deliberation.
12.	29/Misc./03/2022-DC(135) MLS/Evermine50 EES-1	M/s. Meril Life sciences Pvt. Ltd	The firm presented their report before the committee and requested for extension of follow-up. After detailed deliberation, the committee opined for extension of follow up on approved trial to five years.

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GCT Division			
13.	CT/18/22 Online Submission (19927) Empagliflozin	M/s. Labcorp	The applicant has presented protocol amendment version 2.0 dated 20-April-2022 before the committee. The committee noted that in proposed protocol amendment global sample size was increased from 5000 to 6500 however no proposal for increase of no. of sample size from India was submitted to CDSCO. After detailed deliberation, the committee recommended for approval of proposed protocol amendment version 2.0 dated 20-April- 2022. The committee also suggested that no further enrollment should be carried out at clinical trial site- Dr. Sunil Nilkanthrao Washimkar, Govt Medical College and Super Specialty, Nagpur as the site had already enrolled 72 subjects.