Recommendations of the SEC (Cardiovascular & Renal) made in its 125th meeting held on 10.05.2023 at CDSCO HQ New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
FDC Division			
1.	FDC/MA/23/000071 Bisoprolol Fumarate 5mg/5mg/2.5mg/2.5 mg+Cilnidipine 10mg/10mg/10mg/10 mg+Chlorthalidone 12.5mg/6.25mg/12.5 mg/6.25mg tablets	M/s. Ajanta	The firm did not turn up for presentation.
2.	FDC/MA/22/000108 Metoprolol Succinate IP 47.50 mg eq to Metoprolol Tartrate (as extended release tablet) 50mg+Telmisarta IP 40mg + Amlodipine 5mg film coated bilayered tablet	M/s. Ajanta Pharma Ltd.	In light of the earlier SEC recommendation dated 09.06.2022 & 10.06.2022, the firm presented BE study report and Phase III clinical trial study report before the Committee. After detailed deliberation, the committee considered the reports and recommended for grant of permission to manufacture & market the product.
3.	FDC/MA/22/000302 Rosuvastatin + Bempedoic acid (5mg+180mg, 10mg + 180mg & 20mg + 180mg) tablet	M/s. Exemed	In light of the earlier SEC recommendation dated 12.04.2023, the firm presented revised Phase III clinical trial protocol. After detailed deliberation, the committee recommended for grant of permission for conduct of Phase III clinical trial. Further, the result of the study should be submitted to CDSCO for review by the committee.
4.	FDC/MA/22/000242 Bisoprolol Fumarate IP 5mg/2.5mg+ Cilnidipine IP 10mg/10mg Tablets	M/s. Ajanta Pharma Ltd.	The firm did not turn up for presentation.
5.	FDC/MA/23/000008 Ezetimibe 10mg+ Atorvastatin Calcium	M/s. Windlas	In light of the earlier SEC recommendation dated 12.04.2023, the firm presented BE study report and justification for Phase III clinical trial waiver.

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	80mg tablets		After detailed deliberation, the committee considered the report and recommended that firm should present Phase III clinical trial protocol before the SEC.
6.	FDC/MA/23/000098 Bisoprolol Fumarate IP2.5mg/5mg/2.5mg/ 5mg+Telmisartan IP 40mg+ Chlorthalidone IP6.25mg/6.25mg/ 12.5mg/12.5mg film coated tablet	M/s. Ajanta Pharma Limited	The firm did not turn up for presentation.
7.	FDC/MA/23/000127 Bisoprolol Fumarate 5mg/2.5mg+ Cilnidipine 10mg/10mg + Telmisartan 40mg/40mg tablets	M/s. Ajanta Pharma Limited	The firm did not turn up for presentation.
8.	FDC/MA/23/000110 Bisoprolol Fumarate 5mg/2.5mg+ Cilnidipine 10mg/10mg + Telmisartan 40mg/40mg tablets	M/s. Windlas	The firm presented its proposal before the committee along with justification for presenting the BE study and Phase III clinical trial protocol. After detailed deliberation, the committee recommended that the firm should justify the following points before presenting the protocol: 1. The firm should present the justification on rationality for combining this FDC and its significant benefit. 2. Justification on dose titration. 3. International approval status. 4. Scientific literature available from peer reviewed journal in support of combining the 3 drugs in this FDC.
GCT Division			
9.	CT/66/22 (33152) Crovalimab 340 mg/2ml	Ms. Roche	The committee deferred the proposal for next meeting due to non availability of Nephrologists in the meeting.
10.	CT/77/22 (33262) Crovalimab	Ms. Roche	The committee deferred the proposal for next meeting due to non availability of Nephrologists in the meeting.

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
11.	CT/95/21 (23157) OMS721	M/s. Kendle	The firm presented the Clinical Trial Protocol Addendum dated 12-Sep-2022 to the Protocol No. OMS721-IGA-001 before the committee. After detailed deliberation, the committee recommended for approval of the proposed protocol addendum as presented.
12.	CT/149/21 (23501) BI 690517	M/s. Parexel	The committee deferred the proposal for next meeting due to non availability of Nephrologists in the meeting.
13.	CT/17/23 (36110) Finerenone + Empagliflozin	M/s. Labcorp	The committee deferred the proposal for next meeting due to non availability of Nephrologists in the meeting.
14.	CT/133/22 (24127) Sodium Zirconium Cyclosilicate	M/s. AstraZeneca	The committee deferred the proposal for next meeting due to non availability of Nephrologists in the meeting.
15.	CT/20/23 (36440) Inclisiran	M/s. Novartis	The firm presented the Phase III Global Clinical Trial Protocol No. CKJX839D12302, Version 00 dated 12-Dec-2022 (VICTORION-1 PREVENT) before the committee. After detailed deliberation, the committee recommended for the grant of permission subject to the following conditions that: 1. The PI in the study should be cardiologist only. 2. The firm should include equal number of geographically distributed government sites as that of private sites for the study.
16.	CT/111/21 (23793) Inclisiran	M/s. Novartis	The firm presented its proposal of Clinical Trial Protocol amendment to the Protocol No. CKJX839B12302 (VICTORION-2 PREVENT) for the increase in number of patients to be enrolled from India from 700 to 1000 patients. After detailed deliberation, the committee recommended for grant of approval for the proposed protocol amendment for increase in number of patients to be enrolled from India from 700 to 1000 subjects as presented by the firm.

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
Medical Device Division			
17.	CI/MD/2023/83213 Paclitaxel Eluting PTA Balloon Catheter (Mozec™ PEB PTA)	M/s. Meril Life Sciences Pvt. Ltd	The firm presented the proposal before the committee. After detailed deliberation, the committee recommended that the firm should submit PK (Pharmacokinetic) study with same drugs Paclitaxel with the similar device conducted globally before the committee.
18.	MD/PostAppr/2023/13875 Edwards SAPIEN 3 - Edwards Commander Kit	M/s. Edwards Lifesciences Private Limited	The firm did not turn up for the presentation.
19.	CI/MD/2018/7210 Promesa DES Sirolimus eluting self-expandable Nitinol peripheral stent system	M/s. Meril Life Sciences Pvt. Ltd	The firm presented the amended protocol version 3.0.0 dated 06.12.2022 before the committee. The committee observed that there is deviation from the approved protocol. After detailed deliberation, the committee recommended that the firm needs to submit the adequate justification for the proposed change.
20.	CI/MD/2023/71389 Pressure Pace TM System	M/s. JSS Medical Research Asia Pacific Private Ltd.	The firm presented the proposal to conduct the pivotal clinical investigation with PressurePace™ system in the country before the committee. During the presentation the committee noted the following: 1. The objective & need to conduct proposed study was not clear. 2. Pacemaker proposed to be used are of M/s Pacetronix and not of the major manufacturer. 3. The methodology for measurement of cardiac pressure with modified Bruce treadmill study is not efficient to assess the performance. After detailed deliberation, the committee recommended that the firm should submit more justification for the proposed study with the supporting documents to CDSCO for further review by the committee.