Recommendations of the SEC (Cardiovascular & Renal) made in its 135th meeting held on 11.10.2023 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT18/FF/2023/37266 Andexanetalfa powder for solution for infusion 200 mg	M/s. AstraZeneca Pharma India Limited	The firm presented their proposal to import and market Andexanet alfa solution for injection indicated for patients treated with FXa inhibitors (apixaban or rivaroxaban) when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding with waiver of local Phase III clinical trial. The committee noted that the drug is approved in US, Japan, Australia, Switzerland, UK, Canada, EU and there is an unmet medical need. After detailed deliberation, the committee recommended for grant of permission to import and market the drug subject to the condition that the firm should conduct Phase IV clinical trial in the country. Accordingly, the firm should submit the Phase IV protocol to CDSCO for evaluation within three months from the grant of marketing authorization.
FDC Division			
2.	FDC/MA/23/000098 Bisoprolol Fumarate IP 2.5mg/5mg/2.5mg/5mg+ Telmisartan IP 40mg+ Chlorthalidone IP6.25mg/6.25mg/12.5mg/12.5mg film coated bilayeredtablet	M/s. Ajanta Pharma Limited	The firm did not turn up for presentation.
3.	FDC/MA/23/000272 Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5mg/5mg/5mg + Sacubitril and Valsartan as Sodium	M/s. Exemed Pharmaceutical	The firm presented their proposal along with BE study protocol & Phase III clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the BE study & Phase III clinical trial. The result of the BE study should be presented for review by SEC before initiation of the Phase III clinical trial.

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	salt complex 50mg (24mg and 26mg), 100mg (49mg and 51mg) &200mg (97mg and 103mg) tablet		
4.	FDC/MA/23/000288 Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin + Bisoprolol Fumarate IP (10mg+1.25mg, 10mg+2.5mg, 10mg+5mg & 10mg+10mg) tablet	M/s. Exemed Pharmaceutical	The firm did not turn up for presentation.
5.	FDC/MA/19/000106 Efonidipine Hydrochloride Ethanolate +Telmisartan IP (20mg+40mg/ 40mg+40mg) uncoated bilayered tablets	M/s. Zuventus Healthcare Ltd.	In light of the condition mentioned in permission in Form CT-23 dated 30.12.2021, the firm presented the Phase IV clinical trial protocol for FDC of Efonidipine Hydrochloride Ethanolate 40mg + Telmisartan IP 40 mg tablets before the committee. After detailed deliberation, the committee recommended for conduct of the Phase IV clinical trial. The firm should submit the Phase IV clinical trial report to CDSCO for further review by the committee.
6.	FDC/MA/20/000077 Azelnidipine + Metoprolol (SR) 8mg/8mg/16mg/16mg + 25mg/ 50mg/25mg/50mg tablet	M/s. Akums Drugs & Pharmaceuticals Ltd.	In light of the SEC recommendation dated 07.06.2023, the firm presented their proposal along with clarification/justification w.r.t. clinical trial result. After detailed deliberation, the committee opined that the firm should submit raw data of the CT to CDSCO for review by the committee.
7.	FDC/MA/23/000063 Dapagliflozin Propanediol monohydrate 5mg/5mg/10mg/10mg + Metoprolol Succinate IP eq. to	M/s. Exemed Pharmaceuticals	In light of the SEC recommendation dated 06.07.2023 & 07.07.2023, the firm presented their proposal along with BE report & revised Phase III clinical trial protocol with change in indication before the committee. The committee noted that CDSCO has already issued BE & CT NOC on 25.08.2023. However firm has not

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	Metoprolol tartrate (ER) 25mg/50mg/25mg/50 mg tablets		initiated Phase III CT study. After detailed deliberation, the committee considered BE report and recommended for grant of permission to initiate the Phase III CT with the condition that Guideline Directed Medical Therapy (GDMT) for heart failure as a concomitant medication to be allowed for all the subjects. Accordingly, the firm should submit Phase III CT study report to CDSCO for review by the committee.
8.	FDC/MA/23/000293 Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin + Telmisartan (10mg+40mg/ 10mg+80mg) film coated tablet	M/s. Eris Lifesciences Limited	The firm presented their proposal along with BE study protocol & Phase III clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the BE study & Phase III clinical trial. The result of the BE study should be presented for review by SEC before initiation of the Phase III clinical trial.
Medical Device Division			
9.	CI/MD/2021/50669 Pericardial Bioprosthesis Dafodil (1st Brand), Dafodil Neo (2nd Brand), Flomeo (3rd Brand), Freesia (4th Brand)	M/s. Meril Life Sciences Private Limited	The firm presented the 100 patients data as recommended by the SEC (cardiovascular & Renal) dated 08.02.2023 After detailed deliberation, the committee recommended to present the data in the SEC meeting alongwith (cardiothoracic) surgeon.