

Recommendations of the SEC (Cardiovascular) made in its 04th/24 SEC meeting held on 20.02.2024 at CDSCO (HQ) New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
FDC Division			
1.	FDC/MA/23/000227 Bempedoic acid + Atorvastatin Calcium IP eq. to Atorvastatin + Ezetimibe IP (180mg+20mg+10mg)/ (180mg+40mg+10mg) film coated tablet	M/s. Akums Drugs & Pharmaceuticals Ltd.	In light of the earlier SEC recommendation dated 06.09.2023, the firm presented their proposal along with the justification. After detailed deliberation, the committee opined that the firm could not present the detailed justification w.r.t to below points: <ol style="list-style-type: none"> 1. The lower dose of statins along with Bempedoic acid is not approved in the country. 2. The firm has not presented adequate justification/rationale for the proposed triple drug combination. 3. No global data was presented w.r.t. the proposed FDC. After detailed deliberation, the committee did not recommend for approval of the FDC.
2.	FDC/MA/23/000357 Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5mg/10mg + Metoprolol Succinate IP eq. to Metoprolol Tartrate (ER) 25mg/50mg film coated bilayer Tablet	M/s. Mascot Health Series Pvt. Ltd.	The firm presented the proposal along with BE study protocol before the committee. After detailed deliberation, the committee recommended that the reference product should be changed to individual innovator drug in the BE study. Accordingly, the revised BE study protocol should be submitted to CDSCO, for review. Further, after approval from CDSCO the firm should submit BE study report for further review by the committee for taking decision on the Phase III clinical trial protocol.
3.	FDC/MA/24/000002 Sacubitril + Valsartan	M/s. Exemed Pharmaceuticals	The firm did not turn up for presentation.

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	(as sodium salt complex) 50mg (24mg+26mg)/ 100mg (49mg+51mg)/ 200mg (97mg + 103mg)/ 400mg (194mg+ 206mg) Film coated sustained release tablet		
4.	FDC/MA/24/000006 Empagliflozin 10mg/10mg + Metoprolol Succinate IP 23.75mg eq. to Metoprolol Tartrate (ER) 25mg/ Metoprolol Succinate IP 47.50mg eq. to Metoprolol Tartrate (ER) 50mg uncoated bilayered tablet	M/s. Zydus Healthcare Limited	The firm presented their proposal along with BE study protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the BE Study. Accordingly, the firm should submit BE study report for review by the committee and for taking further decision on the Phase III clinical trial protocol.
5.	FDC/MA/24/000008 Dapagliflozin Propanediol Monohydrate 5mg/5mg/5mg + Sacubitril 24mg/49mg/97mg + Valsartan Sodium Salt 26mg/51mg/103mg Film Coated Tablets	M/s. Synokem Pharmaceuticals Ltd.	The firm presented their proposal along with BE study protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the BE Study. Accordingly, the firm should submit BE study report for review by the committee and for taking further decision on the Phase III clinical trial protocol.
6.	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 presented the proposal before the committee along with the Phase III clinical trial protocol with request for BE study waiver. After detailed deliberation, the committee considered the request for waiver of BE study and recommended for grant of permission for conduct of the Phase III clinical trial. The result of the Phase III clinical trial should be presented before the committee

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			for further review.
New Drugs Division			
7.	ND/IMP/23/000037 Sodium Zirconium Cyclosilicate Powder for Oral Suspension (Lokelma 5g & 10g)	M/s. Astrazeneca	The firm presented the proposal for grant of permission to import & market of Sodium Zirconium Cyclosilicate powder for oral suspension 5g & 10g along with justification for clinical trial waiver before the committee. After detailed deliberation, the committee noted that the drug is approved in around 60 countries and there is an unmet medical need. The committee recommended for grant of permission to import & market of applied drug with the condition that the firm should conduct Phase IV clinical trial for which the protocol should be submitted within 3months of approval of the drug for review by the committee.
SND Division			
8.	SND/MA/23/000156 Sacubitril and Valsartan Tablets 25mg	M/s. Dr. Reddy's Laboratories Ltd.	The firm did not turn up for presentation.