

Recommendations of the SEC (Cardiovascular) made in its 06th/24 meeting held on 21.03.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
BA/BE Division			
1.	12-09/2024/BA-BE/MISC-17/DC BABA/CT05/FF/2023 /39132 Torasemide Tablet 50 mg	M/s. Aurobindo Pharma Ltd, Hyderabad-500038	The firm presented protocol No. 0237-23, version No.1.0 dated 05-July-2023. After detailed deliberation, the committee recommended for approval of protocol as presented by the firm based on the published literatures on the study drug.
Medical Devices Division			
2.	CI/MD/2023/97539 Hemodynamx System	M/s. Translumina Therapeutics LLP	The firm didn't turn up for presentation.
SND Division			
3.	SND/IMP/22/000065 & SND/IMP/23/000029 Dapagliflozin Film Coated Tablet 10mg	M/s. Astrazeneca Pharma Limited	The firm presented their proposal for uniformity in package insert and product label with respect to condition No. 3 (Warning condition) of the permission in applications No. SND/IMP/22/000065 & SND/IMP/23/000029 before the committee. The firm has informed that they hold permission for following 5 indications and warning condition: 1) On dated 25/02/2015 indicated for: - In adults aged 18 years and older with type II diabetic mellitus to improve glycemic control. <ul style="list-style-type: none"> • As mono-therapy when diet and exercise alone do not provide adequate glycemic control in patients for whom use of metformin is considered inappropriate due to intolerance. • As add on combination therapy in combination with other glucose-lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycemic control. Warning condition: "To be sold by retail on the prescription of RMP". 2) On dated 03/07/2020 indicated for: - in

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			<p>adults for the treatment of heart failure with reduced ejection fraction. Warning condition: “To be sold by retail on the prescription of RMP”.</p> <p>3) On dated 03/02/2021 indicated for:- the treatment of patients of Chronic Kidney Disease (CKD) up to Stage III (eGFR of greater than or equal to 30 ml/min/1.73m² Warning condition: “To be sold by retail on the prescription of a Specialist only”.</p> <p>4) On dated 23/11/2022 indicated for: - to reduce the risk of sustained eGFR and kidney disease, 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/1.73m². 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. Warning Condition – “To be sold by retail on the prescription of Nephrologist only”.</p> <p>5) On dated 20/07/2023 indicated for:- the treatment of Heart Failure in adult. Warning Condition – “To be sold by retail on the prescription of Cardiologist only”.</p> <p>After detailed deliberation, the committee recommended for change in warning condition for Dapagliflozin film coated tablets 10mg – “To be sold by retail on the prescription of a Specialist only”, for sake of uniformity.</p>
4.	SND-16011(11)/14/2024-e-office Metoprolol Tartarate	M/s. Astrazeneca Pharma Pvt. Ltd.	The firm presented the proposal for update in package insert of Metoprolol Tartarate tablets I.P. 25mg, 50mg and 100mg with respect to contraindications, special warnings and precautions for use

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
	Tablets I.P. 25mg, 50mg, & 100 mg (Betaloc)		<p>and pharmacodynamic properties as per their company core data sheet (CCDS) before the committee.</p> <p>After detailed deliberation, the committee recommended for updation of proposed changes in package insert with the condition that the firm should submit the copy of approval from country of origin.</p>
5.	SND/MA/23/000156 Sacubitril & Valsartan tablets 25 mg	M/s. Dr. Reddy's Lab Limited	<p>The firm had submitted application to manufacture and market of Sacubitril and Valsartan tablets 25mg (as additional strength) indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in patients with chronic heart failure (NYHA Class II-IV) and reduced ejection fraction with BE & CT waiver.</p> <p>However, in light of earlier SEC recommendation held on 09/01/2024 on similar proposal deliberated for another firm wherein committee opined that the firm should provide more justification on the proposed dose and its rationality.</p> <p>Now, the firm has submitted Phase II clinical trial protocol titled "A double blind, multicentre, comparative, Phase II study to evaluate the efficacy and safety of low dose sacubitril/valsartan (12mg/13mg) twice daily of Dr. Reddy's Laboratories Limited in comparison to sacubitril/valsartan (24mg/26mg) twice daily in adult patients with heart failure and reduced left ventricular ejection fraction" and presented their proposal before the committee.</p> <p>After detailed deliberation, the committee opined that the proposed protocol is insufficient to prove the clinical relevance of lower strength of Sacubitril/Valsartan (12mg/13mg). Hence, firm should submit revised protocol with more justification on the proposed dose and its rationality for further review by the committee.</p>

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
6.	ND/CT/23/000099 Inclisiran solution for injection in pre-filled syringe 284 mg/1.5ml	M/s. Novartis Healthcare Private Limited	The firm presented the proposal for grant of permission to conduct phase IV clinical trial with drugs Inclisiran solution for injection in pre-filled syringe 284 mg/1.5ml before the committee. After detailed deliberation, the committee recommended permission for conducting Phase IV clinical trial with drug Inclisiran solution for injection in pre-filled syringe 284 mg/1.5ml as per the protocol presented.
7.	ND/IMP/23/000058 Cleviprex (Clevidipine) 0.5 mg/mL emulsion for injection	M/s. Paviour Pharmaceuticals	The firm didn't turn up for presentation.