

Recommendations of the SEC (Cardiovascular & Renal) made in its 100th meeting held on 06.04.2021 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
1.	ND/MA/21/000122 Bempedoic acid tablet 180 mg	M/s. Exemed Pharmaceuticals	The firm presented the BE and Phase III CT report before the committee. After detailed deliberation, the committee recommended for grant of permission to manufacture and market the drug for the proposed indication.
SND Division			
2.	SND/MA/20/000221 Ticagrelor SR Tablet 120/180 mg	M/s. Akums Drugs	In light of earlier SEC recommendations dated 10.11.2021 & 11.11.2021, the firm presented the raw data of the BE study conducted on Ticagrelor SR Tablet 120/180 mg. On review of the raw data the committee noted that there is considerable variation between the pharmacokinetic parameters of test and reference product. After detailed deliberation, the committee opined that the raw data should be sent to pharmacologist for his/her comments.
FDC Division			
3.	FDC/MA/19/000025 Pantoprazole Sodium + Aspirinashoka (20mg+81mg & 20mg+150mg) Capsules	M/s. Alkem Laboratories	The firm presented their proposal for amendment in the approved Phase III clinical trial protocol. After detailed deliberation, the committee did not agree for the proposed amendment as justification presented was not adequate.
GCT Division			
4.	CT/24/21 Online Submission (24074) Atrasentan	M/s. IQVIA	In light of earlier SEC recommendation dated 10.06.2021, 11.06.2021 and 14.06.2021, the firm presented Phase III clinical trial proposal before the committee. Assessment of Risk vs. Benefit to the patients: The safety profile of the study drugs from preclinical toxicology studies including repeat dose toxicity, Phase I & Phase II clinical study justify the conduct of the trial. Innovation vis-à-vis Existing

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			<p>Therapeutic option: The purpose of the study is to evaluate the effect of atrasentan versus placebo on proteinuria levels at Week 24.</p> <p>Unmet Medical need in the country: The test drug may potentially provide treatment in patients with IgA Nephropathy at risk of progressive loss of renal function.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the study.</p>
5.	CT/70/18 Online Submission (14981) Etelcalcetide	M/s. Amgen Technology	The committee recommended that the proposal should be deliberated in the next SEC meeting in presence of pediatrician.
Medical Device Division			
6.	IMP/MD/2021/44614 Cytosorb (Polymer Based Adsorbent Cytosorb 300ml Device)	M/s. Biocon Biologics Limited	<p>The firm presented their proposal before the committee.</p> <p>After detailed deliberation, the committee observed that there was no randomized clinical trial data of the proposed product.</p> <p>Hence, the committee recommended that the firm should submit the randomized clinical trial data along with the post market surveillance data of the product.</p>
7.	IMP/MD/2021/49932 Navitor Transcatheter Aortic Valve	M/s. St. Jude Medical India Pvt. Ltd.	<p>The firm presented their proposal before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to import and market the Navitor Transcatheter Aortic valve with the condition that the firm should conduct Phase IV clinical investigation on atleast 10 Indian patients. Accordingly, the firm should submit the protocol for Phase IV clinical investigation within 3 months of approval of the product to this office for further review by the committee.</p>
8.	CI/MD/2021/51498 BioMime Branch Sirolimus Eluting Side branch	M/s. Meril Life Science Pvt. Ltd.	<p>The firm presented their proposal before the committee.</p> <p>The committee observed that there is a reduction in the sample size which is not acceptable.</p> <p>After detailed deliberation, the committee recommended that the firm should</p>

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			comply with all the conditions which have already been approved by the committee.
9.	IMP/MD/201/51377 Epic™ Plus Stented Tissue Valve (Aortic and Mitral), Epic™Plus Supra Stented Tissue Valve (Aortic)	M/s. St. Jude Medical India Pvt. Ltd.	<p>The firm presented their proposal before the committee.</p> <p>The proposal was deliberated by the committee along with cardiac surgeon.</p> <p>After detailed deliberation, the committee recommended for grant of import and market permission of epic plus tissue stented valve (aortic and mitral) and epic plus supra stented tissue valve (Aortic) in the country. Also, the firm should submit PMS data every six months.</p>