Recommendations of the SEC (Cardiovascular & Renal) made in its 101st meeting held on 27.04.2022 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/MA/22/000004 Bempedoic Acid 180mg and Ezetimibe 10mg tablet	M/s. Logos	In light of earlier SEC recommendation dated 08.02.2022, the firm presented BE study protocol before the committee. After detailed deliberation, the committee recommended for grant of permission for conduct of the BE study and to submit the results for further review by the committee.
SND Division			
2.	12-35/2019-DC (Pt-Misc-SND) Dabigatran Etexilate Mesilate capsule 75/110/150 mg	M/s. Boehringer Ingelheim	The firm presented the updated package insert for Dabigatran etexilate mesilate capsule 75/110/150mg. After detailed deliberation, the committee recommended for grant of approval for update of the package insert for Dabigatran etexilate mesilate capsule 75/110/150mg as presented.
3.	SND/IMP/21/000092 Sacubitril/ Valsartan 50/100/200mg tablets	M/s. Sandoz Private	In light of earlier SEC recommendation dated 11.01.2022 & 12.01.2022, the firm presented the detailed justification for the proposed expanded indication. After detailed deliberation, the committee recommended for grant of permission for the proposed additional indication "to reduce the risk of cardiovascular death and hospitalization for heart failure in adult patients with chronic heart failure. Benefits are more clear in patients with left ventricular ejection fraction (LVEF) below normal.
FDC Division			
4.	04-03/2017-DC (Pt. Akums) Cilnidipine 20 mg + Telmisartan IP 40mg Tablets	M/s. Akums Drugs & Pharmaceuticals	The firm presented their proposal before the committee along with BE study protocol and requested for Phase III clinical trial waiver. The committee noted that FDC of Cilnidipine 10mg/10mg + Telmisartan 40mg/80mg tablet is already approved by CDSCO for continued manufacturing and marketing.

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			After detailed deliberation, the committee recommended for grant of permission to conduct the proposed BE study. The firm should present the results of the BE study for further consideration.
5.	FDC/MA/22/000096 Clopidogrel bisulphate eq. To clopidogrel 75mg + Atorvastatin calcium eq. To Atorvastin 40 mg tablets	M/s. Pure & Cure Healthcare Pvt. Ltd.	The firm presented their proposal before the committee along with BE study protocol and requested for Phase III clinical trial waiver. The committee noted that the proposed FDC is already approved in hard gelatin capsule form for proposed indication. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed BE study. The firm should present the results of the BE study for further consideration.
6.	FDC/MA/22/000064 Ezetimibe 10mg + Rosuvastatin 20 mg tablets	M/s. Windlas Biotech Ltd.	The firm presented their proposal before the committee along with BE study protocol and requested for Phase III CT waiver. The committee noted that the proposed FDC is already approved in US. Further, the committee noted that FDC of Ezetimibe + Rosuvastatin tablet is approved by CDSCO in various strengths viz. Ezetimibe + Rosuvastatin tablet (10mg + 10mg & 5mg + 10mg). After detailed deliberation, the committee recommended for grant of permission to conduct the proposed BE study. The firm should present the results of the BE study for further consideration.
GCT Division			
7.	CT/70/18 Online Submission (14981) Etelcalcetide	M/s. Amgen technology	In light of earlier SEC recommendation dated 06.04.2022, the firm presented clinical trial protocol amendment 4 dated 03 Sep. 2021 before the committee. The proposal was deliberated in the presence of paediatrician. After detailed deliberation, the committee recommended for grant of approval to the amended protocol.

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8.	CT/63/21 Online Submission (16525) Ziltivelimab	M/s. Novo-Nordisk	The firm presented clinical trial protocol amendment 5 dated 17 Feb. 2022 before the committee. After detailed deliberation, the committee recommended for grant of approval to the amended protocol.
Medical Device Division			
9.	IMP/MD/2022/55988 Mitris Resilia Mitral Valve (Model11400M)	M/s. Edwards Lifescience	The firm presented their proposal before the committee. The proposal was deliberated in the presence of Cardiac Surgeon. After detailed deliberation, the committee recommended for grant of import and marketing permission of Mitris Resilia Mitral Valve in the country. However, the firm should submit PSUR every six months.
10.	IMP/MD/2021/44475 ACURATE Neo2 Aortic Valve	M/s. Boston Scientific	The firm presented their proposal before the committee. The proposal was deliberated in the presence of Cardiac Surgeon. After detailed deliberation, the committee recommended for grant of import and marketing permission for ACURATE Neo2 Aortic Valve for elderly degenerative aortic stenosis of tricuspid anatomy for marketing in the country with the condition that the firm should conduct post marketing clinical investigation in Indian population. Accordingly, the firm should submit the clinical investigation protocol to CDSCO within three months from date of approval for further review by the committee.
11.	IMP/MD/2021/50993 Aortic Transcatheter heart valve bioprosthesis, stent-like framework	M/s. Boston Scientific India Pvt. Ltd.	The firm presented their proposal before the committee. The proposal was deliberated in the presence of Cardiac Surgeon. After detailed deliberation, the committee recommended for grant of import and marketing permission of Aortic

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			Transcatheter heart valve bioprosthesis, stent-like framework for marketing in the country with the condition that the firm should conduct post marketing clinical investigation on Indian population. Accordingly, the firm should submit the clinical investigation protocol to CDSCO within three months from the date of approval for further review by the committee.