Recommendations of the SEC (Cardiovascular & Renal) made in its 119th meeting held on 08.02.2023 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND/MA/22/000083 Polystyrene Sulphate Jelly 20% w/w	M/s. Pharose Remedies	The firm did not turn up for presentation.
FDC Division			
2.	FDC/MA/23/000008 Ezetimibe 10mg + Atorvastatin Calcium 80mg tablets	M/s. Windlas	The firm presented its proposal of BE study along with justification for Phase III clinical trial waiver and BE study protocol. The committee noted that this FDC has been already approved in various strengths. The firm also informed the committee that this product is already approved in USA. After detailed deliberation, the committee recommended for grant of permission to conduct the BE study. The result of the study should be presented before the committee for further review.
3.	FDC/MA/23/000019 Telmisartan 80 mg + Azelnidipine 16 mg tablets	M/s. Mascot Health Series Pvt. Ltd	The firm presented its proposal of BE study along with justification for waiver of Phase III clinical trial as well as BE study. Committee noted that the product is not approved in any country. After detailed deliberation, the committee recommended that the firm should present the BE and CT study protocol before the SEC for review.
Medical Device Division			
4.	IMP/MD/2022/53336 LKT Disposable Perfusion Circuit, Kidney Transporter	M/s. Renovate Biologics Private Limited	The firm did not turn up for presentation.
5.	CI/MD/2022/72489 Sterile Intraosseous Access / Infusion Device (Ozyn-D™)	M/s. Rcupe Lifesciences Private Limited	The firm presented its pilot clinical investigation protocol before the committee.

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			After detailed deliberation, the committee recommended that the protocol of the proposed clinical investigation should be deliberated with expert of emergency medicine. Accordingly, expert of emergency medicine needs to be invited in next meeting.
6.	CI/MD/2021/50669 Pericardial Bioprosthesis (Dafodil (1st Brand), Dafodil Neo (2nd Brand), Flomero (3rd Brand), Freesia (4th Brand))	M/s. Meril Life Sciences Private Limited	The firm presented its post market clinical investigation protocol before the committee. After detailed deliberation, the committee recommended that the firm should submit 100 patients data with one year follow up as per the condition of earlier approval dated 27.11.2019 prior to considering to examine this case.
7.	CI/MD/2022/69694 Aortic valve (Acurate neo2 Aortic valve)	M/s. Boston Scientific India Private Limited	The firm presented its protocol before the committee. After detailed deliberation, the committee recommended for the grant of post market clinical investigation on Indian population subjected to the following: 1. The sample size should be increased to 30, out of which 15 should be with SENTINEL Cerebral protection system. 2. The age of subject included in study should be greater than 65 years. 3. Fifty percent of the study site should be government hospitals.
8.	CI/MD/2022/69781 Delivery System (Acurate neo2 Transfemoral Delivery System)	M/s. Boston Scientific India Private Limited	The firm presented its protocol before the committee. After detailed deliberation, the committee recommended for the grant of post market clinical investigation on Indian population subjected to the following: 1. The sample size should be increased to 30, out of which 15 should be with SENTINEL Cerebral protection system.

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			2. The age of subject included in study should be greater than 65 years. 3. Fifty percent of the study site should be government hospitals.