Recommendations of the SEC (Cardiovascular & Renal) made in its 116th meeting held on 21.12.2022 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/IMP/22/000056 Regadenoson Injection 80 µg/ml.	M/s. Wipro GE Healthcare Pvt. Ltd.	The firm presented their proposal for import and marketing of the drug Regadenoson Injection 80 µg/ml along with justification for clinical trial waiver before the committee. The committee noted that the drug is already approved in 35 countries and marketed in 28 countries including United States & European Union. After detailed deliberation, the committee recommended for the grant of permission to import and marketing of the drug Regadenoson Injection 80 µg/mlwith local clinical trial waiver for the proposed indication subject to the condition that the firm should conduct Phase IV clinical trial in the country for which the protocol should be submitted to CDSCO within two months of approval of the drug for review by the committee.
Biological Division			
2.	BIO/MA/22/000111 Tenecteplase 30 mg, 40 mg and 50 mg in Vial	M/s. Hetero Biopharma Limited	The firm presented the proposal to manufacture and marketing of the drug Tenecteplase 30 mg, 40 mg and 50 mg in vial for the indication "Thrombolytic treatment of suspected myocardial infarction with persistent ST elevation" along with the results of Phase III local clinical trial. The committee noted the results of the Phase III clinical trial. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of the drug subject to the condition that firm should conduct Phase IV clinical trial in 400 subjects. Accordingly, Phase IV clinical trial protocol should be submitted within 3 months of marketing approval.
FDC Division			
3.	FDC/MA/22/000302	M/s. Exemed	In light of the earlier SEC recommendation dated 10.11.2022, the firm presented their proposal along with

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	Rosuvastatin + Bempedoic Acid (5mg + 180 mg,10mg +180mg, 20 mg + 180 mg) Tablets		Phase III clinical study protocol. After detailed deliberation, the committee recommended that: 1. Patients who are not able to tolerate the dosage of Rosuvastatin more than 20mg should be included in the study. 2. Sample size calculation should be revised. In view of above, revised Phase III clinical trial protocol should be submitted to CDSCO for further review by the Committee.
Medical Device Division			
4.	CI/MD/2022/70839 32 EP (Electrophysiology) Medical devices	M/s St. Jude Medical India Pvt. Ltd.	The firm presented their clinical investigation protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed study with the medical device as per protocol submitted by the firm.
GCT Division			
5.	CT/77/22 Online Submission (33262) Crovalimab	M/s Roche	The firm presented Phase III clinical trial protocol no. BO42354 version 3 dated 08 April 2022 before the committee. After detailed deliberation, the committee recommended that the protocol should be revised w.r.t to inclusion/exclusion criteria as below: 1. Biopsy test should be done for confirmation of TMA. 2. Genetic analysis should be done at the screening visit for diagnosis of aHUS. 3. TB subjects should be excluded from the study on the basis of QuantiFERON-TB Gold (QFT) test which should be done at screening visits and subsequent visits. Accordingly, the firm should submit revised protocol along with data of globally enrolled 27 adult subjects before the committee for further review.