Recommendations of the SEC (Cardiovascular) made in its 10th/26 meeting held on 22.07.2026 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Medical Device Division			
1)	CI/MD/2025/174829 Sirolimus-Tirofiban HCl Eluting Coronary Stent System	M/s. Clicebo Solutions Private Limited.	The firm presented the proposal for grant of permission to conduct a pivotal clinical investigation of the medical device, namely "Sirolimus–Tirofiban HCl Eluting Coronary Stent System (DualDES)", manufactured by M/s Zydus Medtech Private Limited, India. After detailed deliberation, the Committee recommended that the proposal may be considered, subject to the following conditions: 1. The applicant shall submit progress reports data of the study to CDSCO at interval of three-months periodically till completion of the study. 2. The clinical investigation shall be conducted at least 50% of the study sites from Government medical institutions.
2)	CI/MD/2025/173589 (Form MD-22) Rigid Tilting Disc Heart Valve Substitute (TTK Chitra - Titanium Aortic Heart Valve and Titanium Mitral Heart Valve)	M/s. TTK Healthcare Limited.	The proposal for the grant of permission to conduct Clinical investigation on the device viz. Rigid Tilting Disc Heart Valve Substitute (TTK Chitra - Titanium Aortic Heart Valve and Titanium Mitral Heart Valve) was put up for deliberation in the SEC (Cardiovascular) meeting. The experts opined that due to the absence of Cardio-Thoracic Surgeon, the proposal is deferred for now and will be taken up in the upcoming SEC meeting in the presence of Cardio-Thoracic Surgeon.
New Drug Division			
3)	ND/IMP/26/000012 Baxdrostat Tablets 1 mg and 2 mg	M/s. AstraZeneca Pharma India Limited.	The firm presented the proposal for grant of permission for Import and Marketing of the drug Baxdrostat Tablets 1 mg and 2 mg along with Phase III Global Clinical Trial Report before the committee. The firm also presented details of Phase III global clinical trial with 47 participation of Indian subjects. The committee noted that the applied drug is approved in USA on 15 May 2026.

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			After detailed deliberation, the Committee noted the clinical data presented by the firm has very less number of Indian patients. Therefore, the firm needs to give clinical data on more number of Indian subject on proposed indication especially in view of serious side effect of hyperkalemia. The committee further noted that the placebo corrected reduction in blood pressure was about 10 mmHg. The committee noted that the firm has not given the cut-off for serum potassium level before initiation of Baxdrostat. Further, the committee noted that there is available medication for the proposed indication and the Baxdrostat would required more clinical data on Indian patients to establish safety and efficacy. In view of the above, the committee recommended that the firm should submit more clinical data on Indian patients for proposed indication for further review by the committee.