Recommendations of the SEC (Haematology) made in its 04th/26 meeting held on 16.04.2026 at CDSCO HQ New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/32/26 Online Submission (55238) VAY736 (Ianalumab)	M/s. Novartis Healthcare Private Limited	The firm presented phase II clinical study protocol no.: CVAY736Q12202B version no. 00 dated 18-FEB-2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
Biological Division			
2.	E-receipt No. 128009 Crizanlizumab 10 mg/mL	M/s. Sandoz Private Limited	The firm did not attend the meeting.
New Drugs Division			
3.	ND/MA/24/000160 Avatrombopag 20 mg tablet	M/s. MSN Laboratories Private Limited	In light of earlier recommendation dated14.05.2025, firm has presented the proposal for grant of permission to manufacture and market Avatrombopag tablet 20 mg along with Phase III Clinical Trial Protocol (Protocol No: AVATROM/MSN/P3/2026, version 1.0 dated 27th Jan 2026) before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct Phase III clinical trial of Avatrombopag tablet 20 mg as per the protocol presented by the firm. The results of Phase III Clinical Trial should be submitted to CDSCO for further review by the committee
SND Division			
4.	SND-11011/12/2026-eoffice Asciminib film-coated tablets 20 mg, 40 mg and 100 mg.	M/s. Novartis Healthcare Private Limited	Firm presented their proposal for updation in prescribing information of Asciminib film-coated tablets 20 mg, 40 mg and 100 mg in line with US approved Package Insert with respect to Drug Interactions and Clinical trials experience. After detailed deliberation, the committee recommended for grant of approval for the proposed updates in the prescribing information as presented by the firm

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
Blood Product Division			
5.	BD PRO-11015(11)/6/2025-eoffice (Comp. No. 30618) Fibrogen-I (Human Fibrinogen EP 0.5 gm/1 gm), Freeze-Dried powder	M/s. Intas Pharmaceuticals Ltd.	The firm has presented the revised protocol (revised as per the recommendations given by the committee during the SEC meeting held on 13.01.2026) for the proposal to conduct phase III Clinical trial titled: "A Prospective, Phase 3, Open-label, Single arm, Uncontrolled Study to Assess the Efficacy and Safety of Fibrogen-I (Human Fibrinogen Injection) in Bleeding Adult Cardiac Surgical Patients with Acquired Fibrinogen Deficiency" vide Protocol No. 0463-25, Version: 1.1 dated 21-Feb-2026. After detailed deliberation, the committee has recommended that: • The firm should submit a revised protocol by including a suitable comparator arm for the study to assess efficacy. • The firm should propose suitable statistically powered sample size. Accordingly, the firm shall submit the revised protocol in line with above recommendations for re-deliberation in the upcoming SEC meeting.