Recommendations of the SEC (Haematology) made in its 10th/25 meeting held on 15.10.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/131/25 Online Submission (51815) VGA039	M/s Worldwide Clinical Trials India Private Limited	The firm presented phase III clinical study protocol no.: VGA039-CP002 version no. 1.0 dated 12-MAY-2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with condition that the firm shall submit supportive pharmacokinetic data in details to CDSCO.
Biological Division			
2.	E-receipt no. 103876 Concizumab solution for injection 15 mg/1.5 mL, 60 mg/1.5 mL, 150 mg/1.5 mL and 300 mg/3 mL (r-DNA origin) in pre-filled pen	M/s Novo Nordisk India Private Limited.	The firm presented a proposal to conduct a PMS study titled, "A Non-Interventional, Observational Study to Investigate the Safety of Concizumab Treatment in Patients with Haemophilia A or B with Inhibitors During Routine Clinical Practice", vide protocol no. NN7415-861 Version 1.0 dated 28 July 2025. After detailed deliberation, the committee recommended for grant of permission to conduct PMS study as per the protocol presented by the firm.
New Drug Division			
3.	ND/MA/24/000006 Sodium Ferric Maltol Capsules 30 mg	M/s Emcure Pharmaceuticals Limited	The firm did not turn up for the presentation.
SND Division			
4.	SND/MA/23/000210 Enoxaparin Sodium Injection 60 mg/0.6 ml prefilled syringe (Ovine source) (s.c) for s/c use.	M/s Virchow Biotech Private Limited	Firm presented their proposal for manufacture and marketing Enoxaparin Sodium Injection 60 mg/0.6 ml prefilled syringe (Ovine source) s.c for approved indication along with Phase III clinical trial and Bioequivalence study protocol before the Committee. After detailed deliberation, the committee recommended for grant of permission to conduct Bioequivalence study and Phase III clinical trial. Further, the firm should submit Bioequivalence report for review by the SEC committee before initiating the Phase III clinical trial