Recommendations of the SEC (Haematology) made in its 11th/25 meeting held on 25.11.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/71/24 Online Submission (41543) REGN7999	M/s PAREXEL International Clinical Research Private Limited	The firm presented Protocol Amendment 4, dated 25-Jun-2025 for waiver of the condition of initial clinical trial permission dated 25 - Sep - 2024, permission to conduct PART B of study in India and Increase in the number of participants in India from 19 to 26 (protocol no. R7999-BTHAL-2350). After detailed deliberation, the committee recommended for approval of Protocol Amendment 4, dated 25-Jun-2025 as presented by the firm.
2.	CT/154/25 Online Submission (52714) Elritercept	M/s IQVIA RDS (India) Private Limited	The firm presented phase III clinical study protocol no. KER-050-D301 Amendment 1 dated 23 June 2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
3.	CT/104/25 Online Submission (50961) Fitusiran (SAR439774)	M/s SANOFI HEALTHCARE INDIA PRIVATE LIMITED	In light of earlier SEC recommendation dated 19.08.2025, the proposal was deliberated again. The firm presented phase III clinical study protocol no. EFC17905 version 1 dated 22 May 2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with condition that firm shall submit reports of any outcomes/events related to thrombosis for first 10 participants to the CDSCO.
Biological Division			
4.	BIO/CT18/FF/2025/51142 Concizumab Injection 15 mg/1.5 mL, 60 mg/1.5 mL, 150 mg/1.5 mL and 300 mg/3 mL, solution for injection (r-DNA Origin)	M/s Novo Nordisk India Pvt. Ltd.	The firm presented a proposal for grant of approval of additional indications of Concizumab Solution for Injection 15 mg/1.5 mL, 60 mg/1.5mL, 150 mg/1.5mL and 300 mg/3 mL, (r-DNA Origin). The committee noted that the subject drug is approved in India since May, 2025 for the routine prophylaxis of bleeding in patients with (1) Haemophilia A (congenital factor VIII deficiency) with FVIII inhibitors and of 12 years of age or more and (2) Haemophilia B (congenital

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			factor IX deficiency) with FIX inhibitors and of 12 years of age or more. After detailed deliberation, the committee recommended for grant of approval for the proposed additional indications where subject drug is indicated for routine prophylaxis of bleeding in patients 12 years of age or more with (1) severe haemophilia A (congenital factor VIII deficiency, FVIII < 1%) without FVIII inhibitors and (2) moderate/ severe haemophilia B (congenital factor IX deficiency, FIX ≤ 2%) without FIX inhibitors; in-line with EMA approval subject to the condition to conduct PMS study in the proposed indications in significant number of subjects. Accordingly, the protocol to conduct the PMS study shall be submitted to CDSCO within 3 months of grant of approval for the proposed indications.
5.	BIO/CT04/FF/2025/51323 Crovalimab solution for infusion (r-DNA origin) 340 mg/2ml (170 mg/ml) in a single-dose vial	M/s Roche Products (India) Pvt. Ltd	The Firm did not turn up for the presentation.
FDC Division			
6.	FDC/MA/25/000165 Heparin Sodium IP 50 IU + Benzyl Nicotinate 2 mg + Sorbic Acid IP 1.97 mg (Preservative) per gram Ointment	M/s Curetech Skincare	In light of DTAB subcommittee report dated 28.12.2021 wherein expert committee recommended "To conduct Phase IV clinical trial to show efficacy and safety of the product, with efficacy as the primary objective in statistically significant number of patients. Protocol should be approved by SEC and study should be completed within one year" for the proposed FDC. Accordingly, the firm presented the Phase IV clinical trial protocol before the committee. After detailed deliberation, the committee opined that: 1. Firm should investigate the patients for undiagnosed bleeding disorder.

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			Such patients should not be enrolled in the study. 2. Monitor the patients for development of Heparin Induced Thrombocytopenia (HIT) Accordingly, the firm should submit revised Phase IV CT protocol to CDSCO for further review by the committee.