Recommendations of the SEC (Haematology) made in its 08h/25 meeting held on 19.08.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/44/23 Online Submission (40618) Cemdisiran 200 mg/ml Solution for subcutaneous Administration + Pozelimab 200 mg/ ml Solution for intravenous or subcutaneous administration	M/s PAREXEL International Clinical Research Private Limited	The firm presented protocol amendment 6 dated 24 April 2025 protocol no. R3918-PNH-2021. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
2.	CT/98/23 Online Submission (40621) Cemdisiran (ALN-CC5) 200 mg/ml Solution for subcutaneous Administration + Pozelimab (REGN3918) 200 mg/ml Solution for intravenous or subcutaneous administration	M/s PAREXEL International Clinical Research Private Limited	The firm presented protocol amendment 5 dated 13 May 2025 protocol no. R3918-PNH-2050. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
3.	CT/70/24 Online Submission (40633) Etavopivat	M/s Syneos Health India Private Limited	The firm presented protocol amendment 7 dated 10 June 2025 protocol no. 4202-HEM-301. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
4.	CT/108/24 Online Submission (40585) Mavorixafor	M/s Novotech Clinical Research India Private Limited	The firm presented for CT Waiver condition that if ECG abnormalities are observed, the PI shall withdraw the subsequent dosing of the drug and re-evaluate the patient for underlying cause protocol no. X4P-001-110. After detailed deliberation, the committee did not recommend CT Waiver condition.
5.	CT/104/25 Online Submission (50961)	M/s SANOFI HEALTHCARE INDIA PRIVATE	The firm presented phase III clinical study protocol no. EFC17905 version 1 dated 22 May 2025.

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	Fitusiran (SAR439774)	LIMITED	After detailed deliberation, the committee has expressed concerned over the adequacy of sample size for proposed Phase III study. The firm shall submit technical justification for adequacy of sample size in all sub-group of proposed study to investigate the safety & efficacy of fitusiran prophylaxis in male participants age 1 to less than 12 year with or without inhibitory antibodies to Factors VIII or IX to CDSCO for further review of committee.
Biological Division			
6.	E-77852 Crizanlizumab 10 mg/mL	M/s. Sandoz Private Limited	Under Discussion.
SND Division			
7.	SND/MA/24/000235 Eltrombopag for oral suspension 12.5 mg and 25 mg	M/s. Zydus Lifesciences Limited	The firm presented the proposal for grant of permission for manufacture and marketing of the Eltrombopag for oral suspension 12.5 mg and 25 mg (Additional Dosage form) along with BE study report and justification for Clinical trial waiver for Proposed indications before the committee. The Committee noted that Eltrombopag tablets 12.5 mg /25 mg/50 mg/75 mg approved by CDSCO. Further, It is also noted that Eltrombopag for oral suspension 12.5 mg and 25 mg also approved in US, UK and various EU countries. After detailed deliberation, the committee recommended for grant of permission to manufacture and marketing of the Eltrombopag for oral suspension 12.5 mg and 25 mg with local clinical trial waiver with condition to conduct Phase-IV study. Accordingly, the firm should submit Phase IV study protocol to CDSCO within 03 months of approval
FDC Division			
8.	FDC/MA/23/000218	M/s Albert David Limited	The firm did not turn up for the presentation.

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	Ferrous Fumarate (eq. to 49.5 mg elemental Iron) 150 mg IP + L-Histidine HCL.H2O 4 mg BP + L-Lysine HCL 25 mg IP + Glycine 10 mg IP + Thiamine Mononitrate (Vitamin B1) 5 mg IP + Riboflavin (Vitamin B2) 3 mg IP + Pyridoxine HCL (Vitamin B6) 1.5 mg IP + Cyanocobalamin (Vitamin B12) 2.5 mcg IP + Folic Acid (Vitamin B9) 500 mcg IP + Ascorbic Acid (Vitamin C) 40 mg IP + Zinc Sulphate 50 mg IP capsule		