

**Recommendations of the SEC (Haematology) made in its 06<sup>th</sup>/25 meeting held on 28.05.2025 at CDSCO HQ New Delhi:**

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>GCT Division</b>			
1.	CT/64/19 Online Submission (38679)  Concizumab	M/s. Novo Nordisk India Pvt. Ltd.	The firm presented protocol amendment version 8.0 dated 31 January 2025 protocol no. NN7415-4307.  After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
2.	CT/108/24 Online Submission (38790)  Mavorixafor	M/s Novotech Clinical Research India Private Limited	The firm presented protocol amendment version 3.0 dated 10 Feb 2025 protocol no. X4P-001-110.  After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm with 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.
3.	CT/42/25 Online Submission (49174)  Etavopivat 200 mg	M/s Novo Nordisk India Pvt Ltd	The firm presented phase IIIb clinical study protocol no.: NN7535-7822 version no. 1.0 dated 03-May-2024. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
<b>Biological Division</b>			
4.	E-84343 r-DNA- 11015(11)/2/2025-  Eculizumab concentrate for solution for infusion 300 mg (10mg/ml) [Soliris]	M/s AstraZeneca Pharma India Ltd	The firm presented the proposal to conduct the Post Marketing Surveillance Study (PMS) in India for Eculizumab concentrate for solution for infusion 300 mg (10mg/ml) (Soliris) titled "A Prospective, Observational, Multicenter, Post Marketing Surveillance Study to assess safety of Eculizumab in Indian patients with Paroxysmal Nocturnal Hemoglobinuria (PNH)" vide study code D7414R00002 Version 1.0 dated 09.04.2025 as per the condition of Marketing Authorization approval.  After detailed deliberation, the committee recommended for grant of permission to conduct the Post Marketing Surveillance Study (PMS) as per the protocol presented by the firm.

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5.	E-81268 and E-81576  Pegylated Erythropoietin 100 mcg/0.3 ml injection	M/s. Cliantha Research Limited	<p>In light of earlier SEC recommendation dated 23.07.2024, the firm presented the safety data of initial ten subjects (five in each arm of test and reference product) for further continuation of the PK/PD study of Pegylated Erythropoietin 100 mcg/0.3 ml injection (PEG-EPO) conducted vide protocol no. C1B02794 Version 02 dated 25.04.2024.</p> <p>The committee noted the interim safety data of initial ten subjects (five in each arm of test and reference product) and recommended for further continuation of the study.</p>