

Recommendations of the SEC (Haematology) made in its 11th/24 meeting held on 09.10.2024 at CDSCO (HQ), New Delhi:

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/16/22 Online Submission (31558) Concizumab	M/s. Novo Nordisk India Pvt. Ltd.	In light of earlier SEC recommendation dated on 18.04.2024, now the firm has presented protocol amendment version 2.0 dated 06 October 2023 protocol no. NN7415-4616 and increase the number of subjects from India. After detailed deliberation, the committee recommended for approval of protocol amendment and increase the number of subjects from 15 to 35 with following conditions:- 1. Patient less than 3 years shall not be enrolled in the study. 2. Informed consent form and patient information sheet should comply the above condition no. 1 and same should be approved by CDSCO. Dr. Rajesh Kashyap didn't participate. Dr. R.K Jena didn't participate.
2.	CT/31/24 Online Submission (34586) Human cell line recombinant Factor VIII	M/s. Allucent (India) Private Limited	The firm presented protocol amendment version 6.0 dated 31 May 2024 protocol no. GENA-22. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
3.	CT/108/24 Online Submission (45065) Mavorixafor	M/s. Novotech Clinical Research India Private Limited	The firm presented phase 3 clinical study protocol no. X4P-001-110 version 2.0 dated 05 July 2024. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
Biological Division			
4.	BIO/CT18/FF/2024/4 4212 Crovalimab solution for infusion 340mg/2ml	M/s. Roche Products (India) Private Limited	The firm presented the proposal for grant of permission to import and market, Crovalimab solution for infusion 340mg/2ml in a single-dose vial indicated for the treatment of paroxysmal nocturnal hemoglobinuria (PNH) based on the data generated from global clinical trials with request for local clinical trial waiver in India.

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			<p>The committee noted that the drug is approved in 35 countries including USA, EU, Japan and other countries. The committee also noted that crovalimab is an orphan drug and proposed for the treatment of rare disease.</p> <p>After detailed deliberation, the committee recommended for grant of permission to import and market the drug with waiver of local Phase III clinical trial with following conditions –</p> <ol style="list-style-type: none"> 1. The drug should be prescribed by hematologist only. 2. The drug should be prescribed for the treatment of hematological disorder PNH patients only. 3. The firm is required to conduct Phase IV study in India. Accordingly, the firm should submit protocol for Phase-IV study within 3 months of grant of permission. <p>The firm should modify the proposed indication in line with USFDA approved indication. Accordingly, the firm should submit the revised Form CT-18 to CDSCO.</p>
New Drugs Division			
5.	ND/MA/24/000006 Ferric Maltol Capsules 30 mg	M/s. Emcure Pharmaceuticals Limited	<p>The firm presented the proposal for grant of permission to manufacture and market Ferric Maltol 30 mg capsule along with BE study report.</p> <p>After detailed deliberation, the committee recommended following:</p> <ol style="list-style-type: none"> 1. Firm needs to submit inter-subject variability data. 2. Also, firm needs to submit time versus concentration data for all subjects who participated in the study for further review. 3. Firm needs to submit justification for Clinical Trial waiver.