

**Recommendations of the SEC (Haematology) made in its 04<sup>th</sup>/25 meeting held on 08.04.2025 at CDSCO (HQ), New Delhi:**

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>GCT Division</b>			
1.	CT/147/22  Online Submission (38084)  VAY736 (Ianalumab)	M/s Novartis Healthcare Private Limited	The firm presented protocol amendment version 05 dated 27 January 2025 protocol no. CVAY736I12301.  After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
<b>Biological Division</b>			
2.	BIO/CT18/FF/2023/38926  Recombinant Human Coagulation Factor VIII for Injection 250IU/1000IU (r-DNA origin)	M/s. Urihk Pharmaceutical Private Limited .	The firm presented the proposal for grant of permission to import and market Recombinant Human Coagulation Factor VIII (SCT800) Injection 250 IU/1000 IU for treatment and prophylaxis of bleeding episodes of hemophilia A patients with request for local clinical trial waiver based on the clinical trial conducted in China.  The firm has claimed that the drug falls under the category orphan drug and there is an unmet medical need in the country. The committee noted that the drug is approved only in China and there is no safety and efficacy data generated from other countries other than China.  After detailed deliberation, the committee did not consider the firm's proposal to import and market the drug product Recombinant Human Coagulation Factor VIII (SCT800) for Injection 250 IU/1000 IU with waiver of Phase III clinical trial.
3.	BIO/CT04/FF/2025/47411  Erythropoietin 4000 IU Pre-filled syringe for intravenous injection	M/s. Azidus Laboratories Limited	The firm presented the proposal to conduct PK/PD study titled "An open label, balanced, randomized, two treatments, two sequences, two periods, single dose, crossover study to evaluate bioequivalence between Recombinant human Erythropoietin 4000 IU Pre-filled syringe for intravenous injection of Iclos Uruguay S.A. and Eprex (Erythropoietin)

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			4,000 IU/mL solution for injection in pre-filled syringe of Janssen-Cilag Ltd in healthy, adult, human subjects after subcutaneous administration through Pharmacokinetic and Pharmacodynamic profiles” vide protocol AZBE072412Version: 1.0 Date: 01-AUG-2024. After detailed deliberation, the committee recommended for grant of permission to conduct the PK/PD clinical study as per the protocol presented by the firm.
4.	E-51459,51559  Crizanlizumab concentrate for solution for infusion 10mg/ml(100mg/10ml)	M/s Sandoz Pvt Ltd	The firm didn't turn up for the presentation.
<b>SND Division</b>			
5.	SND/CT/25/000012  Desidustat Tablets 120 mg	M/s Zydus Lifesciences Ltd	The firm presented the proposal for grant of permission to conduct Phase-III clinical trial of Desidustat Tablets 120 mg along with Phase-III clinical trial protocol (protocol ref No. DESI.23.002, ver 01 dated 23/01/2025) before the committee. Firm presented that, Desidustat tablets 25mg/ 50mg/ 100mg were approved in India for the treatment of Anemia in Adult patient with Chronic Kidney Disease (CKD).  After detailed deliberation, the committee recommended for grant of permission to conduct Phase-III clinical trial of Desidustat Tablets 120 mg for treatment of chemotherapy induced anemia in patients with solid tumor malignancy as per Protocol presented and submit the report to CDSCO for further necessary action.
<b>Blood Product Division</b>			
6.	X-11026/34/2024-BD (E-office: BD PRO-11015(11)/1/2024-eoffice)	M/s. Virchow Biotech Private Limited, Gagillapur Village, Dundigal	The firm has presented the revised protocol (revised as per the recommendations given by the experts during the SEC meeting held on 11.02.2025) for the proposal to conduct

**SEC (Haematology) meeting dated 08.04.2025**

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	Human Normal Immunoglobulin for Intravenous Administration IP/Ph. Eur./BP 5%, 100 mL (IVIG)	Gandimaisamma Mandal, Medchal-Malkajgiri District, Telangana – 500043	<p>phase III Clinical trial titled: “An Open- Label, Multicentre, Phase III Clinical Comparative Study to evaluate the Efficacy, Safety and Pharmacokinetic properties of Human Normal Immunoglobulin in patients with primary immunodeficiency disease” vide Protocol No. VBIVIG/2024-CT1 Version: 2 dated 14.02.2025.</p> <p>After detailed deliberation, the committee has recommended for the grant of permission to conduct Phase III Clinical Trial as per revised protocol No. VBIVIG/2024-CT1 Version: 2 dated 14.02.2025.</p>