Recommendations of the SEC (Hematology) made in its 01st /25 meeting held on 16.01.25 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/104/22 Online Submission (36089) NNC 0365-3769 (Mim8)	M/s Novo Nordisk India Pvt Ltd	The firm presented 26 weeks interim efficacy and safety data of the study for all patients in India as per CT NOC condition no. 1 for protocol no. NN7769-4516. After detailed deliberation, the committee noted and accepted the interim data presented by the firm.
2.	CT/63/19 Online Submission (36492) Concizumab	M/s Novo Nordisk India Pvt Ltd	The firm presented protocol amendment version 11.0 dated 07 October 2024 protocol no. NN7415-4311 (EXPLORER 7). After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
3.	CT/91/24 Online Submission (36585) Etavopivat 200mg	M/s Novo Nordisk India Pvt Ltd	The firm presented protocol amendment version 3.0 dated 30 Sep 2024 protocol no. NN7535- 7807 (HIBISCUS 2). After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
Biological Division			
4.	E-54414 Recombinant Human Erythropoietin alfa Injection	M/s. Intas Pharmaceuticals Ltd.	In light of earlier SEC recommendations dated 05.03.2024, the firm presented the safety data from Indian population including PSUR safety data of the drug Recombinant Human Erythropoietin alfa Injection 3000 IU/0.3ml, 5000 IU/0.5ml, 6000 IU/0.6ml, 2000 IU/1.0ml, 4000 IU/1.0ml, 10000 IU/1.0ml, 40000 IU/1.0ml (PFS) and 20000 IU/2.0ml (vial) to support the changes in Sections 4.2, 4.4 and 4.8 of Package insert. After detailed deliberation, the committee recommended for the approval of updated package insert Version 2of the drug product for proposed changes.

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5.	r-DNA-11016(13)/27/2024-eoffice (E-54034) Romiplostim injection 250mcg/vial	M/s. Enzene Biosciences Ltd	The firm presented the CSR of Phase IV study titled "A phase IV, open label, single-arm, multi-centre clinical study to evaluate the safety and efficacy of Romiplostim in patients with chronic immune thrombocytopenic purpura" conducted vide Protocol No. ALK24-ROMI2 Version: 1.0 dated 15.02.2022. After detailed deliberations, the committee noted the results of the study conducted by the firm.
6.	BIO/CT18/FF/2024/45824 Antihemophilic Factor (Recombinant Factor VIII) 250, 500, 1000, 2000 and 3000 IU Lyophilized Powder for Solution for Intravenous Injection	M/s Bayer Pharmaceuticals Pvt. Ltd	The firm presented the proposal for grant of permission to import and market the drug product Antihemophilic Factor (Recombinant Factor VIII) Octocogalfa 250, 500, 1000, 2000 and 3000 IU Lyophilized Powder for Solution for Intravenous Injectionwith the request for local clinical trial waiver for the following indications- For use in adults and children with hemophilia A (congenital Factor VIII deficiency) for: • On-demand treatment and control of bleeding episodes • Perioperative management of bleeding • Routine prophylaxis to reduce the frequency of bleeding episodes The firm presented that around 4800 patients are exposed to their drug in India since 2019 through donation to Hemophilia Federation of India via WHF. The committee noted that the firm did not present the complete safety and efficacy data from the global clinical trials. After detailed deliberation, the committee recommended the firm to present following information before the committee for further review - 1. Complete data of safety and

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			efficacy from the clinical studies conducted globally along with subset analysis of subjects participated from Asian countries. 2. Safety data in comparison with other Factor VIII drugs used in the centres where HFI donated the drug.