Recommendations of the SEC (Haematology) made in its 05th/24 meeting held on 18.04.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/147/22 Online Submission (31455) Ianalumab (VAY736)	M/s. Novartis	The firm presented protocol amendment version 03 dated 27 Apr 2023 and protocol amendment 04 dated 14 Dec 2023, protocol No. CVAY736I12301. After detailed deliberation, the committee recommended for approval of protocol amendments as presented by the firm.
2.	CT/31/24 Online Submission (42138) Human cell line recombinant Factor VIII	M/s. Allucent	The firm presented Phase III clinical study protocol GENA-22 version 4.0 (India only) dated 20 Oct 2023. After detailed deliberation, the committee recommended for grant of permission to conduct the trial.
3.	CT/16/22 Online Submission (31558) Concizumab Prophylaxis	M/s. Novo-Nordisk	The firm presented protocol amendment version 2.0 dated 06 Oct 2023 and increase the number of subjects from India, protocol No. NN7415-4616. After detailed deliberation, the committee opined the following:- 1. The age limit for pediatric population between 6-12 years shall be approved. 2. The lower age limit shall be defined in the protocol. 3. For recruitment of patients below 6 years, data from respective studies conducted in other countries shall be submitted. Accordingly, the firm shall submit revised protocol and relevant data for further review by the committee.
Biological Division			
4.	r-DNA-11013(12)/2/2024-eoffice Octocog Alfa (Coagulation Factor VIII (recombinant)	M/s. Takeda Biopharmaceuticals India Pvt. Ltd	The firm presented the final clinical study report (CSR) vide No. TAK-761-4009 version 1.1 dated 20th Nov 2023 of clinical study "Phase 4, multicenter, prospective, interventional, post-marketing study in Hemophilia A patients in India receiving ADVATE as on-

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	rFVIII) 500 IU vials and 1000 IU vials		demand or prophylaxis under standard clinical practice" vide protocol No. TAK-761-4009, version 1.0 dated 01 DEC 2022 before the committee. After detailed deliberation, the committee noted the results of the Phase IV clinical trial presented by the firm.
5.	BIO/CT18/FF/2023/40718 Eculizumab Concentrate for solution for infusion 300 mg	M/s. AstraZeneca Pharma India Limited	The firm presented the proposal for grant of permission to import and market Eculizumab concentrate for solution for infusion 300 mg for the indication "the treatment of patients with Paroxysmal nocturnal hemoglobinuria (PNH)" along with request for local clinical trial waiver. The committee noted that the drug falls under the category of orphan drug and there is an unmet need in India. The drug is approved in US and other countries. After detailed deliberation, the committee recommended for grant of permission to import and market of the drug for indication i.e., "the treatment of patients with Paroxysmal nocturnal hemoglobinuria (PNH)" subject to the condition that the firm should conduct Active PMS study. Accordingly, the firm should submit Active PMS study protocol to CDSCO within 03 months of Marketing Authorization for review by the committee.
BA/BE Division			
6.	File No. 12-09/2024/BA-BE/MISC-24/DC BABE/CT05/FF/2023/40878 lenalidomide TDS 8% (50mg/50cm2) and Lenalidomide TDS 5% (31.3 mg/50cm2)	M/s. Raptim Research Ltd., Navi Mumbai-400710	The firm presented the protocol No.: PR/BE/23/250 ver. 00 dated 01.12.2023 for BA/BE study for export purpose. The committee observed that the applied product, transdermal patch of lenalidomide TDS 8% (50mg/50cm2) and Lenalidomide TDS 5% (31.3 mg/50cm2) are not approved Globally. After detailed deliberation, the committee opined that the firm is required to submit animal toxicity data for the applied

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			product(s). Accordingly, the firm should submit the above information for re-deliberation before the SEC.