Recommendations of the SEC (Haematology) made in its 07th/26 meeting held on 14.07.2026 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/84/26 Online Submission (57410) Denecimig	M/s. Novo Nordisk India Pvt. Ltd.	The firm presented phase IIIb clinical study protocol no. NN7769 – 7602 version no. 4.0 dated 13 May 2026. After detailed deliberation, the committee opined that the firm shall submit revised protocol considering the following parameter for further review by the committee: 1. Clearly define the clinical conditions and underlying etiologies of Acquired Haemophilia A (AHA) eligible for inclusion in the study (e.g., malignancy, connective tissue disorders, postpartum AHA, idiopathic AHA, etc.). 2. The inclusion criteria shall specify that adequate representation of patients with both low and high inhibitor titres will be ensured, with appropriate justification for the proposed enrolment strategy. 3. Describe that the investigational product is intended as an adjunct to the current standard-of-care management of bleeding episodes in AHA and not as a replacement for treatment of the underlying cause. 4. Provide details of the efficacy evaluation methodology, including how the treatment effect attributable to the investigational product will be distinguished from the effects of standard-of-care therapy and management of the underlying etiology, considering the heterogeneous clinical presentation of AHA.
Biological Division			
2.	e-receipt 155042/2026/CRU File No.: r-DNA-11016(13)/22/2024-eoffice Crizanlizumab Concentrate for solution for infusion 10 mg/mL (100mg/10 mL)	M/s. Sandoz Private Limited.	The firm did not attend the meeting.