Recommendations of the SEC (Haematology) made in its 12th/25 meeting held on 11.12.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT04/FF/2025/51614 Antihemophilic Factor (Recombinant Factor VIII) PEGylated-aucl 500, 1000, 2000 and 3000 IU lyophilized powder for solution, for intravenous use	M/s Bayer Pharmaceuticals Pvt. Ltd.	The firm presented the proposal for grant of permission to conduct Phase IV clinical trial titled " A prospective, multi-center, non-comparative, open-label, post-authorization, Phase IV study to assess the safety and treatment outcomes of Damoctocog alfa pegol or on demand treatment in patients with Hemophilia A in routine clinical practice in India vide Protocol No. 23089, v1.0 dated 19 Aug 2025. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase IV clinical trial subject to the following conditions- 1. Safety follow up for all patients should be done for 24 weeks for AEs and SAEs. 2. Sample size to be increased to 120 patients considering 8.3% incidence of adverse events. Accordingly, firm should submit revised protocol to CDSCO for further evaluation.
New Drugs Division			
2.	ND/IMP/25/000095 Fitusiran Solution for subcutaneous injection 50 mg/ 0.5 mL (Prefilled Pen) & Fitusiran Solution for subcutaneous injection 20 mg/ 0.2 mL (vial) (Qfitlia)	M/s. Sanofi Healthcare India Private Limited	The firm did not turn up for the presentation.
3.	ND/MA/23/000131 Avatrombopag tablets 20 mg	M/s BDR Pharmaceuticals International Pvt Ltd	In the light of earlier SEC recommendation dated 11.02.2025, firm presented Phase-III Clinical trial protocol of Avatrombopag Tablets 20 mg (Study Code: CT/25/003 Protocol Version No.: Final 00 Dated: 18/09/25) w.r.t. the indication: - treatment of severe thrombocytopenia in adult patients with chronic liver disease who are scheduled

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			to undergo an invasive procedure, before the committee. After detailed deliberation, the committee recommended that firm need to revise the study protocol with following provisions: 1). The platelet function test and point of care testing during the follow-up has to be detailed in the protocol. 2). The proposed treatment group should be stratified according to the platelet count (less than 40,000/ µl or 40,000-50,000/ µl) for adequate representation of 60 mg and 40 mg of drug group. Accordingly, the sample size and randomization proportion should be revised. 3). Firm should clarify their risk stratification (low, moderate and high) on the basis of thrombocytopenia or the procedure itself. Accordingly, the firm should submit the revised Phase-III Clinical trial protocol to CDSCO for further review by the committee.