Recommendations of the SEC (Haematology) made in its 05th/25 meeting held on 14.05.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/117/22 Online Submission (37780) Fitusiran (SAR439774)	M/s Sanofi Healthcare India Private Limited	The firm presented protocol amendment 05 version 1 dated 30 July 2024 protocol no. EFC17574. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
2.	CT/36/25 Online Submission (48829) Plasma Derived Human coagulation factor VIII Product	M/s IQVIA RDS (India) Private Limited	The firm presented phase I/III clinical study Protocol No. SKP0141HemAI/III2024 version No. 2.0 dated 19- MAR-2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with following condition: 1 More geographically distributed government site shall be included. 2 Safety data of already approved product shall be submitted.
Biological Division			
3.	BIO/CT04/FF/2025/47738 Romiplostim powder for solution for injection (250mcg/vial)	M/s. Enzene Biosciences Ltd.	The firm presented the proposal for grant of permission to conduct Phase I clinical trial titled "A single center, randomized, phase-I, double-blind, balanced, pivotal, single period, 3-arm, 2-stage, three-treatment, single-dose, adaptive design, parallel study to assess pharmacokinetic of ENZ210 [Enzene Romiplostim Powder for Solution for Injection (Intravenous administration)] in comparison with US licensed Nplate®-R1 and the EU approved Nplate®-R2 in healthy adult human subjects under fasting conditions" for export purpose vide protocol no. CL-002-25; Version No. 00; Dated: 06.02.2025. After detailed deliberation, the committee

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			recommended for grant of permission to conduct the Phase I clinical trial for export purpose as per protocol presented by the firm subject to the submission of scientific advice of USFDA for the said protocol and published safety data of Nplate (via intravenous route) to CDSCO.
4.	BIO/CT04/FF/2025/47716 Romiplostim powder for solution for injection (250mcg/vial)	M/s. Enzene Biosciences Ltd.	The firm presented their proposal for grant of permission to conduct Phase I clinical trial titled "A single center, randomized, double-blind, balanced, pivotal, two period, four-treatment, single-dose, 2-arm, 2-stage, adaptive design, parallel study to assess pharmacokinetic and pharmacodynamic, safety / tolerability and immunogenicity of ENZ210 [Enzene Romiplostim powder for solution for injection (subcutaneous administration)] in comparison with EU approved Nplate in healthy adult human subjects under fasting conditions" for export purpose vide protocol number CL-001-25 Version 00, Dated 04/Feb/2025. The committee noted that the drug product Enzene's Romiplostim powder for solution for injection for s.c. route is approved for marketing in India. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase I clinical trial for export purpose as per protocol presented by the firm.
5.	BIO/CT18/FF/2025/48107 Marstacimab 150mg/ml Solution for Injection in pre-filled pen	M/s Pfizer Products India Private Limited	The firm presented their proposal for grant of permission to import and market the drug product Marstacimab 150mg/ml Solution for Injection in pre-filled pen based on the results of global clinical trials where India is one of the participating country along with the request of local clinical trial waiver for the following indication:- "For routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients 12 years of age and older with: •hemophilia A (congenital factor VIII deficiency) without factor VIII

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			inhibitors, or •hemophilia B (congenital factor IX deficiency) without factor IX inhibitors The committee noted that the drug is approved in major countries including EU, USA, Japan, Australia and the drug falls under the orphan drug category. After detailed deliberation, the committee recommended for grant of permission to import and market the drug product Marstacimab 150mg/ml Solution for Injection in pre-filled pen with a condition to conduct Phase IV study in India. Accordingly, firm shall submit Phase IV Clinical Trial protocol to CDSCO within 03 months of grant of marketing authorization.
New Drug Division			
6.	ND/CT/25/000007 Belumosudil Tablet 200 mg	M/s Sanofi Healthcare India Private Limited	The firm presented the proposal for grant of permission to conduct phase IV clinical trial with new drug Belumosudil tablets 200mg, before the committee. After detailed deliberation, the committee recommended for the grant of permission to conduct Phase IV clinical trial, as per the presented protocol
7.	ND/26/2025-eoffice Rezurock® (Belumosudil Tablet 200mg)	M/s Sanofi Healthcare India Private Limited	The firm presented the proposal for amendment in Prescribing Information in line with Company Core data sheet (CCDS) Version 3 dated 25-Apr-2024 and Version 4 dated 12-Dec-2024 for drug Rezurock® (Belumosudil Tablet 200mg) before the committee. After detailed deliberation, the committee recommended for approval of amendment in Prescribing Information from CCDS Version 3 and Version 4 for drug Rezurock® (Belumosudil Tablet 200mg).
8.	ND/MA/24/000160	M/s MSN Laboratories	The firm presented for grant of permission to manufacture and market of

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	Avatrombopag 20mg tablet	Private Limited	Avatrombopag tablet 20 mg along with BE study report and justification for Phase III clinical trial waiver, before the committee for Indication: 1) Thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure. 2) Thrombocytopenia in adult patients with chronic immune thrombocytopenia who have had an insufficient response to a previous treatment. The committee noted that there is no unmet medical need and other standard of care drugs are already available for the indication of treatment of primary chronic immune thrombocytopenia (ITP) in adult patients who are refractory to other treatments (e.g. corticosteroids, immunoglobulins).The committee noted that safety and efficacy of applied drug has not been established in Indian population. After detailed deliberation, the committee considered the result of BE study. However, the committee did not recommend for grant of local Phase-III CT waiver and recommended that firm should conduct Phase III clinical trial of applied drug in Indian population for the proposed indication i.e. for the treatment of thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure; for the treatment of thrombocytopenia in adult patients with chronic immune thrombocytopenia (ITP) in adult patients who have had an insufficient response to a previous treatment. Accordingly, firm should submit Phase III clinical Trial protocol to CDSCO for further review by the committee