Recommendations of the SEC (Haematology) made in its 5th/26 meeting held on 12.05.2026 at CDSCO (HQ), New Delhi:

S. No.	File Number, name of drug, strength and dosage form	Name of firm	Recommendations
GCT Division			
1.	CT/79/25 OnlineSubmission (50077) ITU512	M/s. Novartis Healthcare Private Limited	In light of earlier SEC Recommendation dated 15.07.2025, the firm presented the revised protocol for conducting phase I/II clinicalstudy videprotocol no. CITU512A12101, protocol amendment version 02 dated 06Jan 2026. After detailed deliberation, the committee recommendedfor grant of permission to conduct the trial as presented by the firm.
Medical Devices Division			
2.	CI/MD/2025/155102 (Form MD-22) NiADA (Non Invasive Anemia Detection with Artificial Intelligence) Monere Public Health	M/s. Monere AI Private Limited	The firm presented the proposal for grant of permission to conduct Clinical investigationon the deviceviz. NiADA (Non Invasive Anemia Detection with Artificial Intelligence) Monere Public Health manufactured by M/s Monere AI Private Limited After detailed deliberation, the experts opined that the firm shall include the following points in the study protocol: 1. The study should be multi-centric with a minimum of 05 study centres with uniform geographical distribution and at least 50 percent government institutes. 2. The sample size should be increased to a minimum of 50,000 participants. 3. Different groups/ranges of Hb levels must be validated. Accordingly, a revised study protocol should be submitted for further deliberation.
Blood Product Division			
3.	BD PRO-11015(11)/1/2026-eoffice (Comp. No. 32720) Human von Willebrand Factor EP, 600 IU	M/s. Intas Pharmaceuticals Ltd.	The firm has presented the revised protocol (revised as per the recommendations given by the committee during the SEC meeting held on 25-Feb-2026) for the proposal to conduct phase III Clinical trial titled: "A Prospective, Open-label, Uncontrolled,

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	(Freeze Dried Powder)		Phase III Study to Assess the Pharmacokinetics, Efficacy and Safety of plasma-derived von Willebrand factor 600 IU complex containing Anti Haemophilic factor concentrate for On-demand Treatment and Prophylaxis in participants with Von Willebrand disease" vide Protocol No. 0465-25, Version: 2.0 dated 21-Mar-2026. After detailed deliberation, the committee recommended for grant of permission to conduct Phase-III Clinical Trial as per submitted revised protocol.
4.	BD PRO-11015(11)/2/2026-eoffice (Comp. No. 35615) Human Normal Immunoglobulin for Intravenous Administration IP/Ph.Eur./ BP 5%, 100 mL	M/s. Promea Therapeutics Private Limited	The firm has presented the proposal to conduct phase III Clinical trial titled: "An Open-Label, Multicentre, Phase III Clinical Comparative Study to evaluate the Efficacy, Safety and Pharmacokinetic properties of Human Normal Immunoglobulin in patients with primary immunodeficiency disease" vide Protocol No. CT-001-25, Version No: 01 dated 26-Dec-2025. After detailed deliberation, the committee recommended that: • As a patient safety follow-up, a post-infusion observation period of 4 hours should be included in the protocol. • Number of Clinical Trial sites to be increased. Accordingly, the firm should submit the revised study protocol for further review and approval by CDSCO.
Biological Division			
5.	E-receipt No. 128009 Crizanlizumab 10 mg/mL	M/s. Sandoz Private Limited	The matter regarding Crizanlizumab concentrate for solution for infusion 10 mg/mL (100 mg/10 mL) was deliberated by the committee in view of the regulatory action by the European Medicines Agency on the marketing authorisation of Adakveo. The firm had earlier presented the status of ongoing studies before the SEC on 05.03.2024, and it was recommended to submit interim safety and efficacy data of ongoing Phase IV study in India along

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			with PSUR data. The matter was subsequently deliberated again in the SEC meeting dated 19.08.2025, wherein the firm presented the final Clinical Study Report (CSR) of the Phase IV clinical trial titled "An Indian Multi-centric Phase IV study to assess the safety of Crizanlizumab with or without hydroxyurea therapy in sickle cell disease patients with vaso-occlusive crises" conducted under Protocol No. CSEG101A2403. The committee observed that EMA has revoked conditional marketing authorization of Crizanlizumabbased on the review of the STAND study, which did not show a significant difference between crizanlizumab and placebo in reducing painful crises (vaso-occlusive crises).The firm also clarified that Crizanlizumab is currently not launched and being imported into India. Now, after detailed deliberation, the committee observed that no new significant safety concerns had emerged from the available global post-marketing and Phase IV data. However, the committee observed that the efficacy of the product for the intended indication remains inconclusive based on the currently available evidence, including the EMA/CHMP assessment report.The committee also noted that the initial MA was granted to the firm with Phase-III waiver. Accordingly, the committee recommended that the import and marketing permission granted vide no. IMP/BIO/20/000026 dated 26-Mar-2020of the drug product may be discontinued until adequate data establishing the efficacy and favourable benefit-risk profile of the product are made available.
6.	Receipt No. E-144181	M/s. Levim Lifetech Private Limited.	The firm presented the proposal of amendment in clinical trial protocol titled as "A prospective, randomized, double-

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	Romiplostim (r-DNA) powder for solution for Injection 250µg/0.5ml		blind, multi-centre, parallel arm, comparative clinical study to determine the efficacy and safety of Romiplostim Biosimilar manufactured by Levim Lifetech Private Limited with Nplate® manufactured by Amgen in patients with immune thrombocytopenia (ITP)" bearing no. LBL-CT-20-003, from Version 3.2 dated 24.10.2024 to Version 4.0 dated 03 Apr 2026. After the detailed deliberation, the committee recommended the amendment in protocol presented by the firm with Version 4.0 dated 03 Apr 2026.
SND Division			
7.	SND/MA/25/000151 Hydroxyurea Dispersible tablets 50mg, 100mg, 200mg, 250mg, 500mg	M/s. Beta Drugs Limited.	Firm presented the proposal for manufacturing & marketing of Hydroxyurea Dispersible Tablets 50 mg, 100 mg, 200 mg, 250 mg & 500 mg for the applied indication along with proposal for conduct of BE study. After detailed deliberation, the committee recommended for grant of permission to conduct the BE study as per the protocol presented by the firm.