Recommendations of the SEC (Haematology) made in its 08th/25 meeting held on 15.07.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/79/25 Online Submission (50077) ITU512	M/s Novartis Healthcare Private Limited	The firm presented phase I/II clinical study Protocol No.: CITU512A12101 Version No. 01 dated 29-JUL-2024. After detailed deliberation, the committee opined that firm shall submit the following: 1. Primary endpoint must be clearly specified in fetal hemoglobin (HbF) increase >15% (this threshold needs to be justified based on clinical relevance, prior studies, or regulatory guidelines). 2. The Inclusion Criteria for absolute total fetal hemoglobin percentage <15% should be justified. 3. During SEC meeting the presentation regarding the definitions of primary and secondary endpoints were not present as per the submitted protocol. 4. The criteria for efficacy evaluation/ end point must be explicitly defined. 5. Exploratory endpoints such as vaso-occlusive crisis (VOCs) events should be clearly defined and incorporated into the protocol as part of the initial endpoints. 6. The Phase I data, including safety data and hemolysis studies, from either the current study or any other country where the investigational product has been tested. 7. A detailed justification for the proposed sample size and dosing regimen should be included. Accordingly, the firm shall submit the response for further review by committee

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
2	E-77852 Crizanlizumab 10 mg/mL	M/s. Sandoz Private Limited	The firm did not turn up for the presentation.
SND Division			
3	SND/CT/25/000065 Hydroxyurea Oral Suspension 100 mg/ml	M/s. PURE & CURE HEALTHCARE Pvt. Ltd.	Firm has presented proposal for the permission to conduct phase IV clinical trial of Hydroxyurea Oral Suspension 100 mg/ml vide protocol No. SB-ICMR-CT-001 Version No. 1.0 Protocol Date 22-JAN-2024 for the prevention of vaso-occlusive complications of Sickle Cell Disease in patients over 2 years of age. After detail deliberation, the Committee recommended to grant the permission to conduct clinical trial as per protocol presented with following changes: **1.** The sample size should be increased to 200 patients **2.** Recruit clinical trial sites from the Chhattisgarh and Nagpur areas where the disease is prevalent.
FDC Division			
4	FDC/MA/23/000218 Ferrous Fumarate (eq. to 49.5 mg elemental Iron) 150 mg IP + L-Histidine HCL.H2O 4 mg BP + L-Lysine HCL 25 mg IP + Glycine 10 mg IP + Thiamine Mononitrate (Vitamin B1) 5 mg IP + Riboflavin (Vitamin B2) 3 mg IP + Pyridoxine HCL (Vitamin B6) 1.5 mg IP + Cyanocobalamin (Vitamin B12) 2 g IP + Folic Acid (Vitamin B9) 500 g IP + Ascorbic Acid	M/s Albert David Limited	The firm did not turn up for the presentation

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
	(Vitamin C) 40 mg IP + Zinc Sulphate 50 mg IP capsule		
Blood Product Division			
5	X-11026/CTNOC/CT-06/BSV/02/2025-BD (E-office: BD PRO-11015(11)/4/2025-eoffice; E-20438) Human Normal Immunoglobulin for Intravenous use IVIG (Human) 5% Solution.	M/s. Bharat Serums and Vaccines Limited, 3rd Floor, Liberty Tower, Plot No. K-10, Behind Reliable Plaza, Kalwa Industrial Estate, Airoli, Navi Mumbai 400708	The firm has presented the proposal to conduct the Phase-III Clinical trial titled: "An Open Label, Single Arm, Prospective, Multicenter, Phase III Study to Evaluate the Efficacy, Safety and Pharmacokinetics of Human Normal Immunoglobulin For Intravenous Use In Adults And Pediatric Subjects With Primary Immunodeficiency Syndrome" vide Protocol No. BSV_IVIG_PID_2023_03 version Number: 2.0; dated: 10-10-2024. After detailed deliberation, the committee has recommended for the grant of permission to conduct Phase III clinical trial as per the protocol No BSV_IVIG_PID_2023_03 version Number: 2.0; dated: 10-10-2024 with a condition that firm shall submit clinical trial results of the initial 10 pediatric patients to CDSCO(HQ).