

Recommendations of the SEC (Haematology) made in its 02nd/25 meeting held on 11.02.2025 at CDSCO (HQ), New Delhi:

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/87/24 Online Submission (37055) Luspatercept (ACE-536)	M/s PPD Pharmaceutical Development India Private Limited	The firm presented protocol amendment 4.0 dated 25 July 2024 protocol no. ACE-536 -B-THAL-004. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm with following conditions: <ol style="list-style-type: none"> 1. No new herb/traditional medicine/food supplement shall be permitted in the study. 2. Testing for HIV and Hepatitis B and C shall be performed before enrollment of subjects.
Biological Division			
2.	BIO/CT18/FF/2024/4 5578 Concizumab Injection 15mg/1.5mL, 60mg/1.5mL, 150mg/1.5mL and 300mg/3mL	M/s Novo Nordisk India Pvt. Ltd.	The firm presented their proposal for grant of permission for import and marketing of drug Concizumab Injection 15 mg/1.5 ml, 60 mg/1.5 ml, 150 mg/1.5 ml and 300 mg/3 ml Solution for injection in Pre-filled pen based on global clinical trials including Indian patients. The drug is indicated for routine prophylaxis of bleeding in patients with- <ol style="list-style-type: none"> 1. Haemophilia A (congenital factor VIII deficiency) with FVIII inhibitors and of 12 years of age or more. 2. Haemophilia B (congenital factor IX deficiency) with FIX inhibitors and of 12 years of age or more. The committee noted that the drug falls under the orphan drug category and indicated for the rare disease. The committee also noted that there is unmet medical need in the country for the proposed indication. After detailed deliberation, the committee recommended for grant of permission to import and marketing of drug with the following conditions- <ol style="list-style-type: none"> 1. The firm should conduct PMS study for the proposed indications in India.

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			Accordingly, the firm should submit PMS study protocol within three months of approval. 2. The firm should develop procedure and testing facilities for reporting drug levels to the prescribing physician.
SND Division			
3.	SND/MA/24/000201 L-Glutamine Oral Powder 5g sachets	M/s MG Biological Ltd.	The firm did not turn up for presentation.
New Drug Division			
4.	ND/MA/23/000131 Avatrombopag tablets 20 mg	M/s BDR Pharmaceuticals International Pvt. Ltd.	In the light of earlier SEC recommendation dated 09.01.2024 & 10.01.2024, firm presented BE study report of drug Avatrombopag tablets 20 mg and justification for Phase III clinical trial waiver, before the committee for Indication: for the treatment of severe thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo an invasive procedure; for the treatment of primary chronic immune thrombocytopenia (ITP) in adult patients who are refractory to other treatments (e.g. corticosteroids, immunoglobulins). 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 severe

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			<p>thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo an invasive procedure; for the treatment of primary chronic immune thrombocytopenia (ITP) in adult patients who are refractory to other treatments (e.g. corticosteroids, immunoglobulins). Accordingly, firm should submit Phase III clinical Trial protocol to CDSCO for further review by the committee.</p>
Blood Products Division			
5.	<p>X-11026/34/2024-BD (E-office: BD PRO-11015(11)/1/2024-eoffice)</p> <p>Human Normal Immunoglobulin for Intravenous Administration IP/Ph. Eur./BP 5%, 100 mL (IVIG)</p>	<p>M/s. Virchow Biotech Private Limited, Gagillapur Village, DundigalGandimaisa mmaMandal, Medchal-Malkajgiri District, Telangana – 500043</p>	<p>The firm presented the proposal to conduct phase III Clinical trial titled “A prospective, single arm, multicenter clinical study to evaluate the efficacy, safety and pharmacokinetic properties of Virchow’s IVIG in patients with primary immunodeficiency disease” vide protocol No. VBIVIG/2024-CT1, Version 1 dated 02.02.2024.</p> <p>After detailed deliberation, the committee has recommended as follows:</p> <ol style="list-style-type: none"> 1. The protocol is not designed to provide safety and efficacy data of comparator product available in the market 2. The study should be a double arm since the similar product with same indication is available in the market. 3. If patient requires any blood transfusion during study, then it should be excluded from the study and same shall be included in protocol
6.	<p>BSV/CDSCO/CTA/24/102 E- 64387</p> <p>Human Normal Immunoglobulin for Intravenous use in subjects with ITP condition</p>	<p>M/s. Bharat Serums and Vaccines Limited</p>	<p>The firm presented the proposal to conduct phase III Clinical trial titled “An Open- Label, Multicentre, Phase III Clinical Study to evaluate the Efficacy and Safety of Human Normal Immunoglobulin for Intravenous use (IVIG) in Immune Thrombocytopenia (ITP)” vide protocol No.</p>

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			<p>BSV_IVIG_ITP_2023_02, Version No. 02 dated 05.08.2024.</p> <p>After detailed deliberation, the committee has recommended as follows:</p> <ol style="list-style-type: none"> 1. The title of the trial should be changed to “An Open- Label, Multicentre, Phase III Clinical Study to evaluate the Efficacy and Safety of Human Normal Immunoglobulin for Intravenous use (IVIG) in Chronic Immune Thrombocytopenia” 2. Objective of the trial should be clear that trial to be carried out for Indian population. 3. The indications in the protocol within chronic ITP shall include nomenclature like acute bleeding, planned for surgery etc. 4. Chronic ITP to be included in inclusion criteria. 5. The treatment dose shall be evaluated after 14 days. The support of treatment dose if required even after study period shall be included in protocol. <p>The protocol is not designed to provide safety and efficacy data of comparator product available in the market.</p> <p>The study should be a double arm since the similar product with same indication is available in the market.</p> <p>The firm shall submit the revised protocol for consideration of the committee.</p>