

Recommendations of the SEC (Haematology) made in its 3rd /25 meeting held on 06.03.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/141/22 Online Submission (35530) VAY736 (Ianalumab)	M/s Novartis Healthcare Private Limited	In light of earlier SEC Recommendation dated 20.11.2024, now the firm presented protocol amendment version 05 dated 22 Aug 2024 protocol no. CVAY736O12301. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
2.	CT/12/25 Online Submission (47807) PF-06741086 (Marstacimab)	M/s Pfizer Limited	The firm presented Phase 1b clinical study protocol no. B7841014Amendment 1 dated 02December2024. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm
Biological Division			
3.	BIO/CT18/FF/2024/4 5986 Antihemophilic Factor (Recombinant Factor VIII) PEGylated-aucl 500 IU1000 IU/2000 IU/3000 IU	M/s Bayer Pharmaceuticals Pvt. Ltd	The firm presented the proposal for grant of permission to import and market the drug Antihemophilic Factor (Recombinant Factor VIII) PEGylated-aucl 500 IU/1000 IU/2000 IU/3000 IU(Damoctocog Alfa Pegol) with request for waiver of Phase-III & Phase-IV clinical studies. The firm is claiming that drug product is being used in India since the year 2020 by donation through World Hemophilia Association (WHA) to Hemophilia Federation of India (HFI) on compassionate ground. More than 13 million units of drug product is used as on date. The committee noted that drug is currently approved in 53 countries including USA, EU, UK, Australia, Canada, and Japan. The drug falls under the category of orphan drug and indicated for the treatment of rare disease. Further the committee also noted that there is unmet

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			<p>medical need in the country.</p> <p>After detailed deliberation the committee recommended for grant of permission to import and marketing the product Antihemophilic Factor (Recombinant Factor VIII) PEGylated-auc1 500 IU/1000 IU/2000 IU/3000 IU (Damoctocog Alfa Pegol) with the condition to conduct Phase-IV study in India. Accordingly, the firm should submit Phase-IV study protocol within 3 months of import and marketing permission.</p>
4.	BIO/CT18/FF/2023/3 8926 Recombinant Human Coagulation Factor VIII for Injection 250 IU/1000 IU	M/s Urihk Pharmaceutical Private Limited	The firm didn't turn up for the presentation.
5.	BIO/CT18/FF/2024/4 5824 Antihemophilic Factor (Recombinant Factor VIII) 250, 500, 1000, 2000 and 3000 IU Lyophilized Powder for Solution for Intravenous Injection	M/s Bayer Pharmaceuticals Pvt ltd	<p>In light of the earlier SEC recommendation dated 16.01.2025 the firm presented the safety and efficacy data from the clinical studies conducted globally along with subset analysis of subjects participated from Asian countries and Safety data in comparison with other Factor VIII drugs used in the centres where HFI donated the drug for grant of permission to import and market the drug Antihemophilic Factor (Recombinant Factor VIII) 250, 500, 1000, 2000 and 3000 IU Lyophilized Powder for Solution for Intravenous Injection (Octocog alfa) indicated For use in adults and children with hemophilia A (congenital Factor VIII deficiency) for:</p> <ul style="list-style-type: none"> • On-demand treatment and control of bleeding episodes • Perioperative management of bleeding • Routine prophylaxis to reduce the frequency of bleeding episodes <p>The committee noted that the drug is approved in 67 countries including USA, EU, Japan, Canada.</p> <p>The drug falls under the category of orphan drug and indicated for the treatment of rare disease. Further the</p>

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			<p>committee also noted that there is unmet medical need in the country.</p> <p>After detailed deliberation, the committee recommended for grant of permission to import and market of drug with waiver of Phase III clinical trial with condition to conduct Phase IV study.</p> <p>Accordingly, the firm should submit Phase IV study protocol within three months of approval of the product.</p>
SND Division			
6.	SND/MA/24/000201 L-Glutamine Oral Powder 5g sachets	M/s MG Biological Pvt Ltd.	<p>The firm presented the proposal for grant of manufacture and marketing of L-Glutamine Oral Powder 5g (sachets) with indication to reduce the acute complications of sickle cell disease in adult and pediatric patients 5 years of age and older along with the justification for waiver of BE & CT studies before the committee.</p> <p>During the presentation, the firm informed that L-Glutamine is BCS Class I molecule and the applied product is approved in USA in year 2017 for the proposed indication.</p> <p>Firm presented the published clinical PK and PD studies data globally where India is not a part of the study.</p> <p>After detailed deliberation, the Committee recommended that firm should conduct Phase III clinical study on Indian patients to prove the efficacy of applied product to reduce the acute complications of sickle cell disease in adult and pediatric patients 5 years of age and older.</p> <p>Accordingly, the firm should submit Phase III Clinical study protocol to CDSCO for review by the committee.</p>
7.	SND/MA/24/000235 Eltrombopag for oral suspension 12.5 mg and 25 mg	M/s. Zydus Lifesciences Limited	<p>The firm presented the proposal for grant of permission to manufacture and market of Eltrombopag for Oral Suspension 12.5mg and 25mg along with Bioequivalence study protocol and justification for waiver of Phase-III</p>

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			<p>clinical trial before the committee.</p> <p>The committee noted that Eltrombopag for Oral Suspension 12.5mg and 25mg is already approved in US, UK, Europe and also tablet dosage form is already approved in India. Eltrombopag for Oral Suspension 12.5mg and 25mg will be helpful in the dose titration.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct bioequivalence study as per protocol presented by the firm. The firm should submit BE report to CDSCO for further necessary action.</p>
Blood Products Division			
8.	X-11026/63/2024-BD (E-office: Comp. No.:18391; File No.: BD PRO-11015(11)/4/2024-eoffice) Human Fibrinogen EP 0.5 g (Reconstitute with 25 ml of sterile WFI) and 1 g (Reconstitute with 50 ml of sterile WFI)(Freeze Dried Powder)	M/s. Intas Pharmaceuticals Ltd, situated at Plot No-496/1/A&B, Sarkhej-Bavla Highway, Village: Matoda, Taluka: Sanand, Ahmedabad-382213, Gujarat	<p>The firm presented the proposal to conduct phase III Clinical trial titled: “A Single Group, Non-Randomized, Multicenter, Interventional Phase-3 Study to Investigate Efficacy, Safety and Pharmacokinetics of Fibrogen-I™ (Human Fibrinogen Injection) for On-demand Treatment of Acute Bleeding and to Prevent Bleeding During and After Surgery in Patients with Congenital Fibrinogen Deficiency” vide Protocol No. 0394-23 Version: 1.0 Dated 10.07.2024.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct Phase III CT as per applied protocol</p>
9.	28E/BP/07/Intas/14-BD (E-office: Comp. No.: 3838; File No.: BD PRO-11012(13)/2/2024-eoffice) Human von Willebrand Factor EP 600 IU (Freeze Dried Powder)	M/s. Intas Pharmaceuticals Ltd, situated at Plot No 496/1/A&B, Sarkhej-Bavla Highway, Village: Matoda, Taluka: Sanand, Ahmedabad-382213, Gujarat	<p>The firm presented the proposal for grant of permission to manufacture Human von Willebrand Factor EP 600 IU (Freeze Dried Powder) Drug Formulation with local CT Phase-III waiver.</p> <p>After detailed deliberation, the committee recommended that the firm should submit Phase-III CT data along with P_k and P_d data.</p> <p>Accordingly, the firm may submit the protocol etc. for the consideration of the committee.</p>