

Recommendations of the SEC (Haematology) made in its 02nd/26 meeting held on 25.02.2026 at CDSCO HQ New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
Blood product Division			
1.	BD PRO-11015(11)/1/2026-eoffice (Comp. No. 32720) Human von Willebrand Factor EP, 600 IU (Freeze Dried Powder)	M/s. Intas Pharmaceuticals Ltd	<p>In light of the earlier SEC recommendation dated 06.03.2025, the firm presented the proposal for grant of permission to conduct Phase III Clinical trial titled - A Prospective, Open-label, Uncontrolled, 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 Number: 0465-25, Version: 1.0 dated 22-Dec-2025.</p> <p>Wherein, the firm has proposed the sample size of the participants in the trial as 20.</p> <p>After detailed deliberation, the committee recommended that</p> <ul style="list-style-type: none"> • The firm should select and include more clinical trial centers having large number of vWF disease patients • The sample size should be minimum 30. <p>Accordingly, the firm should submit revised Phase III Clinical study protocol to CDSCO for further review by the committee</p>
Biological Division			
2.	BIO/CT04/FF/2025/51614 Antihemophilic Factor (Recombinant Factor VIII) PEGylated-aucl 500, 1000, 2000 and 3000 IU lyophilized powder for solution, for intravenous use	M/s. Bayer Pharmaceuticals Pvt. Ltd.	<p>The firm presented the proposal for grant of permission to conduct Phase IV clinical trial titled, “A prospective, multi-center, non-comparative, open-label, post-authorization, Phase IV study to assess the safety and treatment outcomes of Damoctocogalfapegolf or on demand treatment in patients with Hemophilia A in routine clinical practice in India vide Protocol No. 23089, v1.0 dated 19 Aug 2025” was re-deliberated.</p> <p>The proposal of firm was earlier deliberated in SEC (Haematology) dated</p>

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			<p>11.12.2025, wherein committee made certain recommendations w.r.t aforesaid protocol.</p> <p>Now, firm agreed to amend the protocol to revise sample size as 50 evaluable subjects and 24-week safety follow up of AEs and SAEs for all patients.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct Phase IV clinical trial as per the protocol presented by the firm.</p> <p>Accordingly, the firm should submit the revised protocol incorporating the proposed changes to CDSCO.</p>
3.	<p>BIO/CT04/FF/2025/52 705</p> <p>Antihemophilic Factor (Recombinant Factor VIII) I.P. (r-DNA origin)</p>	<p>M/s. Bayer Pharmaceuticals Pvt. Ltd.</p>	<p>The firm presented the proposal to conduct Phase IV clinical trial titled "HEMOCT INDIA: A prospective, multicenter, open-label, Phase IV post-authorization safety study conducted in India to assess the safety and treatment outcomes of Octocogalfa in real-world practice for on-demand treatment of acute bleeds in previously treated severe Haemophilia A patients in India." vide Protocol No. 23153 dated 17 Oct 2025.</p> <p>The committee noted that the firm agreed to amend the protocol to revise sample size as 50 evaluable subjects and 24-week safety follow up of AEs and SAEs for all the subjects.</p> <p>After detailed deliberation the committee recommended for grant of permission to conduct the Phase IV clinical trial as per the revised protocol presented by the firm.</p> <p>Accordingly, the firm should submit the revised protocol incorporating the proposed changes to the CDSCO.</p>
4.	<p>E-113523</p> <p>Luspatercept powder for solution for injection: 25 mg and 75 mg</p>	<p>M/s. Bristol-Myers Squibb India Pvt. Ltd</p>	<p>The firm presented the proposal for grant of approval for amendment in already approved Phase IV clinical trial protocol bearing no. CA056023 titled as "A Phase 4 Study to Evaluate Safety and Effectiveness of Luspatercept (ACE-536) for the Treatment of Anemia due to IPSS-R Very Low, Low, or Intermediate Risk Myelodysplastic SyndromeS (MDS) with</p>

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			<p>Ring Sideroblasts Who Require Red Blood Cell Transfusions in Subjects Who Have Had Unsatisfactory Response to or Are Ineligible to Erythropoietin Based Therapy and in Subjects With Transfusion Dependent Anemia Due to Beta-Thalassemia” for amendment of the approved protocol.</p> <p>After detailed deliberation, the committee recommended for amendment in protocol no. CA056023, from Amendment no. 02 dated 18.10.2023 to Amendment no. 03 dated 18.09.2025 to include 30 evaluable MDS patients, subject to the condition that firm shall submit the interim report of the clinical trial for those two indications mentioned in study protocol amendment no. 02.</p>
New Drugs Division			
5.	ND/MA/23/000131 Avatrombopag tablets 20 mg	M/s. BDR Pharmaceuticals International Pvt Ltd	<p>In light of earlier SEC recommendations dated 11.12.2025, firm presented revised Phase-III CT Protocol of Avatrombopag Tablets 20 mg (Study Code: CT/25/003 Protocol Version No.: Final 01 Dated: 29/12/25), before the committee.</p> <p>After detailed deliberation, the committee recommended the conduct of Phase III clinical trial, as per the protocol presented</p>
SND Division			
6.	SND/CT/25/000135 Desidustat tablets 25 mg, 50 mg and 100 mg	M/s. Zydus Lifesciences Limited	<p>The firm presented the proposal for grant of permission to conduct Phase-III clinical trial of Desidustat Tablets for treatment of anemia in sickle cell disease along with Phase-IIaCT study results and Phase-III clinical trial protocol before the committee.</p> <p>Firm presented that, Desidustat tablets 25mg/ 50mg/ 100mg were approved in India for the treatment of Anemia in Adult patient with Chronic Kidney Disease (CKD).</p> <p>After detailed deliberation, the committee recommended for the following changes in the proposed protocol:</p> <p>1) In inclusion criteria, revise the</p>

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			<p>Hb level to 6-9 g/dL for both males & females at screening.</p> <ol style="list-style-type: none"> 2) Participants who have received blood transfusion within 90 days prior to the inclusion into the study shall be excluded from the study. 3) At attaining Hb \geq10 g/dL, stop the treatment for 14 days during dose adjustment. 4) Evaluation of Biomarkers like Erythropoietin, Hemoglobin F and Pyruvate kinase should be performed at baseline, at 12 weeks and at 24 weeks/ end of the treatment. 5) The first interim analysis for safety as well as efficacy should be performed when 24 patients complete the study. The second Interim study analysis should be performed when 50% of patients (i.e. 80 patients) complete the study. The threshold for statistical significance should be adjusted accordingly. The study results of the interim analyses should be presented to the SEC. The provisions for the sample size recalculation and post-hoc study power adjustments should be incorporated into the study protocol. <p>Accordingly, the firm shall submit revised protocol for further evaluation by the SEC committee.</p>
FDC Division			
7.	<p>FDC/MA/25/000165</p> <p>Heparin Sodium IP 50IU + Benzyl Nicotinate 2mg + Sorbic Acid IP 1.97mg (Preservative) per gram Ointment</p>	<p>M/s. Curetech Skincare</p>	<p>In light of earlier SEC recommendation dated 25.11.2025, the firm presented the revised Phase IV clinical trial protocol before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the Phase IV clinical trial.</p> <p>Accordingly, the firm should submit the Phase IV clinical trial report to CDSCO for further review by the committee.</p>