

Recommendations of the SEC (Haematology) made in its 01st/26 meeting held on 13.01.2026 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Blood Product Division			
1.	BD PRO-11015(11)/6/2025-eoffice (Comp. No. 30618) Fibrogen-I (Human Fibrinogen E P 0.5 gm/1 gm), Freeze-Dried powder	M/s. Intas Pharmaceuticals Ltd.	<p>The firm has presented the proposal for grant of permission to conduct the Phase-III clinical trial titled: A Prospective, Phase 3, Open-label, Single arm, Uncontrolled Study to Assess the Efficacy and Safety of Fibrogen-I (Human Fibrinogen Injection) in Bleeding Adult Cardiac Surgical Patients with Acquired Fibrinogen Deficiency vide Protocol no. 0463-25 version 1.0 dated 04/11/2025 for export purpose.</p> <p>After detailed deliberation, the committee has recommended the following:</p> <ol style="list-style-type: none"> 1) Justification for Study design includes the 24 subjects only and not having comparator. 2) Justification for including the allogeneic blood products in the primary endpoint. <p>The study protocol shall be revised with respect to the following:-</p> <ol style="list-style-type: none"> 1) The screening period of TTI shall be revised to 6 Months. 2) The inclusion criteria should include limits of fibrinogen. 3) Fibrinogen levels should be measured using automated coagulometre instead of ROTEM. 4) Addition of site with various regions of India to conduct the clinical trial. <p>Accordingly, the study protocol shall be revised and Re-deliberated in the next SEC meeting along with cardiac surgeon and cardiac anesthetic.</p>

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Biological Division			
2.	BIO/CT04/FF/2025/52971 Recombinant Filgrastim injectable solution 300 mcg/ 0.5 mL prefilled syringe	M/s. Azidus Laboratories Limited.	<p>The firm presented the proposal for grant of permission to conduct Phase I clinical trial titled "An open label, balanced, randomized, two treatments, two sequences, two periods, multiple dose, steady state crossover study to evaluate bioequivalence between Filgrastim injectable solution 300 mcg/0.5 mL prefilled syringe of M/s Iclos Uruguay S. A and Neupogen (Filgrastim) injectable solution 300 mcg/0.5 mL pre-filled syringe of Amgen in healthy, adults, human male subjects after subcutaneous administration through Pharmacokinetic and Pharmacodynamic profiles"; vide Protocol No.:AZBE062310, Version:1.0, Date: 27-JAN-2024 for export purpose.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the Phase I clinical trial as per the protocol presented by the firm subject to the condition that the safety data for the first 10 Subjects shall be submitted for further review by the committee.</p>
New Drugs Division			
3.	ND/150/2025-eoffice Rezurock® (Belumosudil Tablet 200 mg)	M/s. Sanofi Healthcare India Private Limited.	<p>The firm presented proposal for updating the prescribing information dated Aug 2025 for drug product, Belumosudil Tablet 200mg as per CCDS version 5 dated 03-Jul-2025 before the committee.</p> <p>The key changes in the proposed prescribing information are under section 4.5 (drugs interaction) and section 5.3 (Pharmacokinetic properties) with respect to Belumosudil drug-drug interaction on sensitive CYP1A2 substrates.</p> <p>After detailed deliberation, the Committee recommended for grant of approval for the proposed update in prescribing information as presented by the firm.</p>

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4.	ND/IMP/25/000095 Fitusiran Solution for subcutaneous injection 50 mg/ 0.5 mL (Prefilled Pen) & Fitusiran Solution for subcutaneous injection 20 mg/ 0.2 mL in vial	M/s. Sanofi Healthcare India Private Limited.	<p>The firm presented the proposal for grant of permission for Import and Marketing of the drug Fitusiran Solution for subcutaneous injection 50 mg/ 0.5 mL in a pre-filled pen & Fitusiran Solution for subcutaneous injection 20 mg/ 0.2 mL in a vial) along with justification for local Phase III Clinical Trial waiver before the committee.</p> <p>The firm also presented efficacy data of international Phase III study & details of Phase III global clinical trial with participation of Indian subjects.</p> <p>The committee noted that the applied drug is approved in US and United Arab Emirates. The committee also noted that there is unmet medical need of applied drug in the country.</p> <p>After detailed deliberation, the committee recommended for grant of permission to import and marketing of Fitusiran Solution for subcutaneous injection 50 mg/ 0.5 mL in a pre-filled pen & Fitusiran Solution for subcutaneous injection 20 mg/ 0.2 mL in a vial) subject to the conditions that the firm should conduct PMS study for which the protocol should be submitted to CDSCO within 3 months of approval of marketing authorization of the drug for further review by the committee.</p> <p>Further, the committee opined that firm should submit revised prescribing information (PI) with inclusion of all adverse events and warning in relevant sections in line with internationally approved PI and submit the updated PI to CDSCO.</p>