

Recommendations of the SEC (Haematology) made in its 08^h/25 meeting held on 19.08.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	E-77852 Crizanlizumab 10 mg/mL	M/s. Sandoz Private Limited	<p>The firm presented the final CSR of Phase IV clinical trial titled “An Indian Multi-centric Phase IV study to assess the safety of Crizanlizumab with or without hydroxyurea therapy in sickle cell disease patients with vaso-occlusive crises” conducted in India vide Protocol No. CSEG101A2403. The committee observed that EMA has revoked conditional marketing authorization of Crizanlizumab based on the review of the STAND study, which did not show a significant difference between crizanlizumab and placebo in reducing painful crises (vaso-occlusive crises).</p> <p>Further, the firm clarified that Crizanlizumab is not being imported in India currently as the transition of MA permission from M/s. Sandoz Private Limited to M/s. Novartis Healthcare Pvt. Ltd. is under process.</p> <p>After detailed deliberation, based on the safety study conducted in India, the committee recommended the firm to submit comparative analysis of safety data from global clinical trials and safety data from Phase IV study conducted in India along with results from submitted India specific PSURs for further review by the committee.</p>