

Recommendations of the SEC (Haematology) made in its 06th/26 meeting held on 16.06.2026 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
1.	ND/MA/24/000160 Avatrombopag 20 mg tablet	M/s. MSN Laboratories Private Limited.	In light of earlier recommendation dated 16.04.2026, firm has presented the proposal for grant of permission to manufacture and market Avatrombopag tablet 20 mg along with revised Phase III Clinical Trial Protocol (Protocol No: AVATROM/P3/MSN/2026, version 2.0 dated 30/APR/2026) before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct Phase III clinical trial of Avatrombopag tablet 20 mg as per the protocol presented by the firm with following condition: The severity of Chronic Liver Disease should be explicitly defined in terms of moderate/severe category by clinical and laboratory criteria under inclusion/exclusion criteria in the protocol. Accordingly, the firm should submit the revised protocol to CDSCO.
SND Division			
2.	SND/CT/25/000135 Desidustat tablets 25, 50 and 100 mg	M/s. Zydus Lifesciences Limited.	In light of earlier SEC recommendations dated 25.02.2026, the firm presented the revised Phase-III clinical trial study protocol for grant of permission to conduct Phase-III clinical trial of Desidustat Tablets for treatment of anemia in sickle cell disease before the committee. After detailed deliberation, the committee recommended to conduct the Phase III clinical trial study, as per the protocol presented.