

Recommendations of the SEC (Haematology) made in its 03rd/26 meeting held on 12.03.2026 at CDSCO HQ New Delhi:

| S. No | File Name & Drug Name, Strength | Firm Name | Recommendations |
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| GCT Division | | | |
| 1. | CT/13/26 Online Submission (54486) DAK539 (Pelabresib) | M/s. Novartis Healthcare Private Limited | The firm presented phase III clinical study protocol no. CDAK539A12303, version no. 00 dated 08 October 2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm. |
| 2. | CT/18/26 Online Submission (54744) Elritercept | M/s. IQVIA RDS (India) Private Limited | The firm presented phase III clinical study protocol no. TAK-226-3001, original dated 01 September 2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with condition that the Sponsor shall provide Post-Trial Access of the Investigational Drug as per NDCT Rules 2019. |
| BABE Division | | | |
| 3. | BABE/CT05/FF/2025/ 53171 Avatrombopag 40 mg Film-coated Tablets | M/s. Veeda Clinical Research Limited | Firm presented the BA/BE study Protocol No. 25-VIN-0569 Version No. 01 Protocol Date 11-NOV-2025 for export purpose only before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the BABE study for export purpose only. |
| FDC Division | | | |
| 4. | FDC/CT/26/000007 Heparin Sodium IP 50 IU + Benzyl Nicotinate 2 mg + Sorbic Acid IP 1.97 mg (Preservative) per gram Ointment | M/s. Zydus Healthcare Limited | In light of DTAB subcommittee report dated 28.12.2021 wherein expert committee recommended "To conduct Phase IV clinical trial to show efficacy and safety of the product, with efficacy as the primary objective in statistically significant number of patients. Protocol should be approved by SEC and study should be completed within one year" for the proposed FDC. Accordingly, the firm presented the Phase IV clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to |

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| | | | conduct the Phase IV clinical trial and the firm should submit the Phase IV clinical trial report to CDSCO for further review by the committee. |