

**Recommendations of the SEC (Haematology) made in its 1<sup>st</sup>/24 meeting held on 17.01.2024 at CDSCO (HQ), New Delhi:**

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>GCT Division</b>			
1.	CT/141/22 Online Submission (29783)  VAY736 (Ianalumab)	M/s. Novartis	The firm presented protocol amendment version 03 dated 27 April 2023, protocol No. CVAY736O12301.  After detailed deliberation, the committee recommended for approval of the protocol amendment as presented by the firm.
2.	CT/84/22 Online Submission (30057)  Decitabine 5mg + Tetrahydrouridine 250 mg (NDec)	M/s. Novo Nordisk India Pvt. Ltd.	The firm presented protocol amendment version 7.0 dated 11 September 2023, protocol No. NN7533-4470.  After detailed deliberation, the committee recommended for approval of the protocol amendment as presented by the firm with condition that subjects from more geographically distributed sites shall be included in the study.  Dr. R.K. Jena did not participate in this deliberation.
3.	CT/165/23 Online Submission (41088)  LNP023 (IPTACOPAN)	M/s. Novartis	The firm was not ready for presentation before the committee.
4.	CT/147/22 Online submission (28110)  VAY736 (Ianalumab)	M/s. Novartis Healthcare Private Limited	In light of earlier recommendation of SEC on 29.11.23 & 30.11.24, the firm presented the proposal for waiver for following conditions in CT NOC for protocol No. CVAY736I12301.  1 Protocol section 6.8.3 w.r.t Rescure therapies should be modified as per current guidelines for treatment of ITP. 2. Background therapy/Rescuse medications, i.e., platelet transfusion, corticosteroids and IVIG, etc. should be provided free of cost to the trial subjects throughout the conduct of the study.  After detailed deliberation, the committee accepted the justification submitted for compliance of conditions of CT NOC as presented by the firm.

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5.	CT/71/23 Online Submission (38023)  VGA039–Monoclonal Antibody	M/s. InVentiv	In light of earlier recommendation of SEC on 29.11.23 & 30.11.24, the firm presented Phase Ia clinical study protocol No. VGA039-CP001 and Phase I (healthy subject) study report for further review by the committee.  After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm
<b>Biological Division</b>			
6.	4-449/Roche/16-BD  Emicizumab Injection (r-DNA origin) Solution for Injection	M/s. Roche Products India Pvt. Ltd.	The firm presented the proposal for compliance of condition imposed in new drug permission issued to import and market Emicizumab solution for injection (r-DNA origin) for the strengths 30mg/mL, 60mg/mL, 105mg/0.7mL and 150 mg/mL i.e., “the firm is required to submit Phase IIIb GCT report as and when it is completed”. The committee noted the results of the Phase IIIb GCT study presented by the firm as part of condition imposed in new drug permission along with PSUR results.
7.	4-52/Intas/PAC- R/Pegfilgrastim/2023- BD (Diary no. 8384)  Pegfilgrastim solution for injection 6mg/0.6mL vial & PFS	M/s. Intas	The firm presented the proposal for approval of revision in package insert for the product Pegfilgrastim (pegylated recombinant human granulocyte colony stimulating factor) solution for injection 6mg/0.6mL single use vial & PFS and 6mg/1.0mL single use PFS in line with innovator product.  After detailed deliberation, the committee recommended for approval of the updated package insert version 02 dated January 2023 for the product Pegfilgrastim (pegylated recombinant human granulocyte colony stimulating factor) solution for injection 6mg/0.6mL single use vial & PFS and 6mg/1.0mL single use PFS.
8.	X-11026/160/2023- BD  Crizanlizumab	M/s. Novartis	The firm did not turn up for the presentation.
<b>SND Division</b>			
9.	SND/MA/23/000271  Hydroxyurea Oral Suspension 100mg/ml	M/s. Pure & Cure Healthcare Private Limited	In light of earlier SEC recommendations dated 10.11.2023, the firm presented Bioequivalence study protocol (Protocol No. VRL-23-030, Version: 1.0 dated:

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			<p>26.12.2023) before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the Bioequivalence study as per protocol presented by the firm and submit report to CDSCO for further review by the committee.</p>