Recommendations of the SEC (Haematology) made in its 03rd/24 meeting held on 05.03.2024 at CDSCO (HQ), New Delhi:

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/143/22 Online Submission (31055) Ianalumab (VAY736)	M/s. Novartis	The firm presented Protocol Amendment version 03 dated 22 May 2023, Protocol Amendment version 04 dated 03 Nov 2023, Protocol No CVAY736Q12301. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
2.	CT/131/22 Online Submission (31236) Marstacimab	M/s. Pfizer	The firm presented Protocol Amendment 2 dated 20 Dec 2023, Protocol No B7841008. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
3.	CT/23/24 Online Submission (41968) Osivelotor (also known as PF-07940367 or GBT021601), 25mg & 100mg Tablets	M/s. Pfizer	The firm presented Phase 2/3 Clinical trial Protocol No C5351004 Amendment 6 dated 08 Feb 2024. After detailed deliberation, the committee recommended for grant of permission to conduct the clinical trial as presented by the firm with conditions that: 1. The recruitment should be done from multiple centers from states of Chhattisgarh, Madhya Pradesh and North Eastern States. 2. Safety profile shall be submitted for review before recruitment of adolescent population.
Biological Division			
4.	X-11026/160/2023-BD Crinzalizumab	M/s. Novartis	In light of regulatory action by EMA on MA of the product Crinzalizumab (Adakveo), the firm presented the status of the ongoing studies with the product Crizanlizumab concentrate for solution for infusion 10mg/mL (100mg/10mL). After detailed deliberation, the committee recommended the firm to submit interim safety and efficacy data of ongoing Phase IV study in India along with PSUR data in Indian population immediately to CDSCO for further evaluation by the committee.

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
5.	Dy. No. 7543 r Human Erythropoeitinalfa Injection	M/s. Intas Pharmaceuticals Ltd.	The firm presented the proposal for revision in Package Insert of rh-EPO (r Human Erythropoeitinalfa injection) 3000 IU/0.3ml, 5000 IU/0.5ml, 6000 IU/0.6ml, 20000 IU/1.0ml (vial). After detailed deliberation, the committee recommended the firm to present safety data from Indian population including PSUR safety data to support the proposed changes in PI. Accordingly, the firm should submit the information to CDSCO for evaluation by the committee.
SND Division			
6.	SND/MA/23/000271 Hydroxyurea Oral Suepension 100mg/ml	M/s. Pure & Cure Healthcare Private Limited	In light of earlier SEC recommendation dated 17.01.2024. Now, the firm presented Bioequivalence report before the committee. The firm has informed that the similar drug Hydroxyurea/hydroxycarbamide 100mg/ml oral solution is approved and available internationally in Austria, Estonia, Ireland, Lithuania, Poland, United Kingdom (MHRA), Scotlandas an Orphan drug for treatment of Sickle Cell Disease. The committee also noted that Hydroxyurea oral suspension 100mg/ml is indicated for rare disease & serious life threatening condition and there is an unmet medical need in the country. After detailed deliberation, the committee recommended for grant of permission to manufacture and marketing of Hydroxyurea Oral Suspension 100mg/ml with clinical trial waiver subject to condition that the firm should conduct Phase-IV clinical trial with appropriate and adequate paediatric population also. In addition to above, firm should fulfil the requirement of CMC data. Accordingly, the firm should submit Phase-IV clinical trial protocol within 03 months to CDSCO from date of approval of the product for further review by the committee.

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
7.	ND/MA/24/000006 Ferric Maltol Capsules 30mg	M/s. Emcure Pharmaceuticals Ltd.	The firm presented its proposal for grant of permission to manufacture and market the drug along with BE study protocol vide no. VRL-24-001, Version no. 2.0, dated 09.01.2024, along with a request to Phase III Clinical trial waiver before the committee. After detailed deliberation, the committee opined that there is unmet medical need. Hence, recommended for the grant of permission to conduct the Bioequivalence study as per the protocol presented. Accordingly, the firm should submit the Bioequivalence study results before the committee for further consideration.