Recommendations of the SEC (Haematology) made in its 08th/24 meeting held on 23.07.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/76/24 Online Submission (43508) Osivelotor (PF-07940367 or GBT021601) Tablets	M/s. Pfizer Limited	The firm presented Phase II/III clinical trial protocol No. C5351005 dated 08.02.2024. After detailed deliberation, the committee recommended for grant of permission to conduct the study with the condition that the firm shall first conduct part A of the study only for first 5 months and present the safety data for further review by the committee.
2.	CT/74/24 Online Submission (43414) Etavopivat 200mg	M/s. Novo Nordisk India Pvt. Ltd.	The firm presented Phase II clinical trial protocol No. 4202-HEM-204 version 3.0 dated 18.03.2024. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase II clinical trial as presented by the firm.
3.	CT/71/24 Online Submission (43293) REGN7999	M/s. Parexel International Clinical Research Private Limited	The firm presented Phase II clinical trial protocol No. R7999-BTHAL-2350, amendment 1, dated 09.04.2024. After detailed deliberation, the committee recommended for grant of permission to conduct only part A of the clinical trial.
4.	CT/70/24 Online Submission (43328) Etavopivat	M/s. InVentiv International Pharma Services Pvt. Ltd.	The firm presented Phase II/III clinical trial protocol No. 4202-HEM-301 version 6.0 dated 10.04.2024. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with condition that the trial shall be treated as Phase III clinical trial only.
5.	CT/91/23 Online Submission (33023) Mim8	M/s. Novo Nordisk India Pvt. Ltd.	The firm presented protocol amendment version 5.0 dated 17.04.2024 protocol No. NN7769-4532. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
6.	CT/39/23 Online Submission (32941)	M/s. InVentiv International	The firm presented protocol amendment version 4.0 dated 14.03.2024 protocol No. AP-0103.

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	SerpinPC	Pharma Services Private Limited	After detailed deliberation, the committee recommended for approval of protocol amendment with condition that the firm shall submit details of the serious adverse events for further review by the committee.
7.	CT/75/21 Online Submission (33149) Marstacimab	M/s. Pfizer Limited	The firm presented protocol amendment 4 dated 23.02.2024 protocol No. B7841007. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
8.	CT/117/22 Online Submission (33481) Fitusiran (SAR439774)	M/s. Sanofi Healthcare India Private Limited	The firm presented protocol amendment 4 version 1 dated 24.05.2023 protocol No. EFC17574. After detailed deliberation, the committee opined that the firm shall submit Justification for protocol amendments along with detailed safety reports and reason for high drop-out rates in the trial for further review by the committee.
Biological Division			
9.	BIO/CT04/FF/2023/37386 Pegylated Erythropoietin 100mcg/0.3 ml injection (PEG-EPO)	M/s. Cliantha	In light of earlier SEC recommendation dated 24.08.2023, the firm presented the revised proposal to conduct PK/PD study titled "A randomized, observer blind, parallel-group, active controlled, single dose study to compare pharmacokinetic, pharmacodyanamic, safety and immunogenicity of Pegylated Erythropoietin 100 mcg/0.3 ml injection (PEG-EPO) of Incepta and Methoxy Polyethylene Glycol-Epoetin Beta 100 micrograms/0.3 ml solution for injection of Roche (Mircera) in healthy adult human subjects" vide protocol No. C1B02794 version 02 dated 25.04.2024. After detailed deliberation, the committee recommended for approval of the study as per the revised protocol subject to the following conditions- 1. First dose of the test drug should be assessed for adverse reaction if any for 24 hours before dosing to

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			the rest of the subjects. 2. The firm should submit the safety data of initial ten subjects (five in each arm of test and reference product) for review by the committee for further continuation of the study.