

Recommendations of the SEC (Haematology) made in its 12th/24 meeting held on 20.11.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	GCT/PostAppr/2024/33481 Online Submission (33481) Fitusiran (SAR439774)	M/s Sanofi	In light of earlier SEC recommendation dated 23.07.2024, now the firm presented protocol amendment 04 version 1.0 dated 24 May 2023 protocol no. EFC17574. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
2.	GCT/PostAppr/2024/35583 Online Submission (35583) PF-06741086 (Marstacimab) Solution for Injection	M/s Pfizer	The firm presented protocol amendment 3 dated 23.07.2024. protocol no. B7841008. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
3.	GCT/PostAppr/2024/35530 Online Submission (35530) VAY736 (Ianalumab)	M/s Novartis	The firm presented protocol amendment version 05 dated 22 August 2024 protocol no. CVAY736O12301. After detailed deliberation, the committee recommended the firm to submit more justification for further review by the committee with respect to discontinuation of the patients as no safety guidelines are existing when the drug is not working.
4.	GCT/PostAppr/2024/35679 Online Submission (35679) Pozelimab and Cemdisiran	M/s Parexel International Clinical	The firm presented protocol amendment 5 dated 25 April 2024 protocol no. R3918-PNH-2021. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm. (Dr. S.P Verma didn't participate.)
5.	GCT/PostAppr/2024/35812 Online Submission (35812) Pozelimab (REGN3918) Cemdisiran (ALN-CC5)	M/s Parexel International Clinical	The firm presented protocol amendment 4 dated 29 April 2024 protocol no. R3918-PNH-2050. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm. (Dr. S.P Verma didn't participate.)

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Biological Division			
6.	BIO/CT18/FF/2024/4414 Luspatercept powder for solution for injection 25 mg and 75 mg	M/s. BMS India Pvt. Ltd.	<p>The firm presented the proposal for approval of additional indication of Luspatercept 25 mg and 75 mg powder for solution for injection i.e. “Luspatercept is indicated in adults for the treatment of transfusion-dependent anaemia due to very low, low and intermediate-risk myelodysplastic syndromes (MDS)” with the request for local clinical trial waiver due to unmet need in the country.</p> <p>The committee has noted that the proposed additional indication is approved in EU & US. The drug comes under the category of orphan drug and for the treatment of rare disease.</p> <p>The committee has also noted that Phase IV study is ongoing in India for indication already approved for the drug.</p> <p>After detailed deliberation, the committee recommended for the approval of proposed additional indication with condition to conduct phase IV clinical study by the means of amending the ongoing phase IV study protocol for inclusion of 30 evaluable MDS patients.</p> <p>Accordingly, the firm required to submit the revised Phase IV clinical study protocol to this office for further evaluation by committee.</p>
7.	r-DNA-11016(13)/27/2024-e-office Romiplostim Injection 250mcg/vial	M/s Enzene Biosciences Ltd.	The firm did not turn up for the presentation.
8.	BIO/CT04/FF/2024/45583 Recombinant Human Albumin	M/s Shilpa Biologicals Private Limited	The firm presented the proposal for the conduct of Phase III clinical trial titled “A Phase III, double blind, parallel, active controlled efficacy, safety and immunogenicity assessment study of Recombinant Human Serum Albumin 20% in decompensated liver cirrhosis patients with ascites or edema” vide Protocol No. NAL/SBPL/P3/2024

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			<p>Version 01 dated 16.09.2024 along with the results of the Phase I study conducted by the firm.</p> <p>After detailed deliberation, the committee recommended for approval to conduct the Phase III study as per presented protocol with the condition that study sites should be geographically distributed and Government sites should be included proportionately.</p>