Recommendations of the SEC (Oncology & Haematology) made in its 129th meeting held on 27.07.2022 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	4-74/Roche/PAC-R-Bevacizumab/2020-BD Bevacizumab	M/s. Roche	The firm presented its proposal for grant of approval for additional indication. The committee observed that proposed indication is already approved for Atezolizumab in combination with Bevacizumab. After detailed deliberation, the committee recommended for grant of approval for the additional indication for updation in the package insert of Bevacizumab.
2.	BIO/CT/19/000108 Durvalumab	M/s. AstraZeneca	The firm presented protocol number D133HC00003 amendment version 4.0 dated 04-04-2022 before the committee. The firm requested that "Urothelial Cancer" indication be removed from the Phase IV study since this indication has been withdrawn from the market for Durvalumab. The committee approved this recommendation. Further, the firm requested to update the sample size for the Phase IV study from 200 to 100 since the indication for "Urothelial Cancer" was removed & since > 225 Indian patients have already been randomized in nearly 12 different Durvalumab based Phase III trials in India. After detailed deliberation, the committee recommended for approval of this proposed amendment in the Phase IV clinical trial protocol in view of the above facts.
3.	BIO/CT04/FF/2022/32472 Pegfilgrastim 6 mg	M/s. Virchow biotech	The firm presented the proposed Phase IV protocol before the committee. After detailed deliberation, the committee recommended for grant of approval of the Phase IV study subject to the following changes in the protocol. 1. The primary endpoint should be safety and secondary endpoint should be efficacy. 2.The number of subjects should not be

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			less than 200. Accordingly, the firm should submit revised protocol to CDSCO for further consideration.
SND Division			
4.	SND/MA/21/000323 Tranexamic Acid spray 10 % w/v	M/s. Shilpa Medicare	The firm presented their proposal for manufacture and market of Tranexamic acid Spray 10% w/v with Phase III clinical trial results before the committee. After detailed deliberation, the committee recommended for grant of permission to manufacture and market Tranexamic acid Spray 10% w/v for the proposed indication.