Recommendations of the SEC (Ophthalmology) made in its 10th meeting held on 24.10.2024 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT04/FF/2024/44735 Ranibizumab Solution for Injection 1.65 mg/0.165 ml (10 mg/mL) in Pre-filledSyringe	M/s Intas Pharmaceuticals Ltd	The firm presented the proposal for the conduct of Phase III b study titled "Single Group, Phase 3b, Open Label, Single-Arm Study to Investigate Usability and Safety of the Pre-filled Syringe Delivering 0.5 mg Intas-Ranibizumab in Participants with Neovascular Age-Related Macular Degeneration" vide Protocol no. 0441-23, Version: 1.3 dated 01.08.2024. After detailed deliberation, the committee recommended for approval to conduct the proposed Phase III b study as per protocol presented by the firm. Note: Dr. Somesh Agarwal did not participate in the deliberation.
2.	BIO/CT04/FF/2023/38367 Ranibizumab Solution for Injection 10 mg/ml	M/s Sun Pharmaceutical Industries Limited	In light of earlier recommendation dated 22.05.2024, the firm presented the proposal for conduct of Phase IV study in the approved indications vide revised protocol ICR/23/004, Version No. 3.0 dated 09.07.2024. After detailed deliberation, the committee recommended for approval to conduct the study as per revised protocol presented by the firm.
3.	BIO/CT04/FF/2024/44244 Bevacizumab injection 1.25mg	M/s Gennova Biopharmaceuticals Limited	In light of earlier recommendation dated 22.08.2024, the firm requested for waiver of condition recommended by the committee that "firm shall submit complete safety and efficacy data for initial 50 patients (25 in each arm) before the committee for evaluation. The continuity of the study shall be allowed after satisfactory evaluation of the safety and efficacy results of the first 50 patients by the committee". The committee noted that the firm has included an independent DSMB in the revised protocol Version 2.0 dated 18.09.2024 who will monitor the safety

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			of trial subjects and DSMB report shall be submitted to CDSCO on regular basis. After detailed deliberation, the committee recommended for approval to conduct the study as per the revised protocol presented by the firm (Version 2.0 dated 18.09.2024)with a condition that firm should submit the DSMB report on the safety of first 50 patients and further on regular basis to CDSCO forthwith.
New Drugs Division			
4.	12-24/12-DC Bibrocathol 2% Eye Ointment	M/s. Ursapharm India Private Limited Delhi	The firm presented the Phase III Clinical trial report for import and marketing of new drugs Bibrocathol 2% eye ointment before the committee. After detailed deliberation, the committee recommended for the grant of permission for import and marketing of new drug Bibrocathol 2% eye ointment to be prescribed by Ophthalmologist only. Firm is required to do post marketing surveillance to establish safety of eye ointment in more number of Indian patients and is required to submit PMS protocol for further deliberation by the committee within 3 months of approval.