Recommendations of the SEC (Ophthalmology) made in its 09th/24 meeting held on 19.09.2024 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT04/FF/2024/44438 Aflibercept Injection 40 mg/ml, 0.278 ml/ vial	M/s. Sun Pharmaceutical Industries Limited	The firm presented the protocol to conduct Phase III clinical study of Aflibercept injection 40mg/mL, 0.278 mL/vial in patients with neovascular age-related macular degeneration titled "A Prospective, Multicenter, Double-Blind, Active-Controlled, Parallel-Group, Phase III Study to Compare the Efficacy, Safety and Immunogenicity of Sun's Aflibercept with Reference Biologic in Patients with Neovascular Age-Related Macular degeneration (wet AMD) vide Protocol No. ICR/24/006, Version No. 1.0; dated 18.6.2024. After detailed deliberation, the committee recommended for conduct of proposed Phase III study with the following changes in the protocol- 1. Follow-up duration of the study should be increased to 6 months and subsequent dose of study drug should be provided to the study subjects if required based on the observation during the follow up study duration. All the proposed primary and secondary efficacy endpoints should be evaluated at 6 months (24 weeks) in addition to the safety. 2. For the standard care treatment, Ranibizumab should be used if required along with other medications. Accordingly, firm should submit the revised protocol to CDSCO for evaluation.
2.	BIO/CT04/FF/2024/44147 Bevacizumab Injection 5mg/0.2ml in vial (Dose-	M/s. Reliance Life Sciences Pvt. Ltd.	The firm presented the protocol to conduct Phase II/III clinical trial of R-TPR-023 (RLS- Bevacizumab Injection 1.25mg (i.e. 0.05 mL of 25mg/mL solution) in patients with neovascular wet AMD titled "A prospective, multicentre,

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
	1.25mg)		randomized, open label, two-arm, parallel group, active control, comparative phase II / phase III clinical study to evaluate efficacy, safety and immunogenicity of R-TPR-023 (RLS-Bevacizumab) / Accentrix® (Ranibizumab) in patients with neovascular (wet) age-related macular degeneration" vide Protocol No. RLS/OPT/2024/03 Version 1.0, dated 12.06.2024. After detailed deliberation, the committee recommended the firm to submit the following- 1. Justification of sample size calculation of the proposed study. 2. Protocol should include provision of standard of care to the study subjects for the other eye during the study. Accordingly, firm should submit the revised protocol and sample size justification for further evaluation by the committee. NB: Dr Somesh did not participate in the deliberation.
New Drug Division			
3.	12-24/12-DC Bibrocathol 2% Eye Ointment (Posiformin 2% Eye Ointment)	M/s. Ursapharm India Private Limited, Delhi	The firm did not turn up for the presentation.