Recommendations of the SEC (Ophthalmology) made in its 03rd/26 meeting held on 17.03.2026 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT21/BO/2025/52762 Bevacizumab Injection 1.25 mg (0.05mL of 25 mg/ml solution)	M/s. Gennova Biopharmaceuticals Limited	The firm presented the proposal for the grant of permission to manufacture Bevacizumab Injection 1.25 mg for sale or distribution for the indication "for the treatment of wet age-related macular degeneration (wet AMD) in adults". The committee noted the results of the Phase III study conducted by the firm to compare the efficacy and safety of Bevacizumab (GBL 1204) with Ranibizumab in patients with Wet Age-Related Macular Degeneration. The committee also noted that the dose of 1.25 mg of bevacizumab is included in the World Health Organization (WHO) Model List of Essential Medicines for intravitreal injection. Further, the committee also noted that EMA has approved the drug Bevacizumab with dose of 1.25 mg every 4 weeks (monthly) in wet AMD in adults. After detailed deliberation, the committee recommended for grant of permission to manufacture and market Bevacizumab Injection 1.25 mg for the indication "for the treatment of wet age-related macular degeneration (wet AMD) in adults" along with a condition that the firm should conduct active PMS study in significant number of patients. Accordingly, the firm should submit protocol for conduct of active PMS study within 3 months of grant of marketing authorization permission

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			to manufacture and market the product.
FDC Division			
2.	FDC/CT/22/000007 Brinzolamide IP 10 mg + Timolol Maleate IP eq. to Timolol 5 mg + Potassium Sorbate IP (as preservative) 0.47% w/v per mL Ophthalmic Suspension	M/s. Sun Pharma Laboratories Limited	In light of earlier SEC recommendation dated 07.04.2022 and as per condition of Form CT-23 dated 09.12.2021, the firm presented Phase IV clinical trial report before the committee. After detailed deliberation, the committee noted and agreed to the result of the clinical trial report. Dr. Purvi Bhagat did not participate in the discussion.