Recommendations of the SEC (Ophthalmology) made in its 08th/25 meeting held on 26.08.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/101/25 Online Submission (50891) T1695 (Tacrolimus)	M/s Syneos Health India Private Limited	Under Discussion.
Biological Division			
2.	BIO/CT18/FF/2025/47607 Aflibercept Injection, 40 mg/mL, in vial form	M/s. Biocon Biologics Limited	The firm presented their proposal for grant of permission to import and market the drug product Aflibercept solution for injection in a vial (40 mg/ml) for the following indications based on the results of global clinical trial conducted in the indication of Diabetic Macular oedema (DME) where India is one of the participating country – • Neovascular (wet) age-related macular degeneration (AMD), • Visual impairment due to macular oedema secondary to retinal vein occlusion (branch RVO or central RVO) • Visual impairment due to diabetic macular oedema (DME) • Visual impairment due to myopic choroidal neovascularisation. After detailed deliberation, the committee recommended for grant of permission to import and market the drug product Aflibercept solution for injection in a vial (40 mg/ml) for applied indications with a condition to conduct Phase IV study in India for indications of macular oedema secondary to retinal vein occlusion (branch RVO or central RVO), myopic choroidal neovascularization (CNV) and neovascular (wet) age-related macular degeneration (AMD) with statistically significant sample size for each

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			indication. Accordingly, firm shall submit Phase IV Clinical Trial protocol to CDSCO within 03 months of grant of marketing authorization permission.
FDC Division			
3.	FDC/MA/23/000027 Moxifloxacin Hydrochloride IP eq. to Moxifloxacixn 0.5 % w/v + Nepafenac 0.1 % w/v + Benzalkonium Chloride Solution IP 0.01 % v/v Ophthalmic Solution	M/s Akums Drugs & Pharmaceuticals Ltd.	In light of earlier SEC recommendation dated 23.03.2023, the firm presented Phase III clinical trial report before the committee. After detailed deliberation, the committee opined that: 1. The firm should provide detailed subgroup analysis for different multicenters and specific clinical conditions. 2. The firm should provide justification for the use of Moxifloxacin in all inflammatory conditions. 3. The firm should provide justification for using QID dose for both Nepafenac and Ketorolac. 4. High dosage of NSAIDs may lead to epithelial toxicity, the firm should clarify whether such prone cases were excluded or not. Accordingly, the firm should submit above data for further review by the committee.