Recommendations of the SEC (Ophthalmology) made in its 12th/25 meeting held on 10.12.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND/CT/25/000117 Pilocarpine Hydrochloride Eye Drops 1.25% w/v	M/s. Sun Pharma Laboratories Limited.	The firm presented the Phase IV clinical trial protocol for the applied product Pilocarpine Hydrochloride Eye Drops 1.25% w/v for treatment of Presbyopia in Adults before the committee. After detailed deliberation, the committee accepted the Phase IV clinical trial protocol as presented by the firm with subject to the following condition: The inclusion and exclusion criteria need to be well defined: 1. Myopic degeneration patients to be included in the exclusion criteria. 2. Patients having a history of Uveitis or having any sign of active inflammation/uveitis. 3. Post-cataract surgery patients are to be excluded. 4. Sample size shall be increased to 500. Accordingly, the firm should submit the revised Phase IV protocol to CDSCO within 15 days.
FDC Division			
2.	FDC/MA/23/000027 Moxifloxacin Hydrochloride IP eq. to Moxifloxacin 0.5% w/v + Nepafenac 0.1% w/v + Benzalkonium Chloride Solution IP (as preservative) 0.01%v/v Ophthalmic Solution.	M/s. Akums Drugs & Pharmaceuticals Ltd.	In light of earlier SEC recommendation dated 26.08.2025, the firm presented the justification before the committee. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of the proposed FDC with the condition that Active PMS study should be conducted. Further, firm shall update prescribing information (product information leaflet) with the followings: 1. The FDC of Moxifloxacin 0.5% w/v + Nepafenac 0.1 % w/v ideally to be used

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			TID. 2. Based on the severity and clinical picture the treating physician may decide the dose. Accordingly, firm should submit revised Prescribing Information (PI) to CDSCO before approval and submit Active PMS study protocol to CDSCO within 3 months of approval of the FDC for review by the committee
3.	FDC/MA/23/000377 Moxifloxacin Hydrochloride IP Equivalent to Moxifloxacin 0.5 % w/v + Nepafenac 0.1 % w/v + Benzalkonium Chloride IP 0.01 % w/v (as preservative) Ophthalmic solution.	M/s. Ajanta Pharma Limited.	In light of earlier SEC recommendation dated 22.02.2024, the firm presented Phase III clinical trial report before the committee. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of the proposed FDC with the condition that Active PMS study should be conducted. Accordingly, the firm should submit Active PMS study protocol to CDSCO within 3 months of approval of the FDC for review by the committee