

Recommendations of the SEC (Ophthalmology) made in its 10th/25 meeting held on 08.10.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	E-receipt no. 93869 Aflibercept (EYLEA)	M/s. Bayer Pharmaceuticals Pvt. Ltd.	The firm presented the CSR of Phase IV study titled “Phase IV interventional post approval trial to assess the safety of intravitreal aflibercept for the treatment of diabetic macular edema (DME) in patients in India” vide Protocol No.: 21974, Version 01 dated 20.12.2021 The committee noted the results of CSR.
SND Division			
2.	SND/CT/25/000107 Atropine Sulfate Ophthalmic Solution USP 0.05% w/v	M/s. Entod Pharmaceuticals Ltd.	The firm presented the proposal to conduct Phase IV Clinical study of Atropine Sulfate Ophthalmic Solution USP 0.05% w/v vide Protocol ID.BCR-EPL-004, Version 1.0 Dated 17 July 2024 before the committee. After detailed deliberation, the committee recommended for approval to conduct the Phase IV Clinical study as per protocol presented by the firm.
3.	SND/MA/25/000168 Atropine Sulphate Ophthalmic Solution IP 0.025% w/v	M/s. Sun Pharmaceuticals Limited	Firm presented their proposal for granting permission for the manufacturing and marketing of the product Atropine Sulfate Ophthalmic Solution IP 0.025% with clinical trial waiver. The firm stated that product Atropine Sulfate Ophthalmic Solution 0.025% (Rejucea Mini Ophthalmic Solution 0.025%) is approved in Japan on 27.12.2024 for inhibition of myopia progression. After detailed deliberation, the committee opined that the published clinical data presented by the firm is not adequate to prove the efficacy of the applied product. Accordingly, committee recommended that the firm should conduct the Phase III clinical trial.
FDC Division			
4.	FDC/MA/21/000132 Netarsudil Mesylate eq. to Netarsudil 0.2	M/s. Pure & Cure Healthcare Pvt. Ltd.	The firm did not turn up for the presentation.

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	mg + Latanoprost IP 0.05 mg + Benzalkonium Chloride IP 0.2 mg (as preservative) per ml Ophthalmic Solution		