Recommendations of the SEC (Ophthalmology) made in its 07th/26 meeting held on 15.07.2026 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/MA/26/000053 Perfluorohexyloctane Ophthalmic Solution 1.338 g/mL	M/s. Mankind Pharma Limited.	The firm presented the proposal for grant of permission to manufacture and market Perfluorohexyloctane Ophthalmic Solution 1.338 g/mL along with phase III Clinical Trial protocol (Study Code COD-26-004, Protocol Version No: 1.0, dated 16-Apr-2026) before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct Phase III clinical trial with the condition that firm should include OSDI questionnaire in the safety parameters. Accordingly, the firm should submit the revised Phase III clinical trial protocol to CDSCO.
SND Division			
2.	SND/MA/24/000241 Voriconazole Powder for Eye Drops 1% w/v	M/s. Protech Telelinks.	The firm did not attend the meeting.
3.	SND/MA/26/000056 Clobetasol Propionate Ophthalmic Solution 0.05%w/v	M/s. Sun Pharma Laboratories Limited.	Firm presented proposal for manufacturing & marketing of Clobetasol Propionate Ophthalmic Solution 0.05 % w/v along with Phase-III Clinical Trial Protocol, before the committee. The committee noted that Clobetasol Propionate Ophthalmic Suspension 0.05% w/v is approved in USA. After detailed deliberation, the committee recommended grant of permission to conduct Phase III Clinical Trial with the following changes in the protocol- 1. An interim analysis of results upon 50% completion of study should be submitted. 2. Intraocular pressure should be monitored throughout the study. Accordingly, firm should submit revised CT Protocol to CDSCO. Note: Dr. Purvi Bhagat did not participate in the discussion.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
4.	SND/MA/26/000061 Atropine Sulphate Ophthalmic Solution IP 0.025%w/v	M/s. Entod Pharmaceuticals Ltd.	The firm presented their proposal for manufacturing and marketing of Atropine Sulphate Ophthalmic Solution IP 0.025% w/v for controlling the progression of myopia in children aged 6 to 12 years, along with the request of Phase III clinical trial waiver. The firm stated that Atropine Sulphate Ophthalmic Solution 0.01% w/v and 0.05% w/v were already approved in India for controlling the progression of myopia in children aged 6 to 12 years, and that the applied strength of 0.025% w/v is an intermediate strength. The firm also informed that, Atropine Sulphate Ophthalmic Solution 0.025% w/v was approved in Australia, Japan and New Zealand since 21.12.2023. After detailed deliberation, the Committee opined that the published clinical data presented by the firm were inadequate to establish the efficacy of Atropine Sulphate Ophthalmic Solution 0.025% w/v for the applied indication in the Indian population. Therefore, the Committee recommended that the firm should conduct a Phase III clinical trial in the Indian population. Accordingly, Phase III clinical trial protocol shall be submitted to CDSCO for deliberation by the SEC.
5.	SND/MA/25/000168 Atropine Sulphate Ophthalmic Solution IP 0.025% w/v	M/s. Sun Pharma Laboratories Limited.	The firm did not attend the meeting.