Recommendations of the SEC (Ophthalmology) made in its 02nd/25 meeting held on 25.02.2025. at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/04/25 Online Submission (47293) Axitinib (OXT TKI)	M/s PFC Pharma Focus India Private Limited	The firm presented phase 3 clinical study protocol no. OTX-TKI-2023-AMD-303 version 4.0 dated 20 November 2024. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
2.	CT/156/24 Online Submission (46889) Vorolanib	M/s Synoes Health India Private Limited	In light of earlier SEC Recommendation dated 08.01.2025, now the firm presented phase 3 clinical study Protocol no: EYP-1901-302 Amendment 1 dated 29-Aug-2024. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
3.	CT/155/24 Online Submission (46922) Vorolanib	M/s Synoes Health India Private Limited	In light of earlier SEC Recommendation dated 08.01.2025, now the firm presented phase 3 clinical study Protocol no: EYP-1901-301 Amendment 1 dated 29-Aug-2024. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
Biological Division			
4.	BIO/CT04/FF/2024/46114 Bevacizumab Solution for Injection 25 mg/mL (Vial 5.75mg/0.23 mL)	M/s. Intas Pharmaceuticals Ltd	The firm presented the protocol to conduct Phase II/III clinical trial titled "A Phase 2/3, Randomized, Double-Masked, Parallel Group, Multicentre, Comparative Clinical Study to Evaluate the Efficacy, Safety, Pharmacokinetics and Immunogenicity of Intas Bevacizumab and Ranibizumab Intravitreal Injection in Participants with Neovascular (wet) Age-Related Macular Degeneration" vide Protocol No. 0235-24A; Version 2.0 dated 10 Sep 2024 After detailed deliberation, the committee recommended for grant of permission to conduct the proposed Phase II/III study

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			with the following conditions-. 1. Protocol should include provision for standard of care to the study subjects for the other eye if required during the study. 2. Firm should submit results of the Phase II clinical study to CDSCO after completion of the study. Accordingly, firm should submit the revised protocol to CDSCO for evaluation. Note: Dr Somesh Agarwal did not participate in the deliberation.
5.	E-59473 Brolucizumab Solution for Injection 120 mg/ml	M/s. Sandoz Pvt Ltd	The firm did not turn up for the presentation.
SND Division			
6.	SND/MA/21/000499 Atropine Sulfate Ophthalmic Solution USP 0.01% w/v	M/s. Indiana Ophthalmics	In light of earlier SEC recommendations dated 20.07.2023. The firm presented justification for waiver of Phase-III clinical trial along with preclinical toxicity data before the Committee. The firm has informed that Atropine Sulfate Ophthalmic Solution USP 0.01% w/v is already approved by CDSCO on 12.01.2021 for the indication to control the progression of myopia in children of 5 years and above. After detailed deliberation, the committee recommended for grant of permission to manufacture and marketing of Atropine Sulfate Ophthalmic Solution USP 0.01% w/v for proposed indication with waiver of local clinical trial subject to condition that the firm should conduct Phase-IV clinical trial. Accordingly, the firm should submit Phase-IV clinical trial protocol to CDSCO within three months from date of approval of the drug for further review by

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			the Committee.