

Recommendations of the SEC (Ophthalmology) made in its 04th/24 meeting held on 25.04.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	2706/23 Brolucizumab solution for Injection 120mg/ml	M/s. Sandoz Pvt. Ltd.	The firm presented the proposal for approval of updated pack insert of Brolucizumab solution for Injection 120mg/ml (Pagenax), from version 14 Dec 2022 to 20 Oct. 2023 in line with the approval of Swissmedic with respect to section dosage/administration, overdose, adverse effects, clinical efficacy & pharmacokinetics. . After detailed deliberation, the committee recommended for grant of approval of updated pack insert dated 20 Oct. 2023 as presented by the firm.
2.	BIO/CT21/BO/2023/39673 Adalimumab 40mg/ 0.4 ml solution for injection	M/s. Shilpa Biologicals Private Limited	The firm presented the proposal for approval of following additional indications by the way of extrapolation in line with the indications of innovator product. 1. Uveitis 2. Paediatric Uveitis After detailed deliberation, the committee recommended the firm to submit the Phase IV clinical study data for consideration of the applied indications.
SND Division			
3.	SND-11011(13)/1/2024-e-office Atropine Sulfate Ophthalmic Solution USP 0.015 w/v	M/s. Entod Pharmaceuticals Limited	The firm did not turn up for presentation.
FDC Division			
4.	FDC/MA/24/000091 Dorzolamide Hydrochloride IP eq. to Dorzolamide 2% w/v + Brimonidine Tartrate IP 0.1% w/v + Isotonic Aqueous Vehicle qs per mL Eye Drops	M/s. Cipla Limited	The firm presented the proposal along with Phase III clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III clinical trial. Accordingly, the firm should submit Phase III clinical trial report to CDSCO for further review by the committee.