Recommendations of the SEC (Ophthalmology) made in its 1st/24 meeting held on 16.01.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT21/FF/2023/39487 Ranibizumab solution for injection	M/s. Reliance Life Sciences Pvt Ltd.	The firm presented the proposal for approval of additional indications by way of extrapolation for the approved drug product Ranibizumab solution for injection 2.3mg/0.23mL (0.5mg dose) and1.38mg/0.23mL (0.3mg dose) in line with the indications approved for the innovator product. In light of earlier SEC recommendations dated 19.12.2023, the firm presented the safety analysis of each of the TEAEs from baseline till AE resolution for the ongoing Phase IV study of the approved product. After detailed deliberation, the committee recommended for approval of the additional indications by the way of extrapolation with the local clinical trial waiver for the additional indications in line with the indications approved for the innovator product with condition that the firm should submit every 6 month report of Post Marketing Surveillance for the additional indication as per rules. (Dr. Somesh Aggarwal did not participate in the discussion).
SND Division			
2.	SND/MA/23/000062 Pilocarpine Hydrocloride Opthalmic Solution 1.25% w/v	M/s. Pure & Cure Healthcare Private Limited	The firm presented proposal for grant of manufacture and market of Pilocarpine Hydroclorideopthalmic solution 1.25% w/v along with clinical trial protocol before the committee. The firm informed that Pilocarpine Hydroclorideopthalmic solution 1.25% is approved in USA since 1974 indicated for the treatment of Presbyopia in adult. After detailed deliberation, the committee recommended for the grant of permission to conduct the Phase-III clinical trial as per protocol presented by the firm subject to following conditions:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			1. Placebo used in this trial shall be free from preservative and should not have any inherent side effect. 2. In exclusion criteria the patient on cholinergic drugs**,** and any drugs with drug interactions with pilocarpine, high myopia, COPD, Bradycardia, blood coagulopathy, retinal pathology and headache shall be excluded. 3. Compensation will be applicable as per NDCT Rules, 2019.
FDC Division			
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	The firm didn`t turn up for presentation.