Recommendations of the SEC (Ophthalmology) made in its 53rd meeting held on 28.01.2022 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	12-01/21-Dc (Pt-363) Carboxy methyl cellulose sodium Eye Drops IP 0.5% w/v	M/s. Allergan India Pvt. Ltd.	The firm presented the proposal of switching Carboxy methyl cellulose sodium Eye Drops IP 0.5% w/v from prescription to non prescription drug before the committee. After detailed deliberation, the committee recommended that the said drug product may be sold by retail without the prescription of a Registered Medical Practitioner. Further, action may be taken as per the rules.
FDC Division			
2.	FDC/MA/21/000132 Latanoprost 0.0500mg + NetarsudilMesylate eq. to Netarsudil 0.2mg)	M/s. Pure & Cure Healthcare Pvt. Ltd.	In light of earlier SEC recommendation dated 30.07.2021, the firm presented their proposal along with revised Phase III CT protocol before the committee. Committee noted that the firm did not submit the ocular toxicity study data generated in GLP accredited laboratory which may be submitted to CDSCO. Further, as regard to Phase III CT protocol after detailed deliberation, committee opined that: 1. The firm should specify the severity of glaucoma in the protocol under inclusion criteria. 2. Advanced cases of Glaucoma should be excluded. 3. Perimetry should be conducted during initial visit and at end of the study and other Glaucoma investigations need to be done at each visit. Accordingly, the firm should submit the revised Phase III CT protocol to CDSCO for further deliberation by the committee.
3.	FDC/MA/21/000021 Ketorolac Tromethamine IP + Phenylephrine Hydrochloride IP (0.3% w/v+1.0% w/v)	M/s. Akums Drugs and Pharmaceutical Limited	The firm did not turn up for the presentation.

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
	Ophthalmic solution		
4.	4-64/2018-DC Ripasudil 0.4% w/v +Timolol 0.5% w/v eye drops	M/s. Ajanta Pharma	In light of earlier SEC recommendation dated 15.12.2019, the firm presented the Phase III CT report before the committee. After detailed deliberation, the committee opined that the applicant should submit following data: 1. Causality assessment report. 2. Details of lost to follow up study subjects. 3. Various steps involved in analyzing the data and details of the software used in statistical assessment of the data. Accordingly, the firm should present the above data before the committee for further consideration.