Recommendations of the SEC (Ophthalmology) made in its 62nd meeting held on 18.01.2023 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND/MA/22/000484 Bimatoprost Preservative Free 0.03 mg/ml Eye Drop, Solution	M/s Medicom International	The firm presented the proposal to import and marketing of Bimatoprost preservative free 0.3mg/ml eye drops solution indicated for treatment of Reduction of elevated intraocular pressure in chronic open-angle glaucoma and ocular hypertension in adults (as monotherapy or as adjunctive therapy to beta-blockers) before the committee. The firm presented that the applied product is approved and being marketed in major key countries like United Kingdom, France, Spain, Netherland, Germany and Canada. Bimatoprost Ophthalmic solution 0.03% is also approved in the India since 08.01.2002. The firm also presented the published literature on following Clinical Studies before the committee along with the therapeutic rationale: • A Randomised, parallel group double-masked trial • A Non- interventional, open-label, prospective study • A Prospective, randomized, investigator-masked, cross-over study • A non-controlled prospective study • A prospective nonrandomized clinical audit After detailed deliberation, the committee recommended for grant of permission to import and marketing with the condition to submit the Post marketing surveillance data to the CDSCO.
FDC Division			
2.	FDC/MA/20/000095 Timolol + Brinzolamide + Brimonidine (5mg/ml + 10mg/ml +2mg/ml) eye drops	M/s Micro Labs Ltd.	The firm did not turn up for presentation.

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
Medical Device Division			
3.	IMP/MD/2019/ 000080 Glaucoma Treatment System (Xen 45)	M/s Allergan India Private Limited	The firm presented their proposal for the waiver of the condition that the firm should conduct Phase IV clinical investigation in India, mention in form MD-27. After detailed deliberation, the committee recommended that the firm is required to conduct Phase IV clinical investigation on Indian population. Accordingly, the firm should submit the protocol of Phase IV clinical investigation within 3 month for committee review.