Recommendations of the SEC (Ophthalmology) made in its 63rd meeting held on 22.02.2023 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT04/FF/2022/ 35115 Ranibizumab solution for injection 10mg/ml	M/s. Lupin Limited	The firm presented its proposal for grant of permission to conduct clinical trial titled "A randomized, open label study to compare pharmacokinetics and safety of Lupin's Ranibizumab with Lucentis® in patients with neovascular age-related macular degeneration" as per protocol No. LRP/LUBT010/2022/001; version 1.0 Date: 10.08.2022. After detailed deliberation, the committee recommended for grant of permission to conduct the study as per presented protocol.
2.	BIO/CT18/FF/2022 /34947 Faricimab 6mg/0.05mL solution for Intravitreal Injection	M/s. Roche Products (I) Pvt. Ltd.	The firm presented the proposal to import and market Faricimab 6mg/0.05mL solution for intravitreal injection indicated for the treatment of Neovascular (wet) age-related macular degeneration (nAMD) and Diabetic Macular edema (DME) with a request for waiver of Phase III clinical trial in the country. The committee noted that the applied drug is approved in 57 countries including USA, Canada, EU, Australia, Japan, UK and the product has novel mechanism of action in comparison to existing products. Further, the firm stated that in the Phase III clinical trials performed globally there were Asian population also. After detailed deliberation, the committee recommended for grant of permission for import and marketing of the drug with local Phase III clinical trial waiver subject to condition that firm should conduct Phase IV clinical trial. Accordingly, Phase IV clinical trial protocol should be submitted within 3 months of marketing approval.
SND Division			
3.	SND/MA23/000003	M/s. Ajanta Pharma	The firm presented the clinical trial protocol No. APL/CT/22/13, version 00 dated 17.08.2022 with a proposal to

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
	Pilocarpine Hydrochloride Solution 1.25 % w/v		conduct the Phase III clinical trial for "treatment of Presbyopia in adults" before the committee. After detailed deliberation, the committee recommended for grant of permission for conduct of the Phase III clinical trial.
FDC Division			
4.	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 the presentation.
Medical Device Division			
5.	CI/MD/2022/70107 Ocufilcon D 55% Water contact Lens, (Ocufilcon D 55% Water) Contact Lens Omafilcon A dual-Focus Contact lenses	M/s. Hyderabad Eye Research Foundation	The firm presented its proposal for pivotal clinical investigation of the proposed product in the country before the committee. After detailed deliberation, the committee recommended for grant of permission for conduct of the pivotal clinical investigation of the proposed product in the country on Indian population.