Recommendations of the SEC (Ophthalmology) made in its 59th meeting held on 28.10.2022 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT/20/000094 Aflibercept Injection 40mg/ml	M/s. Bayer Pharmaceuticals Pvt. Ltd.	The firm did not turn up for presentation.
2.	BIO/CT/20/000161 Brolucizumab injection 120 mg/ml	M/s. Sandoz Private Limited	The firm presented interim safety analysis report of ongoing Phase IV clinical trial as per recommendation of SEC (Ophthalmology) meeting dated 05.11.2021. The committee noted the results of the interim safety analysis of patients who have competed one dosing of the drug. The committee also noted that the firm has submitted three PSUR data to CDSCO up till and there was no additional safety signal identified as informed by the firm. After detailed deliberation, the committee opined that the firm should review all the PSUR data of the drug and present summarized report of the PSUR data along with the Phase IV study report after completion of the study for further evaluation by the committee.
SND Division			
3.	SND/MA/22/000252 Acetazolamide for injection USP 500 mg	M/s. Emcure Pharmaceuticals	The firm presented their proposal of manufacture and marketing permission of Acetazolamide for Injection USP 500mg for the indication of "Glaucoma". Acetazolamide is useful in glaucoma (chronic simple (open-angle) glaucoma, secondary glaucoma, and preoperatively in acute angle closure glaucoma where delay of surgery is desired to lower intraocular pressure) because it acts on inflow, decreasing the amount of aqueous secretion) with justification for local clinical trial and BA/BE study waiver before the committee. The committee opined that the firm presented only few available published data of the Acetazolamide Injection formulation. No pharmacokinetics and

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			safety efficacy data of the said drug product is available in Indian population. After detailed deliberation, the committee recommended that the firm should perform pharmacokinetics study and Phase III clinical study in Indian population to generate safety and efficacy data of proposed formulation in Glaucoma. Accordingly, the firm should submit the respective protocol to CDSCO for further review by the committee.