Recommendations of the SEC (Ophthalmology) made in its 72nd meeting held on 19.12.2023 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT21/FF/2023/38227 Ranibizumab solution for injection 10 mg/ml	M/s. Sun Pharma	In light of the earlier SEC recommendations dated 20.09.2023, the firm presented the proposal for approval of additional indications of 1) Diabetic Macular Oedema (DME) 2. Macular Oedema following Retinal Vein Occlusion (RVO) and 3. Visual Impairment due to Choroidal Neovascularization (CNV) secondary to Pathological Myopia (PM) for the drug Ranibizumab solution for injection 10 mg/ml by the way of extrapolation in line with the approved indications of innovator drug. After detailed deliberation, the committee recommended for approval of the proposed additional indications i.e 1) Diabetic Macular Oedema (DME) 2. Macular Oedema following Retinal Vein Occlusion (RVO) and 3. Visual Impairment due to Choroidal Neovascularization (CNV) secondary to Pathological Myopia (PM) by way of extrapolation in line with the approved indications of innovator drug with a condition to conduct Phase-IV study in Indian patients for the said indications. Accordingly, the firm should submit the Phase IV clinical trial protocol to CDSCO within three months of approval for the proposed indication.
2.	BIO/CT/20/000126 Ranibizumab 10mg/mL	M/s. Reliance Life Sciences	The firm presented their proposal of interim analysis report of the ongoing Phase IV study of Ranibizumab for intra-vitreal injection. After detailed deliberation, the committee noted interim analysis results presented by the firm. Further the committee observed from the presented results that most of the TEAEs were cataract, conjunctival haemorrhage, conjunctival hyperemia, conjunctival oedema, uveitis, vitreous floaters and vitreous haemorrhage. The committee

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			recommended that the firm should submit safety analysis of each of the TEAEs along with complete clinical picture from baseline till AE resolution / end of study. Accordingly the firm should submit the data to CDSCO for further evaluation by the committee.
GCT Division			
3.	CT/40/23 Online Submission (30024) RO7200220	M/s. Roche	The firm presented protocol clarification for fulfilling the condition (i) (Protocol shall be amended to include enrollment in India as presently protocol describes enrollment sites in Japan) of CT NOC for protocol No. GR44278. After detailed deliberation, the committee accepted the justification submitted for compliance of condition (i) of CT NOC as presented by the firm.