

Recommendations of the SEC (Ophthalmology) made in its 52nd meeting held on 22.12.2021 at CDSCO HQ, New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	4-93/Intas/PAC-R/Ranibizumab/2021-BD Ranibizumab	M/s. Intas Pharmaceuticals Limited.	The firm presented the proposal for additional indication (a) proliferative diabetic retinopathy (PDR) in adults. (b) Retinopathy of prematurity (ROP) in preterm infants. After detailed deliberation, the committee recommended for grant of permission for approval of the drug for proliferative diabetic Retinopathy (PDR) in adults. For retinopathy of prematurity (ROP) in preterm infants indication, the firm should submit PSUR data generated in the country for further evaluation by the committee.
New Drug Division			
2.	12-01/21-DC(Pt-363) Carboxy methyl cellulose Sodium Eye Drops IP 0.5% W/v	M/s. Allergen India Pvt.Ltd	The firm didn't turn up for presentation.
GCT Division			
3.	CT/21/19 Online Submission (11919) QL1205/ Ranibizumab	M/s. Kandle	The firm presented the proposed protocol no. QL1205-002, amendment version 4.0 dt. 01-JUN-2021 before the committee. After detailed deliberation, the committee recommended for conduct of the study as per proposed amendment.
Medical Device Division			
4.	4-MD/CT-192/2017-DC Endo Art	M/s. Hyderabad Eye Research Foundation	In light of earlier recommendation dated 05.12.2019, the firm presented the outcome of the study on 2 patients. After detailed deliberation, the committee opined that the data presented so far by the firm is satisfactory. However, the committee recommended for continuation of the study on remaining patient as per the amended protocol.
5.	CI/MD/2021/49984 Artificial Endothelial	M/s. Nextvel Consulting LLP	The firm presented their proposal before the committee.

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
	layer		After detailed deliberation, the committee recommended for grant of permission to conduct the proposed study subject to condition that 50% of sites should be from Government hospitals.