

Recommendations of the SEC (Ophthalmology) made in its 58th meeting held on 22.09.2022 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/CT/18/FF/2019/16128 Propylene Glycol USP 0.600% w/v Lubricant Eye drops	M/s. Alcon Laboratories (India) Pvt. Ltd	The firm presented the Post Marketing Surveillance Study (PMS Study) protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the study as per the presented protocol.
Biological Division			
2.	BIO/CT/20/000008 Ranibizumab Solution for Injection 10 mg/ml	M/s Intas Pharmaceuticals Limited	The firm presented the amendment in already approved Phase III clinical trial protocol titled "A double masked, parallel group, randomized, multicenter, clinical study to compare efficacy and safety of Intas Ranibizumab with Lucentis® in patients with neovascular (Wet) Age-related macular degeneration (AMD)" with Protocol No. 0504-19 Version No. 4.0 dated 10th Feb, 2022. After detailed deliberation, the committee recommended for grant of approval for amendment of the study protocol as presented. N.B: Dr. Somesh Aggarwal did not participate in the deliberation.
3.	BIO/CT/22/000010 Ranibizumab 10 mg/ml	M/s Lupin Limited	The firm presented the Phase IV clinical trial protocol titled "A prospective, multi-center, single arm, open label, Phase IV study to evaluate safety and efficacy of RaniEyes® (Lupin's Ranibizumab for intravitreal injection) in real world clinical practice" vide Protocol Number: LRP/LUBT010/2021/006 Date: 25 January 2022. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase IV study as per the presented protocol.
FDC Division			
4.	FDC/MA/21/000132 Latanoprost 0.0500mg + Netarsudil Mesylate	M/s. Pure & Cure Healthcare Pvt. Ltd.	In light of earlier SEC recommendation dated 28.01.2022, the firm presented the revised Phase III CT protocol as well as justification on ocular toxicity study data before the committee.

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	eq. to Netarsudil 0.2mg Ophthalmic solution		After detailed deliberation, the committee noted that: 1. The individual drug was already approved on 1998 & 2020 by this office. 2. The product is already approved in USA. In view of above, the committee recommended for grant of permission for conducting the Phase III CT study.
GCT Division			
5.	CT/34/22 Online Submission (30676) LUBT017((Proposed Biosimilar to Eylea)	M/s. Lupin	The firm presented the proposed Phase III clinical trial protocol no. LRP/LUBT017/2021/003, version 1.0, dated 14 Mar 2022 before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as per the protocol with the following conditions: 1) The firm should enroll up to 150 subjects from the country. 2) The firm should appoint an independent data safety monitoring committee to monitor and assess the safety of the proposed trial. 3) If the subjects develop CNV in the fellow eye then it should be managed as per the standard of care and the cost of the same should be borne by the sponsor.
6.	CT/49/22 Online Submission (32118) AVT06 (Proposed Biosimilar to Eylea)	M/s. IQVIA	The firm presented the proposed Phase III clinical trial protocol no. AVT06-GL-C01, Version 2.0 dated 21-Dec-2022 before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as per the protocol with a condition that if the subjects develop CNV in the fellow eye then it should be managed as per the standard of care and the cost of the same should be borne by the sponsor.
Medical Device Division			
7.	IMP/MD/2022/59552	M/s. Nextvel Consulting LLP	The firm presented their proposal before the committee. After detailed deliberation the committee

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	Artificial Endothelial Layer (EndoArt®)		recommended for grant of import and marketing permission of the device in the country.