

Recommendations of the SEC (Ophthalmology) made in its 70th meeting held on 20.09.2023 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/IMA/21/000043 Lifitegrast Ophthalmic Solution 5% w/v	M/s Ajanta Pharma Ltd.	The firm didn't turn for presentation.
Biological Division			
2.	BIO/CT/20/000126 Ranibizumab Injection 10 mg/ml	M/s. Reliance Life Sciences.	<p>The firm presented their proposal for amendment in the approved Phase IV clinical trial protocol vide Protocol No. RLS/OPT/2020/03, Ver 1.0 dated 21 May 2023 from Version 1.0 to Version 2.0 dated 28 July 2023 to conduct interim analysis from at least first 50% of enrolled patients.</p> <p>After detailed deliberation the committee recommended for approval of the amendment in the clinical trial protocol from Version 1.0 dated 21 May 2023 to Version 2.0 dated 28 July 2023 to conduct interim analysis.</p>
3.	BIO/CT21/FF/2023/382 27 Ranibizumab Solution for Injection 10mg/ml	M/s. Sun Pharma	<p>The firm presented their proposal for approval of additional indications for already approved drug product of Ranibizumab solution for injection 10 mg/ml.</p> <p>The committee noted that the firm has not yet launched the drug product in the market.</p> <p>After detailed deliberation, the committee recommended that the firm should submit more safety data for consideration of approval of the additional indications.</p>
SND Division			
4.	SND/MA/20/000103 Cetirizine Ophthalmic Solution 0.24% w/v	M/s. Akums Drugs & Pharmaceuticals Private Limited	<p>In light of earlier SEC recommendations dated 25.05.2023, the firm presented revised Phase III clinical trial protocol by including reference arm and justification for sample size before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III clinical trial as per revised protocol presented by the firm.</p>

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FDC Division			
5.	FDC/IMP/19/000045 Sodium Hyaluronate + Polyethylene Glycol 400 (0.15 w/v + 0.4w/v) lubricat eye drops	M/s. Alcon Laboratories (India) Pvt. Ltd.	In light of earlier SEC recommendation dated 08.04.2021, the firm presented the Phase IV clinical trial report before the committee. After detailed deliberation, the committee noted the result of the clinical trial report.
GCT Division			
6.	CT/40/23 Online Submission (37084) RO7200220 Anti-interleukin-6 (IL-6)	M/s. Roche	In light of earlier SEC recommendation dated 21.06.2023, the firm presented Phase III Clinical Trial Protocol no. GR44278, Version 1.0 dated 30 Aug 2022 before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the study subject to condition that the protocol shall be amended to include enrollment in India as presently protocol describes enrollment sites in Japan.