

**Recommendations of the SEC (Ophthalmology) made in its 56<sup>th</sup> meeting held on 26.05.2022 at CDSCO (HQ), New Delhi:**

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>New Drug Division</b>			
1.	ND/MA/22/000043 Liftigrast Ophthalmic Solution 5%	M/s. Ajanta Pharma	<p>The firm presented their proposal of Phase III clinical trial with drug Liftigrast Ophthalmic Solution 5% before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the clinical trial subject to following conditions:</p> <ol style="list-style-type: none"> <li>1. The firm should include 30% improvement in Eye dryness score and Schimer Tear Test in assessment criteria.</li> <li>2. The firm should objectively define inclusion and exclusion criteria including the severity of dry eye disease.</li> <li>3. The firm should include questionnaire as part of every study visit.</li> <li>4. Clarification on the point that IP dosage design and schedule needs to be redesigned to match the minimum required dose of comparator product, CMC which is 4 times.</li> </ol> <p>Accordingly, the firm should submit revised CT protocol to CDSCO for consideration by the committee.</p>
<b>Biological Division</b>			
2.	4-93/Intas/PAC-R- Ranibizumab/2021-BD Ranibizumab	M/s. Intas Limited	<p>The firm presented their proposal for approval of new indication (retinopathy of pre maturity in preterm infants) for Ranibizumab. The firm presented the PSUR data generated with the drug since marketing.</p> <p>After detailed deliberation and considering the fact that the target subjects are infants, the committee recommended for approval of the new indication with a condition that the firm should conduct Phase IV study in target sub-group population after getting the protocol approved and submit the clinical</p>

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			<p>trial data to CDSCO within 1 year of approval for continued marketing of the said indication.</p> <p>Accordingly, the firm should submit protocol for conduct of Phase IV clinical trial within 3 months of said indication approval.</p> <p>Dr. Somesh Aggrawal didn't participate in the deliberation.</p>
3.	BIO/MA/22/000031 Ranibizumab	M/s. Lupin Limited	<p>The firm presented their proposal for approval of additional indications (DME, RVO and CNV) of drug before the committee.</p> <p>After detailed deliberation, the committee recommended for approval of the additional indications.</p>
<b>SND Division</b>			
4.	SND/IMP/22/000008 Dexamethasone Intravitreal Implant 0.7mg	M/s Allergan India	<p>The firm presented their proposal for approval of additional indication for Dexamethasone Intravitreal Implant 0.7mg "for the treatment of diabetic macular edema".</p> <p>The committee noted that the proposed indication is approved by USFDA.</p> <p>After detailed deliberation, the committee recommended for approval of the additional indication "for the treatment of diabetic macular edema" with the condition to conduct active PMS study in 500 patients with follow-up period of six months.</p> <p>Accordingly, the protocol should be submitted within three months of approval of the drug.</p>
5.	SND/MA/21/000499 Atropine Sulfate Ophthalmic Solution 0.01% w/v StabilisedOxychloro complex 0.005% w/v (SOC) as preservative (Change in preservative)	M/s. Indiana Ophthalmics	The firm did not turn up for presentation.
<b>GCT Division</b>			

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6.	CT/05/21 Online Submission (16216)  CT-P42	M/s. Kendle	The firm presented their proposed Phase III protocol no. CT-P42 3.1, amendment version 3.0, dated 14-Jan-2022 before the committee.  After detailed deliberation, the committee recommended for approval of the protocol amendment and to increase the number of subjects from 90 to 104 in India as requested.
7.	CT/24/20 Online Submission (14846)  Brolucizumab	M/s. Novartis	The firm presented their proposed protocol no. CRTH258D2301, amendment version 02, dated 28-Sep-2021 (CONDOR) before the committee.  After detailed deliberation, the committee recommended for approval of the proposed protocol amendment.
<b>Medical Device Division</b>			
8.	CI/MD/2021/51828  Hydrophilic acrylic intraocular lens	M/s. Clinixel Life Sciences Private Limited	In light of earlier SEC recommendation dated 07.04.2022, the firm presented their proposal before the committee.  After detailed deliberation, the committee noted that the proposed device is already in use since 2013 and as per the MDR they are collecting the follow up data and there may be no objection for collection of the outcome data.
9.	CI/MD/2021/52506  AT LISA tri 839MP	M/s. Clinixel Life Sciences Private Limited	In light of earlier SEC recommendation dated 07.04.2022, the firm presented their proposal before the committee.  After detailed deliberation, the committee noted that the proposed device is already in use since 2013 and as per the MDR they are collecting the follow up data and there may be no objection for collection of the outcome data.