

Recommendations of the SEC (Ophthalmology) made in its 67th meeting held on 21.06.2023 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	12-1/2000-DC Gen Teal Lubricant Eye Drop (Methyl Hydroxypropyl Cellulose 0.3% w/v)	M/s. Alcon	<p>The firm presented the proposal of waiver of condition of requirement of prescription of RMP for retail sale of Gen Teal Lubricant Eye Drop (Methyl Hydroxypropyl Cellulose 0.3% w/v).</p> <p>After detailed deliberation, the committee opined that the symptoms of the dry eye diseases are nonspecific and there might be risk of use of Methyl Hydroxypropyl Cellulose 0.3% w/v eye drop for the condition which might require the prescription of R.M.P.</p> <p>Hence the committee did not recommend the waiver of condition of requirements of prescription of RMP for retail sale of Gen Teal Lubricant Eye Drop (Methyl Hydroxypropyl Cellulose 0.3% w/v).</p>
SND Division			
2.	SND/MA/22/000301 Pilocarpine Hydrochloride Solution USP 1.25% w/v	M/s.Entod Pharmaceuticals Ltd.	<p>In light of earlier SEC recommendation dated 22.12.2022, the firm presented the proposal for manufacture and marketing permission of Pilocarpine Hydrochloride Solution USP 1.25%w/v for the treatment of presbyopia in adult along with Phase III clinical trial protocol, before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III clinical trial as per the protocol presented subject to following condition:</p> <ol style="list-style-type: none"> 1. The firm should amend “Subject” instead of “Patient” throughout the clinical trial protocol. 2. In inclusion criteria age group should be mentioned as 45 to 55 yrs (sub-grouped into 40-45 and 50-55 years) instead of 40 to 55 yrs. 3. Female subjects with Menopause or surgically sterile should be included in the trial. 4. No subject with any visually significant cataract should be included

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			<p>in the study.</p> <p>5. Possible adverse reactions of Pilocarpine should be included in the ICD for awareness of the subjects.</p> <p>Accordingly, the firm should submit revised clinical trial protocol to CDSCO for approval.</p>
3.	SND/MA/22/000499 Atropine Sulfate Ophthalmic Solution 0.01% w/v	M/s. Indiana Ophthalmics	The firm did not turn up for presentation.
FDC Division			
4.	FDC/MA/22/000252 Ketorolac tromethamine IP eq. to Ketorolac 3mg + Phenylephrine HCl IP Eq. to Phenylephrine 10mg 1.0% Intraocular Solution	M/s. Aurolab	<p>The firm presented their proposal along with Clinical Investigation Plan before the committee.</p> <p>The committee noted that firm has proposed only one study site in the proposed study with 100 eyes to be enrolled in the study.</p> <p>After detailed deliberation, the committee recommended that the firm should submit a revised structured Phase III CT Protocol as per NDCT Rules, 2019 for review. Further, standard statistical procedure should be adopted for calculation of sample size.</p>
5.	FDC/CT/23/000001 Phenylephrine Hydrochloride 1.0% + Ketorolac 0.3% Intraocular solution	M/s. COD Research Pvt. Ltd	<p>In light of earlier SEC recommendation dated 25.05.2023, the firm presented the proposal along with ocular toxicity study data, rationale & justification as well as Phase II CT Protocol.</p> <p>After detailed deliberation, Committee recommended for grant of permission to conduct the proposed Phase II CT Study. The results of the study should be presented before the committee.</p>
GCT Division			
6.	CT/40/23 Online Submission (37084) RO7200220 Anti- interleukin-6 (IL-6)	M/s. Roche	<p>The firm presented the proposal for grant of permission to conduct Phase III Clinical Trial Protocol no. GR44278, Version 1.0 dated 30 Aug 2022 before the committee.</p> <p>After detailed deliberation, the committee recommended to revise the study protocol as follows:</p> <ol style="list-style-type: none"> 1. SoC should be provided in Arm C

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			<p>(Sham Arm), since subject with uveitic macular edema should not be left untreated.</p> <p>2. Under Inclusion criteria, patients with uveitic macular edema who are non-responders to corticosteroids or have corticosteroids related complications should only be included in the trial.</p> <p>Accordingly, the firm should submit revised protocol for further deliberation by the committee.</p>
7.	<p>CT/122/22 Online Submission (24845)</p> <p>LLBMT1</p>	M/s. CBCC	<p>The firm presented their proposal for protocol version 4.0 dated 03/March/2023 before the committee.</p> <p>After detailed deliberation, the committee opined that comments for proposed protocol amendment version 4.0 dated 03-March-2023 will be provided after examining the study protocols submitted by the firm during presentation. Accordingly, protocol should be forwarded to the members for examination. (Dr. Purvi Bhagat did not participate in deliberation.)</p>
Medical Device Division			
8.	<p>CI/MD/2023/92633</p> <p>Wave Light Ultraviolet Femto second Laser System, Model 1026 (UV fs- Laser)</p>	M/s. Alcon Laboratories Pvt. Ltd.	<p>The firm presented their protocol before the committee to conduct the pilot clinical investigation study for the Wave Light Ultraviolet Femto second Laser System, Model 1026 (UV fs-Laser).</p> <p>After detailed deliberation, the committee recommended for the grant of permission to conduct the pilot clinical investigation study in the country.</p> <p>Further, the firm should submit the pilot clinical investigation report after completing the proposed study to the committee along with clinical investigation plan to conduct larger population study (Pivotal clinical investigation) to assess the safety and performance of the device.</p>