

Recommendations of the SEC (Ophthalmology) made in its 3rd/24 meeting held on 27.03.2024 at CDSCO (HQ), New Delhi:

| S. No | File Name & Drug Name, Strength | Firm Name | Recommendations |
|----------------------------|---|------------------------------------|--|
| Biological Division | | | |
| 1. | BIO/CT21/FF/2023/37090 Adalimumab 100mg/ml | M/s. Enzene Biosciences Limited | In light of the earlier SEC recommendation dated 18.10.2023, the firm presented proposal for approval of additional indications of Adult Uveitis in adults by the way of extrapolation in line with the innovator product. After detailed deliberation, the committee recommended the firm to submit the data of ongoing Phase IV clinical trial for further deliberation and approval of the proposed additional indication. |
| SND Division | | | |
| 2. | SND/MA/22/000301 Pilocarpine Hydrochloride Solution USP 1.25% w/v | M/s. Entod Pharmaceuticals Limited | In light of earlier SEC recommendation dated 22.12.2022& 21.06.2023, 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 report before the committee. The firm informed that the said drug is already approved in USA for the same indication on 28.10.2021. After detailed deliberation, the committee recommended for grant of permission for manufacture and market of Pilocarpine Hydrochloride solution USP 1.25% w/v subject to condition that the firm should conduct Phase IV clinical trial. In addition to above, the firm should fulfill the requirement of CMC data. Accordingly, the firm should submit the Phase IV clinical trial protocol within 3 months from date of approval to CDSCO for further review by the committee. |
| 3. | SND-11011(13)/1/2024-e-office Atropine Sulfate Ophthalmic Solution USP 0.01% w/v | M/s. Entod Pharmaceuticals Limited | The firm did not turn up for presentation. |

