ENTOD Myopia eye drops for children obtains CDSCO approval

The drop is indicated to slow the progression of myopia in children aged 6 to 12 years but brand name and expected timeline of the product has not been disclosed by the company.

Mumbai: Ophthalmic drugs developer ENTOD Pharmaceuticals, eye drops for children with Myopia in the age of 6-12 years has received marketing authorisation from the Central Drugs Standard Control Organisation (CDSCO).

As per the drug maker, "the drop is a new eye formulation developed to slow the progression of myopia in children aged 6 to 12 years."

The product has been approved following the successful completion of Phase 3 clinical trials in India and will be available in the market as a prescription drug, However, company has not disclosed the name, price and commerical launch timelines of the product.

"With myopia rates in India rising from 4 per cent in 1999 to nearly 25 per cent today, and further projections suggesting that by 2050 one in two children could be affected, the need for such a therapy has never been more urgent." Nikkhil K Masurkar, CEO, ENTOD Pharmaceuticals, stated.

Last year, the Mumbai-based drug maker came into the spotlight following a controversy over its eye drop PresVu, reported to reduce dependency on reading glasses for individuals affected by presbyopia.

However, later the DCGI suspended the approval for the drug and prohibited the company from manufacturing and marketing it.

In its official order issued on September 10, 2024 the apex regulator stated that the company tried to justify claims for which approval had not been granted and eye drops have not been approved for any such claim in India that they can reduce the need for reading glasses.

Defending the drug the company CEO had said that, "Our approval by the DCGI was based on a valid controlled clinical trial which successfully demonstrated the efficacy and safety of these eye drops in presbyopia patients.

As per the Company "Similar eye drops with the same active ingredient and concentration have been approved by the US FDA and marketed in the US for the past three years without any serious complications."

Pilocarpine Hydrochloride Ophthalmic Solution USP 1.25 per cent (PresVu) was approved by the Central Drugs Standard Control Organisation (CDSCO) for the treatment of presbyopia in adults.

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