

Sun Pharma secures DCGI nod for semaglutide generic

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Mumbai: Indian pharma major, Sun Pharmaceuticals has secured the country's apex regulator nod to manufacture and market its generic semaglutide formulation for both type-2 diabetes and weight-loss.

The recent approval pertains to the weight-loss indication, which requires higher dosage strengths. Earlier, in December, the company had received approval for the drug's use in the treatment of type-2 diabetes.

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The weight-loss brand will be marketed across five dose strengths —0.25 mg, 0.5 mg, 1 mg, 1.7 mg, and the 2.4 mg maintenance dose.

In India, the molecule will lose its patent exclusivity on March 20, while the innovator's patent in Canada has expired earlier this month.

Sun Pharma has not disclosed the pricing of either brand. The company is yet to announce any initiatives for field force expansion, training, or marketing support for the brands.

“Obesity and diabetes have emerged as two of the most pressing health challenges confronting India and GLP-1 based therapies can play a meaningful role in addressing this growing burden and we are committed to improving access to generic semaglutide across the country after the patent expiry”, said Kirti Ganorkar, MD Sun Pharma.

Smeaglutide, a once-weekly injectable is a GLP-1 receptor agonist, marketed by Novo Nordisk under the brand name Wegovy (weight-loss) and Ozempic (type-2 diabetes).

Initially approved for type 2 diabetes, the drug gained strong clinical backing for chronic weight management, as its GLP-1-mimicking action helps curb appetite and reduce food intake in obese patients.

The novel peptide is the best-selling asset of the Danish drug giant, generating more than \$25 billion in revenue in 2024, with \$17.4 billion from Ozempic and around \$8 billion from Wegovy.

With the molecule approaching patent expiry, generic manufacturers are preparing to enter the market, a move expected to trigger price drop of at least 70 per cent compared with the innovator’s current branded price. Alongside Sun Pharma, Dr Reddy’s, Alkem Laboratories and Zydus Lifesciences have also secured approval for the type-2 diabetes indication, while Torrent, NATCO and MSN have recently gained a favorable recommendation from the subject expert committee (SEC) of CDSCO.

While demand for the molecule’s once-weekly injectable version has remained tepid since its launch in June 2025, domestic drugmakers—with their larger field forces—hold a competitive edge over the innovator in the Indian market and may extract better material results.

However, as the innovator has shown an appetite for aligning prices with market dynamics and evolving competition—including a 37 per cent price cut in India even ahead of the patent cliff—clinicians and analysts believe that further reductions could allow the brand to remain competitive. Consumers may continue to prefer the innovator molecule due to its well-established efficacy, a trend previously observed with Novo's insulin portfolio.

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