Sun Pharma Secures CDSCO Approval for Generic Semaglutide Pill

New Delhi: Indian pharmaceutical major Sun Pharmaceutical Industries has obtained regulatory approval from the Central Drugs Standard Control Organisation (CDSCO) to manufacture and market generic semaglutide tablets in India for treating type-2 diabetes.

The once-daily oral medicine is therapeutically equivalent to Novo's Rybelsus, with approval covering three strengths—3 mg, 7 mg and 14 mg.

According to a recent media report by the ET, Sun Pharma's r-DNA origin formulation will be manufactured at its facility in Kamrup, Assam. The active pharmaceutical ingredient, or raw material, will be procured from Zhongmeihuadong Pharmaceutical, based in Hangzhou, China.

Although semaglutide's patent protection expired in March this year, a separate patent continues to protect its oral formulation in India.

Torrent Pharma, however, became the first company to introduce generic oral semaglutide under the brand names Semalix and Sembolic after the Delhi High Court held that its formulation did not infringe Novo's patent.

Subsequently, Hyderabad-headquartered Dr Reddy's introduced its oral semaglutide brand, Obeda, priced at Rs 99, Rs 135 and Rs 225 per tablet for the 3 mg, 7 mg and 14 mg strengths, respectively, ET reports.

Incretin-based medicines mimic the activity of gut hormones, including GLP-1, to improve glycaemic control. Their use has progressively expanded beyond their initial role in diabetes management.

Semaglutide is a glucagon-like peptide 1 receptor agonist used to improve glycemic control in type 2 diabetes mellitus, treat obesity, and reduce the risk of major adverse cardiovascular events in selected adults. Semaglutide is a glucagon-like peptide 1 (GLP-1) analog used to manage type 2 diabetes along with lifestyle changes, such as dietary restrictions and increased physical activity.

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