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Blockbuster semaglutide set to go off patent, Indian pharma sees a multi-billion-dollar opportunity

Pharma firms are pouncing on opportunity as patents on world's secondbestselling drug, which goes by brand names Ozempic and Wegovy, are expiring in nearly 100 nations.

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New Delhi: As the patents on semaglutide, a popular diabetes and anti-obesity drug that earned its Danish maker Novo Nordisk nearly USD 30 billion in FY25 alone, expire in nearly 100 countries next year, at least 10 Indian drugmakers have sought regulatory approvals to conduct late-stage clinical trials for generic versions of the drug.

Available under the brand names Rybelsus (in pill form), and Ozempic and Wegovy (injectables), semaglutide was the world's second bestselling drug in 2024, second only

to Merck's anti-cancer drug Keytruda. The market for it is estimated to be growing at 40 percent annually.

The patent expiry on oral and injectable versions of semaglutide has paved the way for manufacture and availability of its generic versions, which may slash cost of the drug by 50-70 percent starting next year.

Additionally, this will also lead to the drug's availability in emerging markets and developing countries and territories where it had not been able to reach yet due to supply constraints.

In India, the once-weekly injection of semaglutide, launched in June this year, costs between Rs 17,345 and Rs 26,045 per month, depending on dose strength.

Among the countries where the blockbuster obesity drug is going off patent, the biggest markets are India, Canada, China, South Africa, Brazil and Turkey and UAE. These countries have nearly 33 percent of people globally that can be classified as obese, according to a <u>report</u> by market research firm IQVIA.

"Given the scenario, Indian pharmaceutical exporters are seeing a big opportunity here and if they manage to capture even 10 percent of its current annual sale, it will be huge," Bhavin Mukund Mehta, vice-chairman of Pharmaceuticals Export Promotion Council of India (Pharmexcil), an agency under the Union Ministry of Commerce and Industry, told ThePrint.

Semaglutide belongs to a class of medications known as glucagon-like peptide-1 (GLP-1) receptor agonists and is called a GLP-1RA drug. It mimics the GLP-1 hormone that is released in the gastrointestinal tract in response to eating.

One role of GLP-1 is to prompt the body to produce more insulin, which reduces blood glucose (sugar), and in higher amounts, it interacts with parts of the brain that reduce appetite and signal a feeling of fullness.

Lower strengths of the drug, such as Rybelsus and Ozempic, are prescribed for type 2 diabetes but can also support weight loss, while Wegovy is indicated for those categorised as obese even in the absence of diabetes.

IQVIA has estimated that at least 1 in 3 people living with obesity in the world will live in a country with access to off-patent semaglutide from 2026.

Experts say that while Novo Nordisk has not been able to supply the drug in a large number of countries due to extremely high demand in developed countries despite its high price, the availability of its copycat versions could completely change the dynamic.

Potential to disrupt anti-obesity market

Ever since its launch in 2017 in the US, the drug has been a runaway success, and has propelled Novo Nordisk—a relatively lesser-known Danish drugmaker mainly identified with insulin production earlier—into becoming the most valuable corporation in Europe within a couple of years of the medicine's roll out. In 2024-25, the drug alone brought nearly 70 percent of the company's turnover.

Now, several Indian pharmaceutical companies—including Biocon, Dr Reddy's, Cipla, Zydus, Alkem, Shilpa Medicare, Natco, and Aurobindo Pharma—are in the race to hit the markets with copies of semaglutide, the day it loses patent.

"India being the largest supplier of generics with more than 20 percent share has the potential to disrupt the existing market segment with high quality semaglutide generics," Vivek Tandon, vice president of management consultancy firm Primus Partners, told ThePrint.

Indian pharma giants have been gearing up for this opportunity for many years now, he added.

The global anti-obesity market was estimated to be around \$11 billion this year but is expected to grow to over \$100 billion over the next decade, fuelled by changing lifestyle and dietary patterns worldwide.

In India, the anti-obesity drug market is currently valued at Rs 3,000-3,500 crore, and is projected to grow nearly eightfold to Rs 25,000 crore by 2030.

The country saw the launch of two drugs exclusively to treat the condition, Wegovy and another similar drug Mounjaro by US pharma giant Eli Lilly & Company, this year, while oral semaglutide Rybelsus arrived here in 2022.

Market analysts say that globally, lower manufacturing costs will lead to price reduction of semaglutide due to intense competition.

The introduction of cost-effective, high-quality generic substitutes has the potential to lead to greater adoption of anti-obesity medications, changing them from expensive specialised treatments to accessible first-line interventions, Tandon underlined.

Govt push for drugs going off-patent

A total of 24 blockbuster drugs, with global sales worth \$ 251 billion, are going to lose patents in the US during the period of 2022-2030, offering major business and growth opportunities for Indian pharma companies, a report by the Centre's Department of Pharmaceuticals said last year.

The <u>report named</u> mega-selling anti-rheumatic drug Humira, anti-cancer drugs Keytruda, Opdivo, Revlimid and Avastin and anti-diabetic and obesity drugs Victoza, Januvia and Trulicity, apart from semaglutide, in the list.

A senior DOP official who did not wish to be named told ThePrint that the government's Production-Linked Incentive (PLI) scheme, which incentivises domestic manufacturing, had also spurred significant interest from leading domestic pharmaceutical companies in developing their own version of semaglutide.

"Indian drugmakers have done exceptionally well over the last few weeks by supplying high-quality, cost-effective generic versions of drugs for conditions such as HIV/AIDS and cancer. There is now a chance to repeat that again," the official said.

Industry experts agreed. "I think it's a big win for Indian generics in price-sensitive markets. Indian semaglutide copies could dominate the anti-obesity market mirroring past successes in HIV, hepatitis, and oncology generics," pharmaceutical analyst Salil Kallianpur told ThePrint.

But the impact in the US and European Union, where the patent on the drug is not ending before 2030, will be limited as Novo's patent extensions mean no near-term generics in these lucrative markets, he added.

The anti-obesity market will grow faster but with lower margins due to generics, pushing big pharma towards innovation (oral GLP-1s or combo therapies). Indian drugmakers need to move fast (as Chinese generic makers are also eyeing the copycat semaglutide market), secure partnerships, and invest in manufacturing scale to capture this multibillion-dollar opportunity, Kallianpur said.

Top companies maintained they are excited at the prospect.

"Semaglutide presents a timely opportunity to provide an effective solution for the growing obesity and diabetes burden in India," Vikas Gupta, CEO of Alkem Laboratories, a leading Indian drug manufacturer that makes bestsellers such as Pan and Pan D, told ThePrint.

We aim to leverage our strong research and development capabilities and extensive distribution network across the country to address this demand, he said.

"We are geared up to be among the first ones to launch a generic version of semaglutide in India once the patent expires. Our strategic focus will remain on India, given the scale of unmet need and our stronghold in the market, but we are exploring opportunities in some emerging markets as well for launching this drug," he added.

(Edited by Nida Fatima Siddiqui)