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EDITORIAL ANALYSIS

Semaglutide Goes Generic — Can India's Drug Oversight Keep Up with the Weight-Loss Revolution?

BUSINESS STANDARD

25 March 2026

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CURATED & WRITTEN BY

Bharat Choudhary

UPSC Educator & Content Creator •
linkedin.com/in/epicbharat

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Semaglutide Goes Generic — Can India's Drug Oversight Keep Up with the Weight-Loss Revolution?

Business Standard 25 March 2026 GS2 GS3

BS Business Standard | MAINS RELEVANCE: GS Paper 2 GS Paper 3 |

INTERVIEW ANGLE

"Semaglutide's patent expired on March 20, and Indian companies are launching generics at 50-70% lower prices. How should India balance affordable access with quality assurance for complex biologics?"

WHY IN NEWS

Following the expiry of Novo Nordisk's semaglutide patent on March 20, 2026, multiple Indian pharmaceutical companies — Cipla, Sun Pharma, Dr Reddy's, Biocon, Natco, Zydus, and Mankind Pharma — are preparing to launch generic versions at 50-70% lower prices, even as CDSCO intensifies surveillance against unauthorised GLP-1 sales.

The Editorial Argument

Business Standard argues that while India's pharma industry is well-positioned to democratise access to semaglutide — one of the most transformative drugs of the decade — the country's drug oversight system faces serious quality and counterfeiting risks that could undermine both patient safety and India's global pharma reputation.

The Semaglutide Phenomenon

Semaglutide (brand names: **Ozempic** for diabetes, **Wegovy** for weight loss) is a **GLP-1 receptor agonist** that mimics the incretin hormone, promoting insulin secretion and reducing appetite. It has become the fastest-growing drug category in pharmaceutical history:

PARAMETER	DATA
Global GLP-1 market (2025)	~$40 billion
Novo Nordisk revenue from semaglutide (2025)	~$30 billion
Weight loss efficacy	15-20% body weight reduction in clinical trials
Patent expiry	March 20, 2026
Indian generic price reduction expected	50-70%

Indian Companies Ready to Launch

COMPANY	PREPARATION STATUS
Cipla	ANDA filed, manufacturing ready
Sun Pharma	Clinical trials completed
Dr Reddy's	Biosimilar route
Biocon	Biologics expertise leveraged
Natco	First-to-file advantage in select markets
Zydus	Injectable formulation ready
Mankind Pharma	Domestic market focus

The Quality Challenge

The editorial highlights several risks:

1. **Counterfeiting**: Semaglutide's high demand and injectable format make it a prime target for counterfeit manufacturers
2. **Cold chain**: GLP-1 agonists require 2-8°C storage; India's cold chain infrastructure is uneven
3. **Off-label use**: CDSCO has barred weight-loss drug advertisements, but online promotion continues
4. **Manufacturing complexity**: Semaglutide is a peptide — more complex than small-molecule generics, requiring specialised production facilities
5. **Post-market surveillance**: India's pharmacovigilance system (PvPI) handles only a fraction of adverse drug reactions

CDSCO Regulatory Response

- **Barred weight-loss drug advertisements** to prevent off-label promotion
- **Intensified surveillance and audits** against unauthorised GLP-1 sales

- Government monitoring online pharmacies for prescription compliance
- WHO has flagged counterfeit semaglutide as a global concern

India's Drug Regulatory Architecture

BODY	ROLE
CDSCO	Central regulator — new drug approvals, clinical trials, imports
DCGI	Drugs Controller General of India (heads CDSCO)
State Drug Controllers	Manufacturing and sales regulation
Indian Pharmacopoeia Commission	Drug quality standards
PvPI	Pharmacovigilance Programme of India (adverse event monitoring)
NLEM	National List of Essential Medicines

The Bigger Picture — India's Pharma Opportunity

The semaglutide moment represents a broader pattern: Indian companies excel at manufacturing complex generics at scale, driving down prices globally. The editorial argues this should be paired with regulatory modernisation to maintain credibility:

- India supplies **20% of global generic medicines**
- Indian vaccines covered **60% of global immunisation**
- But India's WHO drug prequalification rejections remain a concern

UPSC RELEVANCE

GLP-1 receptor agonist, CDSCO, DCGI, Drugs and Cosmetics Act 1940, PvPI, NLEM, patent regime under TRIPS

India's pharmaceutical industry; patent expiry and generic drug access; drug quality regulation

Drug regulatory governance; CDSCO capacity; public health policy

📌 FACTS CORNER — KNOWLEDGEPEDIA

SEMAGLUTIDE:

Drug class: GLP-1 receptor agonist

Brand names: Ozempic (diabetes), Wegovy (weight loss)

Original manufacturer: Novo Nordisk (Denmark)

Patent expiry: March 20, 2026

Weight loss: 15-20% body weight reduction

Global GLP-1 market: ~$40 billion (2025)

Indian generic price cut: 50-70%

INDIAN COMPANIES LAUNCHING GENERICS:

Cipla, Sun Pharma, Dr Reddy's, Biocon, Natco, Zydus, Mankind Pharma

DRUG REGULATION IN INDIA:

CDSCO: Central Drugs Standard Control Organisation

DCGI: Drugs Controller General of India

Drugs and Cosmetics Act, 1940

PvPI: Pharmacovigilance Programme of India

NLEM: National List of Essential Medicines (updated 2022)

OTHER RELEVANT FACTS:

India: "Pharmacy of the World" — 3rd largest by volume

Generic share: 20% of global supply

TRIPS Agreement: WTO patent regime (compulsory licensing under Section 84)

Novartis v. Union of India (2013): Section 3(d) upheld, denying evergreening patents

WHO prequalification: quality standard for global procurement

Sources: Business Standard , CDSCO

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