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EDITORIAL ANALYSIS

Semaglutide Patent Expiry — Balancing Drug Access with Regulatory Vigilance

 **THE HINDU**

21 March 2026

SUBJECTS COVERED**SCIENCE & TECH****ECONOMY****SOCIAL ISSUES****GS PAPERS****GS2****GS3****CURATED & WRITTEN BY****Bharat Choudhary**

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Semaglutide Patent Expiry — Balancing Drug Access with Regulatory Vigilance

 The Hindu

21 March 2026

GS2

GS3



The Hindu

MAINS RELEVANCE:

GS Paper 2

GS Paper 3



INTERVIEW ANGLE

"Should India regulate cosmetic use of weight-loss drugs like Semaglutide, or would that restrict patient autonomy?"

WHY IN NEWS

The patent for Semaglutide (marketed as Ozempic for diabetes and Wegovy for obesity by Novo Nordisk) expired on March 20, 2026, triggering the entry of approximately 50 generic brands in India with prices dropping by 20-90%. The Hindu and Indian Express editorials discuss the regulatory challenges of managing this influx.

BACKGROUND — WHAT IS SEMAGLUTIDE?

Semaglutide belongs to a class of drugs called **GLP-1 receptor agonists** (Glucagon-Like Peptide-1). Originally developed for **Type 2 diabetes**, it was subsequently approved for **chronic weight management** after clinical trials showed significant weight loss effects.

HOW IT WORKS

Mimics the **GLP-1 hormone**, which is naturally released after eating

Slows gastric emptying — food stays in the stomach longer, increasing satiety

Reduces appetite by acting on brain receptors

Stimulates insulin secretion and suppresses glucagon — lowers blood sugar

Administered as a **weekly injection** (Ozempic) or daily oral tablet (Rybelsus)

MARKET CONTEXT

Brand	Indication	Original Price (India)
Ozempic	Type 2 diabetes	Rs 8,000-12,000/month
Wegovy	Chronic obesity	Rs 15,000-25,000/month
Generic versions	Both	Rs 1,500-5,000/month (estimated)

THE EDITORIAL'S CORE ARGUMENT

The editorial argues that while the patent expiry is a **public health positive** — making life-saving diabetes medication affordable — it also creates risks that India's regulatory framework is not equipped to handle:

1. Misuse for Cosmetic Weight Loss

GLP-1 drugs are being **misused for cosmetic weight loss** by non-obese individuals seeking rapid weight reduction

Social media influencers and unregulated online pharmacies promote these drugs without medical supervision

Side effects include **pancreatitis, gallbladder problems, thyroid tumours, and severe gastrointestinal issues**

2. India's Diabetes and Obesity Burden

India has approximately **101 million diabetics** (IDF Diabetes Atlas 2024) — second highest globally after China

Obesity prevalence is rising rapidly — NFHS-5 (2019-21) showed **24% of women and 23% of men** are overweight/obese

Affordable generic semaglutide could genuinely help millions — but only if prescribed appropriately

3. Regulatory Gaps

India's **CDSCO (Central Drugs Standard Control Organisation)** approves drugs but has limited capacity for **post-marketing surveillance**

No clear guidelines on prescribing GLP-1 drugs specifically for weight management (vs diabetes)

Schedule H classification means the drug requires a prescription, but enforcement is weak — many pharmacies sell without prescriptions

INDIA AS A GENERICS POWERHOUSE

India produces **20% of the world's generic medicines** by volume and supplies affordable drugs to 200+ countries. The entry of generic semaglutide reinforces India's role in global pharmaceutical supply chains.

KEY PLAYERS EXPECTED TO LAUNCH GENERIC SEMAGLUTIDE

Sun Pharma, Dr. Reddy's, Cipla, Lupin, Biocon – among the ~50 companies filing for approvals

India's **Revised National List of Essential Medicines (NLEM) 2022** does not currently include GLP-1 drugs – inclusion could further reduce prices

POLICY RECOMMENDATIONS FLAGGED

Stricter prescription enforcement – CDSCO should mandate that GLP-1 drugs be sold only with a valid prescription from an endocrinologist or diabetologist

Post-marketing surveillance – Active pharmacovigilance for generic semaglutide, particularly monitoring for rare side effects

Public awareness campaigns – Educate the public about risks of unsupervised use

NLEM consideration – Include semaglutide in the National List of Essential Medicines to ensure price control under DPCO (Drug Price Control Order)

Social media regulation – ASCI (Advertising Standards Council of India) should crack down on unregulated promotion of prescription drugs

UPSC RELEVANCE

GLP-1 receptor agonists, Semaglutide (Ozempic/Wegovy), CDSCO, NLEM 2022, DPCO, IDF Diabetes Atlas.

MAINS GS2:

Health governance – balancing drug access with safety regulation; role of CDSCO; India's pharmaceutical regulation framework.

MAINS GS3:

India as a generics powerhouse – economic significance; pharma industry and patent regime under TRIPS.

★ **FACTS CORNER — KNOWLEDGEPEDIA**

SEMAGLUTIDE:

Class: GLP-1 receptor agonist
 Original developer: Novo Nordisk (Denmark)
 Brands: Ozempic (diabetes), Wegovy (obesity), Rybelsus (oral)
 Patent expired: March 20, 2026
 ~50 generic brands entering Indian market

INDIA'S DISEASE BURDEN:

Diabetics: ~101 million (IDF 2024; 2nd after China)
 Overweight/obese: 24% women, 23% men (NFHS-5, 2019-21)

REGULATORY FRAMEWORK:

CDSCO: Central Drugs Standard Control Organisation (under Ministry of Health)
 NLEM: National List of Essential Medicines (last revised 2022; 384 drugs)
 DPCO: Drug Price Control Order — ceiling prices for NLEM drugs
 Schedule H: prescription-only drugs
 ASCI: Advertising Standards Council of India

INDIA PHARMA:

India produces 20% of world's generic medicines by volume
 3rd largest by volume; 14th by value globally
 TRIPS compliance since 2005 (product patent regime)

Sources: [The Hindu](#), [Indian Express](#)

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