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EDITORIAL ANALYSIS

India's Generic Drug Revolution — Access, Quality, and Regulatory Preparedness

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SUBJECTS COVERED

ECONOMY SCIENCE & TECH SOCIAL ISSUES

GS PAPERS

GS2 GS3

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India's Generic Drug Revolution — Access, Quality, and Regulatory Preparedness

The Indian Express 21 March 2026 GS2 GS3

IE The Indian Express | MAINS RELEVANCE: GS Paper 2 GS Paper 3

INTERVIEW ANGLE

"How can India strengthen post-marketing surveillance for generic drugs without slowing down its role as the pharmacy of the world?"

WHY IN NEWS

Indian Express editorial analyses the broader implications of the Semaglutide (Ozempic/Wegovy) patent expiry on March 20, 2026, with approximately 50 generic brands entering the Indian market — arguing that India must match drug access with regulatory vigilance to maintain its credibility as the "pharmacy of the world."

INDIA'S GENERICS PROWESS — THE GLOBAL CONTEXT

India is often called the **"pharmacy of the world"** — and the numbers justify the title:

Metric	Value
Share of global generic production (by volume)	**20%**
Global rank by volume	**3rd**
Global rank by value	**14th**
Countries supplied	**200+**
US generic drug market share	India supplies **~40%** of US generic demand
Africa's drug supply	India supplies **~60-80%** of anti-retroviral drugs for HIV/AIDS in Africa
WHO prequalified pharma units	India has the **highest number** globally

THE SEMAGLUTIDE CASE — WHY IT MATTERS

The patent expiry of Semaglutide is a microcosm of a broader pattern: **blockbuster drug goes off-patent → Indian generic makers flood the market → prices crash → access improves**. This pattern has played out with:

Imatinib (Gleevec) — cancer drug; Indian generics reduced price from USD 70,000/year to USD 2,500/year

Sofosbuvir (Sovaldi) — Hepatitis C cure; Gilead's price USD 84,000 in the US; Indian generics: under USD 1,000

COVID-19 vaccines — Serum Institute of India produced Covishield at scale for global distribution

The New Challenge with GLP-1 Drugs

Unlike previous generics, Semaglutide raises **unique regulatory challenges**:

Dual-use drug — approved for both diabetes (medical) and weight loss (cosmetic/lifestyle)

Social media-driven demand — influencers promote weight-loss drugs without medical context

Injectable formulation — requires cold chain management and proper administration training

Serious side effects — pancreatitis, gallbladder problems, thyroid tumour risk, severe GI issues

Bioequivalence complexity — peptide-based drugs are harder to replicate than small-molecule generics

REGULATORY ARCHITECTURE — STRENGTHS AND GAPS

Current Framework

Body	Role	Limitation
CDSCO (Central Drugs Standard Control Organisation)	Drug approval, clinical trial oversight, import regulation	Limited capacity for post-marketing surveillance; understaffed
State Drug Controllers	Manufacturing licences, retail pharmacy inspection	Fragmented; quality varies enormously across states
NPPA (National Pharmaceutical Pricing Authority)	Price control under DPCO for NLEM drugs	GLP-1 drugs not yet on NLEM — no price ceiling
Pharmacovigilance Programme of India (PvPI)	Adverse drug reaction monitoring	Reporting is voluntary; low awareness among practitioners

Key Gaps Identified

Post-marketing surveillance — India approves drugs efficiently but has weak systems for tracking adverse events after launch

Prescription enforcement — Schedule H drugs require prescriptions, but pharmacies routinely sell without one

Online pharmacy regulation — e-pharmacies operate in a regulatory grey zone; the **e-Pharmacy Rules** (draft since 2018) remain unnotified

Bioequivalence standards — CDSCO guidelines exist but enforcement is inconsistent for complex biologics and peptide drugs

THE NLEM QUESTION

The **National List of Essential Medicines (NLEM)** determines which drugs are subject to **price control** under the **Drug Price Control Order (DPCO)**:

NLEM Detail	Information
Current version	NLEM 2022 (4th revision)
Total drugs listed	384
Price control mechanism	NPPA sets ceiling price for all NLEM drugs
GLP-1 drugs	**Not currently on NLEM**
Implication	Generic semaglutide prices are market-determined; no regulatory ceiling

The editorial argues that including semaglutide in NLEM could ensure price control — but caution is needed as overly aggressive pricing could discourage Indian manufacturers.

TRIPS AND INDIA'S PATENT REGIME

India transitioned to a **product patent regime** in **2005** under TRIPS (Trade-Related Aspects of Intellectual Property Rights) compliance:

Section 3(d) of the Indian Patents Act — prevents "evergreening" by denying patents to minor modifications of known substances unless they show significantly enhanced efficacy

Compulsory licensing — Section 84 allows the government to issue licences for generic production if the patented drug is unaffordable or unavailable

Natco Pharma v. Bayer (2012) — India's first compulsory licence; for cancer drug Sorafenib (Nexavar)

UPSC RELEVANCE

CDSCO, NLEM 2022 (384 drugs), DPCO, NPPA, Section 3(d) of Indian Patents Act, Natco v. Bayer (2012, compulsory licence), TRIPS (2005 compliance), Schedule H drugs, PvPI.

MAINS GS2:

Health regulation — role of CDSCO; drug pricing policy; e-pharmacy regulation gaps.

MAINS GS3:

India as pharmacy of the world; pharmaceutical industry and IPR regime; TRIPS flexibilities.

📌 FACTS CORNER — KNOWLEDGEPEDIA

INDIA PHARMA — KEY DATA:

India produces 20% of global generic medicines by volume

3rd largest by volume; 14th by value globally

Supplies 200+ countries; ~40% of US generic demand

WHO prequalified pharma units: highest number globally

TRIPS product patent regime: since 2005

REGULATORY BODIES:

CDSCO: Central Drugs Standard Control Organisation (drug approval)

NPPA: National Pharmaceutical Pricing Authority (price control)

NLEM 2022: 384 drugs listed; GLP-1 drugs not included

DPCO: Drug Price Control Order (ceiling prices for NLEM drugs)

PvPI: Pharmacovigilance Programme of India

KEY LEGAL PROVISIONS:

Section 3(d), Indian Patents Act: anti-evergreening provision

Section 84: compulsory licensing

Natco Pharma v. Bayer (2012): first compulsory licence in India (Sorafenib)

Schedule H: prescription-only drug classification

LANDMARK GENERIC DRUG CASES:

Imatinib (Gleevec): USD 70,000 → USD 2,500/year (Indian generic)

Sofosbuvir (Sovaldi): USD 84,000 → under USD 1,000 (Indian generic)

Covishield: Serum Institute mass-produced COVID-19 vaccine

Sources: Indian Express, PIB

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