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# Semaglutide Patent Expiry Opens New Opportunities for Affordable Medicines, Pharmaceutical Innovation and Public Health in India

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## Recent Developments:

- The expiry of **Novo Nordisk's** core **Semaglutide** patent in India has enabled domestic pharmaceutical companies to manufacture affordable **generic GLP-1 receptor agonists**, significantly expanding access to advanced therapies for **Type-2 Diabetes Mellitus** and **obesity**. More than 40 Indian companies are preparing to launch generic products, strengthening India's position in the global generic medicines market.
- The development is expected to improve healthcare affordability, enhance India's pharmaceutical exports and accelerate domestic capabilities in **complex peptide therapeutics**, supported by ongoing policy initiatives such as the **Production Linked Incentive (PLI) Scheme** and patent reforms.

## Semaglutide and GLP-1 Receptor Agonists:

### *About Semaglutide:*

- **Semaglutide** is a **GLP-1 (Glucagon-Like Peptide-1) receptor agonist** originally developed by the Danish pharmaceutical company **Novo Nordisk** for the treatment of **Type-2 Diabetes Mellitus** and **obesity**.
- It mimics the naturally occurring **GLP-1 hormone**, improves insulin secretion in response to elevated blood glucose, suppresses glucagon release, delays gastric emptying and reduces appetite, thereby improving glycaemic control and promoting sustained weight loss.
- Clinical evidence also indicates that Semaglutide lowers the risk of major **cardiovascular events** in eligible high-risk patients, making it an important therapy for metabolic diseases.

### *What are Generic GLP-1 Receptor Agonists?*

- **Generic GLP-1 receptor agonists** are medicines manufactured after patent expiry that contain the same active pharmaceutical ingredient and demonstrate comparable **quality, safety and therapeutic efficacy** as the original patented medicine.
- Their availability promotes wider treatment access by reducing medicine prices while maintaining regulatory standards established by the drug approval authorities.

### *Medical Significance:*

- Semaglutide has transformed the management of **Type-2 Diabetes Mellitus** and **obesity**, two major contributors to the global burden of **Non-Communicable Diseases (NCDs)**.
- It provides an effective long-term non-surgical therapeutic option, reducing disease complications, improving metabolic health and enhancing patients' quality of life.
- Patent expiry is expected to improve affordability and accelerate adoption of advanced diabetes and obesity therapies across low- and middle-income populations.

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## Significance of Patent Expiry for India:

### *Improved Healthcare Access:*

- Affordable generic versions can substantially reduce treatment costs for India's rapidly growing diabetic and obese population, improving access to advanced metabolic therapies.
- Lower prices may reduce dependence on expensive branded medicines and strengthen equitable healthcare delivery, particularly in out-of-pocket healthcare systems.

### *Strengthening Pharmaceutical Exports:*

- Patent expiry in several emerging markets creates opportunities for Indian pharmaceutical companies to expand exports of high-value generic medicines.
- India's established expertise in generic manufacturing can strengthen its position as a leading global supplier of affordable medicines.

### *Technological Advancement:*

- Manufacturing Semaglutide requires advanced capabilities in **peptide synthesis, biopharmaceutical manufacturing, sterile injectable formulations and drug-delivery technologies**.
- Entry into this segment enables Indian pharmaceutical companies to diversify beyond conventional small-molecule generics towards complex biologically active therapeutics.

### *Economic Growth:*

- Growing domestic demand and export opportunities are expected to expand India's pharmaceutical sector through higher investments in **Research and Development (R&D), Active Pharmaceutical Ingredient (API)** manufacturing and advanced formulation technologies.
- Government initiatives such as the **Production Linked Incentive (PLI) Scheme** support domestic manufacturing capacity, reduce import dependence and improve global competitiveness.

## Clinical Implications of GLP-1 Therapies:

### *Benefits Beyond Diabetes Management:*

- GLP-1 receptor agonists improve metabolic control while contributing to sustained weight reduction, improved cardiovascular health and better long-term management of obesity-related disorders.
- Emerging evidence suggests broader therapeutic potential in conditions associated with chronic metabolic dysfunction.

### *Dermatological Effects:*

- Rapid medically assisted weight loss may produce facial volume loss, skin laxity and body contour changes commonly referred to as "**Ozempic face**."
- Excess loose skin following significant weight loss may increase friction-related skin infections, chronic irritation and persistent pigmentation changes.

### *Hair and Nail Health:*

- Rapid weight reduction combined with nutritional deficiencies involving **protein, iron and Vitamin B12** may trigger temporary **Telogen Effluvium**, resulting in excessive hair shedding.
- Nutritional alterations during therapy may also cause brittle nails, nail ridging and slower nail growth.

### *Emerging Anti-Inflammatory Potential:*

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- Early clinical evidence indicates that GLP-1 receptor agonists possess systemic anti-inflammatory properties that may benefit chronic inflammatory disorders such as **Psoriasis** and **Hidradenitis Suppurativa**, particularly among patients with **metabolic syndrome**.
- Further clinical studies are required before these indications become part of routine medical practice.

## Patent System in India:

### *Meaning of Patent:*

- A **patent** is an exclusive legal right granted by the Government to an inventor for a novel, inventive and industrially applicable invention for a period of **20 years** in exchange for complete public disclosure of the invention.
- The patent holder enjoys exclusive rights to manufacture, use, sell, license or import the invention during the patent period.
- After expiry or lapse due to non-payment of renewal fees, the invention enters the **public domain**, allowing unrestricted manufacture by others.

### *Evolution of India's Patent Regime:*

- India's first patent legislation was enacted during the colonial period through **Act VI of 1856**, followed by successive reforms culminating in the **Indian Patents and Designs Act, 1911**, which established the office of the **Controller of Patents**.
- After Independence, the **Bakshi Tek Chand Committee (1949)** and the **Justice N. Rajagopala Ayyangar Committee (1959)** recommended reforms that prioritised national development and public interest.
- The **Patents Act, 1970** replaced the colonial framework by introducing **process patents** for pharmaceuticals and food products while strengthening **compulsory licensing**, laying the foundation for India's globally competitive generic pharmaceutical industry.
- Following India's accession to the **World Trade Organization (WTO)**, successive amendments in **1999**, **2002** and **2005** aligned Indian patent law with the **Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)** while retaining important public health safeguards.
- The **Patents (Amendment) Act, 2005** introduced **product patents**, strengthened **pre-grant** and **post-grant opposition** mechanisms and incorporated **Section 3(d)** to prevent **patent evergreening**.
- Recent reforms including the **Tribunals Reforms Act, 2021**, the **Jan Vishwas Act, 2023** and the **Patents (Amendment) Rules, 2024** have simplified compliance, accelerated examination timelines and improved the efficiency of India's intellectual property ecosystem.

### *Patent Evergreening:*

- **Patent evergreening** refers to the practice of obtaining additional patents for minor modifications such as new formulations, dosage forms or salt variants in order to extend market exclusivity beyond the original patent period.
- **Section 3(d)** of the **Patents Act, 1970** prevents such practices by requiring significant enhancement in **therapeutic efficacy** before granting patents for modified forms of known substances.
- This provision balances **innovation incentives** with **public access to affordable medicines**, making it one of the most significant public health safeguards in India's patent regime.

## Patent Expiry and India's Pharmaceutical Growth:

### *Major Success Stories:*

- Expiry of patents relating to **Atorvastatin**, **Clopidogrel**, **Sildenafil**, **Imatinib** and **Sofosbuvir** enabled Indian pharmaceutical companies to emerge as leading suppliers of affordable generic medicines worldwide.

- The landmark **Supreme Court judgment in Novartis AG v. Union of India (2013)** strengthened the application of **Section 3(d)** by rejecting patent evergreening and reinforcing affordable access to life-saving medicines.
- Patent expiries have significantly contributed to India's emergence as the "**Pharmacy of the World**", supplying affordable medicines to both developed and developing countries.

### Way Forward:

#### *Strengthening Innovation and Accessibility:*

- India should continue balancing **innovation, intellectual property protection** and **public health objectives** through an efficient, transparent and predictable patent ecosystem.
- Greater investment in **peptide therapeutics, biotechnology, API manufacturing** and advanced pharmaceutical research will strengthen long-term competitiveness.

#### *Improving Regulatory Ecosystem:*

- Faster regulatory approvals, stronger quality assurance systems and enhanced pharmacovigilance will improve global confidence in Indian generic medicines.
- Expanding collaborations between industry, academia and public research institutions can accelerate innovation while maintaining affordability.

#### *Enhancing Global Leadership:*

- India should leverage patent expiries to expand exports of complex generics while strengthening domestic manufacturing under the **PLI Scheme** and **Atmanirbhar Bharat** initiatives.
- Continued emphasis on affordable medicines, high manufacturing standards and robust intellectual property governance will reinforce India's position as a global pharmaceutical leader.

### Value Addition for UPSC:

#### *Relevant Constitutional Provisions:*

- **Article 21** – Protection of life and personal liberty, interpreted to include access to healthcare.
- **Article 39(e) & 39(f)** – Directive Principles relating to public health and welfare.
- **Article 47** – Duty of the State to improve public health and nutrition.

#### *Important Acts and International Agreements:*

- **Patents Act, 1970**
- **Patents (Amendment) Act, 2005**
- **Patents (Amendment) Rules, 2024**
- **Tribunals Reforms Act, 2021**
- **Jan Vishwas Act, 2023**
- **TRIPS Agreement**
- **Doha Declaration on TRIPS and Public Health (2001)**

#### *Important Committees and Judgments:*

- **Bakshi Tek Chand Committee (1949)**
- **Justice N. Rajagopala Ayyangar Committee (1959)**
- **Novartis AG v. Union of India (2013)**

### *Keywords for UPSC:*

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- Patent
- Generic Medicines
- GLP-1 Receptor Agonist
- Peptide Therapeutics
- Patent Evergreening
- Section 3(d)
- Compulsory Licensing
- TRIPS
- Active Pharmaceutical Ingredient (API)
- Non-Communicable Diseases (NCDs)

***UPSC Mains Value Addition:***

- The expiry of the **Semaglutide** patent demonstrates how an effective patent regime can simultaneously encourage **innovation**, promote **public health**, expand **access to affordable medicines** and strengthen domestic industrial capabilities. India's balanced approach under the **Patents Act, 1970**, particularly **Section 3(d)**, illustrates how intellectual property protection can coexist with equitable healthcare access, reinforcing India's role as a global leader in affordable pharmaceutical manufacturing