



KAMARAJ IAS ACADEMY
Only IAS Academy by Grandson of "Perunthalaivar Kamarajar"

? Supreme Court Questions Medicine Mark-ups as India Reassesses Drug Price Regulation, Affordability and Patient Protection

Published On: 06-10-2026

Recent Developments:

- The **Supreme Court**, while hearing petitions concerning medicine pricing, generic prescriptions and regulation of medical devices, has questioned the large gap between the **Price to Retailer (PTR)** and **Maximum Retail Price (MRP)** of medicines. The immediate concern arose from an essential cancer medicine reportedly supplied to retailers at about ₹2,700 but carrying an MRP of nearly ₹27,000. The Court asked the Union Government why the **16% retailer margin** used in the DPCO pricing mechanism could not have wider application.
- The proceedings have brought attention to a structural distinction in India's medicine-pricing regime: **scheduled medicines** are subject to ceiling-price regulation, whereas **non-scheduled medicines** generally do not face the same initial price ceiling. The petitions therefore raise questions about launch-price regulation, trade margins, generic prescribing and affordability of life-saving medicines.
- The supplied material identifies the central policy issue as the gap between the formal existence of price regulation and its coverage across the pharmaceutical market.

Why Medicine Pricing Matters for UPSC:

Public Health and Affordability:

- Medicines are a major component of **out-of-pocket expenditure (OOPE)** in India, making drug affordability directly relevant to health equity, financial protection and access to healthcare.
- High medicine prices can create a **catastrophic health expenditure** burden, particularly for patients requiring long-term treatment for cancer, rare diseases, cardiovascular conditions and other chronic illnesses.
- Drug pricing therefore involves a policy trade-off between **affordability, availability, pharmaceutical innovation and industry viability** rather than merely controlling the retail price of individual medicines.

Constitutional Dimension:

- Petitions challenging medicine-pricing practices have invoked **Article 21**, under which the Supreme Court has interpreted the right to life to encompass important dimensions of health and human dignity.
- The constitutional issue is whether unrestricted or weakly regulated pricing of essential medicines can undermine meaningful access to healthcare, particularly when patients have limited bargaining power.

Legal and Institutional Framework:

Essential Commodities Act, 1955:

- The **Essential Commodities Act, 1955 (ECA)** provides the statutory basis for central intervention in the production, supply, distribution and pricing of specified essential commodities.

Kamaraj IAS Academy

Plot A P.127, AF block, 6 th street, 11th Main Rd, Shanthi Colony, Anna Nagar, Chennai, Tamil Nadu 600040

Phone: **044 4353 9988 / 98403 94477 / Whatsapp : 09710729833**

- Section 3 empowers the Central Government to regulate production, supply and distribution where intervention is necessary for maintaining supplies, securing equitable distribution and ensuring availability at **fair prices**.
- The Government uses this enabling framework for pharmaceutical price regulation through the **Drugs (Prices Control) Order, 2013**.

Drugs (Prices Control) Order, 2013:

- The **DPCO, 2013** is the principal regulatory instrument for controlling the prices of specified medicines in India and operates under powers derived from the Essential Commodities Act.
- It introduced a **Market-Based Pricing (MBP)** approach for scheduled formulations, replacing the earlier cost-based approach used under the previous pricing regime.
- The DPCO provides mechanisms for ceiling-price fixation, retail-price fixation for specified new drugs, monitoring of price increases and action against overcharging.

National Pharmaceutical Pricing Authority:

- The **National Pharmaceutical Pricing Authority (NPPA)** was constituted in 1997 as an attached office of the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, with responsibility for pharmaceutical price regulation and medicine availability.
- Its functions include fixing and revising prices, enforcing the DPCO, monitoring the prices of controlled and decontrolled medicines, monitoring availability, identifying shortages and recovering amounts overcharged by manufacturers.
- NPPA can also exercise exceptional powers under **Paragraph 19 of DPCO, 2013** to regulate prices of certain non-scheduled formulations in the public interest.

National List of Essential Medicines and Price-Control Coverage:

National List of Essential Medicines:

- The **National List of Essential Medicines (NLEM)** identifies medicines considered necessary for addressing priority healthcare needs based on disease prevalence, public-health relevance, evidence of efficacy and safety, and comparative cost-effectiveness.
- The latest NLEM available through the Ministry of Health and Family Welfare is **NLEM 2022**. The official NPPA material states that NLEM 2022 contains **388 medicines**, while the supplied source refers to 384 medicines; therefore, the official figure should be preferred for current UPSC notes.
- Medicines included in the relevant schedule of the DPCO are treated as **scheduled formulations** and become subject to the applicable ceiling-price mechanism.

Scheduled and Non-Scheduled Medicines:

- **Scheduled formulations** are medicines covered by the price-control schedule and are subject to notified ceiling prices.
- **Non-scheduled formulations** fall outside the ordinary ceiling-price mechanism. Their prices are not fixed through the same MBP formula, although the DPCO provides restrictions on subsequent price increases and allows intervention in specified public-interest circumstances.
- This distinction is central to the present debate because a medicine may remain outside direct ceiling-price regulation at the time of launch, allowing a high initial MRP to become the base from which later increases are calculated.

How Ceiling Prices Are Calculated:

Market-Based Pricing Mechanism:

Kamaraj IAS Academy

Plot A P.127, AF block, 6 th street, 11th Main Rd, Shanthi Colony, Anna Nagar, Chennai, Tamil Nadu 600040

Phone: **044 4353 9988 / 98403 94477 / Whatsapp : 09710729833**

- Under DPCO 2013, the ceiling price of a scheduled formulation is calculated using the **Price to Retailer (PTR)** of qualifying brands and generic versions having at least **1% market share**, measured through Moving Annual Turnover (MAT).
- The qualifying PTRs are averaged and a **16% notional retailer margin** is added to arrive at the ceiling price. Applicable local taxes are added separately where legally applicable.
- For example, if qualifying medicines have PTRs of ₹8, ₹10 and ₹12, their simple average is ₹10; adding a 16% margin produces a ceiling price of ₹11.60 before applicable taxes.
- The mechanism is therefore based on **existing market prices**, rather than directly calculating the cost of production and adding a regulated return.

Annual Price Revision:

- Ceiling prices of scheduled formulations are subject to annual revision linked to the **Wholesale Price Index (WPI)**, reflecting the broader inflationary movement in wholesale prices.
- This mechanism attempts to balance affordability with the need to prevent regulated prices from becoming disconnected from changes in input costs and general price levels.

Core Structural Challenges:

Limited Coverage of Direct Price Control:

- The major structural issue is that the ordinary ceiling-price mechanism is linked to the essential-medicine framework rather than covering every pharmaceutical product.
- Consequently, a large part of the pharmaceutical market remains outside direct ceiling-price regulation, making the distinction between **essentiality-based regulation and universal affordability regulation** an important policy question.

Market-Based Pricing and Price Anchoring:

- MBP can create a situation in which the regulated ceiling reflects prevailing market prices rather than manufacturing costs.
- If high-priced brands possess sufficient market share to enter the calculation, their PTRs can influence the average and consequently raise the notified ceiling price.
- This creates a policy concern that regulation may sometimes **validate prevailing market prices** rather than independently establish an affordability-oriented benchmark.

Initial Price of Non-Scheduled Medicines:

- The subsequent annual increase restriction for non-scheduled medicines does not necessarily address an excessively high **initial launch price**.
- If a manufacturer establishes a high MRP at launch, a percentage-based restriction on subsequent increases operates on that elevated base.
- The Supreme Court proceedings have therefore brought the distinction between **launch-price regulation and post-launch price regulation** into sharper focus.

Supply and Availability Risks:

- Price regulation can create a second-order policy problem when regulated prices become commercially unattractive for manufacturers.
- If production of low-margin essential medicines becomes financially unsustainable, manufacturers may reduce production or exit particular segments, potentially contributing to **medicine shortages**.
- Effective regulation must therefore combine affordability with continuous monitoring of **availability, production incentives and supply resilience**; NPPA itself identifies shortage monitoring and remedial

action among its responsibilities.

Trade and Hospital Margins:

- Medicine affordability is not determined only by the manufacturer's selling price because the pharmaceutical supply chain includes manufacturers, distributors, retailers, institutional buyers and hospitals.
- The Supreme Court's recent proceedings highlight the possibility that substantial gaps between **PTR and patient-facing MRP** can arise even when a medicine is supplied to the trade at a much lower price.
- The issue becomes particularly significant in hospital pharmacies when patients are required to purchase medicines through designated outlets and cannot easily compare prices across competing pharmacies.

Generic Medicines and Jan Aushadhi:

Generic Versus Branded Medicines:

- **Generic medicines** are marketed under their non-proprietary or approved names rather than proprietary brand names and can substantially reduce medicine expenditure when therapeutically equivalent products are available.
- The Government's **Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP)** seeks to improve access to quality generic medicines through dedicated Jan Aushadhi Kendras.
- According to the official PMBJP website, more than **19,000 Jan Aushadhi Kendras** were functional as of March 2026, with a product basket containing around 2,100 medicines and 300 surgical items.
- The scheme states that Jan Aushadhi medicines are generally priced **50–80% lower than comparable branded medicines** available in the open market.

Why Generic Prescribing Matters:

- Price regulation alone cannot ensure affordability if patients are systematically directed towards higher-priced brands when therapeutically equivalent lower-cost alternatives are available.
- Greater use of **generic prescribing**, transparent substitution practices and informed patient choice can improve price competition, although quality assurance and prescription safety must remain integral to the system.

Special Problem of Patented and Rare-Disease Medicines:

Innovation Versus Affordability:

- Advanced biologics, targeted cancer therapies and rare-disease medicines can remain extremely expensive because of **research and development costs, small patient populations, intellectual-property protection and import dependence**.
- Bringing such medicines under strict price control can improve affordability but may also affect incentives for manufacturers to introduce innovative therapies in India.
- A differentiated policy approach can therefore consider **price negotiation, risk-sharing, public procurement, differential pricing and targeted financial support** rather than relying exclusively on a uniform ceiling-price mechanism.

Trade Margin Rationalisation and Public-Interest Powers:

Paragraph 19 of DPCO:

- Paragraph 19 provides an important regulatory safety valve by allowing the Government to intervene in the prices of certain non-scheduled formulations in the **extraordinary circumstances of public interest**.
- NPPA has previously used such powers for categories including anti-diabetic and cardiovascular medicines, while trade-margin rationalisation has also been applied to selected medical devices and anti-cancer

medicines.

Why Trade Margin Capping Matters:

- **Ceiling-price regulation** controls the maximum permitted price of specified formulations, whereas **trade-margin regulation** focuses on limiting the margin accumulated between procurement and final sale.
- A broader trade-margin approach could address pricing distortions across the supply chain without necessarily requiring every medicine to be placed under a conventional ceiling-price formula.

Way Forward:

Reform Priorities:

- Expand price transparency by improving disclosure of **PTR, MRP, institutional procurement prices and trade margins** wherever legally and operationally feasible.
- Examine whether the existing framework adequately addresses **excessive initial launch prices** of non-scheduled medicines rather than focusing mainly on subsequent annual increases.
- Strengthen **trade-margin rationalisation** for selected high-cost medicines, medical devices and hospital-supplied products where large procurement-to-patient price gaps are demonstrated.
- Strengthen public procurement and Jan Aushadhi distribution so that affordable generic alternatives are physically available, reliable and easily identifiable.
- Use **differential pricing and negotiated procurement** for rare-disease and highly innovative therapies to balance affordability with incentives for pharmaceutical research.
- Improve real-time monitoring of medicine availability so that price interventions do not unintentionally create shortages.
- Strengthen prescription transparency and generic-name prescribing while maintaining appropriate clinical discretion and quality safeguards.

UPSC Perspective: Key Takeaways:

- **GS-II:** The issue connects with the right to health, public-health governance, judicial review, regulatory institutions and welfare-state obligations.
- **GS-III:** Medicine pricing involves pharmaceutical markets, industrial policy, innovation incentives, competition, supply chains and consumer protection.
- **GS-IV:** The case raises questions of **ethical governance, distributive justice, vulnerability and public interest**, particularly where patients lack meaningful bargaining power.
- **Prelims:** Remember the institutional chain — **Essential Commodities Act ? DPCO, 2013 ? NPPA ? scheduled formulations ? ceiling-price regulation.**
- The **16% figure** is important because it is used as the notional retailer margin in the DPCO market-based ceiling-price calculation; it should not be described as a universal statutory profit cap applicable to every medicine.

Value Addition for UPSC:

Conceptual Distinction:

- **Ceiling Price:** Maximum legally permissible price for a scheduled formulation under the applicable DPCO mechanism.
- **PTR:** Price at which the medicine is supplied to the retailer or relevant trade channel for pricing calculations.
- **MRP:** Maximum retail price printed on the medicine package and subject to applicable legal requirements.
- **Market-Based Pricing:** Price-control methodology based primarily on prevailing market PTRs of qualifying products rather than direct production-cost calculation.
- **Trade Margin Rationalisation:** Regulatory approach aimed at controlling excessive margins between procurement and final consumer prices.

Kamaraj IAS Academy

Plot A P.127, AF block, 6 th street, 11th Main Rd, Shanthi Colony, Anna Nagar, Chennai, Tamil Nadu 600040

Phone: **044 4353 9988 / 98403 94477 / Whatsapp : 09710729833**

- **NLEM:** Public-health list identifying medicines considered essential for priority healthcare needs.
- **Policy Dilemma:** Effective medicine-price regulation must simultaneously protect **affordability, availability, quality, competition and innovation.**
- **Mains Linkage:** The central analytical question is not simply whether medicine prices should be capped, but **how India can design a pricing architecture that prevents excessive patient burden without creating shortages or weakening incentives for pharmaceutical innovation.**