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Cancer Drug Price Reset: NPPA Tightens Compliance as Supreme Court Eyes Wider Controls

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Centre caps trade margins at 30 per cent on 137 anti-cancer medicines, expects Rs 2,500 crore in annual savings; NPPA mandates price revisions, disclosures and uninterrupted supplies



The affordability of medicines in India has come under renewed scrutiny after the Supreme Court (SC) questioned the wide gap between procurement prices and maximum retail prices (MRPs) of medicines and medical devices, urging the Centre to consider broader price regulation. The government has capped trade margins at 30 per cent on 137 non-scheduled anti-cancer medicines, with revised prices scheduled to take effect from November 9, 2026. The measure is expected to reduce MRPs by up to 70 per cent and generate annual savings of Rs 2,500 crore for patients. However, the court has questioned why similar controls should not extend to other medicines and medical devices, including through consideration of a 16 per cent retail-margin framework. With the matter scheduled for further hearing on October 27, the case raises wider questions about pharmaceutical pricing, distribution margins and the balance between patient affordability, commercial viability and uninterrupted medicine supplies.

Supreme Court questions steep mark-ups across medicines

The proceedings are part of a broader legal challenge concerning medicine pricing, generic prescriptions and the regulation of medical devices. On October 12, a bench comprising Justices Vikram Nath and Sandeep Mehta questioned why the Centre's intervention was confined to anti-cancer medicines when substantial price disparities existed across other medicines and medical devices.

The court cited the example of an Indian-made cardiac stent reportedly supplied to retailers for around Rs 5,000 but carrying an MRP of Rs 25,000. The bench also questioned the substantial differences between the prices at which manufacturers supply medicines to stockists and the MRPs ultimately charged to patients.

The court asked the government to examine whether a broader retail-margin framework could be introduced, including consideration of a 16 per cent margin. This is the margin incorporated into the price calculation for scheduled medicines under the existing regulatory framework, although applying it universally would require further policy and regulatory consideration.

The Centre informed the court that it had decided to regulate trade margins on anti-cancer medicines. The subsequent notification covering 137 medicines establishes a more extensive framework for oncology pricing, while the court's questions have brought the wider pharmaceutical market into focus. The matter is scheduled for further hearing on October 27, 2026, when the court may consider the government's position on extending price regulation beyond cancer medicines.

NPPA mandates 30 per cent trade-margin cap

The National Pharmaceutical Pricing Authority (NPPA), under the Department of Pharmaceuticals, notified the expanded trade-margin rationalisation measure on October 17, 2026, under Paragraph 19 of the Drugs (Prices Control) Order (DPCO), 2013. The order covers formulations containing any of 137 specified non-scheduled anti-cancer drugs, including patented medicines. The identified medicines include immunotherapies used to treat more than 20 types of cancer, denosumab for certain breast and prostate cancer indications, pegfilgrastim to prevent neutropenia in cancer patients, and bevacizumab for cancers including colorectal, ovarian and cervical cancer.

The list also includes widely used therapies such as pembrolizumab, durvalumab and osimertinib. It extends across branded and generic medicines, domestically manufactured and imported products, and formulations with different dosage strengths, dosage forms, routes of administration and combinations. The list may be updated periodically.

The government expects the measure to reduce the MRPs of the identified medicines by up to 70 per cent, depending on their existing price structures, and generate annual savings of approximately Rs 2,500 crore for cancer patients and their families. The order goes beyond announcing a price cap. It prescribes how manufacturers must calculate revised MRPs, submit pricing information, communicate reductions to the market and maintain supplies. It also establishes monitoring and enforcement obligations for companies, distributors, retailers, hospitals and medical institutions.

Seven-day deadline for pricing disclosures

Manufacturers must submit the revised MRP information to NPPA and the concerned state drug controller within seven days of publication of the order in the Official Gazette. This obligation applies even where the calculation does not result in a change in a product's existing MRP. The submission must include the formulation, approved composition, pack size, brand name, March 2026 PTS/PTD, applicable GST rate, recalculated MRP and pre-revision MRP.

Companies must also issue and submit the applicable price list in Form V through the Integrated Pharmaceutical Database Management System (IPDMS), in accordance with Paragraph 25 of DPCO, 2013. Copies must be provided to state drug controllers, dealers and other relevant entities within the prescribed seven-day period. Failure to submit the required pricing information will be construed as non-reduction of MRP and may trigger action to recover overcharged amounts. The revised

prices must be implemented from November 9, 2026, giving companies a defined period to complete the recalculation, regulatory submissions and market communication requirements.

Mandatory communication to dealers, retailers and consumers

The order requires manufacturers to demonstrate that revised prices have been communicated effectively across the distribution chain. Companies must circulate updated MRP lists to dealers and retailers within seven days for display to consumers. They must also publish advertisements in leading newspapers within the prescribed period, informing dealers, retailers and consumers about the price reductions. In addition, companies must create a dedicated section on their corporate homepage for DPCO-related matters and upload the notification and revised MRP details.

Manufacturers must submit documentary evidence of their compliance when requested by NPPA. This includes batch-wise production details and stock positions held by the company and its distributors at the time of publication of the order. These requirements are intended to ensure that price reductions are reflected not only in manufacturers' declarations but also in the prices displayed and charged at the point of sale. A revised MRP will not, by itself, guarantee lower patient expenditure unless the updated prices reach dispensing points and are reflected in pharmacy and hospital billing systems.

Hospitals and pharmacies face compliance obligations

Hospitals and medical institutions have specific responsibilities because a substantial proportion of anti-cancer medicines is supplied directly to them. They must ensure that the revised MRPs are implemented from November 9 and display updated prices prominently on their websites. Retailers, dealers, hospitals and medical institutions must also display manufacturers' price lists and supplementary price lists at conspicuous locations on their premises, making them accessible to consumers.

State drug controllers will monitor compliance by manufacturers, dealers, retailers, hospitals and medical institutions. Violations must be reported to NPPA, which may initiate proceedings to recover overcharged amounts under the applicable provisions of DPCO, 2013. The framework therefore extends accountability beyond manufacturers to the distribution and dispensing stages, where patients ultimately pay for their medicines.

Production continuity becomes a regulatory obligation

The order also seeks to prevent price controls from disrupting the availability of cancer medicines. Manufacturers must maintain current production levels of the covered formulations. Any company intending to reduce its average monthly production must obtain prior permission from NPPA. Companies planning to discontinue production or imports of covered formulations must submit the prescribed Form IV information at least six months before the intended discontinuation date.

These provisions are particularly significant for specialised oncology medicines, where the withdrawal of a product or a reduction in supply could affect treatment continuity. By linking price regulation with production obligations, the order seeks to ensure that affordability measures do not lead to avoidable shortages. The prescribed prices will remain in force until further orders. Manufacturers may avail themselves of the annual price increase permitted under Paragraph 20(1) of DPCO, 2013, subject to continued compliance with the maximum permissible trade margin.

Patient assistance programmes receive conditional exemption

Quantities supplied free of cost to patients under manufacturers' patient assistance programmes (PAPs) may be excluded from the PTS/PTD and MRP calculations for trade-margin capping, subject to specified conditions. Manufacturers must provide undertakings to NPPA, maintain patient and treatment records, document medicines received and consumed, and ensure that the drugs are used only for their specified purposes.

NPPA retains the right to seek additional information, conduct audits and inspections, and verify programme implementation through third parties. Failure to satisfy the prescribed conditions may result in the loss of the exemption. The provision recognises free-of-cost patient assistance while establishing safeguards to ensure that the exemption is used appropriately.

Non-compliance could trigger recovery proceedings

Manufacturers that fail to comply with the order may be required to deposit the overcharged amount with interest under DPCO, 2013, read with the Essential Commodities Act, 1955. For this purpose, the overcharged amount is calculated as the difference between the MRP excluding GST and the MRP excluding GST determined under the prescribed formula.

The notification also provides that existing price orders relating to the specified drugs, where applicable, will stand superseded following publication of the new order. The financial and regulatory consequences make accurate product-level pricing, timely

disclosures and effective communication essential for manufacturers covered by the notification.

Industry perspective: Affordability must extend to innovation

Arun Asaithambi, Founder and CEO, Katamaran Industries, described the government's move as a patient-focused intervention but emphasised the need to address the underlying economics of drug development alongside distribution margins. “The government's move to cap trade margins on non-scheduled cancer medicines at a proposed 30 per cent is a welcome intervention that puts patients at the centre of drug pricing,” he said.

Asaithambi noted that the measure builds on earlier policy interventions and could help patients manage the cost of completing prescribed therapies. However, he cautioned that margin regulation alone cannot resolve all affordability challenges, particularly for patented therapies.

The cap addresses mark-ups across the distribution and retail chain rather than directly reducing the underlying prices charged by manufacturers. Competition, domestic manufacturing, biosimilar development and the economics of research and development will therefore continue to influence access to innovative oncology treatments.

“Making today's medicines affordable and tomorrow's cheaper to discover are two sides of the same coin,” he said, pointing to the potential role of artificial intelligence, automation and human-relevant disease models in reducing costly failures during drug development. His observations highlight the distinction between reducing distribution margins on existing medicines and lowering the cost of developing and bringing future therapies to market.

In the near term, the priority is a clean transition of existing stock and uninterrupted supply, so lower prices reach patients without any break in their treatment.”

"When a cancer medicine can be sold at 85% below its printed price, as some have been on our platform, the printed price was never the real one. NPPA’s own analysis puts average trade mark-ups on these medicines at around 170%. This reform brings MRPs back in line with reality, so a fair price no longer depends on which pharmacy a patient happens to find. It also changes what pharmacies compete on. Once the price is fair everywhere, what matters is whether the right medicine reaches the patient on time, wherever they live. Four in five cancer patients we serve are treated in a city other than their own, and for them, getting a specialty medicine on time can be as hard as paying for it. That is where the industry’s attention should go next", said **Devashish Singh, Co-founder and CEO of MrMed**.

Oncologists highlight patient access and treatment continuity

For many Indian families, a cancer diagnosis brings two battles: fighting the disease and managing the cost of treatment. The government's decision to regulate trade margins on 137 non-scheduled anti-cancer medicines could offer financial relief, particularly to patients requiring expensive, long-term therapies. The list includes advanced immunotherapies and targeted therapies, alongside other medicines used in cancer care for selected patients with lung, breast, colorectal and other cancers.

“The real significance of this decision is the possibility of making effective cancer treatment accessible to more patients. When the cost of medicines comes down, some families may find it easier to continue treatment rather than delay or discontinue it because of financial pressure. However, treatment decisions must always be guided by the patient's cancer type, stage, biomarkers and overall health—not price alone,” says **Dr Ashish Joshi, Founder, Director and Medical Oncologist, M|O|C Cancer Care**.

For patients, lower medicine prices could reduce out-of-pocket expenditure, particularly for treatment plans involving repeated doses or prolonged therapy. However, the actual savings will depend on the medicines prescribed, the patient's treatment regimen and the extent of the price reduction applicable to each formulation.

Drug price regulation will not address every component of cancer care costs. Diagnostic tests, surgery, radiation therapy, hospitalisation, supportive medicines and follow-up consultations can continue to place a substantial financial burden on patients and their families. The impact of the policy will therefore need to be assessed in terms of both medicine affordability and the broader cost of treatment.

Implementation will be critical. Patients and caregivers can check revised prices with hospital pharmacies and verify applicable MRPs through the National Pharmaceutical Pricing Authority's website or the Pharma Sahi Daam app. Ultimately, the measure's impact will depend on transparent pricing, uninterrupted medicine availability and whether patients realise meaningful savings without compromising the quality or continuity of care.

Broader price regulation raises questions for the industry

The Supreme Court's observations have brought the wider pharmaceutical pricing system into focus. Under the existing framework, scheduled medicines are subject to government-fixed ceiling prices, while non-scheduled medicines operate under a different pricing regime. Manufacturers can generally set initial prices for non-scheduled formulations, subject to applicable restrictions, including limits on subsequent annual MRP increases.

Extending trade-margin controls across the wider pharmaceutical market would require consideration of differences in manufacturing costs, distribution expenses, storage requirements, sales volumes and supply-chain structures. The impact could vary considerably across therapeutic categories and products. For pharmaceutical companies, distributors, retailers and hospital pharmacies, a wider framework could require changes to pricing strategies and commercial arrangements. For patients, the central question is whether regulatory intervention translates into lower out-of-pocket expenditure.

The issue also extends beyond medicines to medical devices and hospital consumables, where differences between procurement prices and patient-facing charges can contribute to treatment costs. For cancer patients, the distinction is particularly important. Trade-margin controls can reduce the final price where excessive mark-ups exist, but they do not directly address all other costs of cancer care, including screening, diagnostics, surgery, radiation therapy, hospitalisation and supportive treatment.

Next hearing could shape the next phase

The November 9 implementation of the anti-cancer drug margin cap marks a defined step in the government's approach to oncology affordability. The detailed NPPA order establishes obligations for manufacturers and healthcare providers covering pricing, disclosures, production continuity and enforcement. However, the Supreme Court's questions have raised the possibility of a broader review of trade margins and medicine pricing across the healthcare system. The next hearing on October 27 will be important in determining the further directions, if any, issued to the Centre on extending price regulation beyond cancer medicines.

For pharmaceutical companies, the immediate priority is to validate product-level pricing against the prescribed reference data, submit the required declarations, update price lists and ensure that revised MRPs are reflected throughout the supply chain by November 9. For NPPA and state drug controllers, the challenge will be to ensure that notified reductions translate into lower patient expenditure while safeguarding the availability of essential cancer therapies.

The larger policy question remains how India can ensure fair medicine prices without undermining a reliable pharmaceutical supply chain. Whether the current intervention remains focused on oncology or becomes a starting point for broader pricing reforms will depend on the government's response and the Supreme Court's further consideration of the issue.

India’s Anti-Neoplastics Market Grows 21.6% as Biosimilars and Targeted Therapies Shape Competition

India’s anti-neoplastics market recorded monthly sales of Rs 609 crore in September 2026, registering year-on-year value growth of 21.6 per cent, according to Pharmarack Technologies’ PharmaTrac data. On a moving annual total (MAT) basis for September 2026, the market was valued at Rs 6,389 crore, highlighting the growing contribution of cancer therapies to India’s pharmaceutical market.

The segment recorded a five-year compound annual growth rate (CAGR) of 13.9 per cent, marginally above the overall Indian pharmaceutical market’s reported growth of 13.5 per cent. The performance reflects sustained demand for oncology treatments, alongside the contribution of new product introductions.

Sharing insights on the market, **Sheetal Sapale, Vice President – Commercial at Pharmarack Technologies,** highlighted the varied growth trends across anti-neoplastic categories. Immunosuppressive and immunostimulating agents, protein kinase inhibitors and plant-based antineoplastics recorded stronger volume-driven growth in September. However, monoclonal antibodies, despite remaining the largest contributing category within the segment, registered negative volume-driven growth.

New-product introductions were an important driver of market expansion. According to Pharmarack’s analysis, the entry and growing acceptance of biosimilars, supported partly by more economical pricing and comparable efficacy, are contributing to the changing dynamics of the monoclonal antibody market.

Company landscape and competition

PharmaTrac’s anti-neoplastics corporate rankings identify Zydus, Intas, Emcure, Hetero and Mankind among the leading companies in the segment. Their positions indicate a significant presence in the anti-neoplastics market, although the available data does not provide company-specific September sales or growth rates to establish which of these companies grew the fastest.

Other companies and brands featured in the supplied market data include AstraZeneca’s Zoladex, Janssen’s Darzalex and Imbruvica, Roche’s Tecentriq and Bristol Myers Squibb’s Opdyta. Opdyta recorded September sales of Rs 26.6 crore, with a reported year-on-year decline of 2.4 per cent. These examples illustrate the differing performance of individual oncology brands within a market expanding at double-digit rates.

With monthly value growth of 21.6 per cent and MAT sales of Rs 6,389 crore, India’s anti-neoplastics market remains a high-growth segment of the pharmaceutical industry. Competition is shaped by established oncology portfolios, targeted therapies and the increasing role of biosimilars. However, identifying the fastest-growing companies and brands will require therapy-specific sales and year-on-year growth figures for each player.

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