NPPA
AFFORDABLE MEDICINES FOR ALL
सभी के लिए वहनीय दवाईयाँ

सत्यमेव जयते

NATIONAL PHARMACEUTICAL PRICING AUTHORITY
DEPARTMENT OF PHARMACEUTICALS
MINISTRY OF CHEMICALS & FERTILIZERS
GOVERNMENT OF INDIA

Azadi Ka Amrit Mahotsav

AUSHADH SANDESH

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दवा वही
दाम सही

Committed Towards Accessibility, Availability & Affordability of Medicines for All

About NPPA...

The National Pharmaceutical Pricing Authority (NPPA), an independent body of experts in the Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals was constituted by the Government of India vide resolution published in the Gazette of India No. 159 dated 29.08.97. The functions of NPPA, inter-alia, includes fixation and revision of prices of scheduled formulations under the Drugs Prices Control Order (DPCO), as well as monitoring and enforcement of prices. NPPA also provides inputs to Government on pharmaceutical policy and issues related to affordability, availability and accessibility of medicines.

The Authority is a multi-member body consisting of a Chairperson, a Member Secretary and three ex-officio members. Two of the three ex-officio members are from Department of Economic Affairs and Department of Expenditure respectively and third member is Drug Controller General of India.

The Drugs (Prices Control) Order, 2013(DPCO, 2013) was notified on 15.05.2013 under the Essential Commodities Act, 1955(EC Act, 1955) and is based on the broad guidelines of the National Pharmaceutical Pricing Policy (NPPP), 2012. The three key principles of the NPPP-2012 are as below:

a. **Essentiality of Drugs:** The regulation of prices of drugs is on the basis of essentiality of drugs as per the medicines under NLEM-2011, NLEM-2015 and NLEM-2022 as amended vide S.O. 5249 dated 11.11.2022 has been incorporated as the First Schedule of DPCO 2013.

b. **Control of Formulations prices only:** The prices of formulations only are to be regulated and not the prices of the Bulk Drugs and the resulting formulations as adopted in the Drug Policy 1994.

c. **Market Based Pricing:** The ceiling prices of medicines are fixed on Market Based Pricing (MBP) methodology.

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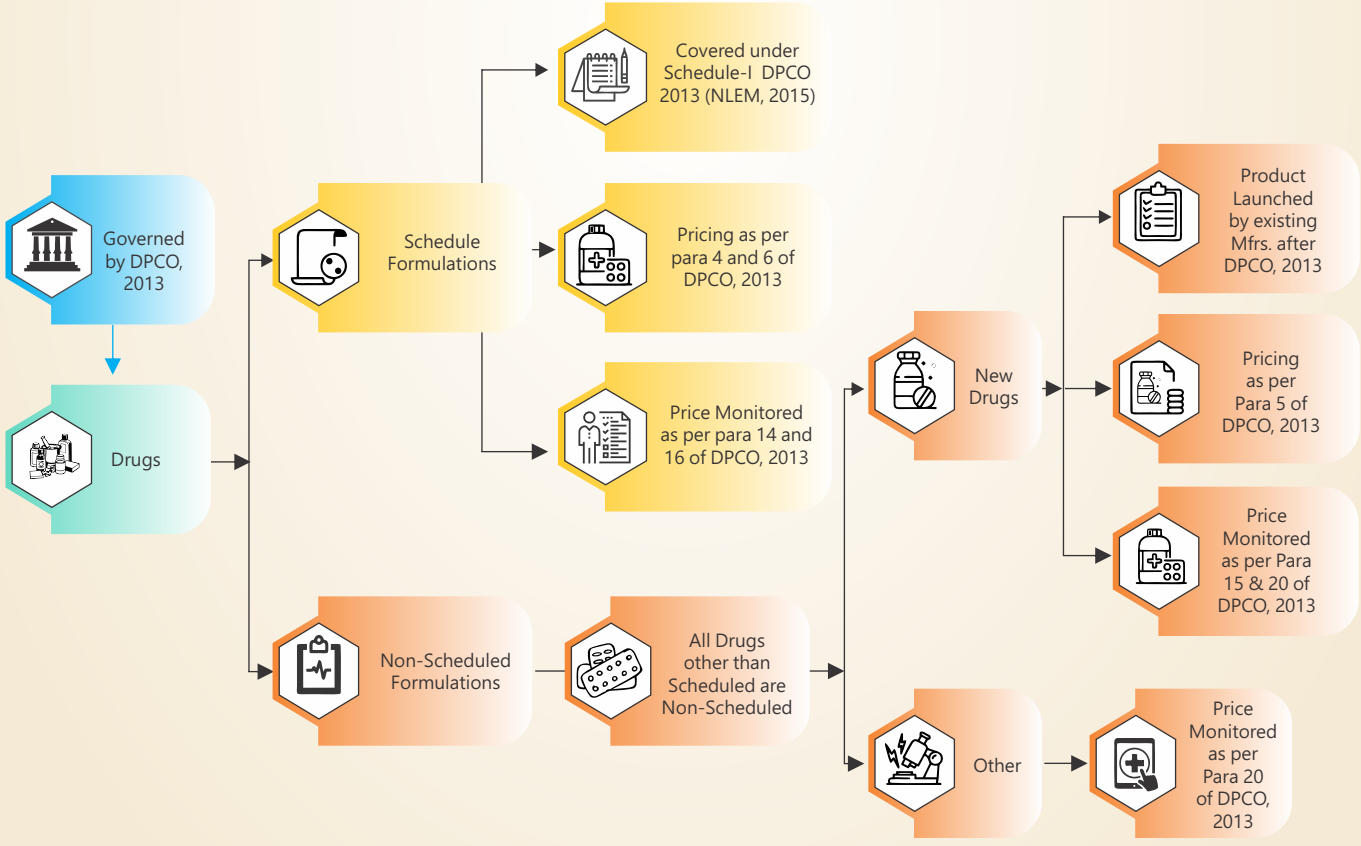


DISCLAIMER:

This is an initiative by NPPA to report current events and affairs related to pharmaceutical industry and the NPPA. This newsletter has been curated purely for informative purposes and do not reflect the official policy or position of NPPA. This newsletter is not intended to be used for any commercial/ official purposes.

You can also give your suggestions/ feedback at: **monitoringnppa@gov.in**

From CHAIRMAN'S DESK

P. Krishnamurthy, IAS
Chairman
National Pharmaceutical Pricing Authority
Department of Pharmaceutical
Ministry of Chemical and Fertilizers
Government of India

It gives me great pleasure to present the **XXIX edition of Aushadh Sandesh,** which captures important developments in pharmaceutical regulation, policy, and innovation.

This edition features an insightful expert article on **Zaynich®,** India's first indigenously discovered novel antibiotic combination to receive approvals from both CDSCO and the USFDA, highlighting the country's growing capabilities in pharmaceutical research and its contribution to addressing the global challenge of antimicrobial resistance. Complementing this, our in-house article, **"Dawa Wahi, Daam Sahi: The Story Behind India's Medicine Prices,"** explains the evolution of India's drug pricing framework and the pivotal role of the National Pharmaceutical Pricing Authority in ensuring that essential medicines remain both affordable and accessible.

This issue also brings you key regulatory developments, including the recent amendments to the **Drugs (Prices Control) Order, 2013,** updates on NPPA's digital initiatives through **IPDMS 2.0,** international regulatory developments, and the noteworthy outreach activities undertaken by the Price Monitoring and Resource Units (PMRUs) across the country. In addition, the FAQ section on **Drug Shortages and Availability of Essential Medicines** seeks to enhance public understanding of an important aspect of pharmaceutical regulation.

As we continue to strengthen a transparent, technology-driven and responsive regulatory ecosystem, the continued cooperation of industry, healthcare professionals, State Governments and citizens remains vital to our shared objective of ensuring affordable, accessible and quality medicines for all.

I extend my best wishes for an enriching and informative reading experience. Together, let us continue our collective efforts towards building a healthier, more affordable, and accessible healthcare system for all.

With best wishes

(Shri P. Krishnamurthy)

PHARMACEUTICAL INNOVATION WATCH

India R&D Answer to a Global Threat: Zaynich® and India's Fight Against Multi Drug-Resistant Infections

An India-discovered antibiotic combination secures CDSCO and USFDA approval, offering a breakthrough therapeutic option against gram negative carbapenem-resistant infections and a case study in what indigenous drug innovation can deliver for public health.

The rising cost of drug resistance

Antimicrobial resistance (AMR) has become one of the more pressing public health challenges facing India's healthcare system. As resistant organisms spread, clinicians increasingly encounter infections that do not respond to standard antibiotics, particularly among critically ill and immunocompromised patients. Several newer beta-lactam/beta-lactamase inhibitor combinations approved in recent years have narrowed but not closed the major treatment gap, showing limited activity against metallo-beta-lactamase (MBL)-producing organisms and OXA-48 producers, two resistance mechanisms of particular concern in Indian hospital settings. Moreover, some of the toughest pathogens widely encountered in Indian hospitals such as Pseudomonas aeruginosa, Acinetobacter baumanii and Klebsiella pneumoniae are also adept a expressing non-enzymatic resistance mechanisms based on drug efflux, impermeability and target mutations which are not possible to be overcomed by any of the newer antibiotics mentioned above. In practice, clinicians are often left combining carbapenems with polymyxins, an approach associated with inconsistent outcomes and considerable toxicity.

A regulatory milestone for Indian drug discovery

Against this backdrop, May 2026 marked a notable development. Zaynich®, a fixed combination of zidebactam (1g) and cefepime (2g), received approval from India's Central Drugs Standard Control Organisation (CDSCO) for the treatment of complicated urinary tract infections (cUTI), including pyelonephritis, in adult patients. The approval was soon followed by approval from the US Food and Drug Administration (USFDA) for the same indication. Notably, this makes Zaynich® the first ever New Chemical Entity discovered, developed and to be commercialised by an Indian pharmaceutical company to receive USFDA approval, a milestone for the India's pharmaceutical industry and research ecosystem. The molecule had also earned the USFDA's Fast Track and Qualified Infectious Disease Product (QIDP) designations, reflecting its intended role in addressing infections for which treatment options remain limited. At the heart of this journey lies the vision of Wockhardt' s Chairman, Dr. Habil Khorakiwala, who dared to believe India could discover, develop and take a world-class innovation to the global stage, and deliver life-saving

treatment to patients facing drug-resistant infections. India now has both the responsibility and the standing to help lead the global response to AMR.

The science behind the combination

Zaynich® pairs Zidebactam, a novel non-betalactam class beta-lactam enhancer with a distinct mechanism of action rather than a conventional beta-lactamase inhibitor with Cefepime, an established fourth-generation cephalosporin. Its development spanned more than fifteen years and included multiple Phase I studies, a Phase II programme in meropenem-resistant infections, and the pivotal global Phase III ENHANCE-1 trial in cUTI and acute pyelonephritis, supplemented by compassionate-use experience in patients with few remaining treatment alternatives. In pivotal Phase 3 study, Zaynich outperformed gold standard drug Meropenem by attaining 20% superiority for the primary end-point of composite cure which covers both successful pathogen eradication and clinical cure at test-of-cure visit. Such remarkable performance has not been shown by any antibiotics approved over past more than fifteen years. The combination is positioned to address Carbepenem-resistant Gram-negative infections with significant unmet treatment needs.

Why this matters for patients and policy

For a country carrying a significant share of the global AMR burden, being the first country with accessibility and availability of a new anti-infective developed, tested, and manufactured in India, has implications beyond the clinic. It signals that Indian pharmaceutical R&D can produce first-in-class molecules capable of meeting global regulatory standards, rather than depending solely on imported or licensed therapies for the most difficult-to-treat infections. It also raises the familiar policy question that accompanies any advanced anti-infective: how to balance fair pricing and broad accessibility with the reasonable incentives needed to sustain long-term investment in antibiotic discovery, an area where global pharmaceutical investment has otherwise been in decline. As Zaynich® moves from regulatory approval toward wider clinical use, its impact on patient access and affordability will be as important a measure of success as its clinical performance.

Looking ahead

Zaynich® is a demonstrated answer to one of the most urgent unresolved problems. As a company that has invested almost three decades in the discovery and development of novel antibiotics, Wockhardt is confident that Zaynich® represents an extraordinary asset: a genuinely differentiated molecule, born in India, validated to the highest global standards, and now available to the patients who need it most. It fills a treatment void that no approved therapy has been able to close, and it does so with a level of clinical evidence that speaks for itself. We do not take that lightly. Wockhardt is deeply committed to working alongside physicians, microbiologists, hospital pharmacists, regulators, policymakers, and patient advocates to ensure that Zaynich® is used appropriately, accessed equitably, and integrated thoughtfully into antimicrobial stewardship frameworks across India and globally. We will invest in education, in real-world evidence generation, in guideline development, and in every conversation necessary to build the ecosystem that a molecule of this significance deserves. Above all, we carry the responsibility of continuing to fight AMR not just through Zaynich®, but as a sustained institutional commitment. India bears a significant share of the global AMR burden, and the world is watching how that burden is addressed. Wockhardt stands ready to lead that effort: in R&D, in the clinic, in policy rooms, and at every point where science meets the patient. Antimicrobial resistance respects no borders, and neither does our resolve to defeat it.

This journey would not have been possible without the relentless work of our scientists at R&D, incredible support of investigators across the world who placed their trust in this science, the hospitals that partnered with us through every stage of clinical development, and the institutions that enabled this effort at a national level ICMR, the Ministry of Health and Family Welfare, and CDSCO. Their commitment, rigour, and belief in indigenous innovation made Zaynich® a reality. We are deeply grateful.

Dawa Wahi, Daam Sahi: The Story Behind India's Medicine Prices

"The true value of a medicine is not measured merely by its scientific innovation, but by whether every patient who needs it can afford to receive it."

Somewhere in India, at this very moment, a patient walks into a neighbourhood pharmacy to purchase medicines for hypertension, diabetes, or an infection. For most people, the purchase lasts only a few minutes. Few pause to wonder why a life-saving medicine costs what it does - or who ensures that the price printed on the strip is fair.

Behind this seemingly routine transaction lies one of the world's most extensive pharmaceutical price regulation systems. It is the result of decades of policy evolution, economic reforms, scientific advancements, and regulatory oversight. The National Pharmaceutical Pricing Authority (NPPA) manages this system by implementing the Drugs Price control Order. Its primary mandate is to balance two specific objectives: **maintaining medicine affordability and availability for patients and supporting a competitive domestic pharmaceutical industry.**

Today, India is widely recognized as the "Pharmacy of the World." The country supplies medicines to more than 200 countries and contributes nearly one-fifth of the global generic medicine supply by volume. At the same time, India's pharmaceutical market is expected to grow from nearly USD 50 billion to approximately USD 130 billion by 2030, reflecting its expanding role in global healthcare (Department of Pharmaceuticals, Annual Report 2024-25)

Fig: India's pharmaceutical market size, today vs. projected 2030 (Department of Pharmaceuticals, Annual Report 2024-25).

The need for Regulating and monitoring medicine prices?

Unlike most consumer products, medicines are purchased out of medical necessity rather than choice. Patients generally rely on prescriptions from healthcare professionals, often in situations where comparing prices or delaying treatment is neither practical nor possible. Coupled with information asymmetry, limited therapeutic substitutes for many essential medicines, and high research and manufacturing costs, these characteristics make the pharmaceutical market particularly vulnerable to market failures.

Without appropriate regulation, excessive medicine prices can restrict access to treatment, reduce adherence to prescribed therapies, and impose significant financial burdens on households. Recognizing these challenges, governments across the world employ pricing interventions such as price negotiations, reference pricing, reimbursement

systems, and direct price controls to improve affordability and equitable access to medicines (World Health Organization, 2023).

India offers a compelling example of this need. Studies have reported price variations of up to 1,100% for the same anti-cancer medicine sold under different brands, illustrating how identical medicines can be priced vastly differently in the absence of effective regulation (Kolasani et al., 2016; Adwal & Baghel, 2019, as cited in Natarajan, Mehra & Rajkumar, 2020). Moreover, medicines account for nearly 70% of out-of-pocket healthcare expenditure in India, making them the single largest contributor to household medical expenses. For millions of patients, particularly those requiring long-term treatment for chronic diseases, even modest increases in medicine prices can compromise treatment adherence and financial security.

It is against this backdrop that India has adopted a targeted approach to drug price regulation. Rather than controlling the prices of all pharmaceuticals, the regulatory framework focuses on essential medicines, seeking to balance patient affordability with the sustainable growth of the pharmaceutical industry. This approach derives its statutory basis from the Essential Commodities Act, 1955, under which successive Drugs (Prices Control) Orders (DPCOs) have been issued to regulate the prices of essential medicines in the public interest.

Evolution of Drug Price Control Orders in India

India's drug price regulation framework has evolved from a system of direct government control over manufacturing costs to one that emphasizes affordable access through market-based regulation. Beginning with price control measures introduced in the early 1960s, successive Drugs (Prices Control) Orders (DPCOs) sought to balance consumer welfare with the growth of the pharmaceutical industry. This gradual policy evolution culminated in the National Pharmaceutical Pricing Policy (NPPP), 2012, which fundamentally reoriented drug price regulation and was implemented through the Drugs (Prices Control) Order (DPCO), 2013.

National Pricing Policy 2012 and DPCO 2013

The National Pharmaceutical Pricing Policy (NPPP), 2012 marked a fundamental shift in India's drug pricing framework by replacing the traditional Cost-Based Pricing (CBP) system with Market-Based Pricing (MBP). Under the earlier regime, medicine prices were fixed based on manufacturers' production costs, a process often criticized for its complexity and administrative burden. The Drugs (Prices Control) Order (DPCO), 2013 operationalized the new framework by determining ceiling prices based on the average market price of medicines with a minimum prescribed market share. The shift aimed to simplify price regulation, enhance transparency, and reduce regulatory intervention while ensuring the affordability of essential medicines. This market-based methodology continues to underpin India's pharmaceutical price control regime today.

Essential Medicines: The Foundation of Price Regulation

An important feature of India's pricing policy is that not every medicine is price controlled. Price regulation primarily applies to medicines included in the National List of Essential Medicines (NLEM), which identifies medicines considered indispensable for addressing the priority healthcare needs of the population. These medicines become Scheduled Formulations under Schedule-I of the DPCO, 2013.

Medicines not included in the Schedule are classified as Non-Scheduled Formulations. Although their prices are not directly fixed by NPPA, they remain subject to monitoring under the DPCO to prevent unreasonable annual price increases and to ensure compliance with applicable provisions.

This distinction enables the Government to focus regulatory interventions on medicines that have the greatest public health significance while preserving market competition for other pharmaceutical products.

The latest revision, NLEM 2022, includes 388 medicines covering 29 therapeutic categories, reflecting India's evolving disease burden and advances in medical science. A selection of the largest categories illustrates the range this regulation covers:

Therapeutic Category	No. of Drugs
Anti-infective Medicines	108
Anti-cancer agents (incl. Immunosuppressive & Palliative Care)	63
Cardiovascular Medicines	30
Hormones, Endocrine Medicines & Contraceptives	25
Medicines used in Anaesthesia	20
Medicines used in Neurological Disorders	20
Medicines used in Psychiatric Disorders	17
Ophthalmological Medicines	16
Immunologicals	18
Gastrointestinal Medicines	14
Analgesics, Antipyretics, NSAIDs & Anti-rheumatic Agents	14
Total (across 29 categories)	**388 (462 with duplication)**

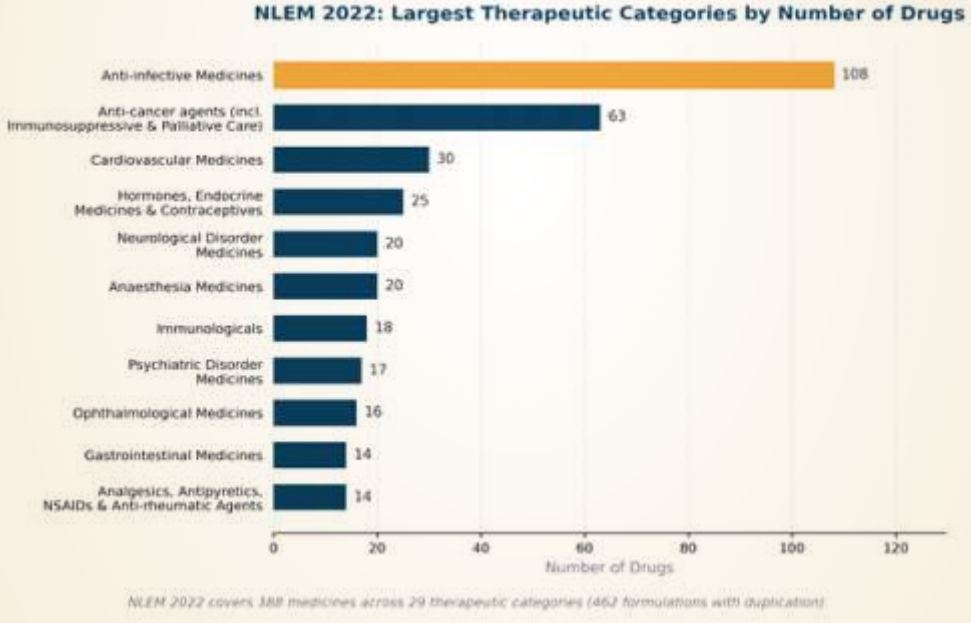


Fig: NLEM 2022 – largest therapeutic categories by number of drugs.

NPPA's Track Record: Impact by the Numbers

As of today, ceiling prices are in force for 935 formulations, of which 776 scheduled formulations were freshly fixed or revised following the NLEM 2022 revision. That revision alone brought an average price reduction of 16.82%, translating into estimated annual savings of ₹3,802 crore for patients across the country.

Fig: Composition of the 935 formulations currently under ceiling-price regulation.

Table: Savings from the NLEM 2022 revision, by therapeutic category

Therapeutic Category	Medicines	Formulations	Annual Savings (₹ Crore)
Anti-infective Medicines	62	174	1,248.92
Anticancer Medicines	59	120	294.34
Cardiovascular Medicines	26	61	474.26
Neurological Disorder Medicines	18	60	154.43
Anti-Diabetic Drugs	8	11	249.73
HIV Management Medicines	20	24	21.93
Psychiatric Disorder Medicines	14	41	42.60
Analgesics, Antipyretics & NSAIDs	11	24	112.80

[Suggested visual: bar chart comparing savings across the categories above]

Fig: Estimated annual savings from the NLEM 2022 revision, by therapeutic category.

NPPA's reach extends well beyond medicines into medical devices

The same conditions that justify regulating medicine prices - necessity-driven purchase, information asymmetry, and limited substitutes at the point of use - apply with even greater force to high-cost medical devices, where patients have little ability to compare options once they are on the operating table. Recognizing this, certain medical devices are notified as "drugs" under the Drugs and Cosmetics Act, 1940, bringing them within the ambit of the DPCO, 2013. This has allowed the NPPA to extend its price-monitoring mandate beyond the pharmacy counter to the operation theatre and diagnostic lab, using both ceiling prices and the Trade Margin Rationalization approach depending on the product.

Ceiling prices on coronary stents, fixed in 2017, delivered price reductions of up to 85% for bare-metal stents and 74% for drug-eluting stents compared to pre-regulation prices. Orthopedic knee implants, regulated the same year, saw prices fall by as much as 69%. Through the innovative Trade Margin Rationalization (TMR) approach - which caps the difference between what a stockiest pays and what a patient pays, rather than fixing the price outright - the prices of over 500 anti-cancer drug brands were brought down by up to 90% as a pilot, and, during the pandemic years in 2021, everyday devices like oxygen concentrators, pulse oximeters, BP monitors, nebulizers, digital thermometers, and glucometers were reined in when they were most in demand and most vulnerable to profiteering.

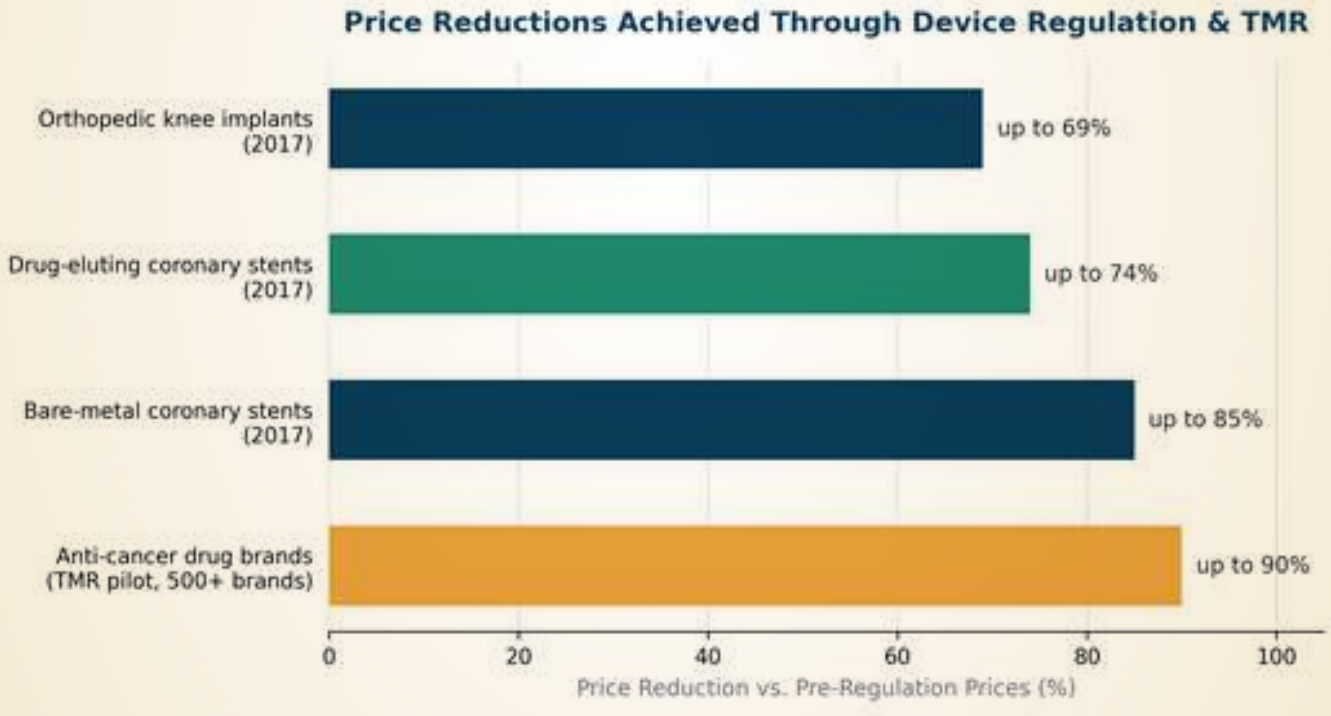
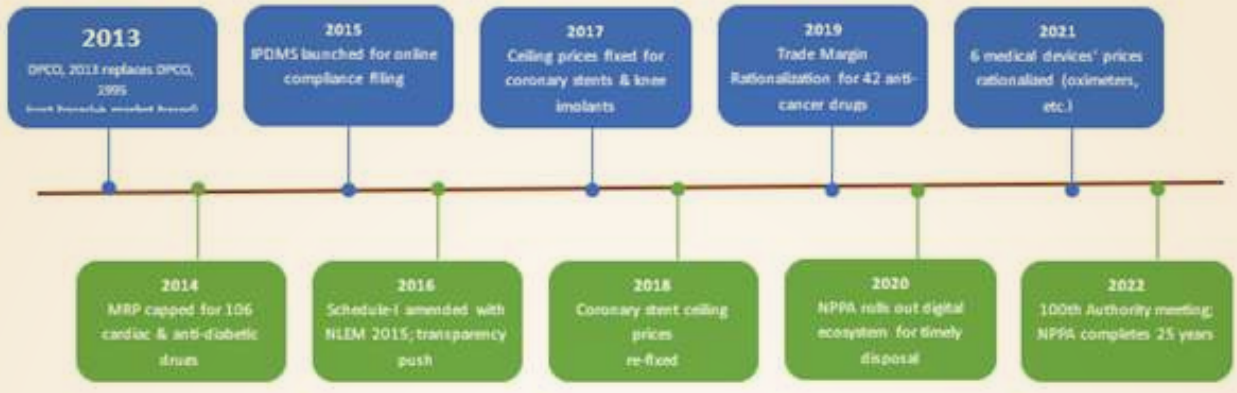


Fig: Price reductions achieved through NPPA's device regulation and Trade Margin Rationalization (TMR), based on figures cited above.



Ensuring Affordable Medicines: The Expanding Role of the NPPA

The role of the NPPA extends far beyond merely fixing the prices of medicines. Once a ceiling price is notified, the real challenge lies in ensuring that patients actually receive medicines at those regulated prices. To achieve this, the NPPA monitors the availability and pricing of essential medicines across the country, investigates cases of overcharging, and enforces compliance with the Drugs (Prices Control) Order, 2013. Its network of 33 Price Monitoring and Resource Units (PMRUs) acts as the eyes and ears of the Authority, conducting market surveys and tracking price violations at the grassroots level. Complementing these efforts are digital initiatives such as the Integrated Pharmaceutical Database Management System (IPDMS) 2.0, which streamlines regulatory compliance, and the Pharma Sahi Daam mobile application or portal, which enables consumers to verify medicine prices, compare brands, and report overcharging. Together, these institutional and technological mechanisms transform the NPPA from a price-fixing regulator into an active guardian of affordable access to essential medicines.

The Global Context: How India's Approach Compares

India's balancing act is not unique in intent, even if it is distinctive in execution. WHO's own Fair Pricing Forum - a global platform on medicine affordability - defines a "fair price" as one that is simultaneously affordable to patients and health systems, and sufficient to sustain industry investment in production and innovation (World Health Organization). That is, almost word for word, the same balance India's DPCO framework has tried to strike since the Hathi Committee first proposed an Essential Medicines approach in 1975 - decades before "fair pricing" became an international policy term.

Where India's model differs from many peer economies is in its emphasis on essentiality and market-based bench marking rather than direct price negotiation or reference pricing against other countries, an approach suited to India's position as both the world's largest generic medicine supplier and a price-sensitive domestic market of over 1.4 billion people.

The Bigger Picture

None of this happens by chance. Behind every price notification lies data collection, market analysis, stakeholder consultation, and increasingly enforcement backed by technology. It is regulation designed not to punish an industry that has made India a global name in affordable healthcare, but to ensure that its success is shared as widely as possible, right down to the patient at the pharmacy counter.

That, in the end, is what Dawa Wahi, Daam Sahi the same medicine, at the right price has always meant: not a slogan, but a promise renewed with every notification, every price revision, and every complaint resolved.

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News related to pricing of drugs

1. Ceiling prices of 935 formulations are effective as on 30.06.2026, of which Ceiling prices for 776 scheduled formulations have been fixed / refixed under National List of Essential Medicines, 2022. There has been average reduction of 16.82% on account of refixation under NLEM, 2022 leading to annual savings of Rs. 3802.11 Crores to the patients. The details of ceiling prices fixed under NLEM, 2022 and savings thereon are as follows:

Therapeutic Category	No. of Medicines	No. of Formulations	Annual Savings (Rs. In Crores)
Anti-infective Medicines	62	174	1248.92
Anticancer Medicines	59	120	294.34
Neurological Disorder Medicines	18	60	154.43
Psychiatric Disorder Medicines	14	41	42.6
Cardiovascular Medicines	26	61	474.26
HIV Management Medicines	20	24	21.93
Analgesics, Antipyretics, Non-steroidal Anti-inflammatory Drugs (NSAIDs)	11	24	112.8
Anti-Diabetic drugs	8	11	249.73
Hormones, other Endocrine Medicines and Contraceptives	16	33	256.41
Others	117	228	946.69
Unique Drugs / Formulations	**332***	**776**	**3802.11**

*Some medicines are listed in various sections. The medicines are counted in both sections, but the formulation is counted only once in one of the sections.

2. Retail prices for 3805 (approx.) new drugs have been fixed under DPCO, 2013 till 30.06.2026. Details of 30 retail prices notified for various formulations based on the decision taken in 146th meetings are as follow:

S. No.	Therapeutic group	Total Number	Type of Formulation	Retail Price fixed Range (Rs.) (Excl. GST) per tablet/per ml
(1)	(2)	(3)	(4)	(5)
1.	Anti Diabetic	6	Tablet/Gel	3.31 – 14.88
2.	Pain / Analgesics	4	Tablet/ Injection	10.05 – 30.58
3.	Cardiovascular	7	Tablet	7.31 – 18.46
4.	Anti-Infective	2	Suspension	3.65- 5.74
5.	Respiratory	1	Tablet	21.22
6.	Vitamins/Minerals	3	Solution/Sachet	9.52-15.88
7.	Others	7	Tablet/solution/Capsule	0.9-127

3. Based on the decision taken in the 147th Authority Meeting, the ceiling prices of certain scheduled medicines were revised under the provisions of Paragraph 19 of the Drugs (Prices Control) Order (DPCO), 2013, in the public interest. The revised ceiling prices are as follows:

Sl. No.	Medicines	Dosage Form & Strength	Unit	Revised Ceiling Price
1	Carboplatin Injection	Injection 10 mg/ml	Per ml	90.74
2	Cisplatin Injection	Injection 1 mg/ml	Per ml	10.89
3	Anti-Tetanus Immunoglobulin	As licensed (250 IU)	Per vial	1,912.02
4	Anti-Tetanus Immunoglobulin	As licensed (500 IU)	Per vial	2,881.19

Key Amendments to the Drugs (Prices Control) Order, 2013

The amendments to the Drugs (Prices Control) Order, 2013 (DPCO, 2013), notified on 30 June 2026 (published on 1 July 2026), introduce significant changes on compliance requirements.

Expansion of Scope of Special Ceiling/Retail Price Fixation - The amendment expands the scope for fixation of special ceiling or retail prices. Earlier, this provision was limited mainly to injections, inhalations, or medicines with unspecified dosage forms or strengths under Schedule I. The revised provision now applies to any drug with a fixed ceiling or retail price, allowing manufacturers to seek special pricing from NPPA where incremental innovation warrants a separate price.

Simplification of Retail Price Approval Process - Another significant change relates to the approval process for existing manufacturers of scheduled formulations. Previously, every existing manufacturer launching a new drug was required to obtain prior approval of the retail price by filing Form I. Under the amendment, where a retail price for the same new drug has already been approved and notified, any other existing manufacturer launching the identical formulation within twelve months is no longer required to obtain fresh prior approval. Instead, such manufacturers are only required to intimate the NPPA of the launch within one month through Form IA. This amendment is intended to promote uniformity in the retail price of identical formulations during the twelve-month period following the initial notification, while also reducing the number of repetitive applications handled by the NPPA.

Record Retention Requirements - The amendment to Paragraph 29 prescribes a record retention period of seven financial years preceding the current financial year. Where proceedings are pending, records must be retained until their final disposal, providing clarity on manufacturers' record-keeping obligations.

IPDMS 2.0:

The Integrated Pharmaceutical Database Management System (IPDMS) is an integrated responsive cloud-based application. It is a system for online information collection, processing and communication portal to monitor and regulate the prices of medicines and medical devices, to ensure availability and affordability of drugs and medical devices in the country. The upgraded IPDMS 2.0 was launched on 29th August, 2022 and the charts given below capture the statistics from April 2025 to June 2026:

Chart1: Total number of registered companies at the end of June 2026

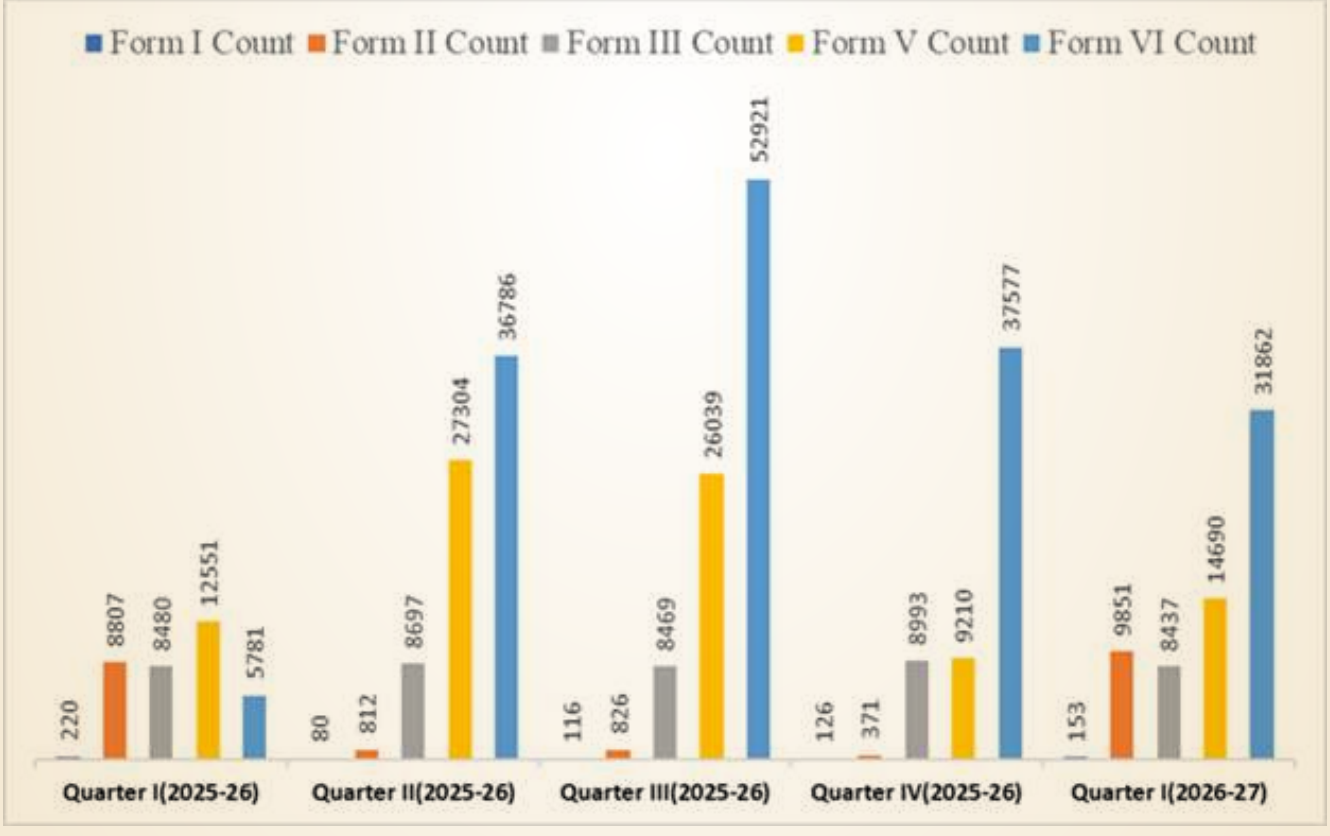

Chart 2: Forms (specified under Schedule II of DPCO, 2013) filed on IPDMS

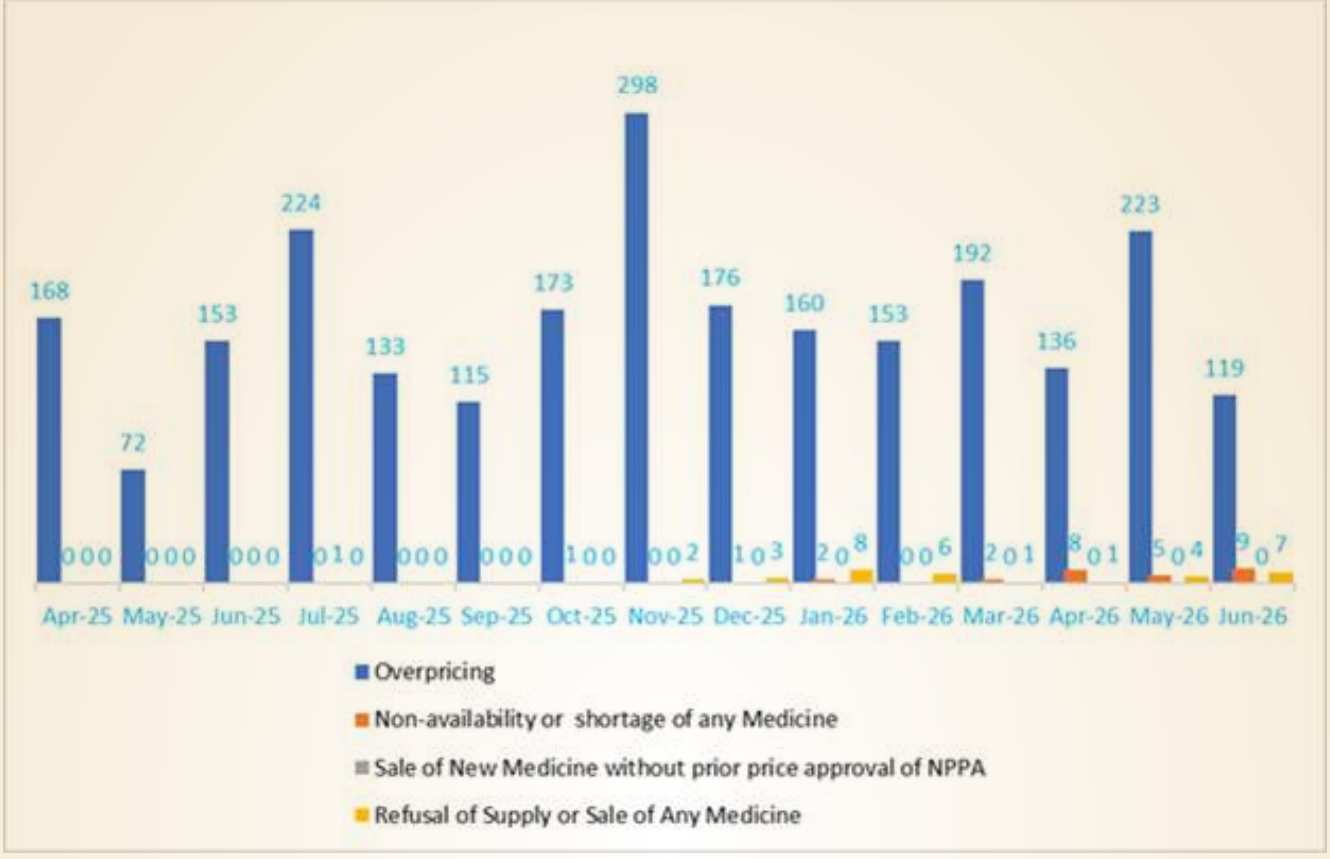

Chart 3: Number of complaints received on IPDMS / Pharma Jan Samadhan / Emails / CPGRAMS

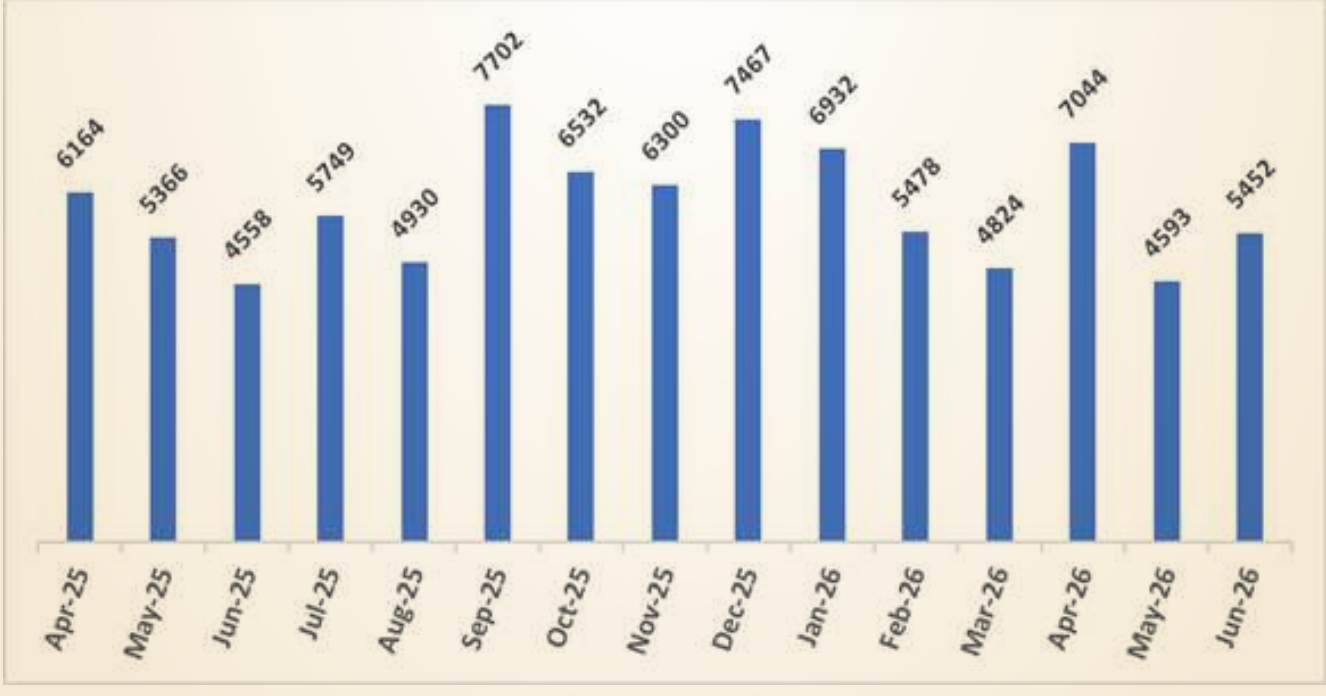

Chart 4: Number of User logins in IPDMS 2.0

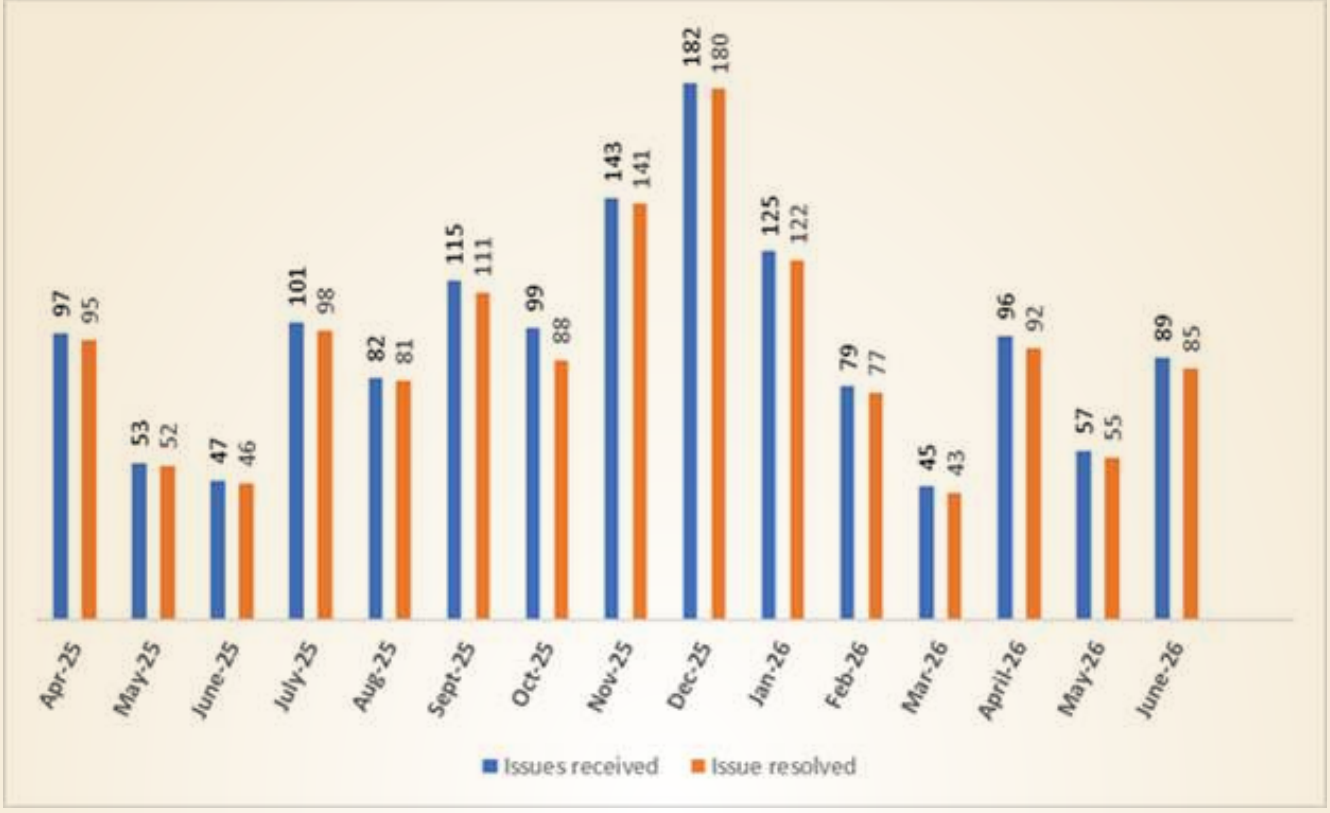

Chart 5: Issues received /resolved

INTERNATIONAL NEWS

FDA Permits Expanded Access for Investigational Pancreatic Cancer Drug (May 01, 2026)

The U.S. Food and Drug Administration has announced that it issuing a "safe to proceed" letter to Revolution Medicines, allowing the sponsor to initiate an expanded access treatment protocol (EAP) for its experimental pancreatic cancer drug, daraxonrasib. The expanded access treatment protocol is for patients with previously treated metastatic pancreatic ductal adenocarcinoma (PDAC). The FDA received the expanded access request from Revolution Medicines on April 28 and signed it on April 30.FDA regulations allow expanded access to investigational drugs for treatment purposes for larger populations under a treatment protocol or treatment investigational new drug application. Per EAP guidelines, requests for expanded access must be submitted to the sponsor by physicians licensed in the U.S. on behalf of eligible patients.

(Read more)

FDA Approves First Treatment for Chronic Hepatitis Delta Virus (HDV) Infection (May 22, 2026)

The U.S. Food and Drug Administration approved Hepcludex (bulevirtide-gmod) injection to treat chronic hepatitis delta virus (HDV) infection in adults without cirrhosis (advanced liver scarring) or with compensated cirrhosis. Bulevirtide is the first FDA-approved treatment for chronic HDV infection, a serious and life-threatening condition that can cause rapid development of liver fibrosis (scarring), liver cancer, liver failure, and even death.

(Read more)

FDA Approves New Indication for Tzield (teplizumab) for Certain Pediatric Patients with Recently Diagnosed Stage 3 Type 1 Diabetes (June 15, 2026)

The U.S. Food and Drug Administration granted accelerated approval to Tzield (teplizumab) for a new indication, to delay the decline of insulin production in pediatric patients ages 8 through 17 years who have been recently diagnosed with Stage 3 type 1 diabetes (T1D). This approval marks the first FDA-approved treatment for this indication and represents an important advancement for children living with type 1 diabetes and their families.

(Read more)

EMA, AMA and African regulatory authorities join forces on Ebola outbreak response (3 June 2026)

EMA's Emergency Task Force (ETF) has engaged with the African Medicines Agency (AMA) and its national regulatory authorities (NRAs), leveraging expertise from the WHO-AFRO African Vaccines Regulatory Forum (AVAREF), to discuss possible clinical trial designs and medical countermeasures to be investigated in the ongoing Ebola outbreak in the Democratic Republic of the Congo (DRC) and Uganda, caused by the Bundibugyo virus. This is the first public health emergency where EMA collaborates with the AMA since it has come into operation, alongside participating African NRAs. This engagement, grounded in the ongoing scientific collaboration between EMA and AMA, is intended to support efficient, coordinated and timely regulatory responses to the outbreak. It also builds on the extensive experience gained through African regulatory collaboration during previous Ebola outbreaks, including joint reviews conducted via AVAREF, as well as the ongoing operationalisation of the AMA.

(Read more)

PMRU IN ACTION: HIGHLIGHTS & FIELD ACTIVITIES

The Price Monitoring Resource Unit (PMRU) is an extended arm of NPPA and is registered as a society. While PMRUs have already been established in 29 States/UTs to strengthen grassroots-level pharmaceutical price monitoring and to create awareness about the initiatives of NPPA for ensuring affordability and availability, the setup of PMRU in the remaining 04 States/UTs is underway. The PMRUs function under the direct supervision of the concerned state drug controllers. During the month of October 2025, several PMRUs conducted State level IEC activities.

STATE LEVEL EVENTS/SEMINARS BY PMRUs

Fifty-Five (55) State and District level Events/Seminars have been organised by 14 (Fourteen) PMRUs in their respective States/UTs, viz. Jammu & Kashmir, Puducherry, Chhattisgarh, Jharkhand, Haryana, Punjab, Rajasthan, Kerala, Uttar Pradesh, Telangana, Assam, Uttarakhand, Himachal Pradesh and Tripura PMRU. These events were aimed at raising awareness among people about Fixation of Ceiling Prices under NLEM 2022 and its significance in Healthcare, Drug Price Regulations under the provisions of DPCO, 2013, Role of NPPA in making drugs affordable and available for all, Functions of PMRUs, Pharma Sahi Daam Mobile App and IPDMS 2.0. Major glimpses of the activities are as follows:

Glimpse of programs: -

1. Jammu & Kashmir PMRU:

2. Puducherry PMRU:

3. Chhattisgarh PMRU:

4. Jharkhand PMRU:

5. Haryana PMRU:

6. Punjab PMRU:

7. Rajasthan PMRU:

8. Kerala PMRU:

9. Uttar Pradesh PMRU:

10. Telangana PMRU:

11. Assam PMRU:

12. Uttarakhand PMRU:

13. Himachal Pradesh PMRU:

14. Tripura PMRU:

OTHER NEWS AND EVENTS

The Price Monitoring Resource Unit (PMRU) serves as an extended arm of NPPA and is registered as a society, functioning under the direct supervision of the concerned State Drug Controller. PMRUs have been established in 33 States/UTs with the objective of strengthening grassroots-level monitoring of pharmaceutical prices and creating awareness regarding NPPA's initiatives aimed at ensuring the affordability and availability of medicines. The establishment of PMRUs in the remaining 03 States/UTs is currently in process. A brief overview of the two PMRUs that conducted IEC activities is provided below.

1. **Jammu and Kashmir PMRU:** Jammu & Kashmir PMRU, established on 31st March, 2020 and categorised under Category-II, operates with five staff (01 Project Coordinator, 02 Field Investigators, and 02 Data Entry Operators/Office Assistants). The unit has been consistently engaged in Information, Education and Communication (IEC) activities and price monitoring activities. To date, the J&K PMRU has conducted a **total of 65 IEC activities** and has reported **1508 violation cases** on the IPDMS portal.

In continuation of its outreach initiatives, Jammu & Kashmir PMRU conducted an IEC activity through a Mass Awareness Campaign on NPPA's vision and the Pharma Sahi Daam Application.

2. **Tripura PMRU: -** The Tripura PMRU, registered on 25th June, 2019 and placed under Category-III, functions with a three-staff (01 Project Coordinator, 01 Field Investigator and 01 Data Entry Operator/Office Assistant). The unit continues to play a crucial role in pharmaceutical price monitoring, consumer awareness, and facilitating compliance with the NPPA's regulatory framework across the State. The Tripura PMRU has undertaken a **total of 76 IEC activities** and has reported **442 violation cases** on the IPDMS portal to date.

In its recent IEC initiatives, Tripura PMRU conducted a District Level Awareness Program. The programme focused on sensitizing participants about the availability of medicines at affordable prices and facilitating access to information on medicine prices through the Pharma Sahi Daam Application.

1. What is the role of NPPA in addressing drug shortages?

NPPA monitors the availability of scheduled formulations and takes appropriate measures to prevent shortages in accordance with the provisions of the DPCO, 2013. Upon receipt of complaints or information regarding shortages, NPPA examines the matter and coordinates with concerned manufacturers, marketers, State Drug Controllers, and other stakeholders to facilitate continued availability of medicines.

2. Is every instance of non-availability considered a drug shortage?

No. Temporary non-availability at a particular pharmacy or hospital does not necessarily indicate a nationwide shortage. Before concluding that a shortage exists, factors such as manufacturing status, stock availability, distribution patterns, and regional demand are assessed.

3. What are the common reasons for drug shortages?

Drug shortages may occur due to various reasons including:

i. Shortage of Active Pharmaceutical Ingredients (APIs) or key raw materials.
ii. Manufacturing or quality-related issues.
iii. Regulatory restrictions or plant shutdowns.
iv. Supply chain and transportation disruptions.
v. Sudden increase in demand.
vi. Commercial decisions by manufacturers.
vii. Natural disasters or public health emergencies.

4. Can a manufacturer discontinue the production of a scheduled formulation without informing the Government?

No. Under para 21 of DPCO, 2013, a manufacturer intending to discontinue production or import of a scheduled formulation is required to issue a public notice give prior notice to the Government as prescribed under para 21 of DPCO, 2013.Government may , in public interest, direct the concerned manufacturer to continue with required level of production or import for a period not exceeding one year, from the intended date of such discontinuation within a period of 60 days of receipt of such intimation.

5. Does NPPA regulate the availability of medicines that are not approved in India?

No. NPPA cannot ensure the availability of medicines that are not approved for manufacture, importer, for marketing in India.

6. How can patients report a shortage of an essential medicine?

Patients or healthcare providers may report shortages to NPPA through NPPA's grievance redressal mechanism, i.e. Pharma Shai Daam App/Portal by providing details such as:

i. Name of the medicine.
ii. Strength and dosage form.
iii. Manufacturer (if known).
iv. Place where the medicine was unavailable.
v. Supporting documents, if any.

Citizens may also report grievance related to shortages through CPGRAMS, email or postal communications. NPPA examines such complaints and takes up the matter with the concerned stakeholders where required.

7. Does a shortage of one brand mean that the medicine is unavailable in the country?

No. The non-availability of a particular brand does not necessarily indicate a shortage of the medicine itself. In many cases, the same formulation may be available from other manufacturers or marketers. NPPA assesses the availability of the formulation across manufacturers, regions and distribution channels before determining whether a shortage exists. Citizens may also refer to Pharma Sahi Dam App/ Portal of NPPA to identify some other brands of a given formulation/ strength/ dosage .

8. Can NPPA take action against artificial shortages?

Where evidence indicates deliberate withholding of supplies or non-compliance with the provisions of the DPCO, NPPA may initiate action in accordance with the applicable provisions of the DPCO, 2013, in coordination with the concerned authorities.

9. Does NPPA monitor the prices of medicines during shortages?

Yes. NPPA monitors compliance with the notified ceiling prices and retail prices of scheduled formulations. Manufacturers of scheduled formulations cannot increase prices beyond the limits permitted under the DPCO, 2013 merely because of a shortage.

10. Does NPPA coordinate with other agencies to address shortages?

Yes. Where necessary, NPPA coordinates with the Department of Pharmaceuticals, CDSCO, State Drug Controllers, manufacturers, marketers, and other stakeholders to assess the situation and facilitate the availability of essential medicines.

REFLECTIONS AND CONTRIBUTIONS

Staff Spotlight" is a dedicated corner of this newsletter that highlights the thoughts, experiences, and efforts of the staff of NPPA. This section brings attention to the diverse voices and talents across our organization.

This Month's Feature-
स्वरचित कविता पाठ

By Ms. Meenakshi Chaurasiya

"आज़ादी का अमृत महोत्सव"

आजादी का इतिहास कहां,
स्याही से लिख पाता है,
यह न जाने कितने दामन को,
गर्व से सूना कर जाता है..

था एक रण जो शहीद हुए है,
दिया जिन्होंने बलिदान सही
कहां कहां न फैलेगा मुल्क में,
जब है इसका अभिमान सही,

कहीं रक्त से लाल हुई है,
जेलों की चारदीवारे भी,
कहीं मिले ही पथ पर शोले,
कहीं कहीं दीवारें भी

रुका नहीं जब दमन चक्र तो,
आते गए सपूत इस भारत के
दिया एक अदम्य सबक जब,
चौतरफा अंग्रेज भी नदारद थे।

इस आजादी ने सही है कितनी,
यातनाएं उसका हिसाब नहीं,
ये देश है अगणित कुर्बानी का,
जिसका जहां में कोई जवाब नहीं

मत तौलो आजादी को किसी,
महज चंद उल्टे हालातों से
यह दे गई है सब खूबसूरती,
चिल्लाते से हवालातों से

उनका जो एक सपना था जो,
पूरा हमे करना होगा अब
सोने की चिड़िया था जो कभी,
इसे फिर वही करना होगा।

आओ हाथ बढ़ाएं हम हर,
अनसुलझे उलझे हालातों से
ले चले देश को फिर आसमा में
अपने दिमागी ख्वालतों से.

हम देश का परचम अब,
ऐसे ही लहराएंगे
आसमा की सितारे भी देखेंगे,
चांद सूरज भी मुस्काएंगे

Feedback and Complaint Redressal

Grievance Redressal

Pharma Jan Samadhan: A web enabled system for grievance redressal – catering to consumers, distributors, dealers, retailers.

Information Dissemination

- **Pharma Sahi Daam:** One can easily search brand name, composition, ceiling price and MRP of the formulation – available to public.
- **Seminars and Workshops** conducted by NPPA and by PMRUs

Collaboration with State Governments

- **PMRU:** To help NPPA to monitor notified prices and ensure availability of medicines.
- To spread awareness regarding the pricing of drugs, etc.

NPPA
AFFORDABLE MEDICINES FOR ALL
सभी के लिए वहनीय दवाईयाँ

NATIONAL PHARMACEUTICAL PRICING AUTHORITY

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