

AUSHADH SANDESH

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A Bi-monthly e-Newsletter

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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.

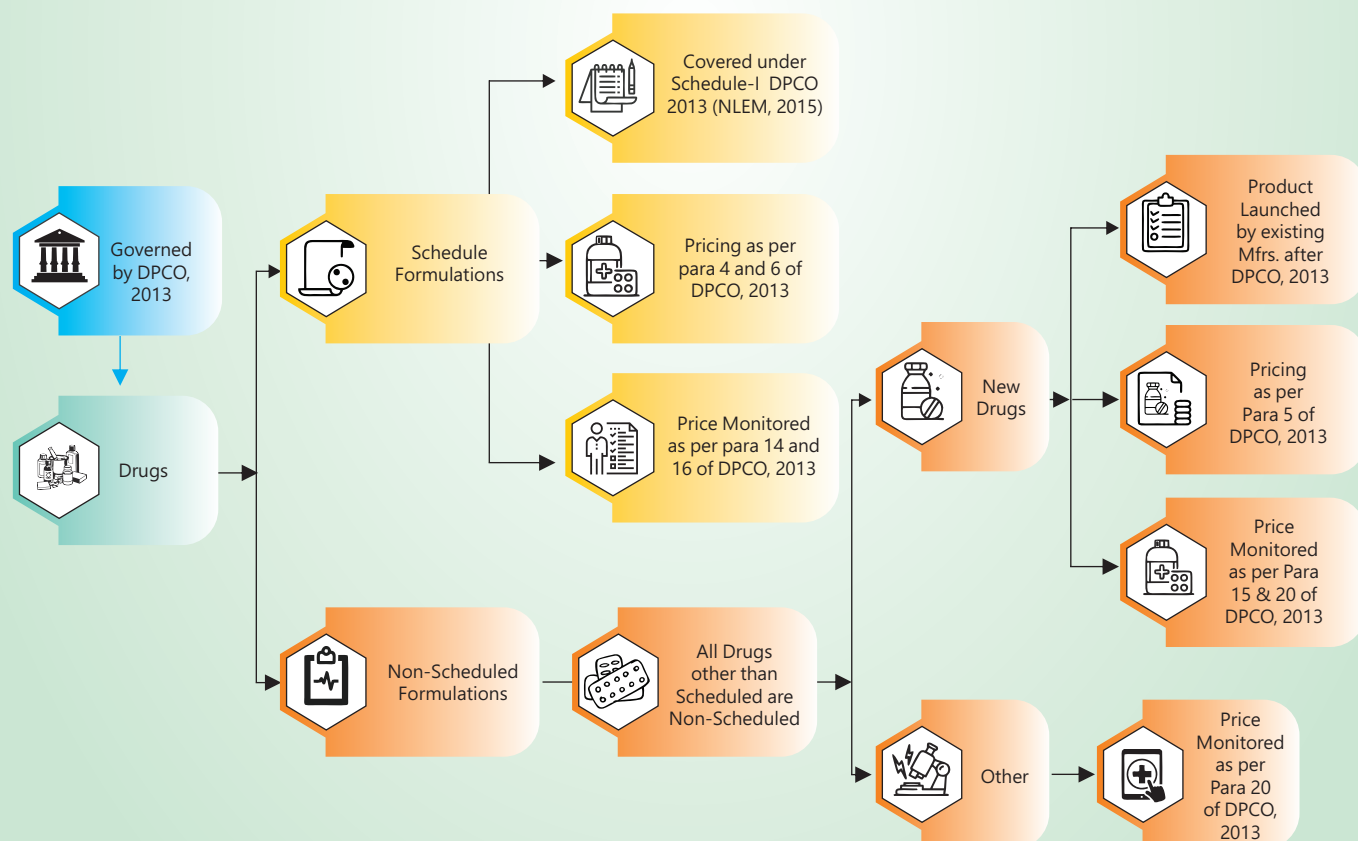
The Authority is a multi-member body consisting of a Chairperson, a Member Secretary and three ex-officio members. Two of the three ex-officio members are from Department of Economic Affairs and Department of Expenditure respectively and third member is Drug Controller General of India.

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:

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

CONTENTS

S.No.	Description	Page No.
1.	From Chairman's Desk	1
2.	Article by NPPA	2
3.	Article by Pharma Expert	6
4.	Regulatory News	11
5.	International News	15
6.	Other News & Events	17
7.	FAQs	21
8.	Staff Spotlight	23



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From CHAIRMAN, NPPA'S DESK



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

It is with immense pleasure I present to you the twenty fourth issue of the NPPA bi-monthly e-newsletter, the AUSHADH SANDESH. Our objective of bringing out the newsletter remains steadfast - to disseminate information that caters to the diverse interests of our stakeholders, thereby fostering informed decision-making and collaboration within the pharmaceutical and med-tech landscape.

This edition features a special article marking 28 years of NPPA's journey, highlighting the evolution of drug price regulation in India from cost-based to market-based pricing, and the expanding role of NPPA in ensuring affordability and availability of medicines and medical devices. The article also outlines key regulatory tools under DPCO, 2013 that empower NPPA to safeguard public interest.

This edition features an insightful article by Dr. Sarita Kumari on **"Cancer Control and Affordable Care: Where Do We Stand?"** a timely reflection on the rising burden of cancer in India and the critical challenges around access, affordability, and equity in care delivery. The piece highlights the deep rural-urban divide, data gaps, and the pressing need for affordable treatment, while also acknowledging NPPA's sustained efforts through price regulation, trade margin rationalization, and retail price controls. As we continue to strengthen policy frameworks, this article underlines the importance of coordinated action in building a more inclusive and responsive cancer care ecosystem.

In continuation of our PMRU activities, twenty-four (24) State and District level Events/ Seminars have been organized by 13 (Thirteen) PMRUs in their respective States/ UTs. 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 the Drugs affordable and available for all, Functions of PMRUs, Pharma Sahi Daam Mobile App and IPDMS 2.0. NPPA wishes good health to all its readers; stay safe, stay healthy.

With best wishes

(Shri P. Krishnamurthy)

28 YEARS OF ENSURING AFFORDABLE MEDICINES FOR ALL - NPPA

National Pharmaceutical Pricing Authority (NPPA) completed 28 years of service in August 2025. It was established on August 29, 1997 as the central authority responsible for ensuring accessible and affordable drugs to the Indian population through price-fixation, revision of prices of various drugs and updating the list of drugs under the price control. The Authority is entrusted with the duty to implement and enforce the provisions of the Drugs (Control Prices) Order (DPCO), 2013. In addition, NPPA is also authorized to control the price of medical devices in accordance with DPCO, 2013. As on date, NPPA has fixed ceiling prices of 933 scheduled formulations, resulting in an average reduction of 16.80% and annual savings of Rs. 3801 crore to the patients.



Brief History

The drug price regulation in the country finds its genesis from the Drugs (Display prices) Order, 1962 and the DPCO, 1963 issued under the Defense of India Act, 1915. The Drugs Price Control Order of 1966 and 1970 were issued under the Essential Commodities Act, 1955, by declaring drugs to be essential commodities. Prior to the setting up of NPPA in 1997, the implementation of DPCOs was primarily undertaken by an independent body of experts in the D/o Chemicals & Petrochemicals. With the setting up of D/o Pharmaceuticals (DoP) in 2008, NPPA is now an attached office.

Currently, the fixation, revision and monitoring of prices is governed by the DPCO, 2013, which was notified under the National Pharmaceutical Pricing Policy, 2012. A paradigm shift in pricing mechanism from the earlier DPCO 1995 to DPCO 2013 was the shift from cost-based to market-based pricing. Also, the drug pricing method transformed from bulk drug pricing to formulation-based pricing. With effect from 2020, all medical devices, viz., stents, knee implants, have also been brought within the category of drugs.

Role and Functions of NPPA

The functions of NPPA, inter-alia, include fixation and revision of prices of scheduled formulations and medical devices under the extant DPCO as well as monitoring and enforcement of their prices. NPPA also provides inputs to the Government on pharmaceutical policy and issues related to affordability, availability and accessibility of medicines and medical devices. Following are the major functions and achievements:

v. Regulating and monitoring the prices of Drugs and Medical devices under DPCO, 2013

- **Fixation of Ceiling Price (CP) (Para 4 & 6 of DPCO):** NPPA fixes the CP of scheduled formulations listed in Schedule-I[1] of DPCO, 2013.
 - o Under the market-based approach, NPPA has fixed the ceiling prices of 933 formulations (777 formulations under the National List of Essential Medicines (NLEM) [2] 2022 & 163 formulations under
 - o Fixation of Retail Price of drugs (Para 15 of DPCO): NPPA fixes the retail price of 'new drugs' as per DPCO, 2013 which are applicable only to the applicant manufacturing/ marketing companies.
 - o NPPA has fixed Retail prices of 3570 New Drugs
- **Price fixation in case of extraordinary circumstances (Para 19 of DPCO):** NPPA is empowered to control and regulate the prices of Drugs that are not under NLEM, under extraordinary circumstances in public interest. Some of the cases where NPPA has used para 19 to cap/regulate the prices of drugs are shown below:
- **Monitoring Availability of Scheduled Formulations (Para 21 of DPCO):** Availability of key medicines at the retail level is being monitored through regular surveys conducted by Price Monitoring Resource Units (PMRUs) in their respective States/ UTs at chemist shops at various locations across the country.
- **Monitoring & Enforcement Activities (Para 14, 15, 20, 24 & 25 of DPCO):** NPPA monitors the prices of scheduled as well as non-scheduled medicines (including new drugs without price approval) under DPCO, 2013 and takes action against companies found overcharging the consumers based on the references received from various sources including the State Drugs Controllers, individuals and complaints reported through grievance redressal websites, 'Pharma Jan Samadhan' and 'Centralized Public Grievance Redress and Monitoring System (CPGRAMS)'.

The resultant savings to citizens as a result of interventions by NPPA may be seen in the chart below.

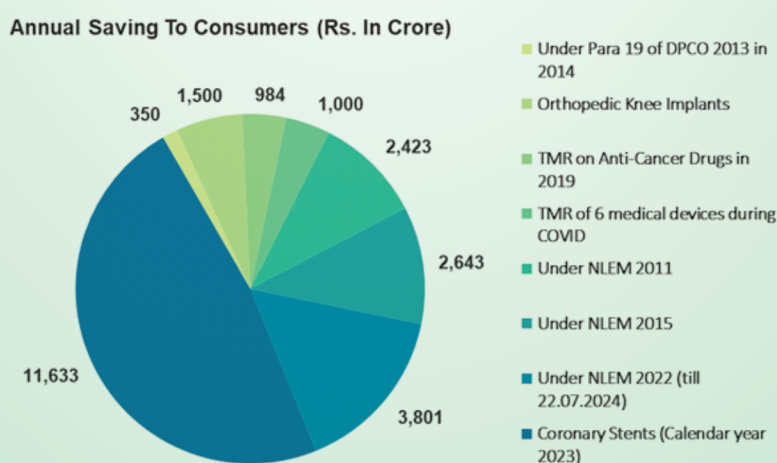


Chart 1: Annual savings to consumers achieved through various price regulation and intervention measures implemented by NPPA over the years.

v. Digital initiatives

Integrated Pharmaceutical Database Management System (IPDMS): It is an integrated online system launched in 2015 with an objective of creating an appropriate mechanism of obtaining market-based data related to drugs which would act as a reliable data base for carrying out various functions. It was upgraded, after extensive discussion with stakeholders to a more technologically responsive cloud-based version- IPDMS 2.0, which was launched on 29th August, 2022. It is a system for online information collection, processing and communication portal to monitor and regulate the prices of medicines and medical devices in the country. Till date, there are 1732 companies and 2,27,717 products registered on IPDMS.

What is Pharam Jan Samadhan (PJS)?

In 2015, the Government introduced PJS, a consumer grievances redressal system, administered by NPPA, to address complaints related to medicine prices, shortage and non-availability, in both online and offline mode. NPPA takes prompt action on the received complaints wherein the status of grievance is provided to the complainant.

Pharma Sahi Daam and Pharma Jan Samadhaan : The Pharma Sahi Daam App available on Android as well as iOS platform allows consumers to verify drug prices, compare brands, and access information in real time, thus

What is IPDMS 2.0?

NPPA operates a cloud-based system called IPDMS 2.0, which helps Pharma companies to submit Form I, II, III, IV, V & VI to the Government. It also assists NPPA in implementing its function and processing of complaints received from various sources regarding Drug prices.

promoting transparency and informed decision-making. It has features like searching of prices for medicines (brand-wise or formulation wise), search latest ceiling prices of scheduled drugs, etc. Citizens can check medicine prices, compare brands, see the composition of different medicines and lodge complaints against non-availability or higher price of medicines through Pharma Jan Samadhan/ Pharma Sahi Daam at (<http://www.nppaindia.nic.in/redressal.html>).

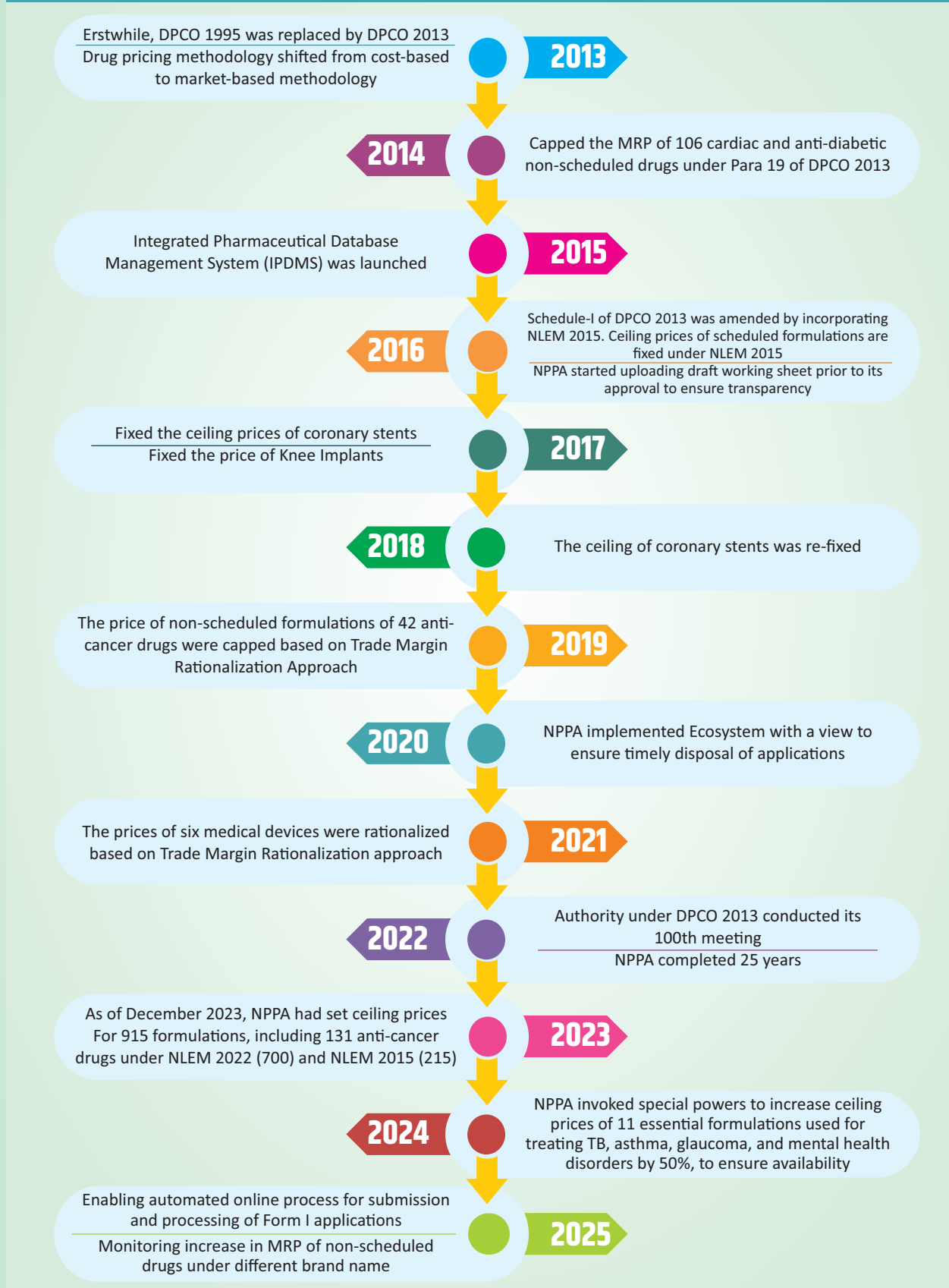
Consumer Awareness, Publicity and Price Monitoring (CAPP) Scheme

CAPP Scheme has two components, viz. (i) Assistance to set-up Price Monitoring and Resource Units (PMRUs), and (ii) Information, education & communication activities to create general awareness and disseminate information regarding the functioning of NPPA, availability of medicines, prices of medicines, etc. PMRUs are societies registered under the Societies Registration Act having its own Memorandum of Association/ Bye laws, in 32 States and they function under the direct supervision of the concerned State Drug Controllers for increasing the outreach of NPPA.

To sum up

Over the past 28 years, National Pharmaceutical Pricing Authority (NPPA) has played a pivotal role in making essential medicines and medical devices more affordable and accessible to millions of Indians. Through its dynamic policy interventions, robust price regulation, digital innovations, and consumer awareness efforts, NPPA has consistently worked towards balancing public interest with industry viability. As it continues to evolve in response to the changing healthcare landscape, NPPA remains a key pillar in ensuring equitable access to quality healthcare in India. The following image highlights the major milestones and key achievements of NPPA over its 28-year journey in ensuring affordable and accessible medicines for all.

MAJOR MILESTONES OF NPPA IN IMPLEMENTATION OF DPCO, 2013



CANCER CONTROL AND AFFORDABLE CARE: WHERE DO WE STAND?

[By Dr. Sarita Kumari, MD, DNB, MCh (Gynaecologic Oncology), AIIMS Delhi.]

(Fellow International College of Robotic Surgeons Editorial Fellow and Early Career Editorial Board Member
International Journal of Gynaecological Cancer)

1. Burden of Cancer and Rising Cancer Cases

Cancer is one of the rapidly growing non-communicable diseases in India. According to data from the National Cancer Registry Programme (NCRP), the incidence of cancer cases is projected to rise from 1.46 million in 2022 to 1.57 million in 2025. Among all cancer types, lung cancer in males and breast cancer in females remain the leading sites. In the childhood age group, lymphoid leukaemia is the most common, followed by brain and nervous system cancers in both sexes.

Globally, there is typically a two to four-year lag between the collection of cancer registry data and the publication of results. For timely planning, monitoring, and evaluation of cancer control efforts, access to recent statistics is essential. In India, this data is largely collected through Population-Based Cancer Registries (PBCRs), which rely on active and retrospective data abstraction. Trained registry staff typically collect data from multiple sources, including hospitals, diagnostic laboratories, and vital statistics departments, following a standardised format. This process is both time-intensive and resource-heavy, delaying real-time reporting and the availability of current cancer statistics.

A significant reason for this delay is that cancer is not a notifiable disease in India. Without mandatory reporting, the cancer surveillance system remains fragmented and inefficient. Hence, the burden is likely to be way more than what is registered/reported.

2. Disparities in Cancer Data Collection

India's current NCRP coverage stands at only 16.4%, with urban population coverage at 31.6% and rural at a mere 9.5% (Figure 2). Moreover, in most states, the rural component of Population-Based Cancer Registries (PBCRs) is either absent or underreported. This creates a serious gap in understanding cancer patterns across the country.

Major challenges of PBCRs in India are low coverage and urban dominance. Additionally, life expectancy in India has increased from 45 years at independence to over 65 years today, which is reflected in a growing elderly population—particularly in urban areas where access to healthcare is better. While cancer can occur at any age, incidence rises with advancing age.

About 50% of India's cancer burden lies in the 40–64 age group, which is younger than global trends where most cases occur in those aged 65 and above. This shift highlights the role of access to care and lifestyle-related risk accumulation in urban cities, where oncology treatment personnel—such as medical, radiation, and surgical oncologists—and diagnostic facilities are largely concentrated in metro cities.



Figure 1: Pie chart depicting the Urban versus Rural NCRP coverage (%)

The lower rural coverage—less than one-third of the urban rate—can be attributed to several factors, most notably low awareness, lack of follow-up systems, and cultural barriers. Despite this limited data capture, cancer mortality rates in rural areas are nearly twice as high, pointing to deeper systemic issues in access and outcomes.

3. The rural Cancer Care Crisis

Cancer care in rural India is trapped in a vicious cycle of poor infrastructure, low awareness, and limited access to trained specialists. Rural populations, already burdened by socioeconomic disadvantages and low formal education, often lack awareness of key risk factors for common cancers.

One of the most concerning trends observed by oncology teams is the mismanagement of curable cancers, where early-stage cases are handled by non-oncologists or treated without adherence to oncology principles, leading to irreversible progression. Conversely, terminal or advanced cancers which require only palliative care are subjected to aggressive or misdirected interventions, resulting in poor outcomes and unnecessary suffering.

These repeated experiences discourage other patients in the community from seeking help, worsening the cycle of late detection, delayed referrals, and fear-based avoidance. This situation is made worse by myths surrounding cancer treatments and the deep-rooted stigma that prevents open dialogue about cancer within families and communities.

It is also noted that in our male-dominated societies, fewer females are brought to the tertiary cancer care centres for treatment which can reflect in the higher male: female ratios in most hospital-based registries. The effectiveness of cervical, breast and oral cancer screening methods in cancer prevention and control is well-evident; however, the cancer screening uptake in India remains a cause of concern, e.g. for cervical cancer, it is a meagre 1%. Women, particularly from rural areas, face several cultural and social hurdles that are responsible for poor cancer screening compliance. These cases can be considered to be notifiable like communicable diseases in India.

Furthermore, in cities, the families face cultural shock with no place to stay and difficulties in commuting. Additionally, they also tend to face the loss of job and daily wages in the transition. This leads to an increased case of refusal, abandonment or noncompliance of treatment. Many go back once their limited finances are exhausted.

Yet, despite these hardships, many from rural areas are still compelled to seek treatment in urban cancer centres, where support systems and specialists are more accessible. But with cancer care becoming increasingly expensive, and the majority of healthcare in India being self-funded. Cancer care treatment remains unaffordable for many.

4. Affordability: The Other Cancer Crisis

Though the financial burden per cancer patient in India is one of the lowest reported globally (\$641 as compared to \$86,758 in the USA), even this remains out of reach for many patients in India, where the average income in some regions is less than \$75 per month. One of the most important challenges today is not just to find a cure for cancer, but to make cancer care affordable and accessible. Limited access to support systems, combined with the concentration of treatment resources in urban centres, further intensifies the financial burden on patients and their families. The cost of cancer care often pushes households into acute economic distress or even insolvency. According to the World Health Organization (WHO) estimates, out-of-pocket (OOP) expenditure on cancer-related hospitalization in India is nearly 2.5 times higher than the average cost of hospitalization for other conditions. Among all non-communicable diseases, cancer leads to the highest rate of catastrophic health expenditure.

In the absence of robust health financing mechanisms, patients are frequently forced to rely on distress financing. Nearly 60% of households take loans, and 32% depend on contributions from friends and relatives to meet cancer treatment expenses. It is estimated that more than half of India's cancer patients seek treatment in the private sector, where OOP expenses account for approximately 65% of total health expenditure. These high costs not only delay treatment initiation and cause dropouts but also lead to worsened clinical outcomes.

Improving the availability and affordability of cancer drugs is critical. Timely access to essential medicines, especially during early and potentially curable stages, can greatly improve survival rates. In this context, price regulation of common anti-cancer drugs becomes a vital step toward ensuring affordability and enabling timely treatment.

5. Measures taken by the Government to make Cancer Treatment affordable and accessible

5.1 Cancer Drug Pricing Regulation by the National Pharmaceutical Pricing Authority

With affordability becoming a key barrier in cancer care, currently, the prices of drugs are regulated through the Drug (Prices Control) Order, 2013 (DPCO). National Pharmaceutical Pricing Authority (NPPA) fixes/revises the ceiling price of the scheduled medicines specified in the first schedule of the Drugs (Price Control) Order, 2013. Among these are anti-cancer medicines, which are included under Schedule I, Section 7: "Anti-cancer agents including immunosuppressives and medicines used in palliative care", encompassing 63 drugs across 132 formulations.

a. Ceiling Price Control on 131 Anti-Cancer Drugs : NPPA, under the provisions of DPCO, 2013 has notified ceiling prices for 131 scheduled anti-cancer formulations. All manufacturers are required to price their products within this ceiling price (plus applicable GST). Price revisions based on the National List of Essential medicines (NLEM), 2022 have led to an average 21.06% reduction in ceiling prices compared to NLEM 2015, generating estimated annual savings of ₹294 crore.

b. Retail Price Fixation for New Anti-Cancer Drugs : NPPA vide order S.O. 1041 (E) dated 27th February 2019 put a cap of 30% Trade Margin on 42 selected non-scheduled anti-cancer medicines under 'Trade Margin Rationalization' approach. The Maximum Retail Price (MRP) of 526 brands of these medicines was reduced up to 90% thereby resulting in annual savings of around Rs. 984 crore to the patients. It made a significant difference in MRP and patient bills for high-value injectable and oral drugs used in long treatment cycles.

Further, NPPA continues to monitor retail prices for new anti-cancer formulations, particularly those not yet classified under scheduled drugs.

c. Ensuring Uniformity and Compliance : To support fair pricing and transparency, NPPA has enforced strict compliance protocols as per the provisions of DPCO, 2013 (Figure 3):

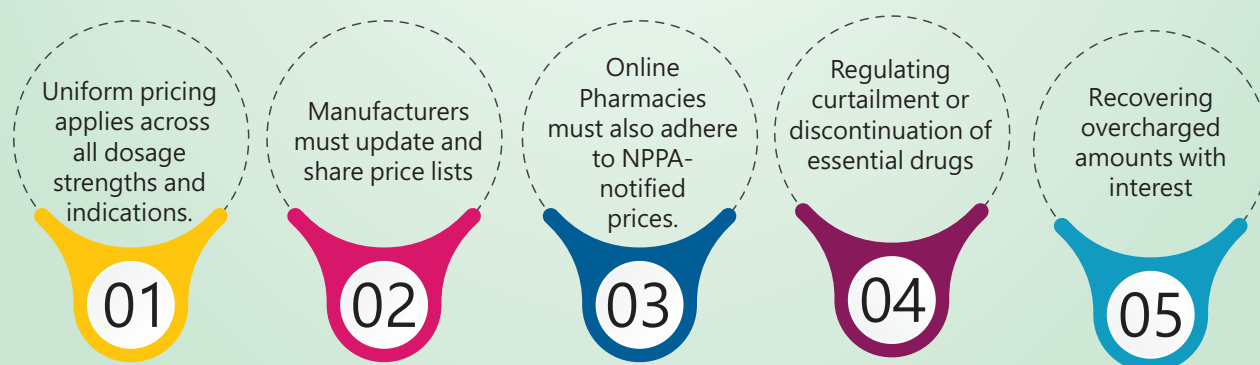


Figure 3: NPPA's Protocols for Compliance and transparency

5.2. Other key initiatives of the Government of India

To promote domestic manufacturing of drugs, the Department of Pharmaceuticals is implementing the Production Linked Incentive (PLI) Scheme for Pharmaceuticals with a total financial outlay of ₹15,000 crore, with scheme tenure till the financial year 2027-28. 54 anti-cancer drugs are being manufactured under this scheme.

Under Ayushman Bharat Pradhan Mantri Jan Arogya Yojana (AB-PMJAY), health assurance/insurance cover of ₹5 lakh per family per year for secondary or tertiary care hospitalisation to about 60 crore beneficiaries is being provided. The treatment packages under AB-PMJAY are comprehensive and cover various treatment-related aspects, including drugs and diagnostic services. Further, under Pradhan Mantri Bhartiya Janaushadhi Pariyojana, quality medicines are offered through Jan Aushadhi Kendras at rates that are typically 50% to 80% lower than the prices of branded medicines available in the market. Moreover, financial assistance is provided to poor patients belonging to families living below poverty line, who suffer from major life-threatening diseases including cancer, under the umbrella scheme of Rashtriya Arogya Nidhi (RAN) and the Health Minister's Discretionary Grant (HMDG). Financial assistance of up to ₹15 lakh is provided under the Health Minister's Cancer Patient Fund under the umbrella scheme of RAN, and assistance of up to ₹1.25 lakh is provided under HMDG to defray part of the treatment cost.

5.3. GST and Customs Relief on Life-Saving Therapies

The Government of India has also introduced tax interventions to ease the cost burden of cancer treatment:

- **GST exemptions** on select essential cancer drugs.
- **Customs duty reductions** for imported life-saving biologics and advanced therapies.
- **Targeted exemptions** for high-cost treatments such as **CAR-T cell therapy**, where prices may cross 1 crore per cycle without tax relief.

These steps are particularly important for patients seeking access to advanced, targeted treatments for rare or resistant cancers.

6. Conclusion:

Cancer in India is a growing challenge. Cancer registries cover only a small part of the population, and reporting is not mandatory. The high cost of treatment further adds to the problem. Rural areas often lack the basic facilities needed for early detection and treatment. This creates a clear gap between cities, where care is available, and villages, where people are left with very few options.

The need of the hour is stronger



cancer monitoring systems, better rural healthcare, and more awareness so that people can get checked at an early stage.

Making cancer a notifiable disease and ensuring affordable treatment for all could go a long way in closing the gap in care. The Government has taken several steps, such as caps on prices of drugs, insurance schemes, and tax breaks on essential therapies, to address the challenge. Several international cancer awareness days are observed globally to highlight the importance of prevention, early detection, and treatment. World Cancer Day, marked on February 4th, is the most prominent, uniting people and organizations to raise awareness and push for action. Cancer Awareness months like the Breast Cancer Awareness Month in October; Lung, stomach and pancreatic cancer awareness month in November, Childhood Cancer Day on February 15th, not only spread awareness but also inspire policy changes and support for those affected by cancer across the world.

Thus, a multi-dimensional approach by all stakeholders is the way forward in addressing the challenge of the rising burden of cancer. Focus on awareness, social support, affordable and accessible healthcare, particularly in rural areas, needs to be centrestage.

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 Inputs for NPPA Bi-Monthly E-Newsletter

1. Ceiling prices of 933 formulations are effective as on 02.09.2025 of which Ceiling prices for 770 scheduled formulations have been fixed / refixed under National List of Essential Medicines, 2022. There has been average reduction of 16.80% on account of refixation under NLEM, 2022 leading to annual savings of Rs. 3801.06 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	113	222	945.64
Unique Drugs / Formulations	328*	770	3801.06

*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. As on 02.09.2025, 268 Authority meetings have been conducted of which 136 meetings have been conducted under DPCO 2013. The details of the recent meetings are given as below:

Meeting No	Held on	Prices Approved & Notified
Meeting No. 268th (overall) & 136th meeting under DPCO 2013	28.08.2025	Retail prices for 42 formulations notified vide S.O 3974(E) Dated 29.08.2025 Separate ceiling price for 2 formulations viz. Meropenem 500mg and 1000mg powder for injection in Dual Chamber bags by M/s Gufic Biosciences Limited notified vide S.O. 3979(E) dated 28.08.2025.
Meeting No. 267th (overall) & 135th meeting under DPCO 2013	30.07.2025	Retail prices for 37 formulations notified vide S.O 3563(E) Dated 01.08.2025. Ceiling Price for 4 scheduled formulations notified vide 3562(E) Dated .01.08.2025

REGULATORY NEWS

3. Retail prices for 3561 (approx.) new drugs have been fixed under DPCO, 2013 till 02.08.2025. Details of 79 retail prices notified for various formulations based on the decision taken in 135th and 136th meetings are as follow:

S. No.	Therapeutic group	Total Number	Type of Formulation	Retail Price fixed Range (Rs.) (Excl. GST) per tablet/per ml/ per vial/ per gm
(1)	(2)	(3)	(4)	(5)
1.	Anti Diabetic	29	Tablet	11.02-35.29
2.	Analgesic, anti-inflammatory and Arthritis	7	Tablet/ Capsule/Infusion	3.41-15.01
3.	Cardiovascular	16	Tablet/Capsule/Oral drop	5.88-25.61
4.	Vitamins/Minerals/ Nutrients	2	Tablet/Oral solution	12.09-15.17
5.	Anti-Infective	19	Tablet/Injection/ Ointment/ Suspension	0.41-1938.59
6.	Anti -Hypertensive	2	Tablet	16-20.15
7.	Others	4	Tablet	5.15-131.58

IPDMS 2.0:

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 2024 to August 2025:

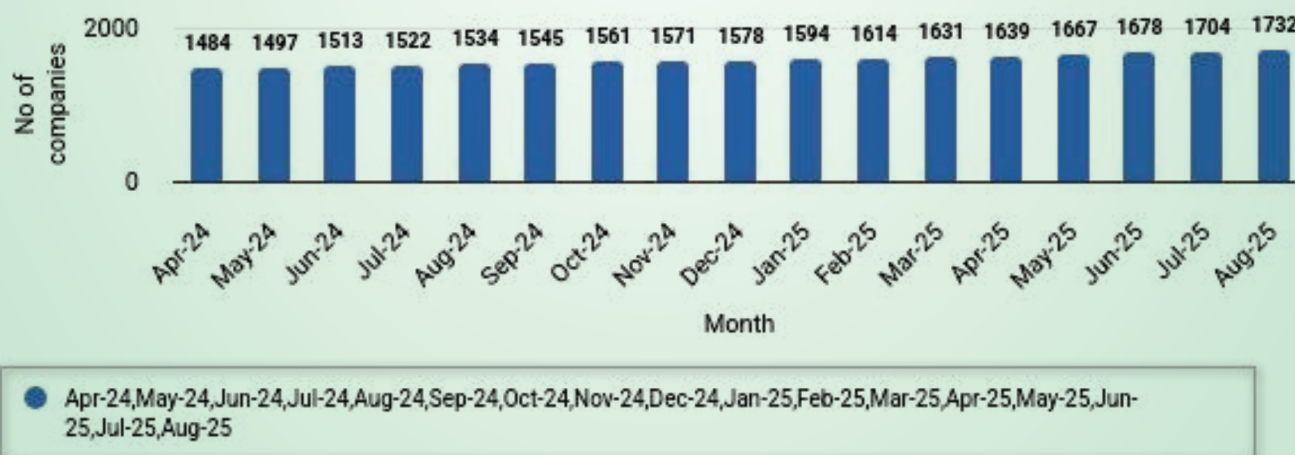


Chart1: Total number of registered companies at the end of August 2025

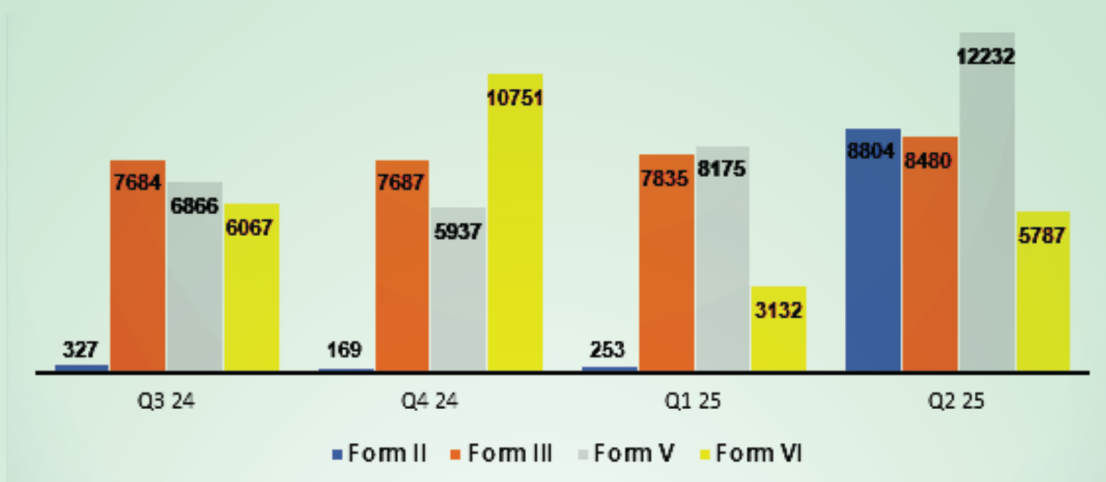


Chart 2: Statutory forms filed on IPDMS



Chart 3: Total number of Form I filed on IPDMS

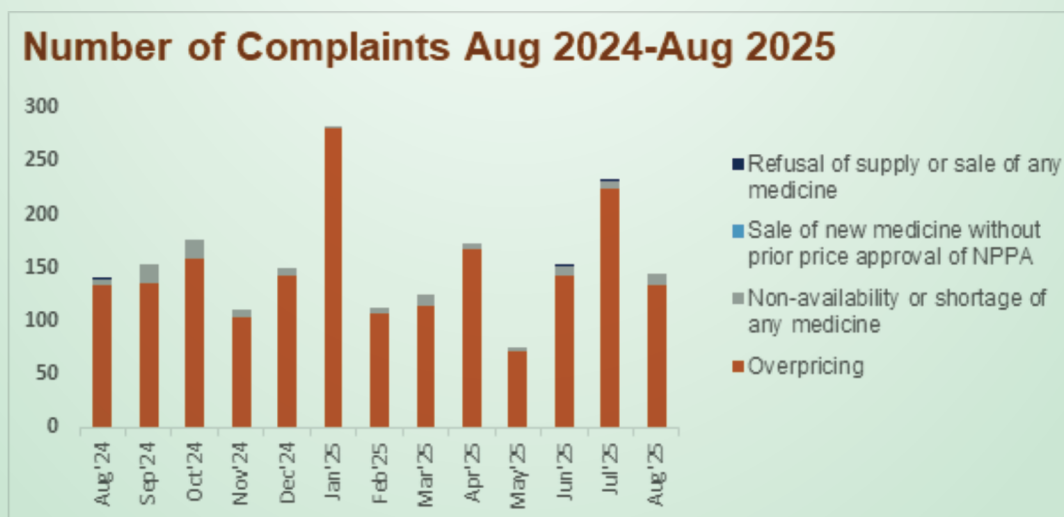


Chart 4: Number of complaints received on IPDMS/ Pharma Jan Samadhan

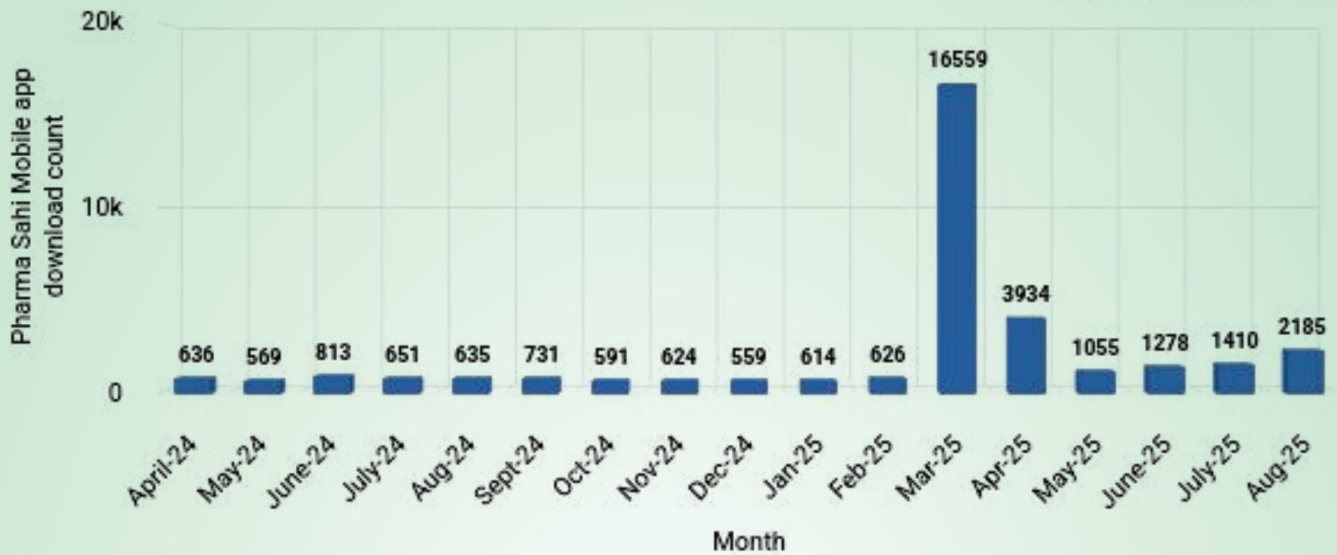


Chart 5: Number of Pharma Sahi Daam Mobile app downloads



Chart 6: Number of User logins in IPDMS 2.0

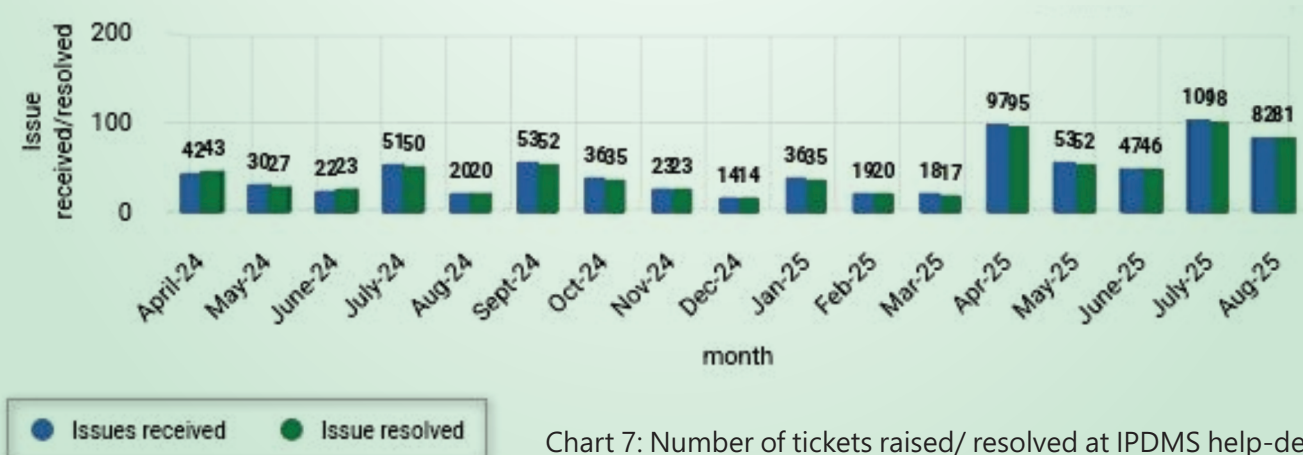


Chart 7: Number of tickets raised/ resolved at IPDMS help-desk

FDA Begins Real-Time Reporting of Adverse Event Data (August 22, 2025)



The U.S. Food and Drug Administration began daily publication of adverse event data from the FDA Adverse Event Reporting System (FAERS). This represents a significant step forward in modernizing the agency's safety monitoring infrastructure and demonstrates its commitment to radical transparency and real-time protection of public health. FAERS is the FDA's primary database for collecting and analyzing adverse event reports, serious medication errors, and product quality complaints for prescription drugs and therapeutic biologics, containing reports submitted by healthcare professionals, consumers, and manufacturers.

[\(Read More\)](#)

FDA Approves First Immunotherapy for Recurrent Respiratory Papillomatosis (August 14, 2025)



The U.S. Food and Drug Administration approved Papzimeos (zopapogene imadenovec-drba), a first-of-its-kind non-replicating adenoviral vector-based immunotherapy for the treatment of adult patients with recurrent respiratory papillomatosis (RRP). RRP is a rare, chronic disease caused by persistent human papillomavirus (HPV) 6 or 11 infection, leading to the growth of benign tumors in the respiratory tract, most commonly the larynx. The disease is associated with significant morbidity, including voice changes, breathing difficulties, and airway obstruction. There are currently no approved medical therapies that eliminate the need for repeated surgical procedures. With an estimated 1,000 new cases diagnosed annually in the U.S., RRP represents a rare disease with significant unmet medical need. Until today, no therapies have been approved for RRP. Papzimeos is administered via subcutaneous injection and is designed to stimulate an immune response against cells infected with HPV types 6 and 11—the causative agents in RRP. The therapy offers a novel mechanism of action distinct from traditional treatments, which have relied primarily on repeated surgical interventions.

[\(Read More\)](#)

FDA Requires Major Changes to Opioid Pain Medication Labeling to Emphasize Risks (July 31, 2025)



INTERNATIONAL NEWS

The U.S. Food and Drug Administration is requiring safety labeling changes to all opioid pain medications to better emphasize and explain the risks associated with their long-term use. These changes follow a public advisory committee meeting in May that reviewed data showing serious risks—such as misuse, addiction, and both fatal and non-fatal overdoses—for patients who use opioids over long periods. Tragically, the new drug application for OxyContin was initially approved without study data supporting its long-term use to treat pain in many patient populations for which it has been prescribed. The updated labeling change reflects robust data from two large FDA-required observational studies, called postmarketing requirements (PMR) 3033-1 and 3033-2, which recently provided new data on how long-term opioid use can lead to serious side effects. After reviewing those results, public comments, medical research and recognizing the absence of adequate and well-controlled studies on long-term opioid effectiveness, the FDA decided to require safety labeling changes to help health care professionals and patients make treatment decisions rooted in the latest evidence.

[\(Read More\)](#)

FDA Takes Steps to Restrict 7-OH Opioid Products Threatening American Consumers (July 29, 2025)

Food and Drug Administration y is taking a bold step to protect Americans from dangerous, illegal opioids by recommending a scheduling action to control certain 7-hydroxymitragynine (also known as 7-OH) products under the Controlled Substances Act (CSA). The FDA is specifically targeting 7-OH, a concentrated byproduct of the kratom plant; it is not focused on natural kratom leaf products. 7-OH is increasingly recognized as having potential for abuse because of its ability to bind to opioid receptors. The FDA is releasing a new report to educate the public about the health concerns of 7-OH and its distinction from the kratom plant leaf. This recommendation follows a thorough medical and scientific analysis by the FDA and is one of several efforts to address the agency's concerns around the growing availability and use of 7-OH opioid products. There are no FDA-approved 7-OH drugs, 7-OH is not lawful in dietary supplements and 7-OH cannot be lawfully added to conventional foods.

[\(Read more\)](#)



CANCER-RELATED AWARENESS EVENTS IN INDIA

In July and August, the key cancer-related awareness events in India are Sarcoma Awareness Month in July and World Lung Cancer Day on August 1st, along with the World Head and Neck Cancer Day on July 27th. The Sarcoma Awareness Month emphasizes raising awareness for sarcoma (bone cancer), while World Lung Cancer Day focuses on the risks, prevention, and early detection of lung cancer. World Head and Neck Cancer Day promote screening and early diagnosis of cancers in the head and neck region.

The National Pharmaceutical Pricing Authority (NPPA) has implemented several measures to make cancer drugs more affordable and accessible in India. It has fixed ceiling prices for 131 scheduled anti-cancer formulations under the National List of Essential Medicines (NLEM), resulting in a 21% price reduction and annual savings of ₹294.34 crore for patients. Retail prices for 28 anti-cancer formulations have also been fixed under DPCO, 2013, and trade margins on 42 non-scheduled anti-cancer medicines have been capped at 30%, reducing MRPs by around 50% and saving ₹984 crore annually. Additionally, customs duty and GST rates were reduced on select cancer drugs, and price reduction directions were issued to companies. The government supports domestic manufacturing through the ₹15,000 crore Production Linked Incentive (PLI) Scheme, with 54 anti-cancer drugs produced under it. Schemes like Ayushman Bharat, Jan Aushadhi, AMRIT, Rashtriya Arogya Nidhi, and the Health Minister's Discretionary Grant provide financial support and low-cost medicines to patients, significantly enhancing affordability and access to cancer treatment across the country.

8/20/25, 11:35 AM Press Release: Press Information Bureau
<https://www.pib.gov.in/PressReleaseDetail.aspx?PRID=21542172/3>

Celebrating NPPA 28th Foundation Day: Upholding Affordable and Equitable Access to Medicines

The National Pharmaceutical Pricing Authority (NPPA), established on 29th August 1997, celebrates its Foundation Day each year to reflect on its journey, achievements, and future goals in ensuring affordable access to medicines across India. As the key regulatory body under the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, NPPA plays a pivotal role in maintaining price stability in the pharmaceutical sector while balancing the interests of industry and public health.



OTHER NEWS AND EVENTS

STATE LEVEL EVENTS/SEMINARS BY PMRUs

Twenty-four (24) State and District level Events/ Seminars have been organized by 13 (Thirteen) PMRUs in their respective States/ UTs, viz. Puducherry, Ladakh, Jammu & Kashmir, Haryana, Uttarakhand, Meghalaya, Madhya Pradesh, Goa, Mizoram, Chhattisgarh, Jharkhand, Assam, 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 the 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: -



OTHER NEWS AND EVENTS



OTHER NEWS AND EVENTS





FREQUENTLY ASKED QUESTIONS

1. Why is cancer a major public health concern in India?

Cancer is one of the leading causes of death globally and in India. As of 2023, over 14 lakh new cancer cases were estimated in India. Rising incidence, late detection, and treatment costs make it a critical healthcare challenge.

2. What is the Government of India doing to prevent and control cancer?

The government has implemented a multi-pronged approach including:

- National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS) for early screening and awareness.
- Establishment of cancer centers at district and tertiary levels.
- Financial assistance for treatment through schemes like Ayushman Bharat and HMCPF.
- NPPA making Anti-Cancer drugs affordable and available by regulating the MRP and trade margins in cancer drugs
- Investment in research and innovation, such as CAR-T cell therapy.

3. What initiatives were announced in the Union Budget 2025-26 for cancer care?

Key highlights include:

- Setting up of 200 Day Care Cancer Centres in 2025–26.
- Customs duty exemptions on 36 lifesaving drugs and medicines for cancer and rare diseases.



4. How does Ayushman Bharat support cancer patients?

Under Ayushman Bharat – PMJAY, eligible families receive free cancer treatment, including:

- Chemotherapy
- Radiotherapy
- Surgical oncology

Over 90% of registered cancer patients have commenced treatment under this scheme, ensuring financial protection.

5. What is the Health Minister's Cancer Patient Fund (HMCPF)?

HMCPF is a component of the larger Rashtriya Arogya Nidhi (RAN) scheme, established in 2009 to provide financial assistance to poor cancer patients living below the poverty line or those belonging to States/UTs whose NFSA data is integrated with the NHA's IT platform. Eligible patients can receive one-time financial assistance of up to ₹15 lakh for their treatment at Regional Cancer Centres (RCCs), Tertiary Care Cancer Centres (TCCCs), State Cancer Institutes (SCIs), and other government hospitals with cancer facilities. Financial aid is released to the treating hospital/institute, not directly to the patient.

6. What is the National Cancer Grid (NCG)?

The National Cancer Grid (NCG) has been created to form a union of cancer centres in India which could provide uniform and high standards of cancer care, follow uniform evidence-based guidelines for management of patients, develop human resource adequately trained to fulfill the cancer healthcare needs of the entire nation, and conduct collaborative clinical research of a high standard. The union would help to ensure provision of same quality of care to patients from any part of the country.

The NCG network has 287 member institutions, providing standardized, high-quality, affordable cancer treatment across India.

8. Are there any customs duty exemptions for cancer drugs?

Yes, the Government of India has exempted 36 lifesaving drugs used in cancer, rare, and chronic diseases from Basic Customs Duty. Additionally, some drugs under Patient Assistance Programs are also fully exempted.

9. What are the challenges ahead in cancer control in India?

Despite progress, challenges remain in:

- Equitable access to care in remote regions.
- Early detection and screening coverage.
- Rising cancer burden due to lifestyle factors and aging population.

Source: <https://www.pib.gov.in/PressReleasePage.aspx?PRID=2102729>

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



पल्लव कुमार चित्तेज, उप निदेशक
द्वारा लिखित

राष्ट्रीय औषध मूल्य निर्धारण प्राधिकरण उर्फ "एनपीपीए" का सफल 28वाँ साल

सफलता का उत्सव — 28वाँ साल,
जनहित में गूँज उठा एनपीपीए का कमाल।
फार्मा सही दाम — जन-जन की पहचान,
सेहत की रक्षा "दवा वही, दाम सही" — यही है अरमान।

तीन सिद्धांतों पर टिकती है एनपीपीए की डोर,
जनहित की खातिर रखती है बहुत कड़ा जोर।
डीपीसीओ के तहत, तय करती दवाओं के दाम,
हर मरीज तक पहुँचे दवा — यही इसका काम।

मूल्य निर्धारण, निगरानी, प्रवर्तन — ये ज़िम्मेदारी निभाती है,
हर जरूरतमंद को दवा सुलभ करवाती है।
दामों पर रखती है पैनी सी नजर,
जनता को मिले राहत — यही इसका सफर।

आवश्यक दवाओं की हर कमी को करती एनपीपीय दूर,
हर कदम पर करती है संतुलन का सूर।
बिना रुके, बिना थके निभाती है कर्म,
जन-स्वास्थ्य सेवा है इसका परम धर्म।

डिजिटल प्लेटफॉर्म से फैली जागरूकता,
हर नागरिक में जागी नई प्रबुद्धता।
फार्मा जन समाधान का उज्ज्वल प्रयास,
जनता का भरोसा — सरकार का विश्वास।

रक्षा करती है कीमतों की, दवाओं की सस्ती राह,
एनपीपीए की कोशिश है, हर रोग का उपचार।
हर घर तक दवाओं की पहुँच हो सरल,
मूल्य नियंत्रण से सबका जीवन बने सफल।

सस्ता, सुलभ हर दवा है मानव का अधिकार,
एनपीपीए करवाती है यह सपना साकार।
22 सितंबर से जीएसटी में कटौती — राहत का उपाय,
हर घर तक पहुँचा — आशा का सन्देश नया नया निकाय।

दवाओं के दाम अब और हुए सुलभ-सस्ते,
जनता के चेहरे खिले हुए हँसते।
स्वास्थ्य और जीवन के लिए, जो करती काम,
एनपीपीए की भूमिका, सदा बनी रहे सम्मान।

आओ हमसब मिलकर करें यह संकल्प महान,
विकसित भारत बने — सबका स्वप्न हो समान।
एनपीपीए की सेवा "सबके लिए वहनीय दवाईयाँ" - रहे सदा अमर,
जन-स्वास्थ्य की ज्योति - चमके हमेशा प्रखर।

जय हिन्द, जय भारत !!

पल्लव कुमार चित्तेज
उप निदेशक





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.



NATIONAL PHARMACEUTICAL PRICING AUTHORITY

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www.nppa.gov.in | Helpline No.: 1800 111 255 (10 am to 6 pm on working days)

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