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

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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.

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: **monitoring-nppa@gov.in**

From CHAIRMAN'S DESK

सत्यमेव जयते

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 third 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 year marks the tenth anniversary of the launch of the Integrated Pharmaceutical Database Management System (IPDMS) by NPPA. The IPDMS has been central to NPPA's mission of ensuring transparency, accountability, and efficiency in drug price regulation. Over the past decade, it has grown from a regulatory form filing platform into a robust digital infrastructure supporting price monitoring, inter-agency coordination, and citizen-centric services. The article, "IPDMS: A Ten-Year Journey Towards Enhancing Transparency and Compliance in Pharma Pricing," captures this evolution and underscores the increasing importance of digital tools in regulatory governance.

I am also pleased to share a thought-provoking article by Dr. Rohit Kumar, MD, DM, that brings to light the critical challenges and opportunities in asthma care, particularly in the Indian context . While the article commends the efforts of the NPPA for regulating inhaler prices in India, making them more affordable compared to global standards, it rightly points the various significant barrier to inhaler accessibility and the urgent need to address the existing gaps . This article is not only informative but also a timely reminder for all healthcare professionals and policymakers to work collaboratively in breaking down these barriers.

In continuation of our PMRU activities, Twenty Six (26) State and district-level events/Seminars have been organized by 28 (Twenty-eight) 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)

ASTHMA – MAKING INHALED THERAPY ACCESSIBLE TO ALL!

(By Dr. Rohit Kumar MD, DM)

Dr. Rohit Kumar is Associate Professor and Head, Department of Pulmonary & Critical Care Medicine at Vardhaman Mahavir Medical College and Safdurjung Hospital, New Delh and has received the Fellowship of Innovative Physicians Forum in New Delhi

What is asthma?

According to GINA (Global Initiative for Asthma), asthma is a heterogeneous disease, usually characterized by chronic airway inflammation. It is defined by the history of respiratory symptoms, such as wheeze, shortness of breath, chest tightness and cough, that vary over time and in intensity, together with variable expiratory airflow limitation.

In simple terms, it is a long-term condition that affects the lung airways (the tubes that carry air in and out of lungs). In asthma, the airways can become inflamed and narrowed at times. This makes it harder for air to flow out of your airways when you breathe out.

Prevalence – Global and India

In my MBBS lectures, I often begin by asking how many students have asthma or have a close relative or neighbour affected by the condition. Over the years, an increasing majority of students have responded with confirmation, emphasizing the prevalence of asthma in our community.

Globally, an estimated 300 million people suffer from asthma, and its prevalence continues to rise, particularly in developing nations and among children. The condition affects between 1% and 29% of the population across different countries. The Global Asthma Network (GAN) Phase I study reported an overall prevalence of current asthma symptoms at 9.1% in children, 11.0% in adolescents, and 6.6% in adults. While asthma rates are generally higher in developed nations, there has been a noticeable increase in cases in urbanizing developing regions, likely due to lifestyle and environmental changes.

The impact of asthma is particularly alarming when considering mortality rates. The Global Burden of Disease (GBD) collaboration estimated that in 2019, asthma caused 461,000 deaths worldwide—over 1,000 per day. This is especially concerning given that many of these deaths are preventable with proper management and timely intervention.

In India, the GBD (1990–2019) study estimated the total burden of asthma at 34.3 million cases, accounting for 13.09% of the global asthma burden. Furthermore, the study attributed 13.2 deaths per thousand people to asthma in India, underscoring the urgent need for improved awareness, diagnosis, and treatment strategies.

What is inhaled therapy

Inhaled therapy for asthma involves delivering medication directly into the airways using an inhaler, which can be a nebulizer, dry powder inhaler (DPI), or metered-dose inhaler (MDI). This can can quickly relieve symptoms and reduce inflammation of the airways.

Advantages of inhaled therapy (compared to the usual oral treatments)

Oral medications must first be absorbed after ingestion and then circulate throughout the body before reaching the target organs. This process requires relatively large doses of medication, as the

drug is distributed systemically, often delaying its onset of action. Additionally, this widespread distribution increases the risk of side effects, as high concentrations of the drug reach multiple organs.

In contrast, inhaled therapy delivers minute amounts of medication (in micrograms) directly to the airways, minimizing systemic absorption and significantly reducing the risk of side effects. GINA recommends that asthma patients be treated with an inhaled long-acting bronchodilator (such as formoterol or salmeterol) in combination with inhaled corticosteroids.

Regular use of inhaled medications, particularly inhaled corticosteroids, can greatly improve asthma control and decrease the frequency of asthma attacks. In severe cases, inhaled corticosteroids can also reduce the need for oral corticosteroids, which are associated with more serious systemic side effects.

"Make Inhaled Treatments Accessible for ALL"

World Asthma Day is an annual event organized by the GINA to improve asthma awareness and care around the world. The day calls attention to the health issue and the struggles of asthma suffers. It is held on the first Tuesday in May. This year the GINA has chosen the theme **"Make Inhaled Treatments Accessible for ALL".** Doctors and allied health care professionals are called upon to ensure that every person with asthma is prescribed evidence-based, essential, inhaled corticosteroid-containing medication to prevent the continuing avoidable morbidity and mortality from asthma.

Figure 1. The infographic from GINA about world asthma day

GINA had stated that in low-middle-income countries, **lack of availability or high cost of inhaled medicines,** especially inhaled corticosteroid-containing inhalers, are major contributors to the fact that 96% of global asthma deaths occur in these countries.

What are hinderances in access to inhaled therapy?

Globally, several factors can prevent asthma patients from using appropriate inhalers, including: Addressing these challenges requires targeted

Societal and Psychological Factors – Cultural beliefs, social stigma, and feelings of embarrassment associated with inhaler use.

Socioeconomic Barriers – High medication costs and lack of insurance coverage.

Health Literacy and Knowledge – Poor understanding of asthma management and incorrect inhaler usage techniques.

Systemic Barriers – Limited access to healthcare services, along with inadequate education and support.

interventions, including affordable healthcare policies, better patient education, and efforts to reduce societal stigma surrounding inhaler use.

Pricing

The cost of medication is often considered the most significant barrier to patient access. Several factors influence drug pricing, including research and development expenses (such as costs associated with clinical trials), manufacturing and distribution, profit margins, and market competition. Additionally, the rarity of a disease can drive prices higher due to limited demand and the extensive research required. By this logic, medications for common conditions like asthma should be more affordable.

Another crucial factor influencing drug costs is the pricing regulations implemented by different countries. Various nations have distinct systems for regulating and determining medication prices, which directly impact affordability. In India, the National Pharmaceutical Pricing Authority (NPPA) plays a key role in ensuring accessibility by setting ceiling prices for essential medicines.

Price Control in India

The cost of asthma inhalers in India is significantly lower than in many other countries. Table 1 illustrates the price difference for Turbuhaler Symbicort, manufactured by AstraZeneca, highlighting the impact of effective negotiations with manufacturers in securing affordable pricing for essential medicines. Price regulation plays a crucial role in ensuring that these life-saving treatments remain accessible to all.

Reputed pharmaceutical companies, committed to patient-centric care, have upheld their responsibility to make essential medicines widely available. This affordability is largely enabled by the extensive demand for essential medications in India. Despite price regulations, the high volume of sales ensures that manufacturers continue to operate profitably while maintaining accessibility for patients.

Over the years, while the price of inhalers has increased, NPPA-regulated inhalers have remained affordable. Table 2 compares the cost of two commonly used inhalers for asthma treatment. The commendable efforts of the NPPA have played a crucial role in ensuring that the cost of inhaled medications in India does not become a barrier to accessing life-saving essential treatments for patients in need.

Table 1. Price of Turbuhaler Symbicort (manufactured by AstraZeneca)

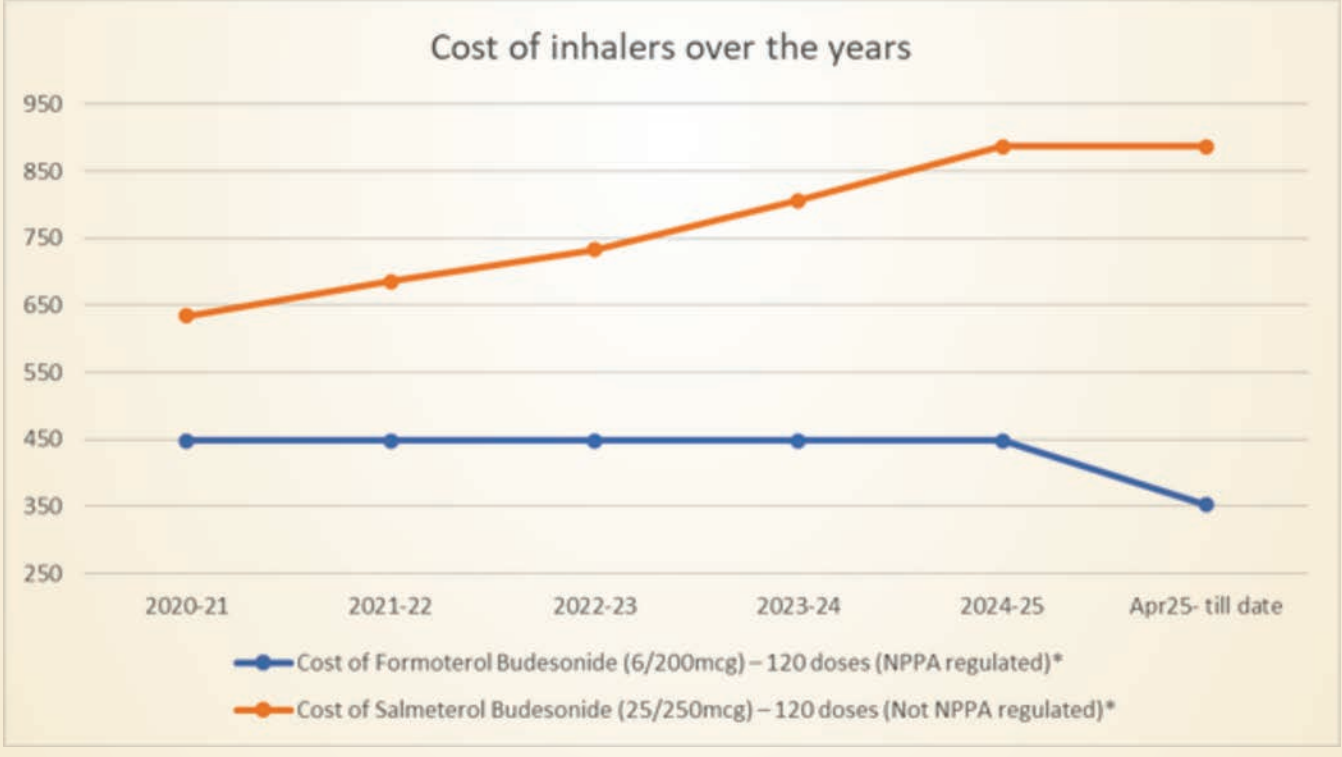
Medication Turbohaler Symbicort 160/4.5	Cost	Cost in Rs.
India	Rs. 686	~
USA*	USD 87.5	7536.61
UK*	Pounds 14.50	1693.02
Germany*	Euro 59.11	5877.96
Australia	AUD 35.99	2009.39
Singapore	SD 41.51	2787.02
Japan	¥5,000 to ¥8,000	2987 - 4779.20
Sri Lanka	LKR 5078	1456.88

*Without insurance #This is based on the current exchange rates
^ The cost mentioned is the cheapest available on the country's online websites (while for India the maximum retail price is mentioned)

Table 2. Maximum Retail Price of Formoterol budesonide and Salmeterol Budesonide inhalers in India over the years.

	Cost of Formoterol Budesonide (6/200mcg) – 120 doses (NPPA regulated) *	Cost of Salmeterol Budesonide (25/250mcg) – 120 doses (Not NPPA regulated) *
2020-21	Rs. 448	Rs. 634.39
2021-22	Rs. 448	Rs. 685.14
2022-23	Rs. 448	Rs. 733.09
2023-24	Rs. 448	Rs. 806.39
2024-25	Rs. 448	Rs. 887.02
Apr25- till date	Rs. 352.12	Rs. 887.02
* The price mentioned is of Foracort 200 and Seroflo 250 manufactures by the same company (Cipla)		

Figure 2. Maximum Retail Price of Formoterol budesonide and Salmeterol Budesonide inhalers in India over the years



Correct and timely diagnosis and treatment

Another significant barrier to inhaler accessibility is incorrect or delayed diagnosis. Due to a lack of awareness and poor understanding, patients often seek medical advice only during asthma exacerbations and are treated with oral medications (such as steroids and antihistamines) for short or extended durations instead of receiving appropriate, guideline-based therapy, such as inhaled corticosteroids. To address this issue, patients must be educated about asthma, including its potential to be life-threatening, so they seek timely medical advice, receive

appropriate treatment, and are referred to pulmonologists when their condition does not improve.

Correct inhaler technique

An important aspect of asthma management is not just prescribing the appropriate inhaler but also ensuring proper administration technique. In my practice, whenever I notice that a patient is not improving despite using inhalers, an incorrect inhaler technique is often the underlying cause. Physicians must take the time to explain each step thoroughly and verify the patient's understanding by having them demonstrate the technique before leaving the OPD. Additionally, patients require regular retraining, and they can benefit from instructional videos on correct inhaler techniques available on various manufacturer websites and reliable social media platforms.

Social stigma

A common obstacle in the acceptance of inhalers are the various myths and misconceptions about its use in the general public. These have to be aggressively debunked for patients to understand the important roles that inhaled therapy can play in the effective management of asthma and possibly prevent an asthma related death.

It is essential to promote social awareness campaigns that eliminate the stigma surrounding inhaler use and emphasize their significance in asthma treatment. By sharing the success stories of renowned athletes and celebrities who have effectively managed their asthma with inhalers and achieved their dreams, we can inspire patients to embrace inhaler use with confidence.

Conclusion

The 2025 World Asthma Day theme—'Making Inhaled Therapy Accessible to ALL'—led me to reflect deeply on the realities faced by asthma patients in India. While the National Pharmaceutical Pricing Authority (NPPA) has played a commendable role in making inhalers

Table 3. Common Myths about asthma and the actual facts.

Myths about inhalers	Facts about inhalers
Inhalers are addictive	Inhalers not addictive. People use it as they need the medicine toreduce the inflammation of the airways. (While explaining this, I often give my example of wearing spectacles!! I am not addicted to my spectacles obviously. Till I wear my spectacles, I see clearly and once I take them off, I don't. In the same way, people use inhalers to reduce the inflammation of the airways and if they stop using the inhalers, the symptoms recur.)
Inhalers should only be used for severe cases	Inhalers can be beneficial for managing asthma at all levels of severity, and are often the preferred method
Inhalers stunt growth	Inhaled steroids, when used in appropriate doses, have minimal impact on a child's growth, and the benefits of controlling asthma far outweigh any potential risks
Inhalers have dangerous side effects	Inhalers have only minimal side effects as therapy minute amounts of the drug (in micrograms) are delivered directly to the airways
Inhalers are the last resort	Inhaled medications are often the first line of treatment for asthma and can be more effective than oral medications

more affordable and accessible by classifying them as essential medicines, our responsibility doesn't end there. We must simultaneously strengthen early and accurate diagnosis, ensure consistent and evidence-based treatment, and place greater emphasis on training patients in the correct use of inhalers. Equally important is our effort to dispel the myths and reduce the social stigma surrounding inhaler use, so that patients can confidently adopt and adhere to this life-saving therapy without hesitation or shame.

Afterall, for asthma patients, breathing easy isn't a luxury; it's their right.

References:

- GINA 2025. https://ginasthma.org/2025-gina-strategy-report/
- The Global Asthma Network Report

References of the websites from which the price is noted: (Can be deleted in the final article)

USA: Symbicort Prices, Coupons, Copay Cards & Patient Assistance - Drugs.com

UK: Symbicort Turbuhaler (Budesonide/Formoterol Fumarate) - United Pharmacies (UK)

Germany: Symbicort Turbuhaler 160/4,5 µg/Dosis 120 ED 1 St mit dem E-Rezept kaufen - Shop Apotheke

Australia: Buy Symbicort 400/12mcg Turbuhaler 60 Dose - Budesonide + Formoterol (Eformoterol) online at Chemist Warehouse

Singapore: Symbicort Turbuhaler powder for inhalation 160 mcg / 4.5 mcg / dose, 60 doses — Made in Sweden — Free Delivery

Srilanka: SYMBICORT TURBU. 160/ - Buy Medicine | Best Online Pharmacy in Sri Lanka | Pharmacies in Sri Lanka | Buy Medicines Online Sri Lanka

IPDMS : A TEN- YEAR JOURNEY TOWARDS ENHANCING TRANSPARENCY AND COMPLIANCE IN PHARMA PRICING

This year marks the tenth anniversary of the launch of the Integrated Pharmaceutical Database Management System (IPDMS) by the National Pharmaceutical Pricing Authority (NPPA). Launched in June, 2015 with the objective of creating a transparent, efficient, and technology-driven interface between the NPPA and stakeholders, IPDMS has since evolved into a critical instrument for regulatory compliance and price monitoring under the provisions of the Drugs (Prices Control) Order (DPCO), 2013.

Origin and Evolution

The shift from the cost-based pricing model of DPCO, 1995 to the market-based mechanism under DPCO, 2013 underscored the need for reliable and comprehensive market data. DPCO, 2013 provides that initially the source of market-based data shall be the data available with pharmaceutical market data specializing company. The Government may in due course of time come out with other appropriate mechanism of collecting/ obtaining the market data relating to drugs. NPPA developed IPDMS, which was launched by the Hon'ble Union Minister of Chemicals and Fertilizers, Shri Ananth Kumar on June 25, 2015. Through this effort, the NPPA in due course wanted to establish an appropriate mechanism of obtaining market-based data related to drugs. Need was also felt to meet the requirement of having a database containing Price to retailer (PTR) and MAT value for each strength and dose of drugs NLEM and new drug for their price fixation. Further NPPA would be able to access price data with respect to scheduled and non-scheduled drugs for monitoring their prices as per provisions of DPCO, 2013.

Initially developed in collaboration with the National Informatics Centre (NIC), IPDMS enabled manufacturers[1] to file applicable forms as prescribed under Schedule II of DPCO, 2013. By July 31, 2022, the system had onboarded 981 companies and 89,553 products.

Recognizing the need for a more robust, scalable, and user-centric system, NPPA undertook a major technological upgrade and launched IPDMS 2.0 on August 29, 2022, with technical support from the Centre for Development of Advanced Computing (C-DAC). This enhanced version of the platform introduced a host of new functionalities to accommodate the evolving needs of NPPA and stakeholders. IPDMS 2.0 provides a unified digital ecosystem for pharmaceutical manufacturers, marketers, importers, and distributors to file all mandatory returns in Forms I to VI prescribed in Schedule II of DPCO, 2013. From April 1, 2025, submission of Form I applications for New Drug retail price approvals have been mandated to be submitted only through IPDMS 2.0, reinforcing its central role in the regulatory ecosystem.

The platform's multi-instance architecture allows concurrent access by NPPA, state-level Price Monitoring and Resource Units (PMRUs), and reporting pharma entities, with role-based access controls, ensuring data security and operational efficiency.

Functional Scope and Benefits of IPDMS for Pharmaceutical Companies

The expanded functionality of IPDMS 2.0 supports real-time data management through features such as dynamic reporting tools, interactive dashboards, alert systems via SMS and email, and integration with NPPA's consumer-facing mobile applications/ platforms like Pharma Sahi Dam and Pharma Jan Samadhan. This seamless integration ensures that stakeholders not only stay updated with the latest ceiling price orders and regulatory timelines but also receive real-time insights into the processing status of their applications. Some of the major

[1] Any person who manufactures or imports or markets drugs for distribution or sale in the country.

functionalities on IPDMS 2.0 are as under

a. Filling regulatory forms and benefits to stakeholders.

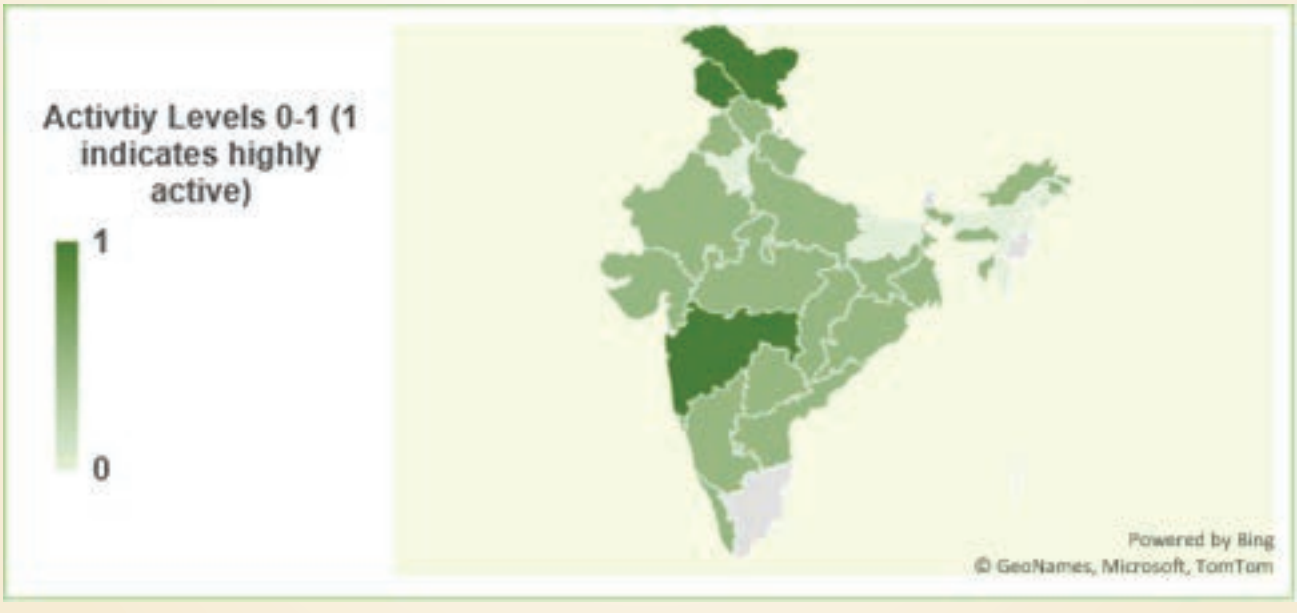
IPDMS 2.0 enables pharmaceutical manufacturers (includes any person who manufactures/ marketers/ imports drugs/Medical device for distribution and sale) to digitally submit all applicable Forms, thereby streamlining compliance and reducing administrative effort. Its structured digital formats support accurate, traceable submissions in line with the provisions of the Essential Commodities Act, 1955, and DPCO, 2013, while maintaining a complete audit trail. By simplifying regulatory processes and offering real-time connectivity with NPPA, the system empowers all stakeholders to align efficiently with provisions of DPCO, 2013, making IPDMS a strategic tool for both regulatory compliance and internal business planning.

b. Centralized oversight and internal Coordination

IPDMS plays a central role in NPPA's internal operations vis. processing worksheets , monitoring overcharge cases, issuing electronic notices and facilitating inter-departmental coordination. Its integration with PMRUs enables centralized oversight of NPPA over the activity of PMRUs and timely and consistent implementation of price control measures across all states. PMRUs report all their activities including i) Surveys about availability of medicines; ii) Information, Education and Communication (IEC) activities, and iii) monitoring price compliances under provisions of DPCO, 2013, on the IPDMS portal. In figure 1. the PMRU wise level of activity has been shown.

c. Empowering Consumers Through Digital Integration

IPDMS seamlessly integrates public-facing platforms developed by the NPPA a) Pharma Sahi Dam app[2]; and b) Pharma Jan Samadhan (PJS) app[3]. These citizen centric apps have enhanced transparency in drug prices and streamlined the reporting and redressal of individual complaints against overcharging, non-availability of drugs. From Figure 2, it can be seen that more than 98% of the total complaints that are reported by Individual complainant to NPPA are through the PJS portal.



*In 5 States/UTs PMRUs are not established/ functioning. These are represented in the shade-Grey

Figure 1: PMRU wise level of activity

[2] enables consumers to access information about various pharmaceutical drugs and also lodge complaint

[3] which enables users to file complaints regarding over charging, refusal, shortage and New Drug.

Figure 2: Mode of reporting individual complaints

Platform Usage: A Snapshot

a. Registration of Manufacturers and the pharma drugs, MD.

The adoption of IPDMS has been growing steadily in the Industry, as evidenced by the statistics of registration in Figure 3. In February 2023, NPPA organised a capacity-building programme that offered comprehensive training to pharmaceutical industry stakeholders on how to register with and effectively use IPDMS functionalities for filing required forms.

b. Regulatory Reporting

As a part of regulatory requirements pharma manufacturers are required to submit all the applicable scheduled forms to the Government. Figure 4 depicts a comprehensive view of yearly submission of scheduled Form I to V by manufacturers done in IPMDS Ver 1.0 (2015-2021) and IPDMS ver 2.0 (from 2022 to 2025)

Figure 3: Statistics of Pharma entities on IPDMS (2015-2025)

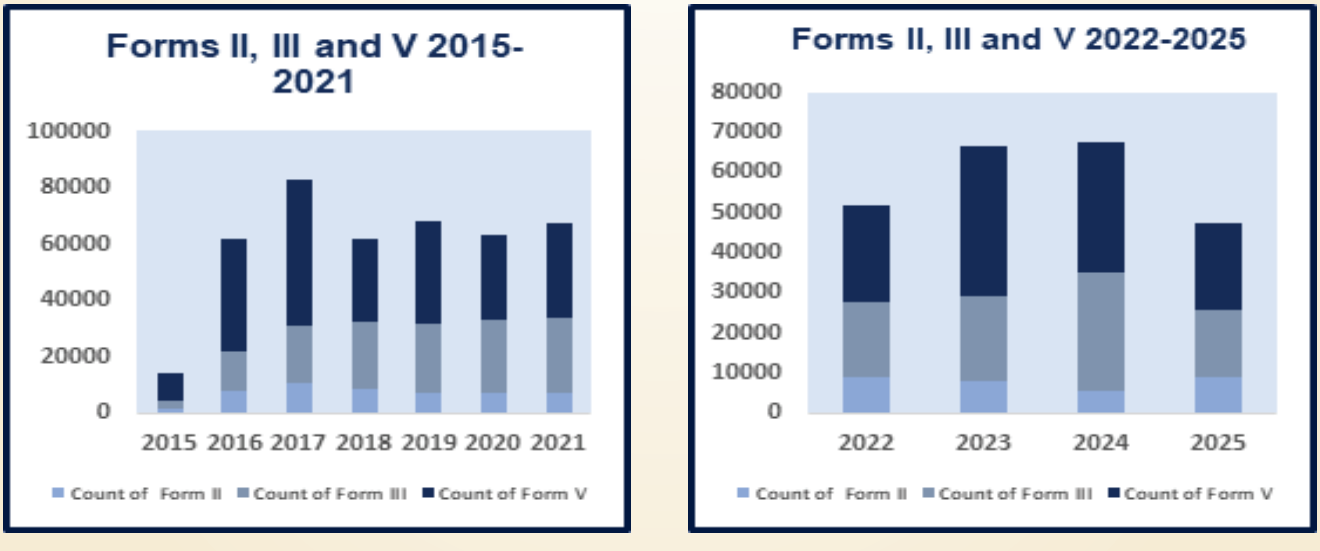


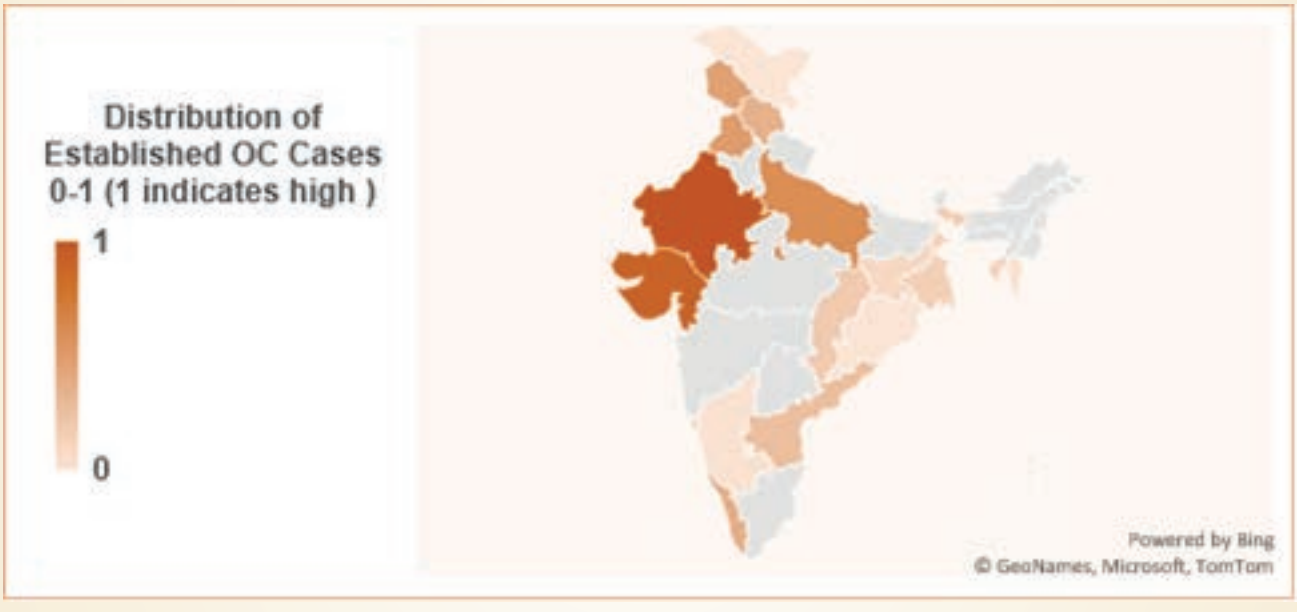
Figure 4: Year wise filling of Form II, III & V

c. Price Monitoring

Monitoring and enforcement of prices of drugs as per provisions of DPCO, 2013, is one of the primary functions of the NPPA. The likely cases of overcharge that are reported on the IPDMS are examined by the NPPA under the provisions of DPCO, 2013. Based on this examination, cases have been established as instances of overcharging. A thematic representation of state wise distribution of established[4] overcharge cases is shown in Figure 5.

Conclusion

As IPDMS moves into its next phase, it is evolving from a technology platform into a cornerstone of transparent, data-driven tool for pharmaceutical price regulation. Looking ahead, the focus will be on reinforcing timely and consistent submissions of forms, expanding stakeholder registration and participation, and building user capacity across the board. By aligning regulatory needs with digital innovation, IPDMS is well-positioned to foster a more accountable and inclusive ecosystem. Ultimately, this will enable NPPA to more effectively carry out its mandate of price regulation and ensure availability, affordability and accessibility of essential medicines.



*Shade grey represents the states/UTs where either there is not an established PMRU or where there are no established OC cases found

Figure 5: State wise Distribution of established Overcharge Cases

[4] The data on established overcharge cases (Figure 5) represents cases where examination has been completed.

REGULATORY NEWS

News related to pricing of drugs

1. Ceiling prices of 930 formulations are effective as on 07.07.2025 of which Ceiling prices for 764 scheduled formulations have been fixed / refixed under National List of Essential Medicines, 2022. There has been average reduction of 16.84% on account of refixation under NLEM, 2022 leading to annual savings of Rs. 3792.78 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	172	1248.92
Anticancer Medicines	59	120	294.34
Neurological Disorder Medicines	18	60	154.43
Psychiatric Disorder Medicines	14	41	42.6
Cardiovascular Medicines	25	59	473.86
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	220	937.76
Unique Drugs / Formulations	328*	764	3792.78

*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 07.07.2025, 266 Authority meetings have been conducted of which 134 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. 265th (overall) & 133rd meeting under DPCO 2013	29.05.2025	i. Retail prices for 41 formulations notified vide S.O. 2469(E) dated 03.06.2025.
266th (overall) & 134th meeting under DPCO 2013	26.06.2025	i. Retail prices for 71 formulations notified vide S.O. 3001(E) dated 04.07.2025. ii. Separate retail price for M/s GlaxoSmithKline Asia Private Limited of Each sachet containing Paracetamol I.P. 500 mg and Phenylephrine HCl I.P. 10 mg under para 11(3) of DPCO 2013 notified vide S.O. 2999(E) dated 04.07.2025. iii. Approval of separate ceiling price of 5 IV fluids in special packaging by M/s Cartel Lifescience Pvt. Ltd. notified vide S.O 2998(E) and 3000(E) dated 04.07.2025.

3. Retail prices for 3482 (approx.) new drugs have been fixed under DPCO, 2013 till 07.07.2025. Details of 112 retail prices notified for various formulations based on the decision taken in 133rd and 134th 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	65	Tablet	9.90-35.19
2.	Analgesic, anti-inflammatory and Arthritis	8	Tablet/Suspension	0.53-15.39
3.	Cardiovascular	4	Tablet/Capsule	3.65-54.29
4.	Vitamins/Minerals/ Nutrients	6	Tablet/Capsule/ Syrup/ Drops/Sachet	0.23-14.64
5.	Anti-Infective	13	Tablet/Injection/ Suspension/Gel	1.46-1036.60
6.	Others	16	Tablet/Capsule/Inhaler/ Injection/Suspension/Drops	0.93-11966.64

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 June 2025:

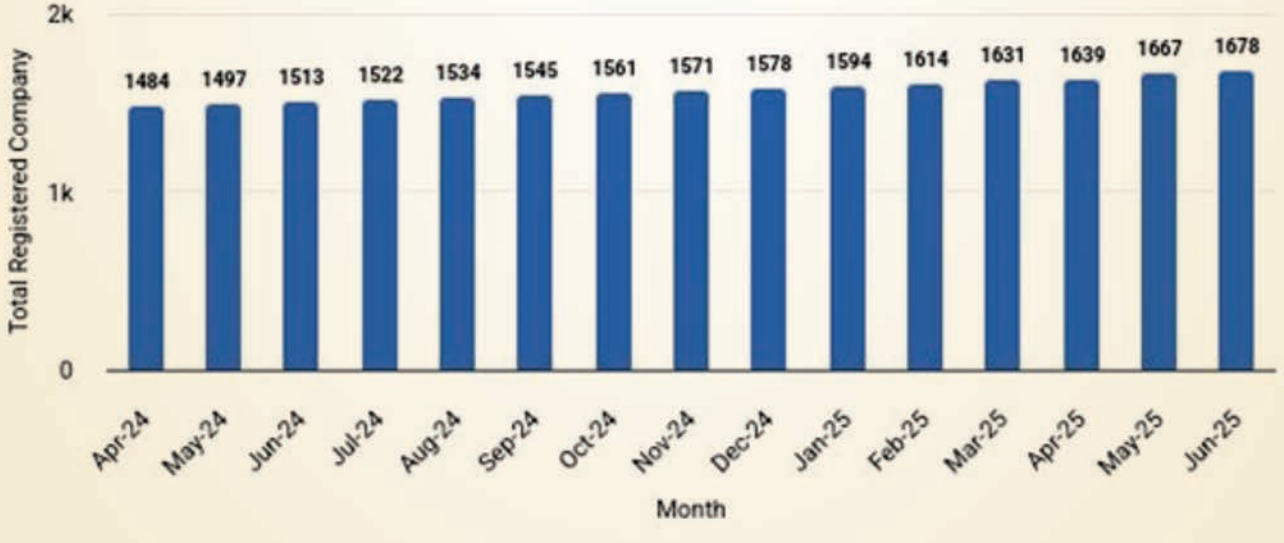


Chart1: Total number of registered companies at the end of June 2025

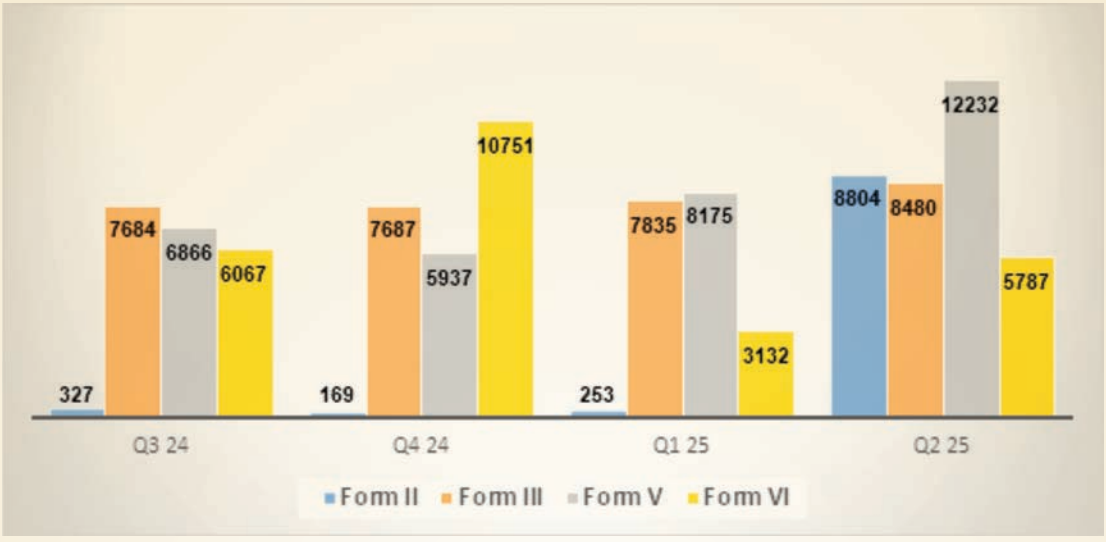


Chart 2: Quaterly Statistics- Forms filed on IPDMS

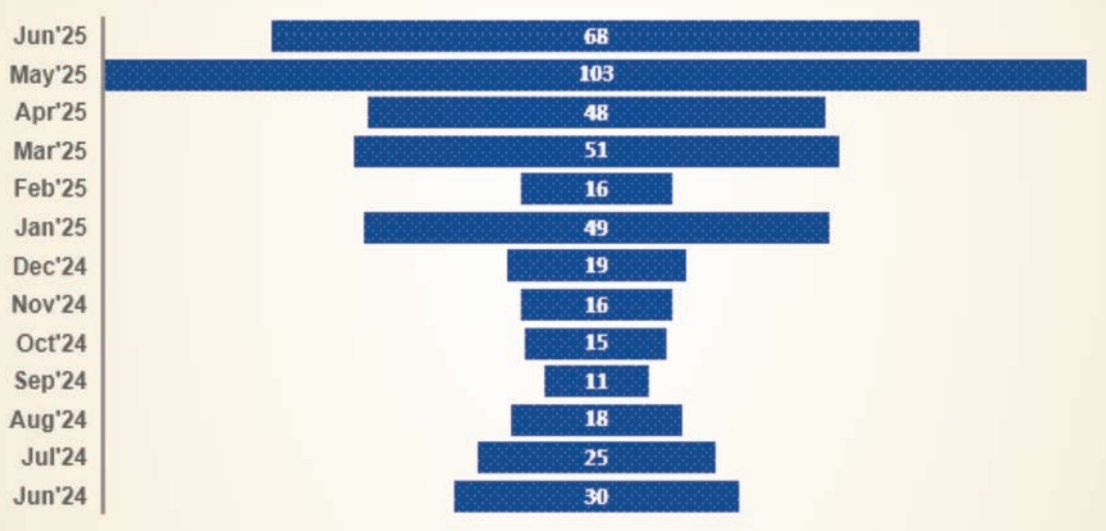


Chart 3: Total number of Form I filed on IPDMS

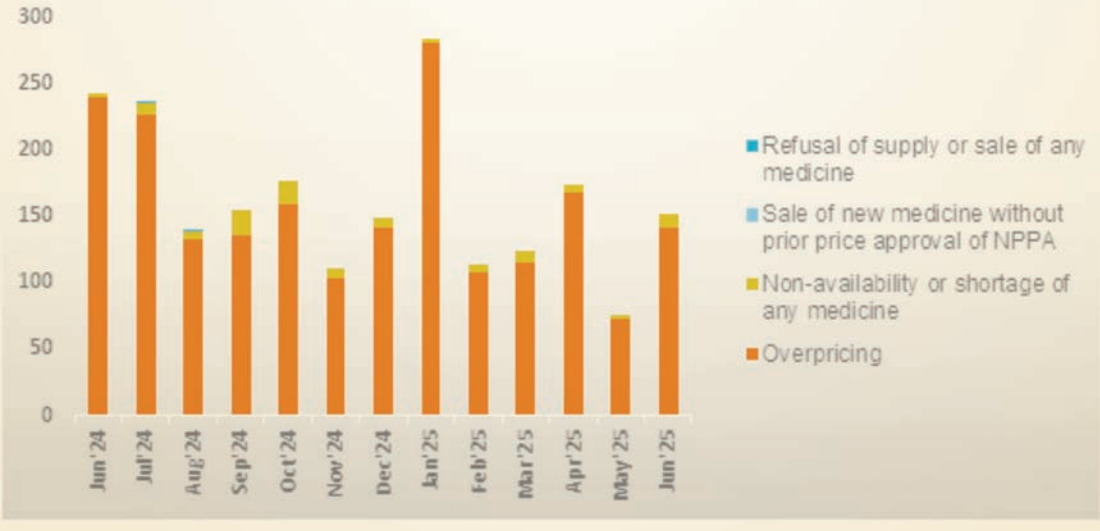


Chart 4: Number of complaints received on IPDMS/ Pharma Jan Samadhan

Chart 5: Number of Pharma Sahi Daam Mobile app downloads

Chart 6: Number of User logins in IPDMS 2.0

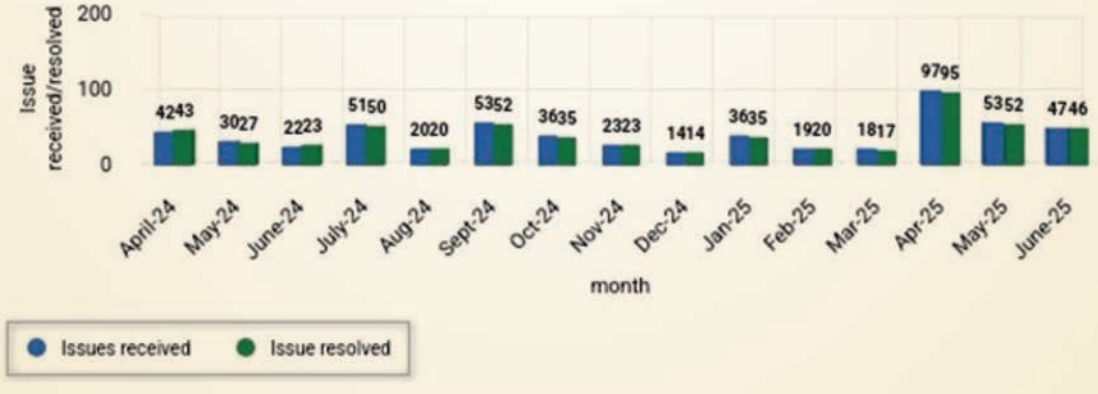


Chart 7: Number of tickets raised/ resolved at IPDMS help-desk

INTERNATIONAL NEWS

Measures to minimise risk of suicidal thoughts with finasteride and dutasteride

As per the press release dated (8 May 2025 EMA stated that Suicidal thoughts confirmed as side effect of finasteride tablets; no direct link found for dutasteride EU-wide review of available data on finasteride and dutasteride medicines, EMA's safety committee, PRAC, has confirmed suicidal ideation (suicidal thoughts) as a side effect of finasteride 1 and 5 mg tablets. The frequency of the side effect is unknown, meaning that it is not possible to estimate it from available data. Most cases of suicidal ideation were reported in people using 1 mg finasteride tablets, which are used to treat androgenetic alopecia (hair loss due to male hormones). A warning about mood changes, including depression, depressed mood and suicidal ideation, is already included in the product information for finasteride medicines. Patients who experience mood changes should seek medical advice and, if taking finasteride 1 mg, should also stop treatment.

(Read more)

Changes to the use of antibiotic azithromycin 23 May 2025

As per the press release dated 23 May 2025, EMA has recommended several changes to the way the antibiotic azithromycin is used in the EU, including the removal of certain indications. These recommendations aim to optimise the use of this common antibiotic and minimise the development of antimicrobial resistance – the ability of microorganisms to become resistant to antimicrobials. Azithromycin has been used for decades to treat a wide range of infectious diseases, both in children and adults. It is included in the World Health Organization (WHO) list of essential medicines

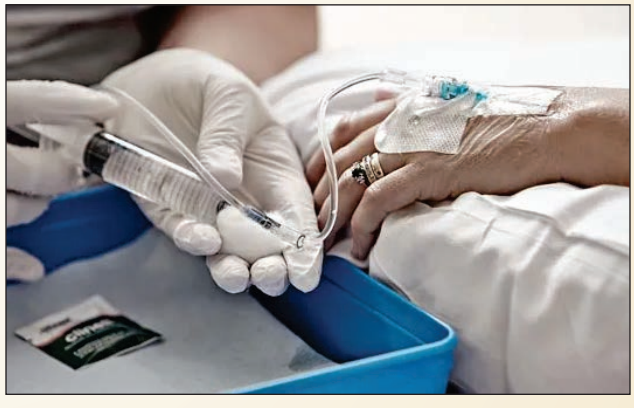
(Read more)

PRAC concludes eye condition NAION is a very rare side effect of semaglutide medicines Ozempic, Rybelsus and Wegovy

As per the press release dated 06 June 2025, EMA's safety committee PRAC has concluded its review of medicines containing semaglutide following concerns regarding a possible increased risk of developing non-arteritic anterior ischemic optic neuropathy (NAION), an eye condition that may cause loss of vision. Semaglutide, a GLP-1 receptor agonist, is the active substance in certain medicines used in the treatment of diabetes and obesity (namely Ozempic, Rybelsus and Wegovy). After reviewing all available data on NAION with semaglutide, including data from non-clinical studies, clinical trials, post-marketing surveillance and the medical literature, PRAC has concluded that NAION is a very rare side effect of semaglutide (meaning it may affect up to 1 in 10,000 people taking semaglutide).

(Read more)

FDA Eliminates Risk Evaluation and Mitigation Strategies (REMS) for Autologous Chimeric Antigen Receptor CAR T cell Immunotherapies Agency determines the safety and effectiveness of these immunotherapies can be assured without a REMS (June 27, 2025)



The U.S. Food and Drug Administration announced today that it has eliminated the Risk Evaluation and Mitigation Strategies (REMS) for currently approved BCMA- and CD19-directed autologous chimeric antigen receptor CAR T cell immunotherapies. These products are gene therapies that are currently approved to treat blood cancers, such as multiple myeloma and certain types of leukemia and lymphoma.

(Read More)

INTERNATIONAL YOGA DAY - 21st June 2025

Officers from NPPA, celebrated #International Day of Yoga with enthusiasm, embracing **'Yoga for One Earth, One Health'.** Promoting wellness, harmony & a healthier planet through collective practice. #YogaForWellness #IDY2025 #InternationalDayofYoga2025Glimpses #Yoga #InternationalYogaDay2025 #IDY2025 #YogaDay2025 #YogaForOneEarthOneHealth

OTHER NEWS AND EVENTS

The meeting of Governing Body of PMRU Jharkhand was held in Ranchi and was attended by key stakeholders, including Secretary, Health, Government of Jharkhand, Director, NPPA, representatives from the State Drug Control Department, health officials, and other Governing Body members. As a member of the PMRU Governing Body, Shri. Kumar Aman Bharti , Director, NPPA reviewed the unit's performance and emphasized the critical role of PMRUs in enabling the implementation of the Drugs (Prices Control) Order and facilitating consumer awareness on drug pricing.

State Level Events/ Seminars by PMRUs

Twenty-Six (26) State and district-level events/Seminars have been organized by 28 (Twenty-eight) PMRUs in their respective States/UTs, viz. Puducherry, Kerala, Ladakh, Jammu & Kashmir, Rajasthan, Haryana, Uttar Pradesh, Punjab, Maharashtra, Chhattisgarh 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: -


NPPA
LADAKH PRICE MONITORING AND RESOURCE UNIT
PHARMA SAHI DAAM MOBILE
LPMRU
LADAKH PRICE MONITORING AND RESOURCE UNIT
About us :
MONITOR THE PRICE OF MEDICINES
ENSURE THE ACCESSIBILITY, AVAILABILITY & AFFORDABILITY
MEDICINE FOR ALL
RAISING CONSUMER AWARENESS
Information about:
Monitor notified price of medicine.
LPMRU


NPPA
BENEFITS TO THE CONSUMERS

OTHER NEWS AND EVENTS


SWACHHTA SHAPATH (PLEDGE)
Mahatma Gandhi dreamt of an India which was not only free but also clean and developed.
Mahatma Gandhi secured freedom for Mother India.
Now it is our duty to serve Mother India by keeping the country neat and clean.
I take this pledge that I will remain committed towards cleanliness and devote time for this.
I will devote 100 hours per year, that is two hours per week, to voluntarily work for cleanliness.
I will neither litter not let others litter.
I will initiate the quest for cleanliness with myself, my family, my locality, my village and my work place.
I believe that the countries of the world that appear clean are so because their citizens don't indulge in littering nor do they allow it to happen.
With this firm belief, I will propagate the message of Swachh Bharat Mission in villages and towns.
I will encourage 100 other persons to take this pledge which I am taking today.
I will endeavour to make them devote their 100 hours for cleanliness.
I am confident that every step I take towards cleanliness will help in making my country


Thank You
For Your
Attention

OTHER NEWS AND EVENTS


NPPA
AL PRICE
(TPMRU)

FREQUENTLY ASKED QUESTIONS

1. What is a medical device?

All devices including an instrument, apparatus, appliance, implant, material or other article, whether used alone or in combination, including a software or an accessory, intended by its manufacturer to be used specially for human beings or animals which does not achieve the primary intended action in or on human body or animals by any pharmacological or immunological or metabolic means, but which may assist in its intended function by such means for one or more of the specific purposes of

i. diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder;
ii. diagnosis, monitoring, treatment, alleviation or assistance for, any injury or disability;
iii. investigation, replacement or modification or support of the anatomy or of a physiological process;
iv. supporting or sustaining life;
v. disinfection of medical devices; and
vi. control of conception.

2. Who regulates medical devices in India?

Medical devices in India are regulated by the **Central Drugs Standard Control Organization (CDSCO)** under the **Ministry of Health and Family Welfare.** Certain devices are regulated under the **Medical Devices Rules, 2017.**

3. What is a medical device notified as drugs?

Government of India regulates 24 class of medical devices which have been notified/regulated as drugs for quality control and price monitoring under Drugs & Cosmetics Act, 1940 and Drugs & Cosmetics Rules, 1945.

4. Do medical devices require registration in India?

Yes. All medical devices require registration and licensing with CDSCO. Only entities that have obtained the appropriate license from CDSCO can manufacture or import medical devices. These include domestic manufacturers and authorized Indian agents for foreign manufacturers.

5. What is the difference between Class A, B, C, and D medical devices?

Medical devices are classified based on risk:

- Class A – Low risk (e.g., tongue depressors)
- Class B – Low to moderate risk (e.g., hypodermic needles)
- Class C – Moderate to high risk (e.g., infusion pumps)
- Class D – High risk (e.g., heart valves, pacemakers).

6. Are there price controls on medical devices?

Yes, the National Pharmaceutical Pricing Authority (NPPA) regulates and monitors the prices of Medical Devices notified as drugs. 4 medical devices viz. (i) Cardiac Stents (ii) Drug Eluting Stents (iii) Condoms and (iv) Intra Uterine Device (Cu-T) are scheduled medical devices for which ceiling prices are fixed by the National Pharmaceutical Pricing Authority (NPPA). These 4 medical devices are under price control. As regard remaining non-scheduled medical devices which are notified/regulated as drugs, NPPA is currently monitors Maximum Retail Prices (MRPs) under Para 20 of the DPCO, 2013 to ensure that no manufacturer/ importers can increase the MRP more than ten percent in preceding twelve months.

7. What is Form VI under the DPCO, 2013, and who is required to file it?

Form VI is the official proforma prescribed under the Drugs (Prices Control) Order (DPCO), 2013 for submitting the price list of medical devices to the National Pharmaceutical Pricing Authority (NPPA). This form includes critical pricing details such as the Maximum Retail Price (MRP), prices to distributors and retailers, applicable GST rates, and other related information. All manufacturers and importers of medical devices are required to submit Form VI to NPPA whenever there is a revision in the MRP of any medical device.

8. What should a hospital or clinic do before purchasing medical devices?

They should ensure:

- The device is registered/licensed with CDSCO
- The manufacturer/supplier provides valid documentation
- The device has proper certification and warranty
- It complies with applicable safety standards

9. How can consumers report problems with a medical device?

Consumers can report problems with a medical device through:

- Materiovigilance Programme of India (MvPI)
- Emailing CDSCO or using their Sugam portal
- Reporting Complaints regarding overcharging, non- availability of MD on Phara Jan Samadhan (PJS) Portal, and contact NPPA via email monitoring-nppa@gov.in or Toll free helpline no. 1800111255.

10. Where can I find a list of approved medical devices in India?

You can visit the **CDSCO website (https://cdsco.gov.in)** or access the **SUGAM portal** for details on registered and approved medical devices.

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.

सत्यमेव जयते

NPPA
AFFORDABLE MEDICINES FOR ALL

भारत सरकार
रसायन एवं उर्वरक मंत्रालय
औषध विभाग
राष्ट्रीय औषध मूल्य निर्धारण प्राधिकरण
Government of India
Ministry of Chemicals & Fertilizers
Department of Pharmaceuticals
National Pharmaceutical Pricing Authority

No. 33011/01/2025-IT(NPPA) **Date:** 4 July 2025

Circular

Subject: Change of Official Website Domain from nppaindia.nic.in to nppa.gov.in w.e.f. 15th July 2025-reg

To
All Stakeholders, Industry Representatives, and Members of the Public.

This is to inform all concerned that the official website domain of the **National Pharmaceutical Pricing Authority (NPPA)** will be changed from **www.nppaindia.nic.in** to **www.nppa.gov.in** with effect from **15th July 2025**.

2. The new domain **nppa.gov.in** will serve as the official source for all notifications, circulars, public notices, pricing orders, data reporting systems, and other relevant updates issued by NPPA.

Key Points:

- The current website **www.nppaindia.nic.in** will be **redirected** to the new domain for a transitional period.
- All stakeholders are advised to **update their records**, bookmarks, and systems accordingly.

3. We request all stakeholders and the general public to take note of this change and ensure continued access to official information and services from NPPA via the new domain.

4. For any queries or assistance, please contact us through email us at: nppa@nic.in, pallav.chittej@gov.in (effective from 15th July 2025).

Thank you for your cooperation.

04/07/2025

(Kumar Aman Bharti)
Director (Admn/IT)
National Pharmaceutical Pricing Authority (NPPA)
Ministry of Chemicals and Fertilizers
Government of India

AFFORDABLE MEDICINES FOR ALL
सभी के लिए वहनीय दवाईयाँ

NATIONAL PHARMACEUTICAL PRICING AUTHORITY

3rd / 5th Floor, YMCA Cultural Center Building 1, Jai Singh Road, New Delhi, India

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

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