

AUSHADH SANDESH

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A Bi-monthly e-Newsletter

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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:

- 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.

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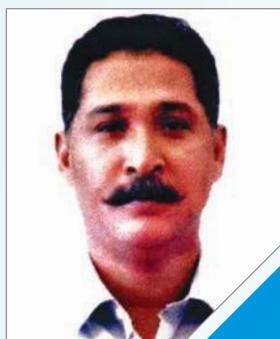
DISCLAIMER:

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

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



From CHAIRMAN'S DESK



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

It is with immense pleasure I present to you the twenty second 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.

During this period NPPA has enabled submission of Form I application for retail price fixation of new drugs through IPDMS 2.0 only, with effect from April 1, 2025. This has been implemented with the primary objective of streamlining the application process and ensuring that the processing of such applications is done in a time bound manner.

I am also pleased to acknowledge the insightful article titled "**India's Obesity Crisis: Opportunity amidst challenges for Pharma,**" thoughtfully prepared by the NPPA team. The article sheds light on the growing obesity crisis in India, which is rapidly emerging as a serious public health concern. It underscores how this escalating issue is not only prompting urgent attention from domestic healthcare stakeholders but also drawing significant interest from global pharmaceutical companies. These companies are increasingly viewing India as a key market for weight loss medications, recognizing both the medical need and the commercial potential in addressing this concern. The article offers a timely and comprehensive perspective on how industry players are aligning their strategies to respond to this dual objective of improving public health while tapping into a market with immense scope for growth.

In continuation of our PMRU activities, twenty-eight (28) state and district-level events/seminars have been organized by eleven PMRUs in their respective states / UT. These events were aimed at creating awareness about fixation of ceiling prices of scheduled drugs under NLEM 2022 and its significance in healthcare, drug price regulations under the provisions of DPCO 2013, the role of NPPA in making the drugs affordable and available for all, the 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)

INDIA'S OBESITY CRISIS: OPPORTUNITY AMIDST CHALLENGES FOR PHARMA

(By NPPA Team)

Disclaimer: The views or opinions expressed in the article are solely of the individuals involved and do not necessarily represent those of the NPPA and its employees

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INTRODUCTION

Obesity has emerged as one of the most pressing global health challenges of the 21st century, prompting the observance of World Obesity Day every year on March 4, to raise awareness and promote coordinated efforts to address this growing epidemic. As India grapples with an escalating obesity crisis, global pharmaceutical companies are turning their attention to the growing demand for weight loss/anti-obesity drugs in the country. With obesity rates on the rise and becoming a significant health concern, India presents a booming market for pharmaceutical companies who are eager to tap into this untapped potential. However, market entry and expansion are dependent on myriad factors like R&D and manufacturing capabilities, affordability and accessibility issues, sociocultural perceptions around obesity treatment, etc. This article explores the dual narrative of opportunity and challenge in this area, analysing how global and domestic pharmaceutical companies are positioning themselves in India's obesity management space and what action may be necessary to facilitate its sustainable development.



PRESENT SCENARIO: Analysis of market data

Obesity has reached alarming levels in India, with a significant proportion of the population struggling with obesity linked co-morbidities such as diabetes, hypertension, and heart disease. According to the National Family Health Survey-5 (NFHS-5), roughly one in every four Indians, both men and women, are overweight or obese, and a recent published study^[1] estimates that by 2050, India could have over 450 million overweight or obese adults. As a result, it is likely that there would be an increased usage of medications to treat obesity and obesity linked co-morbidities.

As per studies, it is observed that following drugs are prevalently being used in India for treatment of type-2 diabetes, and weight loss management:

- **SEMAGLUTIDE:** Targets brain centres that regulate appetite, especially after eating, help in reducing food intake, slowing stomach emptying prolonging the feeling of fullness.
- **LIRAGLUTIDE** Stimulates insulin secretion in response to glucose, lowers plasma

- **ORLISTAT** promotes weight loss by reducing dietary fat absorption in the intestines.

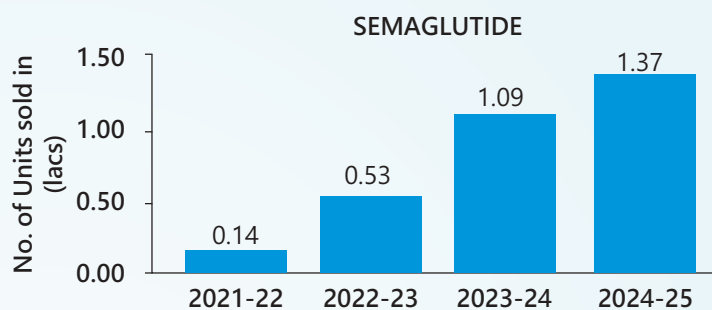
As the above drugs are also prescribed for weight management, the trend in their annual sale in Indian market can serve as an important indicator for estimating the demand for weight loss/weight management drugs in India. Accordingly, the market available data of the no. of units these drugs being sold has been examined.

As per analysis of market data in Graph 1, 2 & 3, it is observed that the sale of type-2 diabetes and weight loss drugs viz. Semaglutide, Orlistat and Liraglutide has showcased upward growth trajectory in Indian markets from the year 2021 to Feb 2025 with Semaglutide registering 10 times increase in its sale in a period of just 5 years. This clearly shows an increasing demand for these medicines in India during the period 2022 to 2025.

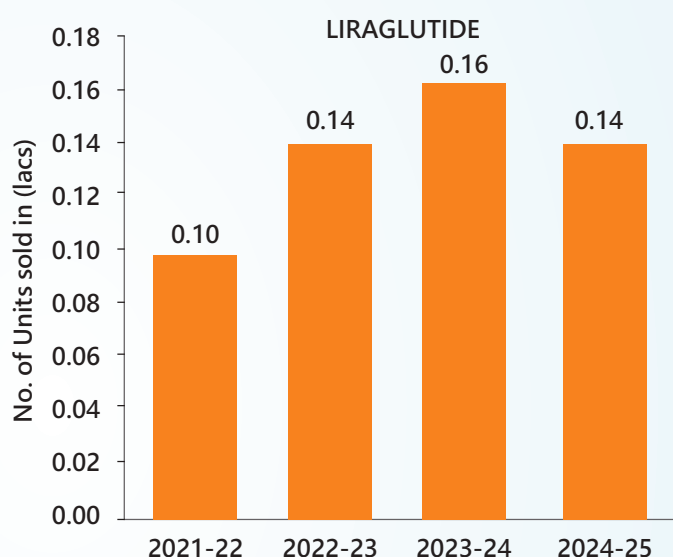
OBESITY AND DIABETES MANAGEMENT DRUG SUPPLY IN INDIA : Opportunities and Challenges

To tap this unprecedented demand for type 2 diabetes and weight management drugs, several Pharmaceutical companies^[2] such as Novo Nordisk, Eli Lilly, and AstraZeneca, Intas, Cipla which have made breakthroughs with obesity treatment drugs in Western markets, are either in the stage of introducing these innovations in India or are already major suppliers in the Indian market. These drugs have been shown to help patients lose significant amounts of weight, and clinical studies highlight their potential to reduce the risks associated with obesity related diseases. However, the path to success for the pharmaceutical industry in India is fraught with unique challenges. The demand for weight management medications in the Indian context is shaped by several critical factors, including affordability, accessibility, and the practicality of drug administration methods.

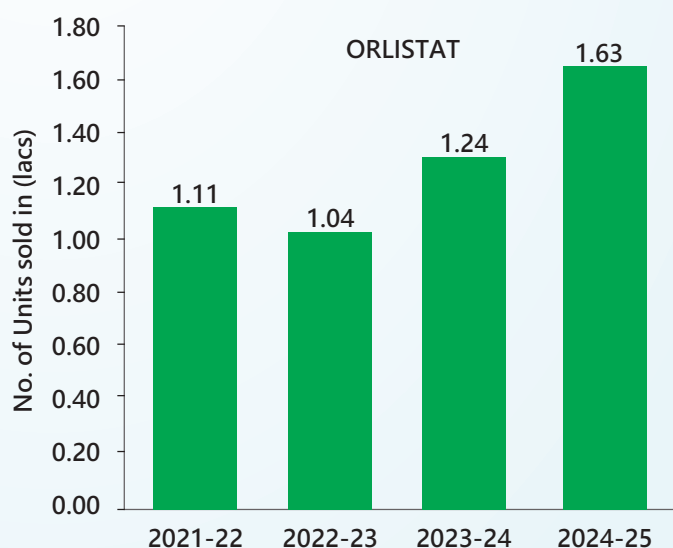
As per market data, it is observed that obesity treatment drugs are expensive and this can be



Graph 1- Semaglutide: Year wise (Feb 2021- Feb 2025)
no. of units sold



Graph 2- Liraglutide: Year wise (Feb 2021- Feb 2025)
no. of units sold



Graph 3- Orlistat: Year wise (Feb 2021- Feb 2025)
no. of units sold

a major challenge in a price-sensitive market like India. For example, some of these drugs which costs around \$1,000 per month in the U.S., is unlikely to be affordable for a wide base of population in India. While global pharma companies may lower prices to cater to Indian consumers, the high cost of research and development, along with production and distribution expenses, could still make it difficult for these companies to offer affordable pricing on a large scale.

Moreover, many of the current pharmacological treatments for weight management, are administered via subcutaneous injections, on a regular basis. While these therapies have demonstrated substantial efficacy in clinical trials, their injectable nature may limit widespread adoption, particularly among individuals who prefer oral medications for reasons of convenience, comfort, or accessibility. This general preference for oral administration^[3] suggests that the development of effective weight management pills could significantly broaden the reach and impact of anti-obesity interventions.

India's unique healthcare landscape and the existing gap in the anti-obesity drug market present a strategic opportunity for the domestic pharmaceutical industry to contribute meaningfully to sustainable healthcare development. While several Indian pharmaceutical companies have expressed intentions to enter the obesity drug market, their current capabilities may have posed constraints. The Indian pharma companies may make use of this window of opportunity by exploring strategic collaborations with global players. By pursuing partnerships for in-licensing, distribution, and local manufacturing, Indian firms can accelerate access to these medicines across diverse regions in India. Furthermore, dedicated investment in R & D capacity and in the development of active pharmaceutical ingredients (APIs) for weight management drugs can not only reduce dependence on imports but also position India as a key global supplier in this emerging therapeutic area.

In addition to the above factors, the cultural dimension also plays a vital role in usage of anti-obesity drugs in India. Indians have historically been less focused on weight loss treatments compared to Western countries. Cultural attitudes towards body image are even more complex. While obesity is increasingly seen as a health risk, there is a social stigma around the idea of dieting or taking medication for weight loss. Public perception could impact the uptake of weight loss drugs, especially if they are viewed as a last resort rather than a preventive measure.

In conclusion, while global and domestic pharmaceutical companies recognize the immense potential of the Indian market for weight loss drugs, several factors complicate their ability to capitalize on this opportunity. The high cost of treatment and cultural attitudes toward obesity treatment are some of the barriers that need to be addressed before these drugs can become a mainstream solution in India. Nevertheless, as the obesity crisis continues to grow, and awareness around the associated health risks increases, pharmaceutical companies may find ways to overcome these challenges, offering affordable and accessible solutions to the Indian market

^[1] Lancet 2025; 405: 813–38; Global, regional, and national prevalence of adult overweight and obesity, 1990–2021, with forecasts to 2050: a forecasting study for the Global Burden of Disease Study 2021; GBD 2021 Adult BMI Collaborators*

^[2] <https://www.outlookbusiness.com/in-depth/novo-nordisk-and-eli-lilly-bring-weight-loss-contest-to-india>
<https://www.livemint.com/companies/eli-lilly-weight-loss-drug-anti-obesity-drug-mounjar-o-diabetes-drug-glp-1-ozempic-cipla-dr-reddy-s-lupin-mankind-pharma-11742461296043.html>

^[3] (Smith et al., 2022; Johnson & Lee, 2021) Research paper has shown that patient adherence and acceptance are often higher with oral formulations compared to injectable therapies, especially in chronic disease management contexts.

News related to pricing of drugs

- Ceiling prices of 930 formulations are effective as on 13.5.2025 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.

- As on 13.5.2025, 264 Authority meetings have been conducted of which 132 have been conducted under DPCO 2013. The details of the recent meetings are given as below:

Meeting No. 263rd (overall) & 131st meeting under DPCO 2013, held on dated 25.03.2025

Prices Approved & Notified

- Retail prices for 80 formulations notified vide S.O. 1490(E) dated 27.03.2025.
- Ceiling price of the formulations were revised based on Wholesale Price Index (WPI) @ 1.74028% for the year 2024 over 2023 with effect from 1.4.2025. Accordingly, NPPA issued following notifications-
 - Revised ceiling price (WPI adjusted) of 748 scheduled formulations of Schedule-I (NLEM 2022) under Drugs (Prices Control) Order, 2013 notified vide S.O. 1489(E) dated 27.3.2025
 - Revised ceiling price (WPI adjusted) of 152 scheduled formulations of Schedule-I (NLEM 2015) under Drugs (Prices Control) Order, 2013 notified vide S.O. 1487(E) dated 27.3.2025
 - Revised ceiling price (WPI adjusted) of 6 scheduled formulations of Schedule-I (NLEM 2011) under Drugs (Prices Control) Order, 2013 notified vide S.O. 1488(E) dated 27.3.2025

- d. Revised ceiling prices (WPI adjusted) of 6 Other IV Fluids with packages having special features of Schedule-I under Drugs (Prices Control) Order, 2013 notified vide S.O. 1486(E) dated 27.3.2025
- e. Revised ceiling prices (WPI adjusted) of 8 IV Fluids with packages having special features of Schedule-I (NLEM 2015) under Drugs (Prices Control) Order, 2013 notified vide S.O. 1485(E) dated 27.3.2025.
- f. Revised ceiling price of (i) Piperacillin 2gm+Tazobactam 250mg and (ii) Piperacillin 4gm+Tazobactam 500 mg under Drugs (Prices Control) Order, 2013 (NLEM 2022) notified vide S.O. 1475(E) dated 27.3.2025.
- g. Revised ceiling prices (WPI adjusted) of 4 pack size of ringer lactate injection with packages having special features of schedule-I (NLEM 2015) under drugs (prices control) order, 2013 notified vide S.O. 1474(E) dated 27.3.2025.
- h. Revised ceiling prices (WPI adjusted) for two (2) Coronary Stents notified vide S.O. 1473(E) dated 27.3.2025

Meeting No. 264th (overall) & 132nd meeting under DPCO 2013* held on dated 29.04.2025

- i. Retail prices for 84 formulations notified vide S.O. 20233(E) dated 6.5.2025.
- ii. Ceiling price of 9 scheduled formulations under NLEM, 2022 were notified vide S.O. 2027(E) dated 6.5.2025.
- iii. Separate retail price of 3 formulations under para 11(3) of DPCO 2013 notified vide S.O. 2024(E) dated 6.5.2025.
- iv. Revision of ceiling price of Iohexol 300mg iodine/ml (from 17.13 per ml to 19.74 per ml) based on Review Orders passed by DoP, notified vide S.O. 2026(E) dated 6.5.2025.

3. Retail prices for 3370 (approx.) new drugs have been fixed under DPCO, 2013 till 13.5.2025. Details of 164 retail prices notified for various formulations based on the decision taken in 131st and 132nd 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	88	Tablet	8.12-33.23
2	Analgesic, anti-inflammatory and Arthritis	9	Tablet/Gel/ Suspension/Injection	0.53-14.75
3	Anti-hypertensive	14	Tablet	9.10-16.29
4	Cardiovascular	21	Tablet/Capsules	10.28-54.29
5	Vitamins/Minerals/Nutrients	6	Tablet/Solution	0.88-15.03
6	Anti-Infective	7	Tablet/Injection/ Suspension	3.72-1036.60
7	Others	19	Tablet/Capsule/Respule/ Injection/Suspension/ Granules/Vaginal Film	0.53-2673

News related to pricing of Medical devices

NPPA, vide S.O. 1488, 1489, and 1473 dated March 27, 2025, issued notifications regarding the fixation and revision of the ceiling prices of Medical Devices i.e Condoms, IUDs, and Coronary stents respectively, based on the Wholesale Price Index (WPI) increase of 1.74028% for the year 2024 over 2023, in accordance with Paragraph 16(2) of the DPCO, 2013, read with Paragraph 13(2) of DPCO, 2013.

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 April 2025:

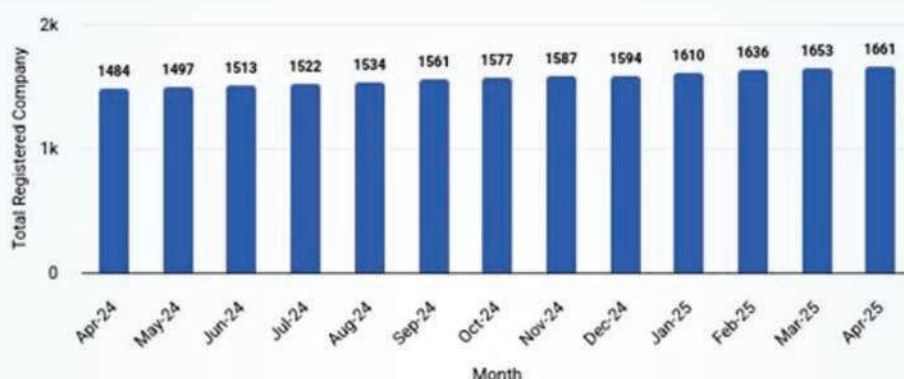


Chart1: Total number of registered companies at the end of April 2025

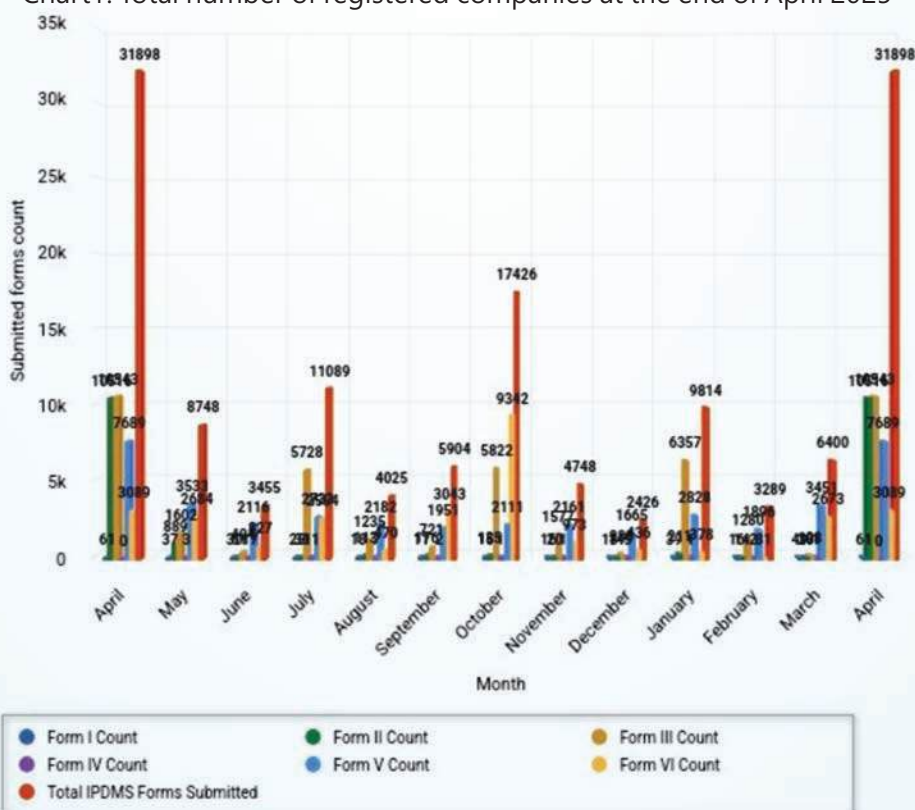


Chart 2: Number of statutory forms filed on IPDMS as on 30 April 2025

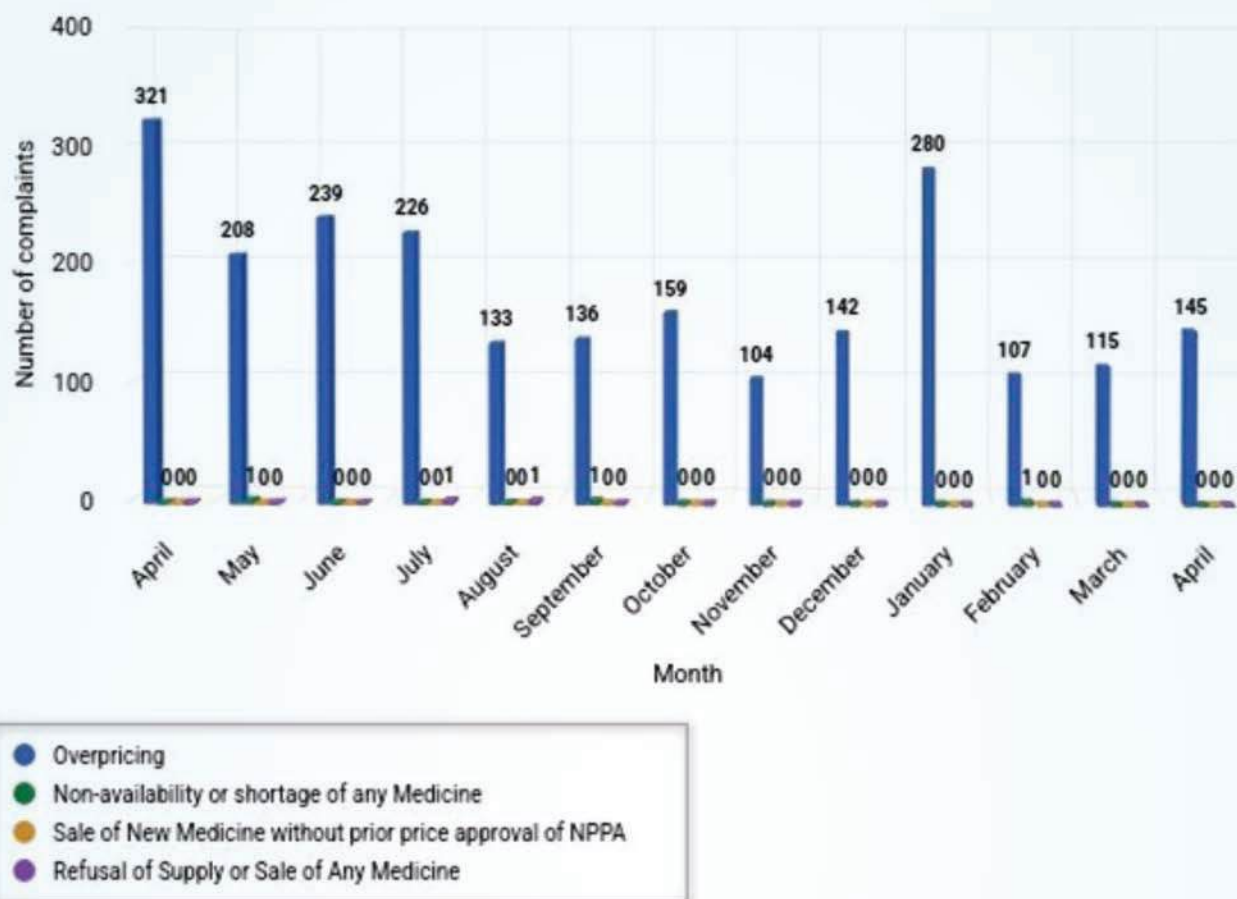


Chart 3: Number of complaints received on IPDMS/ Pharma Jan Samadhan

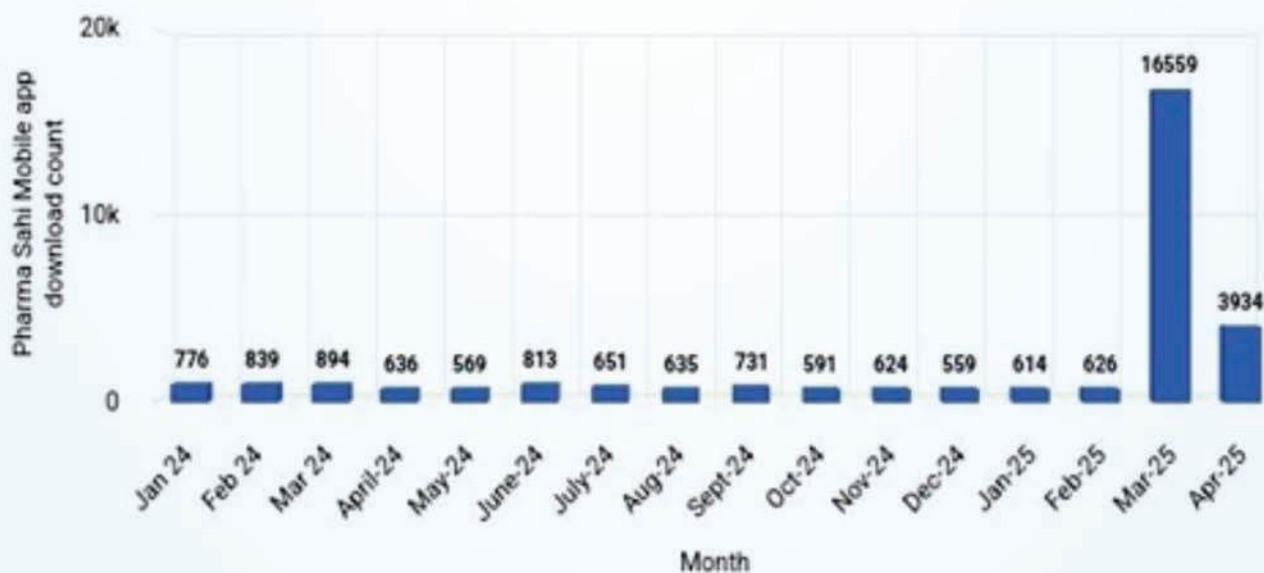


Chart 4: Number of Pharma Sahi Daam Mobile app downloads



Chart 5: Number of User logins in IPDMS 2.0



Chart 6: Number of tickets raised/ resolved at IPDMS help-desk

INTERNATIONAL NEWS

FDA Grants Marketing Authorization of First Home Test for Chlamydia, Gonorrhea and Trichomoniasis (March 28, 2025)



The U.S. Food and Drug Administration granted marketing authorization to Visby Medical for the Visby Medical Women's Sexual Health Test. This is the first diagnostic test for chlamydia, gonorrhea and trichomoniasis that can be purchased without a prescription and performed entirely at home. The test is intended for females with or without symptoms and delivers results in approximately 30 minutes. According to the Centers for Disease Control and Prevention's Sexually Transmitted Infections (STI) Surveillance Report, more than 2.2 million cases of chlamydia and gonorrhea were diagnosed and reported in the U.S. in 2023. Additionally, it is estimated that trichomoniasis is the most prevalent nonviral STI worldwide, affecting approximately 2.6 million people in the U.S., according to the CDC's treatment guidelines. Typically, all three infections can be treated with antibiotics, but if left untreated, can cause serious health complications for patients, including infertility.

[\(Read more\)](#)

FDA Approves Novel Treatment for Hemophilia A or B, with or without Factor Inhibitors Medication Can be Given Up to Once Every 2 Months (March 28, 2025)

The U.S. Food and Drug Administration approved Qfitlia (fitusiran) for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients 12 years of age and older with hemophilia A or hemophilia B, with or without factor VIII or IX inhibitors (neutralizing antibodies). Hemophilia A and hemophilia B are genetic bleeding disorders caused by a



dysfunction or deficiency of coagulation factor VIII (FVIII) or IX (FIX), respectively. Patients with these hemophilias are unable to clot properly and may bleed for a longer time than normal after injury or surgery. They may also have spontaneous bleeding in muscles, joints and organs, which can be life-threatening. These bleeding episodes are typically managed by either on-demand, episodic treatment or prophylaxis using products containing FVIII or FIX, or a product that mimics a factor.

[\(Read more\)](#)

FDA Announces Plan to Phase Out Animal Testing Requirement for Monoclonal Antibodies and Other Drugs (April 10, 2025)



The U.S. Food and Drug Administration is taking a groundbreaking step to advance public health by replacing animal testing in the development of monoclonal antibody therapies and other drugs with more effective, human-relevant methods. The new approach is designed to improve drug safety and accelerate the evaluation process, while reducing animal experimentation, lowering research and development (R&D) costs, and ultimately, drug prices.

[\(Read More\)](#)

CAPACITY BUILDING OF STATE DRUGS REGULATORS OF BIHAR

NPPA participated in 09th Regional Training Programme on "Capacity Building of State Drugs Regulators of Bihar held during 03rd – 05th March, 2025 at Bihar Institute of Public Administration & Rural Development (BIPARD), Gaya, Bihar and delivered a presentation on the topic "Drug Price Control Order".



STATE LEVEL EVENTS/ SEMINARS BY PMRUs:

Twenty Eight (28) State and District level Events/ Seminars have been organized by 11 (Eleven) 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 for making awareness to 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 glimpse of the activities are as follows:

Glimpse of programs:



OTHER NEWS AND EVENTS



OTHER NEWS AND EVENTS



OTHER NEWS AND EVENTS



OTHER NEWS AND EVENTS





1. What are regulatory bodies for drugs/pharmaceuticals/medicines, and why do they matter?

Regulatory bodies for drugs/pharmaceuticals/medicines are organizations—usually run by governments—that make sure the medicines we take are safe, effective, and of high quality. Their job is to protect people's health by making sure no harmful or fake medicines reach the public.

2. How do these organizations help people?

They:

- Ensure that medicines are tested properly before being used
- Ensure quality, safety and efficacy of medicines that are being marketed
- Prevent unsafe or poor-quality drugs from being sold
- Monitor medicines even after they're on the market to catch any side effects
- Respond quickly to health risks by recalling dangerous products

3. Who are the main regulatory bodies around the world?

Here are some of the major ones:

- FDA** (U.S. Food and Drug Administration) – USA
- EMA** (European Medicines Agency) – European Union
- CDSCO** – National Drugs Regulatory Authority of India
- NPPA** - Regulatory body in India that controls the prices of pharmaceutical drugs

4. How do these agencies make sure a medicine is safe?

Before any new medicine can be given to people, these agencies look at:

- Results from lab and animal testing
- Clinical trials with human volunteers
- How the medicine is made and stored
- Whether the medicine's benefits outweigh the risks

5. What happens if a company doesn't follow the rules?

If a company breaks safety or quality rules, regulatory bodies can:

- Warn the company
- Stop the sale of the medicine
- Force a recall
- Shut down unsafe factories
- Take legal action to protect the public

6. What is pharmacovigilance, and why is it important?

Pharmacovigilance means carefully watching how medicines behave after they're in use. Sometimes, side effects only show up after a drug has been widely used.

Agencies collect reports and take action when something goes wrong, helping to keep people safe.

7. How do these organizations support people in need?

Many regulatory agencies work with humanitarian groups to ensure people in crises—like refugees or those in disaster zones—get access to safe medicines. They also help speed up access to essential drugs during emergencies, like during disease outbreaks or pandemics.

8. Are all medicines held to the same standards worldwide?

Not always, but international groups like the **World Health Organization (WHO)** and **International Council for Harmonisation (ICH)** work to create global standards. That way, everyone—no matter where they live—can trust the medicines they receive.



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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