NPPA
AFFORDABLE MEDICINES FOR ALL
सभी के लिए वहनीय दवाईयाँ

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

सत्यमेव जयते

Azadi Ka Amrit Mahotsav

AUSHADH SANDESH

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A Bi-monthly e-Newsletter

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 first 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.

I am happy to note that an insightful article titled "Evolution of drug pricing policy in the country" has been put together by the NPPA team. It gives a bird's eye overview of the evolution of the drug pricing policies in the country and the consequent Drugs Price Control Orders that were brought in. The changes in policies over period of time are influenced by myriad factors like changes in technology; global economic scenario; domestic socio-economic conditions. Currently NPPA is implementing the Drugs Price Control Order, 2013 that operationalizes the National Pharmaceutical Pricing Policy, 2012.

In continuation of our PMRU activities, nine (09) state and district-level events/seminars have been organized by six PMRUs in their respective states / UT. These events were aimed at making people aware of the fixation of ceiling prices 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)

Evolution of Drug Pricing Policies in the country

(By: NPPA Team)

A wide variety of products such as food grains, textiles, fertilizers etc., were regulated under the Essential Commodities Act, 1955 (EC, Act 1955) but not drugs. In the aftermath of World War-II there was shortage of essential medicines in the country and during the Indo-China war in 1962, the prices of medicines increased substantially. Therefore, the price control over drugs was first introduced in the country in 1962 under the Defence of India Act, 1915 with the promulgation of the Drugs (Display of Prices) Order, 1962 and the Drugs (Control of Prices) Order, 1963. These orders led to freezing of the prices of drugs with effect from 01.04.1963. Thereafter, a series of price control orders were notified through various orders in the country from time to time based on different principles. The span of control of prices as well as the nature of control of prices under various orders has varied as per the underlying principles in the respective Drug Policies.

Drugs Prices Display and Control Order, 1966

According to the Drugs Prices Display and Control Order of 1966, it was obligatory for manufacturers of drugs to obtain prior approval of the Government if prices of such formulations were to be increased. However, based on the industry representations regarding increase in prices of raw materials and packing materials, which were not frozen, the Government amended the 1966 Order in August 1968. According to this amendment[1]:

- Formulations sold under pharmacopoeia names were exempted from price approval
- Prices of existing formulations were increased on a case-by case basis after studying the cost structure and appropriateness for the increases sought by manufacturers
- New drugs developed through original research and marketed for the first time were also exempted from price control.

In the meantime, in 1966 itself the government also requested the Tariff Commission (TC) to examine the cost structure of 18 essential bulk drugs and their formulations. The TC submitted its **"Report on the Fair Selling Prices of Drugs and Pharmaceuticals"** to the Government in August 1968. Based on the Commission report, the government on 30th April 1970 undertook following steps[2]:

Prices of 18 bulk drugs, 49 formulations studied by TC and other formulations too were brought under price control based on "cost-plus" formula. Detailed formula for calculating the retail price was given along with the percentage of markup.

It was also informed that a suitable order incorporating the formula would be promulgated soon.

Drugs (Price Control) Order, 1970

Accordingly, Drugs (Price Control) Order, 1970 was promulgated on 16th May 1970 under the Section 3 of the EC Act, 1955 as was the Drugs Prices Display and Control Order, 1966. It was the first comprehensive price control order and the formula fixed was as under:

$$RP = (MC + CC + PC) \times (1 + MU \div 100)$$

Where, RP=Retail Price, MC=Material Cost, CC=Conversion cost or cost of formulation, PC=Packing charges and includes cost of packing material and packaging expenses, MU=Mark-up meant to cover forwarding charges, promotion expenses, after sales service and trade commission up to the retail level

The mark-up fixed ranged from 75% in the case of formulations to 150% for new drugs i.e. those containing new entities. The mark-up could be increased to 100% in case of new combinations of existing drugs. Manufacturers thus had the option of fixing prices within the ceiling of 75% mark-up for 18 essential drugs, and 150 for others. This was, however, subject to the condition that gross profit before tax did not exceed 15% of sales[3]. Hence, the DPCO, 1970 involved direct control on the profits of the companies and indirect control on selected essential drugs while capping remaining medicines at their prevailing price[4].

Drug Policy-1978 and the Drugs Prices (Control) Order, 1979

Based on the recommendations of Hathi Committee, the government evolved the first Drug Policy of India which was promulgated in March 1978 (DP, 1978) and the Drugs Prices (Control) Order 1979 (DPCO, 1979). The stated objectives of the DP, 1978 were[5]:

a. Country should be self-reliant in technology;

b. There should be self-sufficiency in drugs; and

c. Quality drugs should be adequately available at reasonable prices.

DPCO, 1979 was promulgated on 31st March 1979 and price control was imposed on 370 bulk drugs and formulations made therefrom. Based on Hathi Committee recommendations, the bulk drugs were classified into three categories based on their therapeutic efficacies. The three categories were authorized different levels of mark-ups as indicated below:

i. Category I of the third schedule of DPCO,1979 (Life-saving): 40% (23 No. of drugs)

ii. Category II of the third schedule of DPCO,1979 (Essential): 55% (20 No. of drugs)

iii. Category III of the third schedule of DPCO,1979 (Less essential): 100% (327 No. of drugs)

Formulations made from these 370 drugs constituted more than 80% of the market and the formulations considered most essential were given a lower mark-up so as to keep their prices low. The formula for working out the retail price was:

$$RP = (MC + CC + PM + PC) \times (MU + 100)/100 + \text{taxes}$$

Where, RP: Retail Price, MC: Material Cost, CC: conversion cost, PM: Packing Material Cost, PC: packing cost, MU: Mark-Up.

In the case of the imported formulations[6], the prices were fixed differently. The landed cost was to form the basis for fixing its price along with such margin as the government may allow from time to time. Usually, a maximum margin of 50% on the landed costs was provided for fixing maximum retail prices (MRPs). Provisions in DPCO-1979 were made for encouraging R&D activity by way of exempting the prices of locally conducted research and R&D-developed new products from control.

The concepts of fixation of the retention price and pooled price and fixation of leader prices of formulations were introduced in DPCO, 1979. A provision of Drug Prices Equalization Account (DPEA) for collecting excess amounts from companies was also introduced. If the companies had utilized bulk drugs produced at lower

prices than the prices allowed/considered for price fixation of their formulations, excess amount was to be deposited in DPEA. However, the implementation of DPEA created different kinds of administrative problems and led to litigation[7]. Currently, Department of Pharmaceuticals (DoP), Government of India is the custodian of the DPEA.

Drugs Prices (Control) Order, 1987

The **Drug Policy 1986** was implemented through the Drugs Prices (Control) Order, 1987 (DPCO, 1987) and it also drew from the recommendations of the Kelkar Committee Report. In DPCO, 1987, the numbers of bulk drugs under price control were significantly reduced from 370 to 142.

As laid down in the DP, 1986; in the DPCO 1987, two categories of formulations and bulk drugs (required to make such formulations) were promulgated to be price controlled. The terminology of "mark-ups" was changed to MAPE.

Drugs Prices (Control) Order, 1995 (DPCO,1995)

Based on the New Drug Policy, 1994, the new DPCO was announced in 1995. 74 bulk drugs were identified (listed in Schedule-I) for which the prices were to be controlled under DPCO, 1995. These represented 40% of the total market[8]. NPPA was also set-up in 1997 and it continued with the implementation of DPCO, 1995. The NPPA fixed/revised the prices on the basis of the DPCO formula giving MAPE of 100% on the ex-factory cost of the medicine. Under DPCO-1995, the prices of bulk drugs and formulations were fixed on the basis of actual costs plus a mark-up and the prices of formulations (final drugs) were fixed on a cost based formula, as follows :

$$\text{Retail Price} = (\text{M.C} + \text{C.C.} + \text{P.M.} + \text{P.C.}) \times (1 + \text{MAPE}/100) + \text{E.D.}$$

Where M.C denotes material cost including drug cost and other pharmaceutical aids; C.C. indicates conversion cost; P.M. means packing material cost of formulation; P.C. connotes packing of shipment; MAPE denotes Maximum Allowable Post-Manufacturing Expenses which includes trade margin as well as distribution and promotion costs and E.D. indicates excise duty.

National Pharmaceutical Pricing Policy, 2012 (NPPP, 2012)

NPPP, 2012 was notified on 07.12.2012. The key principles for regulating the prices of essential drugs were identification of 'essentiality' of medicines/formulations; intent to control the prices of essential formulations only and not the bulk drugs used in the making of such formulations; and the prices of essential medicines to be determined based on 'market based' information.

The NPPP-2012 was essentially the 'modified' concept of Drug Policy-2002 where the intention announced was to control the price of 'essential medicines' based on the market capture of such formulations as determined and published by reputed private organizations like the ORG-MARG utilizing the MAT values of essential formulations in each therapeutic category. The NPPP, 2012 envisages regulation of the prices of formulations only, identified on the basis of essentiality of drugs. Further, the basis of fixing the ceiling price of formulations has been changed from cost based to Market Based Pricing (MBP) in NPPP-2012. Thus, as per NPPP-2012, the three aspects of the regulation of prices of drugs are as follows:

- **Essentiality of drugs** as specified under National List of Essential Medicines (NLEM): Price of medicines is fixed because they are considered essential.
- **Regulating the prices of formulations only** (i.e., medicines used by consumers and not applicable to any

upstream products such as bulk drugs or intermediaries), as opposed to regulation of both bulk drugs and their formulations under DPCO-1995.

- Fixing the ceiling price of formulations through Market Based Pricing (MBP) as opposed to cost based pricing in DPCO-1995 as it is easy to obtain price data than cost data.

Drugs (Prices Control) Order, 2013 (DPCO-2013)

Based on the principles of NPPP, 2012, the DPCO-2013 was notified on 15th May, 2013 under section 3 of the EC Act, 1955. It marked the shift from Cost Based Pricing (CBP) to Market Based Pricing (MBP). Also, prices of formulations were to be fixed instead of bulk drugs.

- To conclude, it can be opined that enabling provisions for drug price control are embedded in different statutes as indicated in **Figure1 below.**

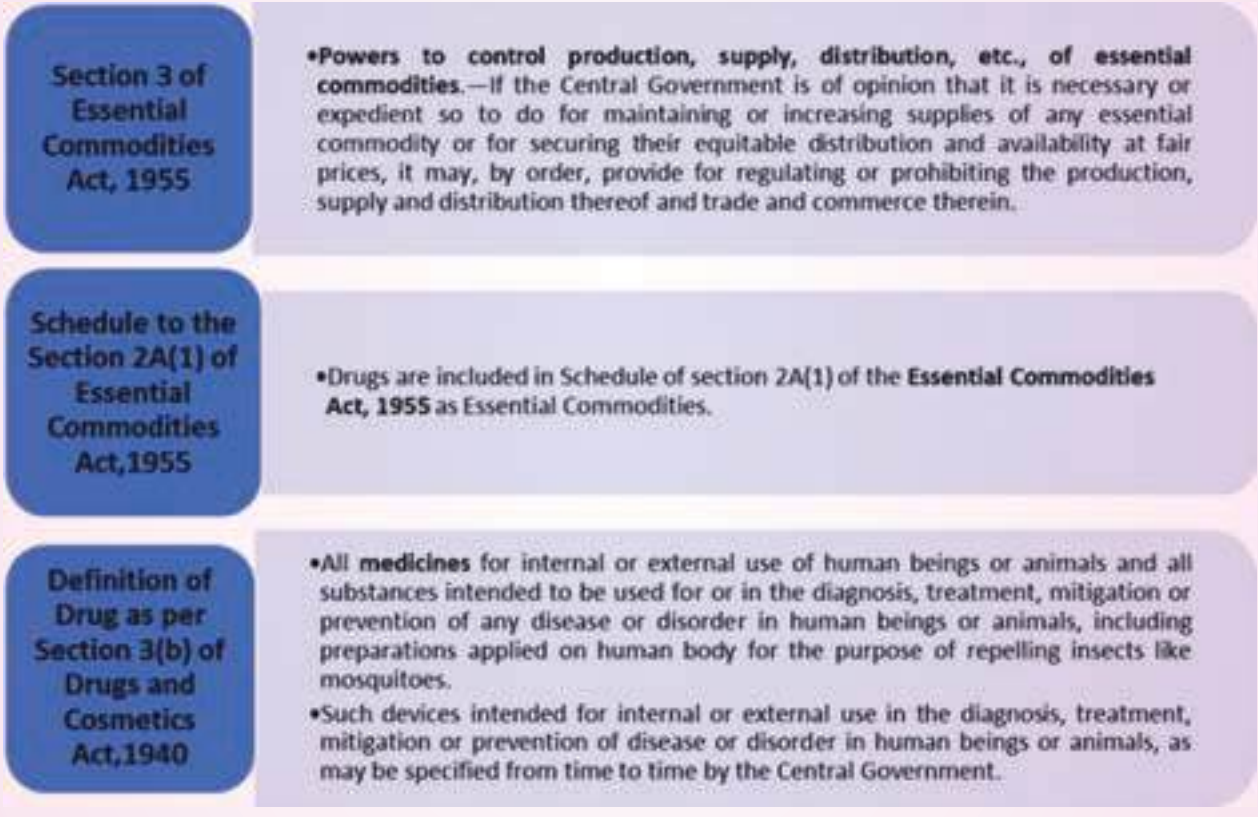

Figure 1: Enabling provisions for Drug Price Control

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[1] Discussion paper#236: Government's Policies and Growth of Pharmaceutical Industry in India 1947-2018: A Review Prasanta Kumar Ghosh, RIS

[2] https://indianculture.gov.in/flipbook/1032

[3] Joseph, R.K. (2015). Pharmaceutical Industry and Public Policy in Post-reform India

[4] Ajay Bhaskarabhatla, 2018. "Regulating Pharmaceutical Prices in India," India Studies in Business and Economics, Springer, number 978-3-319-93393-1, June.

[5] https://www.epw.in/journal/1978/21/special-articles/new-drug-policy.html

[6] Discussion paper#236: Government's Policies and Growth of Pharmaceutical Industry in India 1947-2018: A Review Prasanta Kumar Ghosh, RIS

[7] ibid

[8] https://pharmaceuticals.gov.in/policy/pharmaceutical-policy-2002

REGULATORY NEWS

News related to pricing of drugs

1. Ceiling prices of 928 formulations are effective as on 12.3.2025 of which Ceiling prices for 755 scheduled formulations have been fixed / refixed under National List of Essential Medicines, 2022 as follows:

Therapeutic Category	No. of Medicines	No. of Formulations
Anti-infective Medicines	62	171
Anticancer Medicines	59	119
Neurological Disorder Medicines	18	59
Psychiatric Disorder Medicines	14	41
Cardiovascular Medicines	25	59
HIV Management Medicines	20	23
Analgesics, Antipyretics, Non-steroidal Anti-inflammatory Drugs (NSAIDs)	11	24
Anti-Diabetic drugs	8	11
Hormones, other Endocrine Medicines and Contraceptives	16	33
Others	112	215
Unique Drugs / Formulations	327*	755

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

2. Retail prices for 3206 (approx.) new drugs have been fixed under DPCO, 2013 till 12.03.2025. As on 12.03.2025, 262 Authority meetings have been conducted of which 130 have been conducted under DPCO 2013. The details of the recent meetings are given as below:

Meeting No.	Held on	Prices Approved & Notified
261st (overall) & 129th Meeting under DPCO 2013	29.01.2025	(i) Retail prices for 42 formulations notified vide S.O. 660 (E) dated 07.02.2025. (ii) Revision of Ceiling price of 2 scheduled formulation viz. • Azithromycin Tablet 250mg from ₹11.65 to ₹11.67 per tablet • Amoxicillin (A) + Clavulanic acid (B) Powder for Injection 1 g (A) +200mg (B) from ₹140.66 to ₹141.65 perviral based on review orders passed by of DoP. The prices were notified vide S.O. 659(E)dated 07.02.2025 read with S.O. 910(E) dated 20.2.2025 (iii) Revision of Retail Price of Each film coated tablet containing Cilnidipine IP 20mg Telmisartan IP 40mg for M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Glenmark Pharmaceuticals Limited based on review orders passed by of DoP. The price is notified vide S.O. 661 (E)dated 07.02.2025.
262nd (overall) & 130th Meeting under DPCO 2013		(i) Retail prices for 53 formulations notified vide S.O. 1094(E) dated 05.03.2025.

3. Details of retail prices notified for various formulations based on the decision taken in 129 and 130th meetings are as follows:

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	36	Tablet/ Solution	0.40-19.01
2	Analgesic, anti-inflammatory and Pain management	14	Tablet/Capsule/Suspension	0.52-33.25
3	Anti-bacterial	4	Tablet/Gel/ Suspension	3.72-17.61
4	Anti-hypertensive	5	Tablet	6.26-15.07
5	Cardiovascular	16	Tablet/Capsule	5.75-53.70
6	Vitamins/Minerals/ Nutrients	1	Tablet	12.31
7	Anti-Infective	3	Tablet/ Suspension	2.00-132.58
8	Others	16	Tablet/ Capsule Suspension/Drops/Enema	0.73-39.08

4. The Authority in its 130th Meeting held on 25.2.2025 decided that w.e.f. next financial year i.e. 01.04.2025, Form I applications shall be accepted only through IPDMS 2.0. Accordingly, O.M. dated 6.3.2025 was issued clarifying that the application in Form I for retail price fixation of new drugs filed only through IPDMS 2.0 shall be considered for processing by NPPA. In case any difficulty is encountered in filling the form I on IPDMS 2.0, the applicants may report the same on following email- nppa-ipdms@gov.in and pricing-nppa@gov.in .

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 Apr'24 to Feb'25:

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

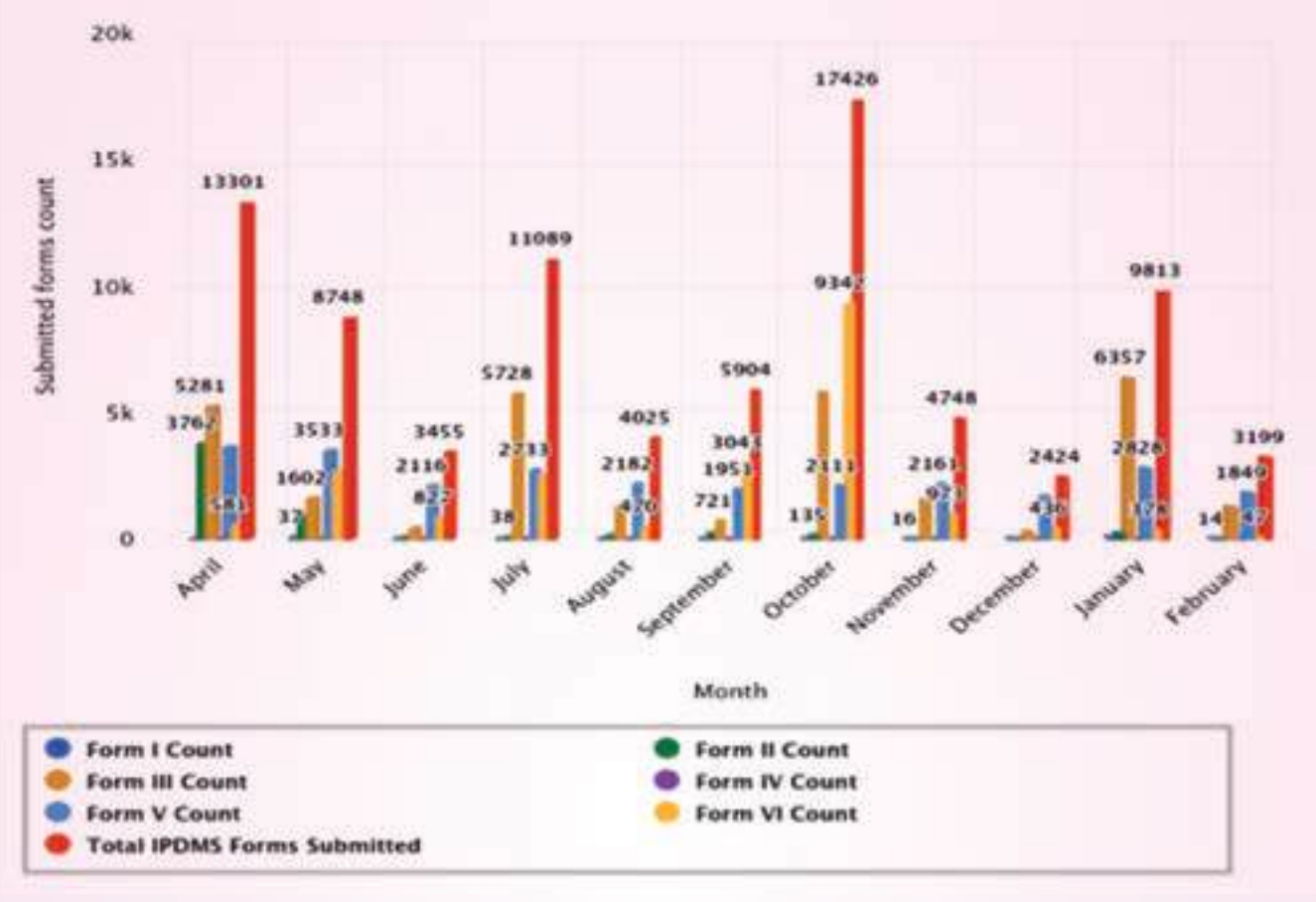

Chart 2: Number of statutory forms filed on IPDMS as on 28th February 2025

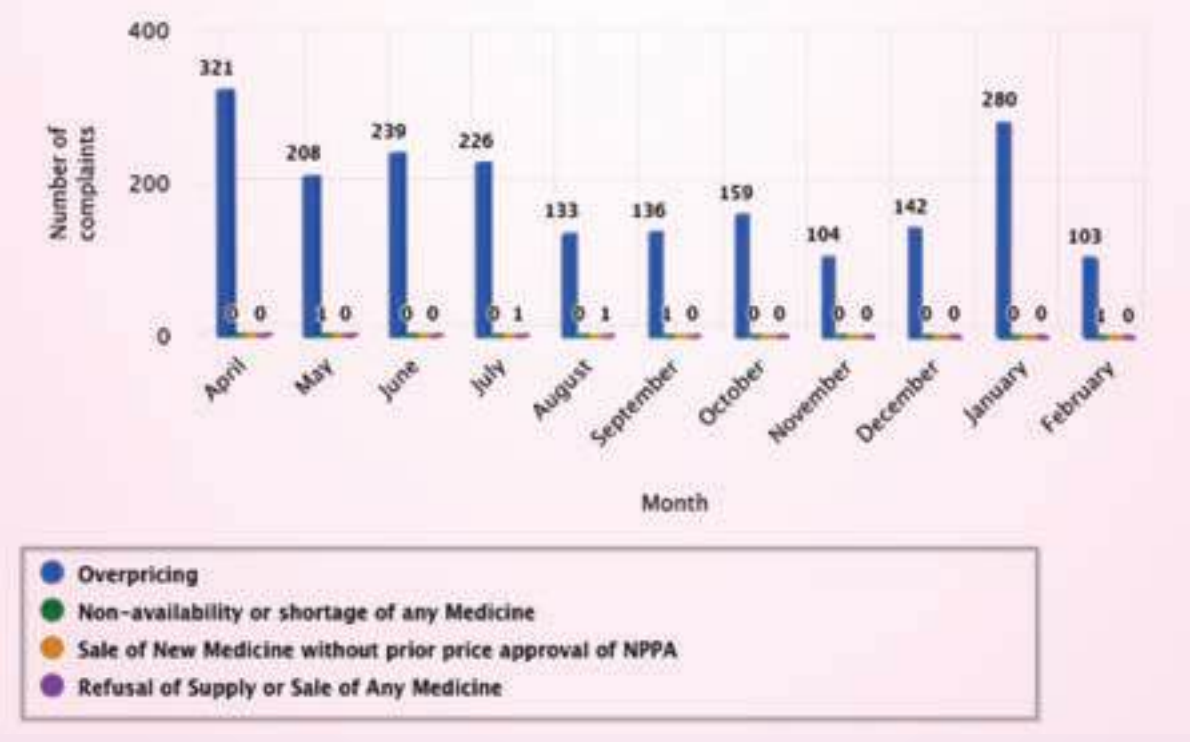

Chart 3: Number of complaints received on IPDMS/ Pharma Jan Samadhan

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 Issues Comprehensive Draft Guidance for Developers of Artificial Intelligence-Enabled Medical Devices Guidance Shares Strategies to Address Transparency and Bias, while Providing Key Considerations and Recommendations on Product Design, Development and Documentation (January 06, 2025)

The U.S. Food and Drug Administration issued draft guidance that include recommendations to support development and marketing of safe and effective AI-enabled devices throughout the device's Total Product Life Cycle. The guidance, if finalized, would be the first guidance to provide comprehensive recommendations for AI-enabled devices throughout the total product lifecycle, providing developers an accessible set of considerations that tie together design, development, maintenance and documentation recommendations to help ensure safety and effectiveness of AI-enabled devices. This guidance complements the recently issued final guidance on predetermined change control plans for AI-enabled devices, which provides recommendations on how to proactively plan for device updates once the product is on the market.

(Read more)

FDA Proposes Framework to Advance Credibility of AI Models Used for Drug and Biological Product Submissions (January 06, 2025)

The U.S. Food and Drug Administration issued draft guidance to provide recommendations on the use of artificial intelligence (AI) intended to support a regulatory decision about a drug or biological product's safety, effectiveness or quality. This is the first guidance the agency has

issued on the use of AI for the development of drug and biological products.

The FDA has substantial experience in reviewing regulatory submissions with AI components. Since 2016, the use of AI in drug development and in regulatory submissions has exponentially increased. AI can be used in various ways to produce data or information regarding the safety, effectiveness, or quality of a drug or biological product. For example, AI approaches can be used to predict patient outcomes, improve understanding of predictors of disease progression and process and analyze large datasets (e.g., real-world data sources or data from digital health technologies).

(Read more)

FDA Approves Novel Non-Opioid Treatment for Moderate to Severe Acute Pain First Drug Approved in New Class of Non-Opioid Pain Medicines; Agency Continues to Take Steps to Support New Approaches for Pain Management (January 30, 2025)

The U.S. Food and Drug Administration approved Journavx (suzetrigine) 50 milligram oral tablets, a first-in-class non-opioid analgesic, to treat moderate to severe acute pain in adults. Journavx reduces pain by targeting a pain-signaling pathway involving sodium channels in the peripheral nervous system, before pain signals reach the brain. Journavx is the first drug to be approved in this new class of pain management medicines. Pain is a common medical problem and relief of pain is an important therapeutic goal. Acute pain is short-term pain that is typically in response to some form of tissue injury, such as trauma or surgery. Acute pain is often treated with analgesics that may or may not contain opioids.

Read more)

FDA Alerts Patients of Potential to miss Critical Safety Alerts Due to Phone Settings When Using Smartphone-Compatible Diabetes Devices Missed Alerts Can Be Caused by Hardware and Software Changes, Updates and Configurations (February 05, 2025)

The U.S. Food and Drug Administration is alerting patients of a safety concerns regarding diabetes devices, such as continuous glucose monitors (CGMs), insulin pumps and automated insulin dosing systems, that rely on a smartphone to deliver critical safety alerts. Users of these smartphone-compatible diabetes devices can configure alert settings, such as which alerts to receive, how often and how the alerts are delivered (e.g. audible, vibration, text only) through the app on their phone. The FDA has received medical device reports in which users report these alerts are not being delivered or not being heard, in cases where the users thought they had configured the alerts to be delivered. In some cases, missing these alerts may have contributed to serious harm, including severe hypoglycemia (low blood sugar), severe hyperglycemia (high blood sugar), diabetic ketoacidosis (when the body does not have enough insulin to use blood sugar for energy) and death.

(Read more)

FDA Approves First Rapid-Acting Insulin Biosimilar Product for Treatment of Diabetes (February 14, 2025)

The U.S. Food and Drug Administration approved Merilog (insulin-aspart-szjj) as biosimilar to Novolog (insulin aspart) for the improvement of glycemic control in adults and pediatric patients with diabetes mellitus. Merilog, a rapid-acting human insulin analog, is the first rapid-acting insulin biosimilar product approved by the FDA. As a rapid-acting insulin, Merilog helps to lower mealtime blood sugar spikes to improve control of blood sugar in people with diabetes. The approval is for both a 3 milliliter (mL) single-patient-use prefilled pen and a 10 milliliter (mL) multiple-dose vial. Merilog is the third insulin biosimilar product approved by the FDA and joins the two long-acting insulin biosimilar products approved in 2021 by the FDA. Approval of biosimilar products can increase patient access to safe and effective treatment options.

(Read more)

FDA Approves First Treatment for Cerebrotendinous Xanthomatosis, a Rare Lipid Storage Disease (February 21, 2025)

The U.S. Food and Drug Administration approved Ctexli (chenodiol) for the treatment of cerebrotendinous xanthomatosis (CTX) in adults. Ctexli is the first FDA-approved drug to treat CTX, a very rare lipid storage disease. CTX is a genetic metabolic disorder caused by a mutation in a gene called CYP27A1 resulting in a deficiency of the enzyme that is important in the body's ability to break down fats. Due to reduced bile acid production in the liver, patients with CTX are unable to break down cholesterol in a normal way, resulting in deposition of atypical cholesterol metabolites (substances that result from the breakdown of cholesterol) in various places in the body including the brain, liver, skin and tendons, leading to damage to those organs and tissues. Ctexli works to replace deficient levels of one of the bile acids, reducing the abnormal deposits of cholesterol metabolites thought to be responsible for clinical abnormalities in CTX.

(Read more)

Capacity Building of State Drugs Regulators of Tamil Nadu, Kerala and Karnataka

NPPA actively participated in 08th Regional Training Programme on "Capacity Building of State Drugs Regulators" of Tamil Nadu, Kerala and Karnataka organized by Central Drugs Standard Control Organization in collaboration with Department of Drugs Control Administration, Government of Tamil Nadu held at Anna Administrative Staff College, Chennai from 06th – 08th January, 2025.

State Level Events/ Seminars by PMRUs

Nine (09) State and District level Events/ Seminars have been organized by 6 PMRUs in their respective States/ UTs viz. Puducherry, Kerala, Goa, Jharkhand, Ladakh, 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:

OTHER NEWS AND EVENTS

FREQUENTLY ASKED QUESTIONS

1. What are rare diseases?

Rare diseases are medical conditions that affect a small percentage of the population. In many regions, a disease is considered rare if it affects fewer than 1 in 2,000 people. These diseases can range from genetic conditions to autoimmune disorders and more.

2. How many rare diseases are there?

There are over 7,000 known rare diseases, and new ones are discovered regularly. Collectively, rare diseases affect an estimated 400 million people worldwide.

3. What are the different causes of rare diseases?

Rare diseases can be caused by:

- Genetic mutations may be Inherited from parents or caused by new mutations.
- Environmental factors like Exposure to toxins or infections that trigger rare conditions.
- Immune system dysfunction like Autoimmune diseases where the body's immune system attacks healthy cells.

4. How are rare diseases diagnosed?

Diagnosis can be challenging and may take time due to the rarity and complexity of these diseases. Diagnosis of rare diseases typically involves:

- A thorough medical history and physical exam
- Genetic testing or biomarker analysis
- Imaging studies (X-rays, MRIs) to assess internal organ damage
- Special blood tests or tissue biopsies

5. Does India have a National Rare Disease Policy?

Ministry of Health & Family Welfare launched National Policy for Rare Diseases (NPRD) in March 2021. The key features of NPRD, 2021 are as under:

The rare diseases have been identified and categorized into 3 groups as below:

Group 1: Disorders amenable to one-time curative treatment.

Group 2: Diseases requiring long term/lifelong treatment with relatively lower cost of treatment.

Group 3: Diseases for which definitive treatment is available but challenges are to make optimal patient selection for benefit, very high cost and lifelong therapy.

Currently, 63 rare diseases are included under National Policy for Rare Diseases on recommendation of Central Technical Committee for Rare Diseases (CTCRD).

Feedback and Complaint Redressal

Grievance Redressal

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

Information Dissemination

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

Collaboration with State Governments

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

NPPA
AFFORDABLE MEDICINES FOR ALL
सभी के लिए वहनीय दवाईयाँ

NATIONAL PHARMACEUTICAL PRICING AUTHORITY

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