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

Shri Kamlesh Kumar Pant, IAS
Chairman
National Pharmaceutical Pricing Authority
Department of Pharmaceuticals
Ministry of Chemicals & Fertilizers
Government of India

It is with great pleasure that I bring to you the Fifteenth issue of the NPPA bi-monthly e-Newsletter NPPA that strives to disseminate information catering to the interests of the different stakeholders. For this edition of the e-newsletter, NPPA team has tried to throw light on the use of Antibiotics and their classification. World Health Organisation's (WHO) AWaRe (Access, Watch and Reserve) classification of antibiotics has been used to analyse different facets of prescription and sales data to throw light on use of antibiotics.

I am happy to share that NPPA under Consumer Awareness, Publicity and Price Monitoring (CAPPM) Scheme has set up the 31st Price Monitoring and Resource Unit (PMRU) in the UT of Lakshadweep on 25th January, 2024. Growing network of PMRUs is helping NPPA to percolate the benefits of DPCO, 2013 at grass-root level to the consumers at large.

I am also happy to share that in the continuation to webinar series, Forty-three (43) State and District level Events/ Seminars have been organized by 16 PMRUs in their respective States/ UTs viz. Puducherry, Telangana, Jammu & Kashmir, Kerala, Uttar Pradesh, Goa, Jharkhand, Ladakh, Madhya Pradesh, West Bengal, Mizoram, Maharashtra, Chhattisgarh, Haryana, Punjab and Tripura. These events were aimed at generating awareness 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. etc.

I trust with effort of the editorial team, the Newsletter would help stakeholders stay up-to-date with the latest information on government policies/programmes and upcoming events etc.

NPPA wishes good health to all its readers; stay safe, stay healthy.

With best wishes

(Kamlesh Kumar Pant)

An analysis of Antibiotics use as per WHO AWaRe classification

(By: NPPA Team)

Introduction

The serendipitous discovery of penicillin by Alexander Fleming, a bacteriologist at St. Mary's hospital, London in 1928 and its introduction in 1940s for treatment purposes of various bacterial infections is one of the greatest advances in therapeutics. Penicillin which was first isolated from the fungus Penicillium was later on isolated from other microorganisms, which led to a new term, antibiotics. Penicillin heralded the dawn of the 'age of antibiotics'[1].

Using similar discovery and production techniques, researchers discovered many other antibiotics in the 1940s and 1950s: streptomycin, chloramphenicol, erythromycin, vancomycin, and others[2]. The antibiotics are used for treatment of bacterial infections.

There are several ways of classifying antibiotics. The most common classification schemes are based on their molecular structures, mode of action and spectrum of activity. Others include route of administration (injectable, oral and topical). Antibiotics within the same structural class generally show similar pattern of effectiveness, toxicity and allergic potential side effects. Some common classes of antibiotics based on chemical or molecular structures include Beta-lactams, Macrolides, Tetracyclines, Quinolones, Aminoglycosides, Sulphonamides, Glycopeptides and Oxazolidinones[3].

Rise of Antimicrobial resistance (AMR)

Antimicrobials - including antibiotics, antivirals, antifungals and antiparasitic - are medicines used to prevent and treat infections in humans, animals and plants. Antimicrobial resistance (AMR) occurs when bacteria, viruses, fungi and parasites change over time and no longer respond to medicines making infections harder to treat and increasing the risk of disease spread, severe illness and death[4]. AMR remains one of the top global public health threats facing humanity and was associated with the death of close to 5 million people globally in 2019[5].

As part of AMR, the global rise in antibiotic resistance poses a significant threat, diminishing the efficacy of common antibiotics against widespread bacterial infections. The 2022 Global Antimicrobial Resistance and Use Surveillance System (GLASS) report highlights alarming resistance rates among prevalent bacterial pathogens. Median reported rates in 76 countries of 42% for third-generation cephalosporin-resistant E. coli and 35% for methicillin-resistant Staphylococcus aureus are a major concern. For urinary tract infections caused by E. coli, 1 in 5 cases exhibited reduced susceptibility to standard antibiotics like Ampicillin, co-trimoxazole, and fluoroquinolones in 2020. This is making it harder to effectively treat common infections[6].

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[1]https://www.acs.org/education/whatischemistry/landmarks/flemingpenicillin
[2]https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5403050/
[3]http://www.bluepenjournals.org/ijambr/pdf/2016/October/Etebu_and_Arikekpar.pdf
[4]https://www.who.int/health-topics/antimicrobial-resistance
[5]https://www.who.int/news/item/08-02-2024-who-medically-important-antimicrobial-list-2024

AWaRe (Access, Watch and Reserve) classification of WHO

The AWaRe (Access, Watch and Reserve) classification of antibiotics was developed in 2017 by the WHO Expert Committee on Selection and Use of Essential Medicines as a tool to support antibiotic stewardship efforts at local, national and global levels. Antibiotics are classified into three groups: **Access, Watch and Reserve,** taking into account the impact of different antibiotics and antibiotic classes on antimicrobial resistance, to emphasize the importance of their appropriate use.

Includes antibiotics that have activity against a wide range of commonly encountered susceptible pathogens while also showing lower resistance potential than antibiotics in the other groups.

Selected Access group antibiotics are recommended as essential first or second choice empiric treatment options.

Includes antibiotic classes that have higher resistance potential and includes most of the highest priority agents among the Critically Important Antimicrobials for Human Medicine and/or antibiotics that are at relatively high risk of selection of bacterial resistance.

Selected Watch group antibiotics are recommended as essential first or second choice empiric treatment options for a limited number of specific infectious syndromes.

This group includes antibiotics and antibiotic classes that should be reserved for treatment of confirmed or suspected infections due to multi-drug-resistant. Reserve group antibiotics should be treated as "last resort" options.

These antibiotics should be accessible, but their use should be tailored to highly specific patients and settings, when all alternatives have failed or are not suitable.

AWaRe list is updated every two years[7].The latest classification released by WHO in 2023 has a total of 257 medicines classified under three categories i.e., **Access (87), Watch (141) and Reserve (29).**

Results of the National Centre for Disease Control (NCDC) Survey

The National Centre for Disease Control's "Report of the First Multicentric Point Prevalence Survey of Antibiotic Use at 20 NAC-NET Sites[8]" for the period November 2021 to April 2022 reveals that 45% patients were prescribed antibiotics for therapeutic indications, while 55% were prescribed for prophylactic purpose. The survey also found that only 38% of the prescriptions were from Access group of antibiotics, 57% of the prescriptions were from the Watch group and only 2% were from the last resort Reserve Group.

Analysis of Sales of Antibiotics in Pharmatrac Database as per AWaRe classification

An analysis was undertaken of the antibiotics in retail channel based on the November 2023 market-based database of Pharmatrac available with NPPA. Data for ninety-five antibiotic medicines was captured and category wise details are as under:

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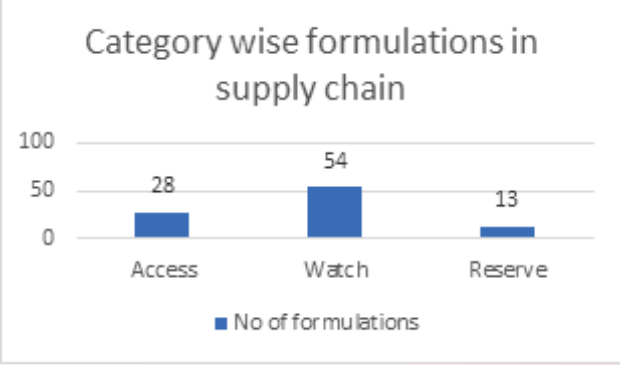
[6]https://www.who.int/news-room/fact-sheets/detail/antimicrobial-resistance
[7]https://www.who.int/publications/i/item/WHO-MHP-HPS-EML-2023.04
[8]https://pib.gov.in/PressReleasePage.aspx?PRID=1992467

Category	Number of formulations in supply chain of Indian market (% of drugs under supply chain)
Access	28 (29%)
Watch	54 (57%)
Reserve	13 (14%)

Source: Pharmatrac Database, November 2023



Of the total formulations in three categories, 29% are in Access group, 57% in Watch and 14% are from Reserve group. This data matches the prescription data for the Watch category as per NCDC study. However, there is variance in Access and Reserve categories. NCDC report indicates that only 2% of the antibiotics prescribed were from Reserve category while number of antibiotics from Reserve category form 14% of the total antibiotics available.

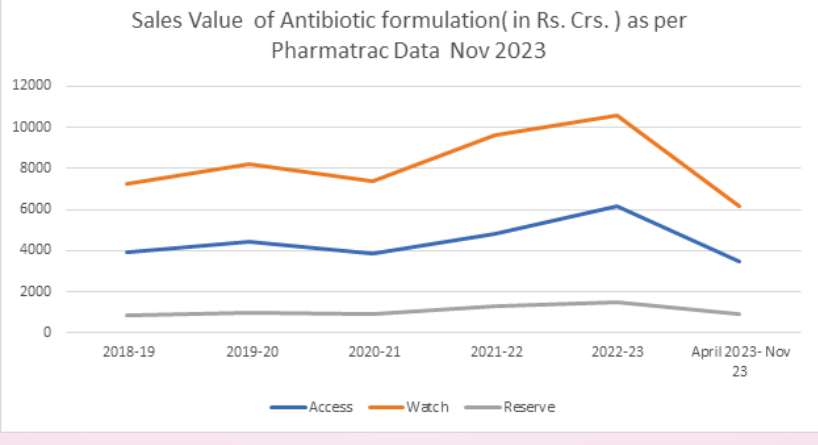
Sales Trend in last 5 years

An analysis of sales trend of these antibiotics for the last five years reveals that there is Compounded Annual Growth Rate (CAGR) of 11% in the sales vales over the period of last 5 years. The maximum annual growth of 16% is observed in the reserve category drugs, where only few medicines are in the supply chain. The second highest annual growth i.e. 12% is in the Access category. Watch group medicines have shown the growth rate of 10%. However, Access group of antibiotics showed a growth of 27% in 2022-23 over 2021-22 as shown in Table below:

Table 1: Sales Value of Antibiotic formulation(in Rs. Crore) and CAGR

Category	2018-19	2019-20	2020-21	2021-22	2022-23	April 2023-Nov 23	CAGR 2022-23 over 2018-19	Growth 2022-23 over 2021-22
Access	3905	4459	3837	4813	6130	3486	12%	27%
Watch	7223	8202	7350	9608	10578	6148	10%	10%
Reserve	832	956	944	1286	1511	929	16%	18%
Total	**11960**	**13617**	**12130**	**15706**	**18219**	**10563**	**11%**	**16%**

Source: Pharmatrac Database, November 2023



Sales of Top 5 antibiotics in different groups

As per the sales value in 2022-23 top 5 selling antibiotic in different categories are as under:

Table 2: Top 5 antibiotics sale in various categories

Category	Total Sales value of all the formulation in supply chain during 2022-23 (Rs crore)	Top five antibiotics	Sales value (2022-23)	Sales value (2022-23) of Top 5	% (col 5/ cov col 2)
1	2	3	4	5	6
Access	6130	Amoxicillin/clavulanic-acid	3415	5096	83
		Amikacin	720		
		Amoxicillin	346		
		Clindamycin	318		
		Cefalexin	297		
Watch	10578	Cefpodoxime-proxetil	1245	5899	56
		Ceftriaxone	1231		
		Meropenem	1149		
		Azithromycin	1138		
		Cefixime	1135		
Reserve	1511	Faropenem	438	1207	46
		Linezolid	382		
		Ceftazidime/avibactam	133		
		Fosfomycin_IV	127		
		Colistin_IV	127		

Total sales in the Watch category are the highest followed by Access group and then the Reserve Group. However, as per sales data around 8.29% were from Reserve group while NCDC prescription data for this group was only 2%. This may indicate that more antibiotics from Reserve group are being sold than what is captured through prescription data.

Conclusion

Given its importance for human health, the Government of India has developed a National Action Plan on Antimicrobial Resistance (NAP-AMR) 2017–2021. Strengthening the knowledge and evidence base through surveillance of AMR is one of the five key strategies of this action plan. A comprehensive strategy which is well aligned with activities under the National Action Plan-AMR, including stewardship efforts targeting pharmacists and evidence-based targeted awareness campaigns for all stakeholders, may be required to curb the inappropriate use of antibiotics.

REGULATORY NEWS

News related to pricing of drugs

- Ceiling prices for 731 scheduled formulations (National List of Essential Medicines, 2022) and Retail prices for 2734 non-scheduled formulations have been fixed under DPCO, 2013 till 29th February 2024.
- As on 29th February, 253 Authority meetings have been conducted of which 121 are under DPCO 2013. The details of the recent meetings are given as below:

Meeting No.	Held on	Prices Approved & Notified
251th (overall) & 119th Meeting under DPCO 2013	15.12.2023	(i) Retail prices for 19 formulations notified vide S.O. 15(E): dated 01.01.2024.
252nd (overall) & 120th Meeting under DPCO 2013	24.01.2024	(i) Retail prices for 39 formulations notified vide SO. S.O. 423(E) dated 02.02.2024.
253rd (overall) & 121st	20.02.2024	(i) Ceiling prices of 31 formulation were notified vide Meeting under DPCO 2013S.O. dated 938 (E) dated 28.02.2024 and S.O. 939 (E) dated 28.02.2024. (ii) Retail prices for 69 formulations notified vide SO. S.O. 937 (E) dated 28.02.2024.

- Details of retail prices notified for various formulations based on the decision taken in 119th ,120th and 121stAuthority 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	51	Tablets	8.04 – 16.33
2	Analgesic & anti-inflammatory	3	Tablets	5.14 – 21.80
3	Anti-Bacterial	2	Tablets	40.03 - 56.98
4	Anti-hypertensive	4	Tablet	10.39 – 16.24
5	Cardiovascular	12	Tablet / Capsule	5.35 – 19.21
6	Lower & upper respiratory tract infection	6	Tablet/Injection/ Suspension	3.10-1598.75
7	Pain Management	2	Tablet/Spray	3.12 – 21.80
8	Anti-Infective	5	Tablet/Injection/ Suspension	1.36-1584.24
9	Vitamins/Minerals/ Nutrients	2	Tablet/Oral Drops	5.53 – 8.03
10	Anti-Allergic	4	Syrup	0.94 – 1.22
11	Others	36	Capsule / Tablet/ Injection / Drop/Gel	0.90 – 15817.49

➲ Details of ceiling prices notified for various formulations based till 29.02.2024 under NLEM, 2022 :

Therapeutic Category	No. of Medicines	No. of Formulations
Anti-infective Medicines	62	163
Anticancer Medicines	59	118
Neurological Disorder Medicines	18	59
Psychiatric Disorder Medicines	14	41
Cardiovascular Medicines	25	58
HIV Management Medicines	20	23
Analgesics, Antipyretics, Non-steroidal Anti-inflammatory Drugs (NSAIDs)	11	25
Anti-Diabetic drugs	8	11
Hormones, other Endocrine Medicines and Contraceptives	16	33
Others	107	200
Grand Total	**320***	**731**

*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.

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 below charts showcase the statistics for the last six months:

Chart1: Total number of registered companies at month end

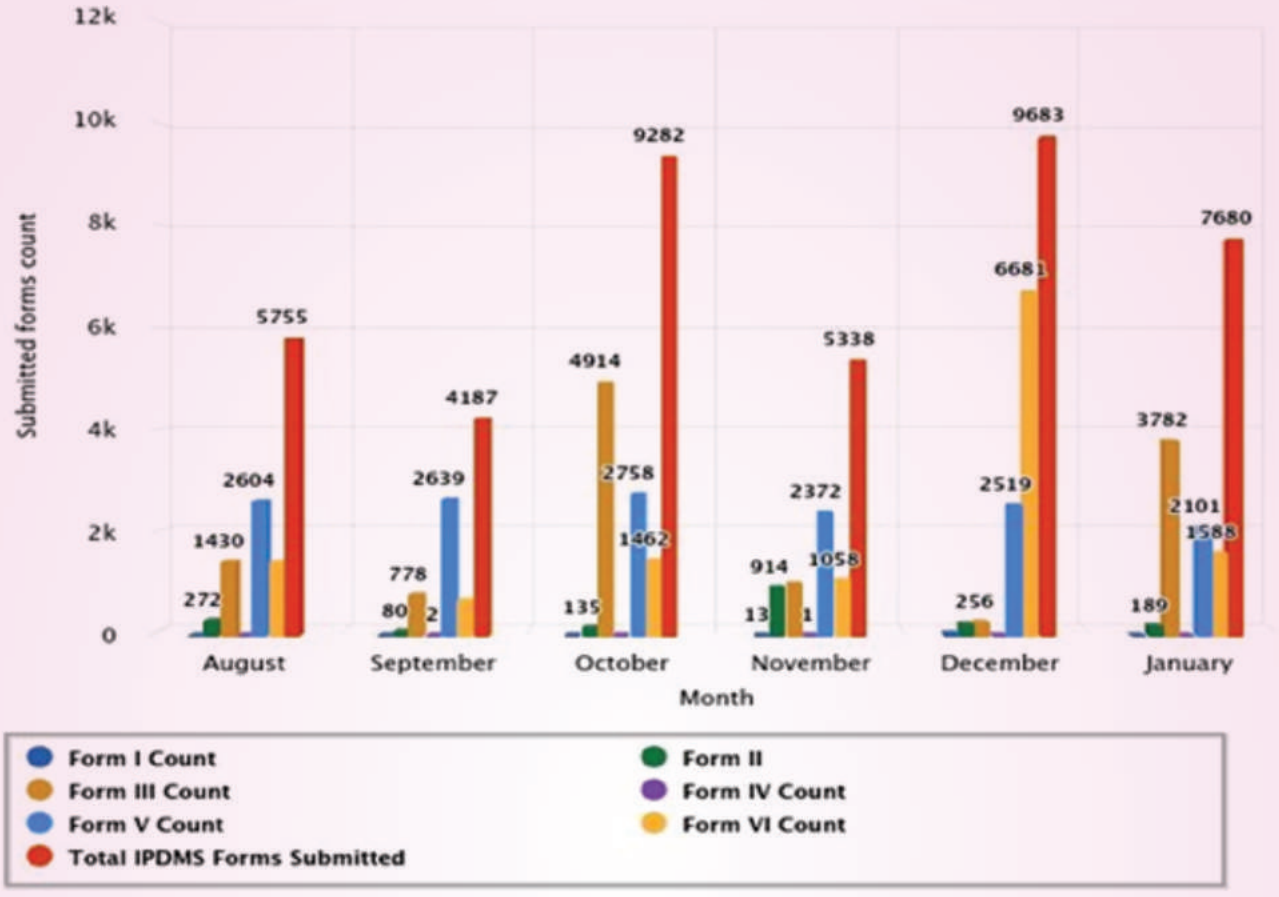


Chart 2: Number of statutory forms filed on IPDMS

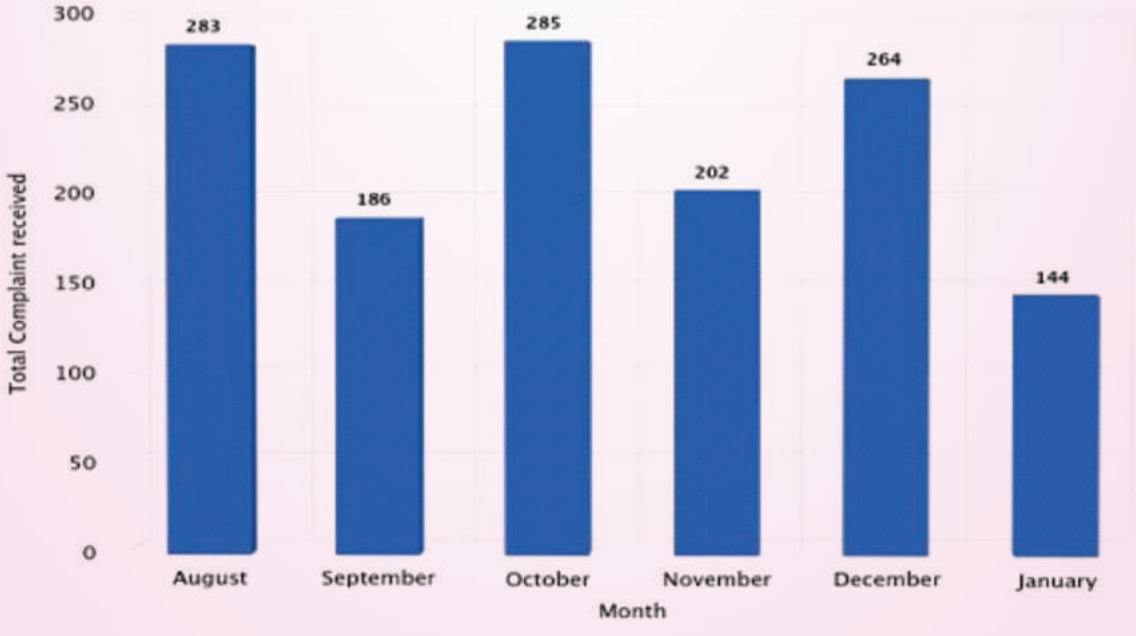


Chart 3: Number of complaints received on IPDMS/ PJS app

Chart 4: Number of Pharma Sahi Daam Mobile app downloads

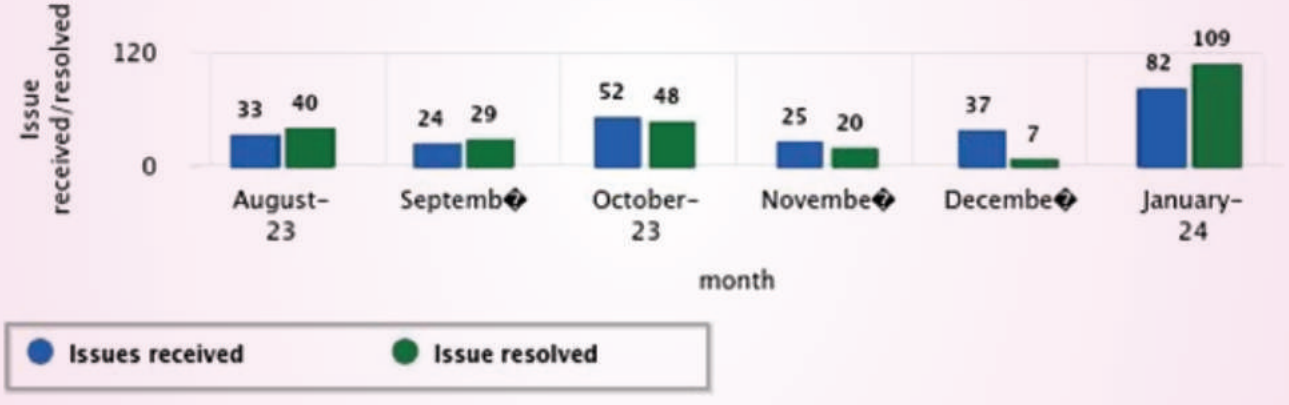


Chart 6: Number of tickets raised/ resolved at IPDMS helpdesk

INTERNATIONAL NEWS

FDA Facilitates Broader Adoption of Vaporized Hydrogen Peroxide for Medical Device Sterilization (January 08, 2024)

The U.S. Food and Drug Administration is announcing that it considers vaporized hydrogen peroxide (VHP) to be an established method of sterilization for medical devices, recognizing VHP's long history of safety and effectiveness. This update will facilitate broader adoption of VHP as a sterilization method for the medical device industry, is part of the agency's multi-pronged approach to reducing the use of ethylene oxide (EtO) where possible and further supports the agency's efforts to advance medical device supply chain resiliency.

Read more

FDA Approves First Cellular Therapy to Treat Patients with Unresectable or Metastatic Melanoma (February 16, 2024)

The U.S. Food and Drug Administration approved Amtagvi (lifileucel), the first cellular therapy indicated for the treatment of adult patients with a type of skin cancer (melanoma) that is unable to be removed with surgery (unresectable) or has spread to other parts of the body (metastatic) that previously has been treated with other therapies (a PD-1 blocking antibody, and if BRAF V600 mtation positive, a BRAF inhibitor with or without a MEK

inhibitor).

Read more

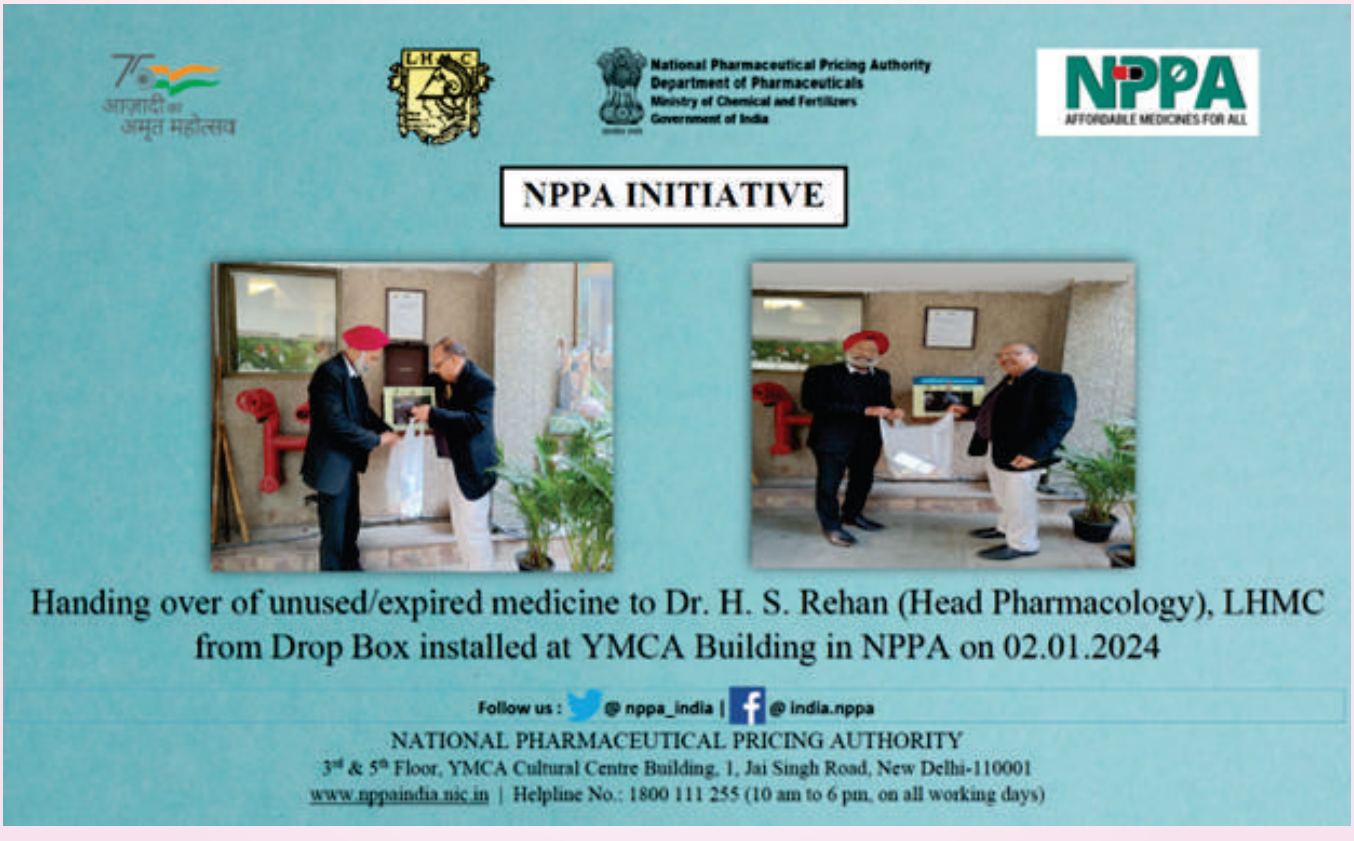
FDA Approves First Medication to Treat Severe Frostbite (February 14, 2024)

The U.S. Food and Drug Administration approved Aurlumyn (iloprost) injection to treat severe frostbite in adults to reduce the risk of finger or toe amputation. Frostbite can occur in several stages, ranging from mild frostbite that does not require medical intervention and does not cause permanent skin damage, to severe frostbite when both the skin and underlying tissue are frozen and blood flow is stopped, sometimes requiring amputation. Iloprost, the active ingredient in Aurlumyn, is a vasodilator (a drug that opens blood vessels) and prevents blood from clotting. Read more

PRICE MONITORING AND RESOURCE UNIT (PMRU)

NPPA under Consumer Awareness, Publicity and Price Monitoring (CAPPM) Scheme has set up the 31st Price Monitoring and Resource Unit (PMRU) in the UT of Lakshadweep on 25th January, 2024. Now, NPPA has its presence in the 31 States/ UTs viz. Kerala, Gujarat, Odisha, Rajasthan, Punjab, Haryana, Tripura, Nagaland, Uttar Pradesh, Andhra Pradesh, Mizoram, Jammu & Kashmir, Karnataka, Telangana, Maharashtra, Goa, Madhya Pradesh, Chhattisgarh, Jharkhand, Puducherry, West Bengal, Ladakh, Himachal Pradesh, Bihar, Uttarakhand, Meghalaya, Arunachal Pradesh, Chandigarh, Assam, Dadra and Nagar Haveli and Daman and Diu and Lakshadweep. This will help NPPA to trickle down the benefits of DPCO, 2013 at grass-root level with the help of PMRUs to ensure that consumer at large is benefitted.

NPPA Initiative for handling of unused/expired medicine



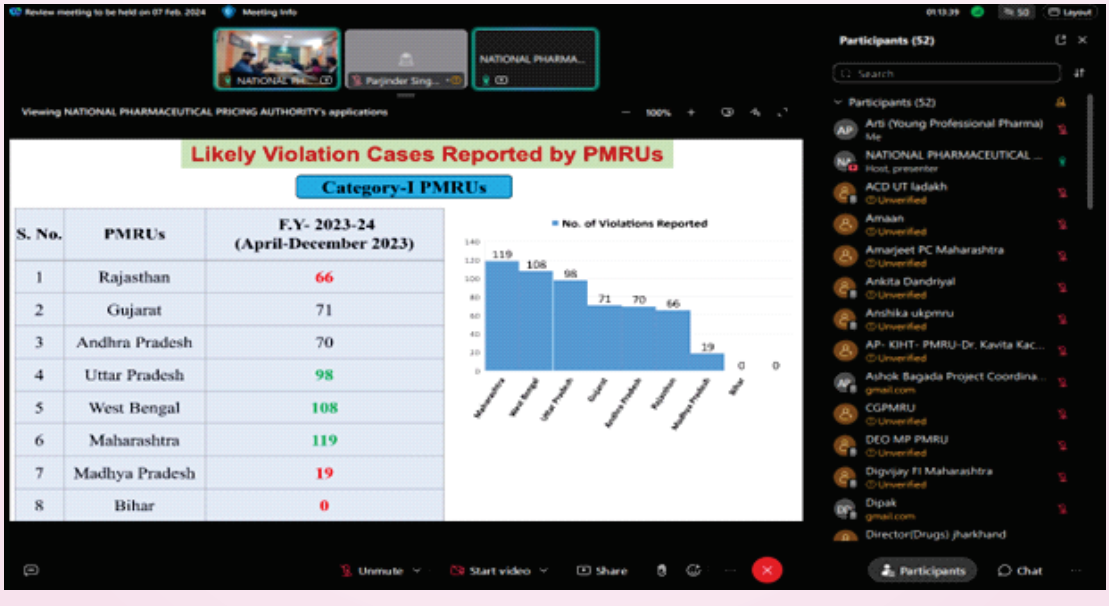
OTHER NEWS AND EVENTS

Webinars for Price Monitoring and Resource Units in the Sates/UTs

In the continuation to webinar, web meeting was organized by NPPA under the chairmanship of Hon'ble Chairman, NPPA with SDCs/ FDA along with Price Monitoring and Resource Units in the States/ UTs as follows:

Date	Webinar
07.02.2024	Activities undertaken by PMRUs during April 2023 to December 2023

The main aim of meeting was to discuss and review the progress of activities undertaken by the PMRUs during the period from April 2023 to December 2023.



S. No.	PMRUs	F.Y- 2023-24 (April-December 2023)
1	Rajasthan	66
2	Gujarat	71
3	Andhra Pradesh	70
4	Uttar Pradesh	98
5	West Bengal	108
6	Maharashtra	119
7	Madhya Pradesh	19
8	Bihar	0

State Level Events/ Seminars by PMRUs

Forty-three (43) State and District level Events/ Seminars have been organized by 16 PMRUs in their respective States/ UTs viz. Puducherry, Telangana, Jammu & Kashmir, Kerala, Uttar Pradesh, Goa, Jharkhand, Ladakh, Madhya Pradesh, West Bengal, Mizoram, Maharashtra, Chhattisgarh, Haryana, Punjab and Tripura. 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:

FREQUENTLY ASKED QUESTIONS

o How does the NPPA regulate drug prices?

The NPPA regulates drug prices by fixing the Ceiling Prices of essential medicines under the provisions of the Drugs (Prices Control) Order (DPCO). It monitors and controls the prices of scheduled drugs and formulations to prevent overpricing and ensure affordability. DPCO, 2013 further mandates monitoring of retail prices in respect of non- scheduled formulations allowing a price increase of up to 10 percent during preceding 12 months. Instances of overcharging are dealt with by NPPA under the relevant provisions of DPCO 2013

o What are the key functions of the NPPA besides price regulation?

Besides price regulation, the NPPA performs functions such as monitoring drug prices, fixing/revising ceiling prices, regulating the prices of new drugs, resolving disputes related to pricing, conducting investigations, and issuing guidelines to promote transparency and accountability in the pharmaceutical sector.

o How does the NPPA handle complaints related to drug pricing?

The NPPA has mechanisms in place to receive and address complaints related to drug pricing. Stakeholders, including consumers, pharmaceutical companies, and healthcare providers, can submit complaints to the NPPA for investigation and resolution.

o Does the NPPA conduct inspections or audits of pharmaceutical companies?

Yes, the NPPA conducts inspections, audits, and market surveys to monitor compliance with pricing regulations, ensure transparency in pricing practices, and detect instances of overcharging or other violations.

o How does the NPPA promote transparency in drug pricing?

The NPPA promotes transparency in drug pricing by publishing information related to draft working sheets, drug prices, price notifications, guidelines, and other relevant documents on its official website. Consultations are also held to solicit feedback from stakeholders.

o What measures does the NPPA take to prevent unethical practices in drug pricing?

The NPPA takes various measures to prevent unethical practices in drug pricing, including strict enforcement of pricing regulations, imposition of penalties for violations, conducting investigations into pricing irregularities, and promoting awareness among stakeholders about their rights and responsibilities.

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.

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NATIONAL PHARMACEUTICAL PRICING AUTHORITY

3rd / 5th Floor, YMCA Cultural Center Building 1, Jai Singh Road, New Delhi, India
www.nppaindia.nic.in | Helpline No.: 1800 111 255 (10 am to 6 pm on working days)

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