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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A Bi-monthly e-Newsletter

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 immense pleasure that I present to you the Sixteenth issue of the NPPA bi-monthly e-Newsletter, NPPA. Our objective with this 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 landscape.

I am delighted to note that an insightful article has been contributed by Chaaya Iyengar Raje from the Department of Biotechnology, NIPER, Punjab shedding light on the critical challenge of Antimicrobial Resistance (AMR) in healthcare-an issue of paramount importance in our collective efforts towards public health.

In this edition, the NPPA Pricing team delves into the trends surrounding the Retail Price fixation of 'New Drugs' under the ambit of the Drug Price Control Order (DPCO), 2013. Over the past decade, retail price fixation of 2799 new drugs has been carried out till March 31, 2024, marking significant strides in ensuring accessibility and affordability of essential medicines. As India continues to evolve as the fifth largest economy and the largest democracy globally, our commitment to enhancing healthcare accessibility remains unwavering.

In continuation of our webinar series, thirty-seven (37) State and District level Events/Seminars have been successfully organized by seventeen PMRUs across various states and union territories. These events aimed at fostering awareness about the fixation of Ceiling Prices under the National List of Essential Medicines (NLEM) 2022 and its significance in healthcare, elucidating Drug Price Regulations under the provisions of DPCO, 2013, outlining the functions of PMRUs, and acquainting stakeholders with the Pharma Sahi Daam Mobile App and IPDMS 2.0, etc.

I extend my gratitude to the NIPER expert, NPPA Pricing Division for their insight articles and the editorial team for their relentless efforts in curating this newsletter, which I trust will serve as a valuable resource to keep stakeholders abreast of the latest regulatory news, policies, events, and more.

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

With best wishes

(Kamlesh Kumar Pant)

ANTIMICROBIAL RESISTANCE (AMR)- A CRITICAL CHALLENGE TO HEALTHCARE.

(By Dr Chaaya Iyengar Raje, Department of Biotechnology, National Institute for Pharmaceutical Education and Research (NIPER), Phase X, Sector 67, SAS Nagar, Punjab 160062, INDIA.)

Antimicrobials are therapeutics used to treat fungal, viral, protozoan or bacterial pathogens. Antimicrobial resistance (AMR) is the emergence of highly drug-resistant clinically relevant pathogens that threaten to overwhelm healthcare facilities. The upsurge in these drug resistant pathogens is primarily driven by the indiscriminate use of antibiotics. Unless tackled on a war footing, the world may very soon enter a "pre-antibiotic era" wherein even common medical procedures and infections will be impossible to treat. The gravity of the situation can be gauged from that fact that bacterial AMR alone was responsible for 1.27 million deaths worldwide in 2019.

AMR is a manmade problem that has arisen due the widespread and often injudicious use of antibiotics in healthcare settings, agriculture, livestock and poultry industries. Furthermore, over-the-counter availability of antibiotics and release of untreated effluents in sewage exacerbates the conditions for emergence of drug resistant pathogens. The presence of antibiotics ensures that pathogens with altered genetic traits or mutations evolve and survive this selection pressure, leading to the genesis of drug resistant strains.

A concerted effort by policy makers, epidemiologists, healthcare workers, pharmacists and biomedical, veterinary, agricultural and environmental scientists is the required to resolve this multifaceted challenge. The problem of AMR is acknowledged globally and nationally with several initiatives being undertaken to address the issue.

In May 2015, the World Health Assembly (WHA), Member States adopted a Global Action Plan on AMR (GAP-AMR). Subsequently, WHO launched the Global Antimicrobial Resistance and Use Surveillance System (GLASS) as a part of the GAP-AMR initiative. This strategy is aimed at collating country and region wise epidemiological, clinical and population wise data on AMR worldwide.

In 2017, the WHO released its first ever list of twelve "priority pathogens" identifying those bacterial pathogens that pose the utmost threat to human health. The list mentioned pathogens falling in the critical, high and medium priority pathogen categories, identified based on their increasing drug resistance **(https://www.who.int/publications/i/item/WHO-EMP-IAU-2017.12.).** Subsequently, in 2022 the WHO also released the fungal pathogen priority list **(https://www.who.int/publications/i/item/9789240060241).**

Among the bacterial pathogens of concern, the ESKAPE group refers to Enterococcus faecium, Staphylococcus aureus, Klebsiella pneumoniae, A. baumannii, Pseudomonas aeruginosa and Enterobacter species that pose a serious threat to healthcare. This group consists largely of Gram-ve organisms that have limited treatment option. It is also relevant that among this group carbapenem resistant strains of Acinetobacter baumannii, Pseudomonas aeruginosa and Enterobacteriaceae (extended spectrum β lactamase i.e ESBL producing) are also listed as priority pathogens. Cryptococcus neoformans, Aspergillus fumigatus, Candida auris and Candida albicans are included in the fungal critical priority list, with several other pathogens listed in the high and medium category.

Another disease of concern is tuberculosis (TB), which continues to be the major cause of death due to infectious disease, only briefly surpassed by COVID-19 during the pandemic. It is of particular concern for

India, since the country accounts for ~25% of the global burden. Multidrug resistant (MDR) strains of TB are non-responsive to the two first-line drugs Rifampicin and Isoniazid. However, the extensively drug resistant strains (XDR) of TB are refractive to both first and second-line drugs. After almost 40 years, in 2012 a new and innovative drug - Bedaquiline was given emergency approval by FDA for the treatment of drug resistant TB, which was followed closely by approval of Pretomanid and Delaminid. However, the rapid emergence of resistance against these drugs is already reported. This is an extremely alarming scenario, considering the extensive time needed for pre-clinical, clinical research and introduction in treatment regimens.

Apart from bacterial pathogens, there is also a growing concern regarding fungal pathogens that infect patients with other underlying medical conditions, such as those admitted in Intensive Care Units (ICU), undergoing invasive surgical procedure or on immunosuppressive treatment. Fungal infections are extremely recalcitrant to treatment and there are currently only a few limited classes of antifungals available for treatment.

Overtime, drug resistance is also evolved in HIV, reducing the effectiveness of antiretroviral drugs used for blocking viral replication. The occurrence of drug resistant malaria is a major threat across malaria endemic countries. Artemisinin based combination treatments are recommended as first line treatment for therapy, however, partial resistance is reported against both Artemisinin and the partner drugs are being increasingly reported. Similarly, resistance has been reported to drugs used to treat neglected tropical diseases which include leprosy, helminthic diseases and leishmaniasis.

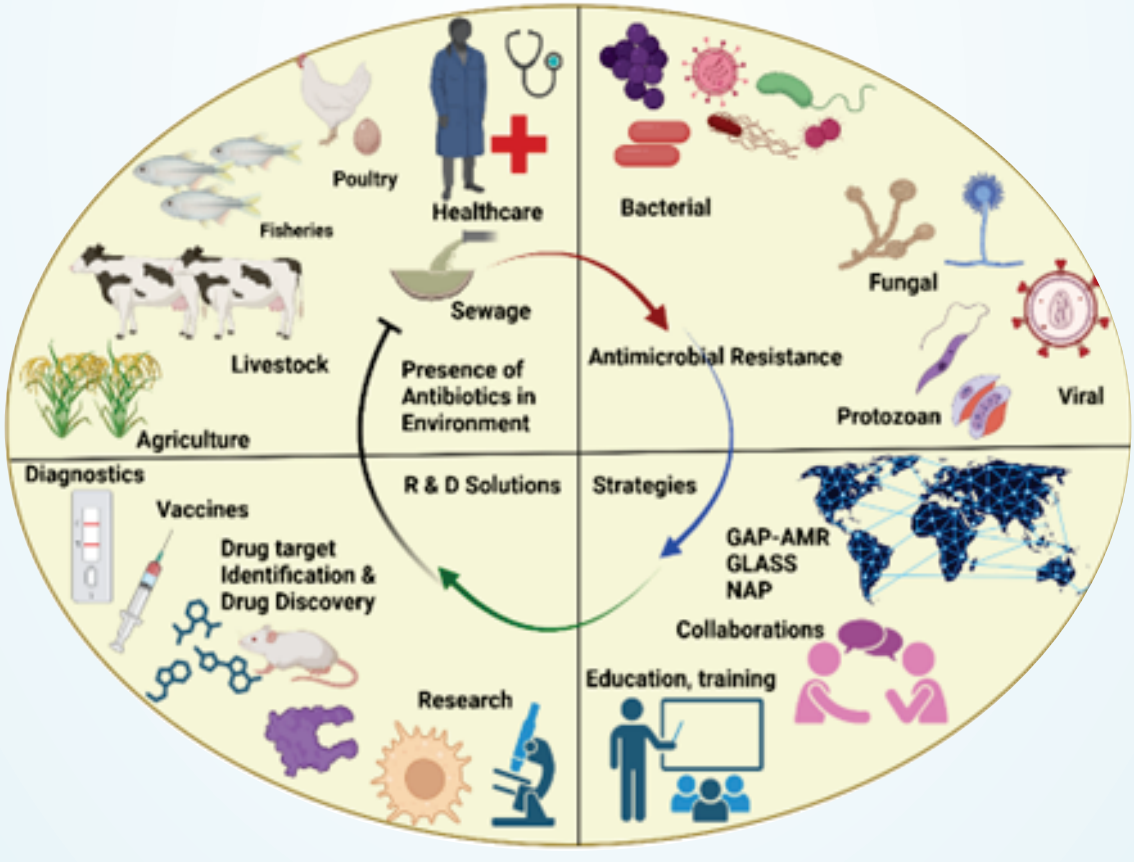


Figure: Describes the (i) sectors where antibiotics are used (ii) Development of resistance in human pathogens (iii) Co-ordination, planning and education (iv) Research and Development objectives to tackle AMR. Created with BioRender.com

ARTICLE BY EXPERT

Since AMR recognizes no borders, halting its spread can only be achieved by the determined and collective effort of countries worldwide. It requires co-ordinated action across multiple sectors such as food, agriculture, livestock, fisheries and healthcare. The GAP-AMR is a step in this direction, where countries have committed to implement the issues within country specific National Action Plans as part of a One Health approach. A quadripartite joint secretariat consisting of the World Health organization (WHO), Food and Agriculture Organization (FAO), World organization for Animal Health (WOAH), UN Environment programme (UNEP) was established in 2020 to co-ordinate with stake holders and co-ordinate efforts to tackle AMR. The WHO has also introduced the concept of World AMR Awareness week (WAAW) from 18th to 24th November each year, as an opportunity to raise awareness and educate the public about AMR. Antimicrobial Stewardship programs are focused at educating and guiding health workers to prescribe and administer antimicrobials. The WHO has developed Access, Watch and Reserve (AWaRe) classification of antibiotics, to ensure appropriate selection, dose, route of administration and duration of treatment for ~30 infections that commonly afflict children and adults.

Till date, 178 countries have developed National Action Plans for monitoring and implementation of AMR related issues. In addition, initiatives have been launched by individual countries and agencies such as MRC (UK), NIH-NIAID (US), JPIAMR (Sweden) and Delhi Declaration (India). The Delhi Declaration (2017) was an inter-ministerial consensus which recognized the threat of AMR and envisaged six strategic commitments towards addressing AMR. These include:

i. Increasing awareness about AMR through education;

ii. Strengthening knowledge by surveillance programs across various sectors;

iii. Introducing effective preventive and control strategies to limit the spread of infections;

iv. Optimizing and regulating the use of antibiotics for human health and agriculture;

v. Promote investments in mission mode for AMR activities, research, innovations, drug discovery, vaccines and diagnostics; and

vi. Commit to fostering national and international collaborations.

Last but not the least, is the fact that drug discovery pipelines for the discovery of new antibiotics are exhausted. The WHO recently identified only 27 antibiotics in the clinical or pre-clinical stage against the priority pathogens, of which only 6 were classified as novel. Innovations towards the development of new drugs, drug delivery, vaccines and diagnostics are the cornerstone for tackling AMR. In this context, the advent of Artificial intelligence (AI) based drug discovery would be a useful tool to accelerate drug discovery. Additionally, research to exploit non-conventional therapies such as phage based, antimicrobial peptides and natural products may be rewarding.

The Global Antibiotic Research and Development Partnership, AMR Action Fund in concert with WHO as well as individual governments are co-coordinating to support research and development in these areas. In India, support for AMR related activities are incorporated into the Swasth Bharath, Swachh Bharath and Swachh Swasth Sarvatra government sponsored initiatives. In conclusion, multi-pronged approach with continued regulatory guidelines, surveillance and robust R & D infrastructure will be crucial to meet this challenge.

TRENDS IN RETAIL PRICE FIXATION OF 'NEW DRUGS' UNDER DPCO, 2013

Pricing Division, NPPA

1. Historical background of price regulation of drugs in India:

Amongst other items, drugs are included in the Schedule of the Essential Commodities Act, 1955 and are hence considered as essential. They have been under price control since early 1960's. Cost based pricing came into effect with the notification of Drugs (Prices Control) Order of 1979. This was the underlying principle of the Drugs (Prices Control) Order, 1987 and the Drugs (Prices Control) Order, 1995 (DPCO, 1995). There was a shift towards market-based pricing in the National Pharmaceutical Pricing Policy, 2012 (NPPP, 2012) and accordingly, Drugs (Price Control) Order, 2013 was notified on 15th May 2013.

2. New Drugs under DPCO,2013

DPCO, 2013 aims to make available essential medicines at reasonable price through the instrumentality of price control. Ceiling prices are fixed for the scheduled drugs and the prices are monitored for rest as per para 20 of the DPCO, 2013. Also, retail prices are fixed for a new drug (as defined in 2(u) under DPCO, 2013), which is also non-scheduled formulation under DPCO, 2013. New drug is a formulation launched by an existing manufacturer of a drug of specified dosages and strengths as listed in the NLEM by combining the drug with another drug either listed or not listed in the NLEM or a formulation launched by changing the strength or dosages or both of the same drug of specified dosages and strengths as listed in the NLEM. In addition, as per Para 19 of the DPCO-2013 gives power to the NPPA to control the prices of drugs that are not under the NLEM under extraordinary circumstances in public interest.

ARTICLE ON PRICING OF NEW DRUGS

Till 31.03.2024 ceiling prices of 923 scheduled formulations (733 formulations under NLEM, 2022 and 190 under earlier NLEMs) and retail prices for 2799 non-scheduled new drugs have been fixed under DPCO, 2013. Around sixty-one percent of the retail prices fixed are for treatment of non-communicable diseases (NCDs).

3. Retail prices fixed for drugs used to treat non-communicable diseases:

NCDs refer to a group of medical conditions or diseases that are not mainly caused by an infectious agent, result in long-term health consequences and often create a need for long-term treatment and care, with slow progression and are the result of a combination of genetic, physiological, environmental and behavioural factors. (1)

NCDs kill approximately 41 million people (71% of global deaths) worldwide each year, including 14 million people who die too young between the ages of 30 and 70. NCDs are rapidly increasing globally and reached epidemic proportions in many countries, largely due to globalization, industrialization, and rapid urbanization with demographic and lifestyle changes, thus imposing harm/burden on the socioeconomic development of the country.

India is also experiencing a rapid health transition with a rising burden of Non-Communicable Diseases (NCD) surpassing the burden of communicable diseases like water-borne or vector-borne diseases, TB, HIV, etc. In India, nearly 5.8 million people (WHO report, 2015) die from NCDs every year or in other words 1 in 4 Indians has a risk of dying from an NCD before they reach the age of 70. The NCDs like Cardiovascular diseases, Cancer, Chronic Respiratory Diseases, Diabetes and other NCDs are estimated to account for around 60% of all deaths, thus making them the leading causes of death. NCDs cause considerable loss in potentially productive years of life. (2)

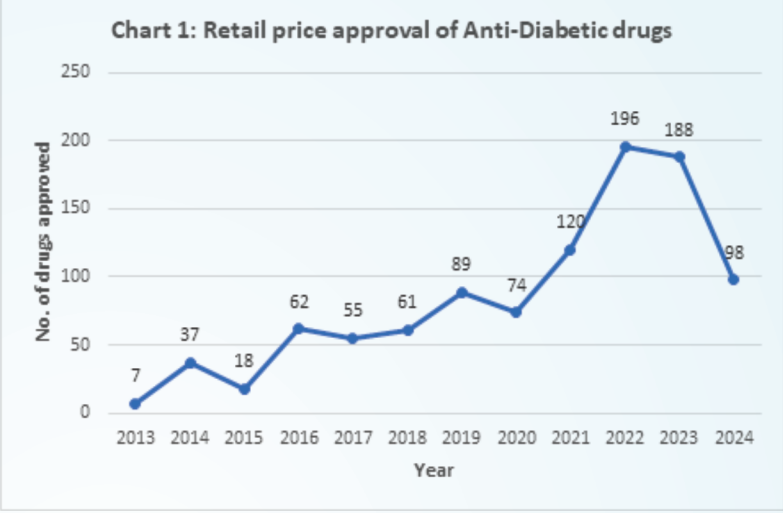
NPPA has contributed to affordable medical care in India by virtue of pricing of drugs used to treat NCDs. Since 2013, out of 2799 retail prices, 1713 retail prices have been fixed for NCDs which constitutes anti-cancer formulations (53), anti-diabetic formulations (1005) Cardio-vascular formulations (502) and anti-hypertensive (153). The year-wise prices notified are given in Table-1.

Table-1 : Retail price approval for drugs used in treating NCDs during past twelve years

Year	Anti-Cancer	Anti-Diabetic	Cardiovascular	Anti-Hypertensive
2013	-	7	9	
2014	3	37	17	
2015	2	18	16	
2016	7	62	22	1
2017	4	55	24	
2018	13	61	153	
2019	3	89	47	18
2020	4	74	48	20
2021	9	120	79	28
2022	3	196	32	37
2023	4	188	34	44
2024 (3 months)	1	98	21	5
	53	**1005**	**502**	**153**

Diabetes & anti-diabetic drugs:

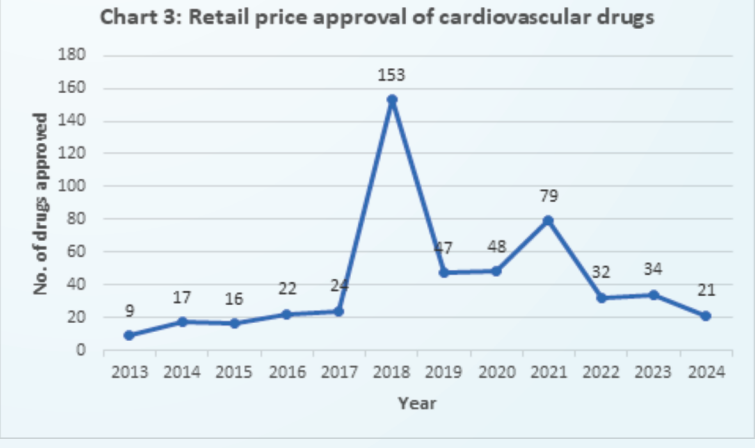
The most effective management of diabetes mellitus demands an approach involving both lifestyle modifications with oral pharmacologic agents for optimal glycaemic control, particularly as type 2 diabetes mellitus progresses with continued loss of pancreatic beta-cell function and insulin production (3). Following the expiry of patents of anti-diabetic drugs like Linagliptin, Sitagliptin, etc., NPPA has notified the retail prices of such off-patented anti-diabetic drugs to several domestic companies and hence, maximum number of retail prices has been notified under anti-diabetic drugs category in the years 2022 and 2023.



Further, there was a considerable reduction in the price of the drug after the expiry of the patent like, the MRP of FDCs of 'Vildagliptin + Metformin' tablet which was in the range of Rs. 25.00-Rs. 27.00 per tablet during the patented period and came down in the range of Rs. 7.00-9.00 per tablet after the expiry of the patent and the MRP of the FDCs of 'Dapagliflozin + Metformin' tablet which was in the range of Rs. 56.00-Rs. 57.00 per tablet during the patent period came in the range of Rs. 11.00-Rs. 12.00 per tablet after the expiry of the patent.

Anti-cancer drugs:

Cancer isa complex series of disease condition and is the second most common cause of death globally, surpassed only by cardiovascular disease. One of the hallmarks of cancer is uncontrolled cell division and resistance to cell death due to repeated exposure of carcinogens (4). Owing to increased occurrence of cancer and worldwide prevalence during the last decade, it has posed a great challenge to the health care professionals. Given the high costs of drug development, drugs used in the treatment of cancer are typically expensive (5). Retail prices of 53 anti-cancer drugs have been notified in the past 10 years.



Cardiovascular diseases (CVD):

CVDs such as ischaemic heart disease and cerebrovascular such as stroke account for 17.7 million deaths and are the leading cause of mortality due to NCD.(6) According to WHO, India accounts for one-fifth of these deaths worldwide especially in younger population. CVDs strike Indians a decade earlier than the

western population and the burden due to CVD in India is higher than the global level. Cardiovascular diseases tend to affect patients in the most productive years of their lives and result in catastrophic social and economic consequences. (7) NPPA has regulated the price of drugs used in the treatment of Cardiovascular diseases by notifying retail prices of 502 drugs and 153 anti-hypertensives in the past 10 years.

4. Retail prices fixed for drugs used to treat diseases other than NCDs:

New drugs used in the treatment of major NCDs account for significant proportion i.e. around sixty-one percent for which retail prices have been fixed. Out of the total retail prices fixed around twenty-two percent are used in the treatment of other NCDs like Non-Steroidal Anti-Inflammatory Drug (NSAIDs), gastro-intestinal agents, drugs used in the treatment of diseases of respiratory system, Central Nervous System and gynecological disorders. Thus, over the past decade, of 2799 new drugs for which retail prices have been fixed till 31.03.2024, eighty three percent are used in the treatment of non-communicable diseases; fourteen percent are used in the treatment and prevention of communicable diseases caused by various pathogens; and remaining three percent include miscellaneous drugs including Vitamins, mineral supplements and others.

India, the fifth largest economy and largest democracy of the world has been consistently improving its health-care facilities. NPPA has also been contributing towards this endeavor by making medicines accessible and affordable.

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News related to pricing of drugs

- Ceiling prices for 923 scheduled formulations (including 733 formulation under NLEM,2022) were fixed/revised based on WPI increase of (+) 0.00551% in pursuance to Para 16(1) of DPCO, 2013.
- Retail prices for 2799 non-scheduled formulations have been fixed under DPCO, 2013 till 30th April 2024.
- As on 30th April, 254th Authority meeting have been conducted of which 122nd is under DPCO 2013. The details of the recent meetings are given as below:

Meeting No. 252nd (overall) & 122nd Meeting under DPCO 2013 held on 20.03.2024

Prices Approved & Notified

(i)	Retail prices for 65 formulations notified vide S.O. 1558(E) & 1559(E) dated 26.03.2024.
(ii)	Revised Ceiling price (WPI adjusted) of 726 scheduled formulations of Schedule-I (NLEM 2022) under Drugs (Prices Control) Order, 2013 vide S.O. 1547(E) dated 26.03.2024.
(iii)	Revised Ceiling price (WPI adjusted) of 169 scheduled formulations of Schedule-I (NLEM 2015) under Drugs (Prices Control) Order, 2013 vide S.O. 1548(E) dated 26.03.2024.
(iv)	Revised Ceiling price (WPI adjusted) of 6 scheduled formulations of Schedule-I (NLEM 2011) under Drugs (Prices Control) Order, 2013 vide S.O. 1549(E) dated 26.03.2024.
(v)	Revised Ceiling price (WPI adjusted) of 3 scheduled formulations of Schedule-I (NLEM 2022) under Drugs (Prices Control) Order, 2013 based on Review order vide S.O. 1550(E) dated 26.03.2024.
(vi)	Revised ceiling price (WPI adjusted) of 2 Coronary Stents vide S.O. 1551(E) dated 26.03.2024.
(vii)	Revised ceiling price (WPI adjusted) of 8 IV Fluids with packages having special features under Schedule-I (NLEM 2015) under Drugs (Prices Control) Order, 2013 vide S.O. 1552(E) dated 26.03.2024.
(viii)	Revised ceiling price (WPI adjusted) of 4 pack size of Ringer Lactate injection with packages having special features under Schedule-I (NLEM 2015) under Drugs (Prices Control) Order, 2013 vide S.O. 1553(E) dated 26.03.2024.
(ix)	Revised ceiling price (WPI adjusted) of 2 (i) Piperacillin 2gm+Tazobactum 250mg and (ii) Piperacillin 4gm+Tazobactum 500 mg under Schedule-I (NLEM 2022) under Drugs (Prices Control) Order, 2013 vide S.O. 1554(E) dated 26.03.2024.
(x)	Revised ceiling price (WPI adjusted) of Metronidazole Injection IP (0.5% w/v) in 100ml pack under Schedule-I (NLEM 2022) under Drugs (Prices Control) Order, 2013 vide S.O. 1555(E) dated 26.03.2024.
(xi)	Revised ceiling price (WPI adjusted) of Mannitol Injection 20% in 100ml pack under Schedule-I (NLEM 2022) under Drugs (Prices Control) Order, 2013 vide S.O. 1556(E) dated 26.03.2024.
(xii)	Revised ceiling price (WPI adjusted) of Dextrose Injection (25% w/v) in 100ml pack under Schedule-I (NLEM 2015) under Drugs (Prices Control) Order, 2013 vide S.O. 1557(E) dated 26.03.2024.

REGULATORY NEWS

➲ Details of retail prices notified for various formulations based on the decision taken in 122nd Authority 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	42	Tablets	7.92 – 17.23
2	Analgesic & anti-inflammatory	1	Tablets	3.58
3	Gastrointestinal Agent	2	Tablets	7.14 – 7.35
4	Anti-hypertensive	1	Tablet	14.60
5	Cardiovascular	1	Tablet	10.26
6	Vitamins/Minerals/Nutrients	3	Tablet/Syrup/ oral solution	4.97 – 13.60
7	Pain Management	1	Tablet/Syrup	0.95 – 17.84
8	Anti-Infective	7	Tablet/ Suspension	3.18 – 17.46
9	Others	7	Capsule / Tablet/ Injection / Drop/Gel	3.17 – 1696.43

➲ Details of ceiling prices notified for various formulations under NLEM 2022 based on the decision taken up to 122nd Authority Meeting, are as follows:

Therapeutic Category	No. of Medicines	No. of Formulations
Anti-infective Medicines	62	165
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)	12	25
Anti-Diabetic drugs	8	11
Hormones, other Endocrine Medicines and Contraceptives	16	33
Others	107	200
Grand Total	**320***	**733**

*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 few months:

Chart 1: Total number of registered companies at month end

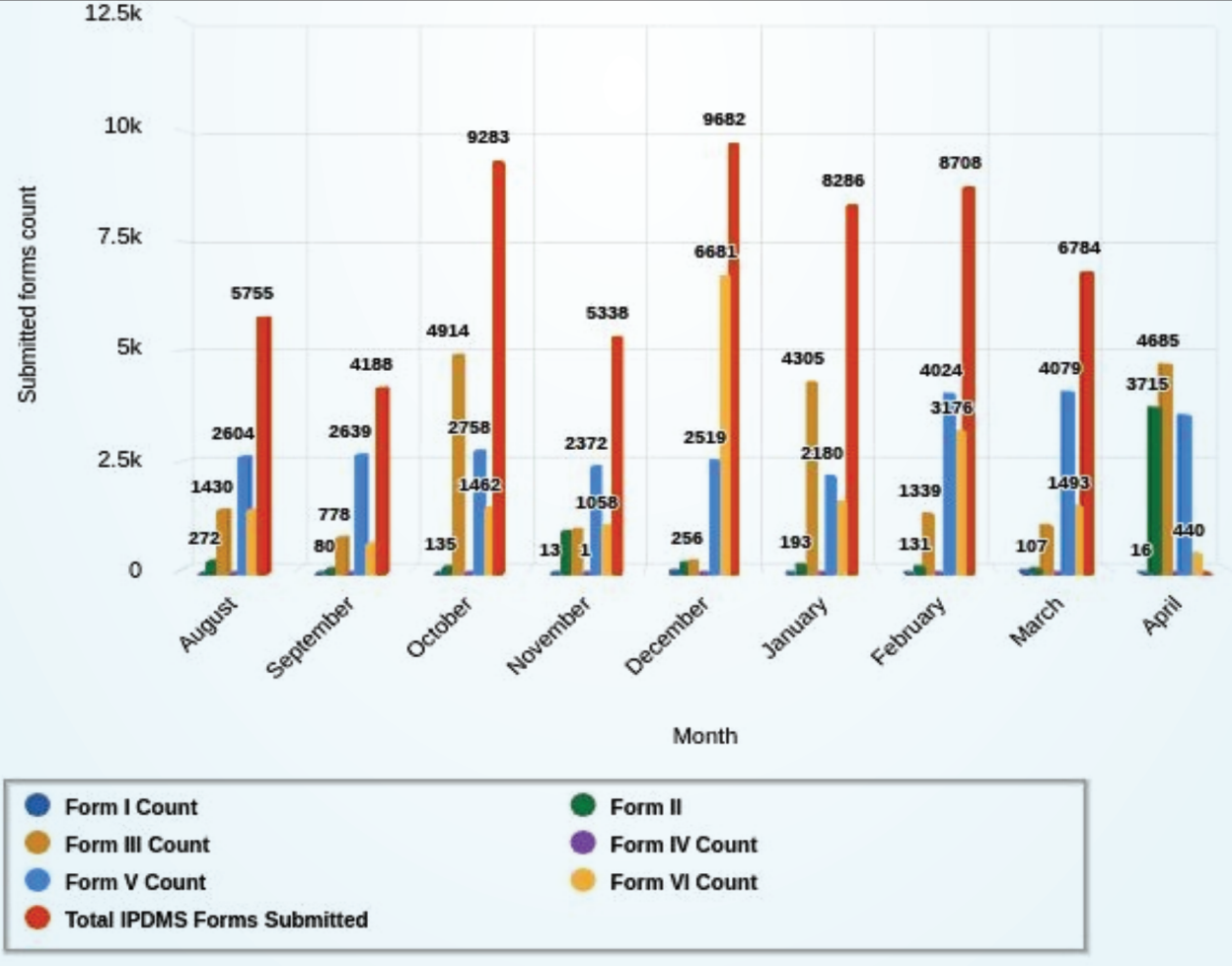


Chart 2: Number of statutory forms filed on IPDMS 2.0

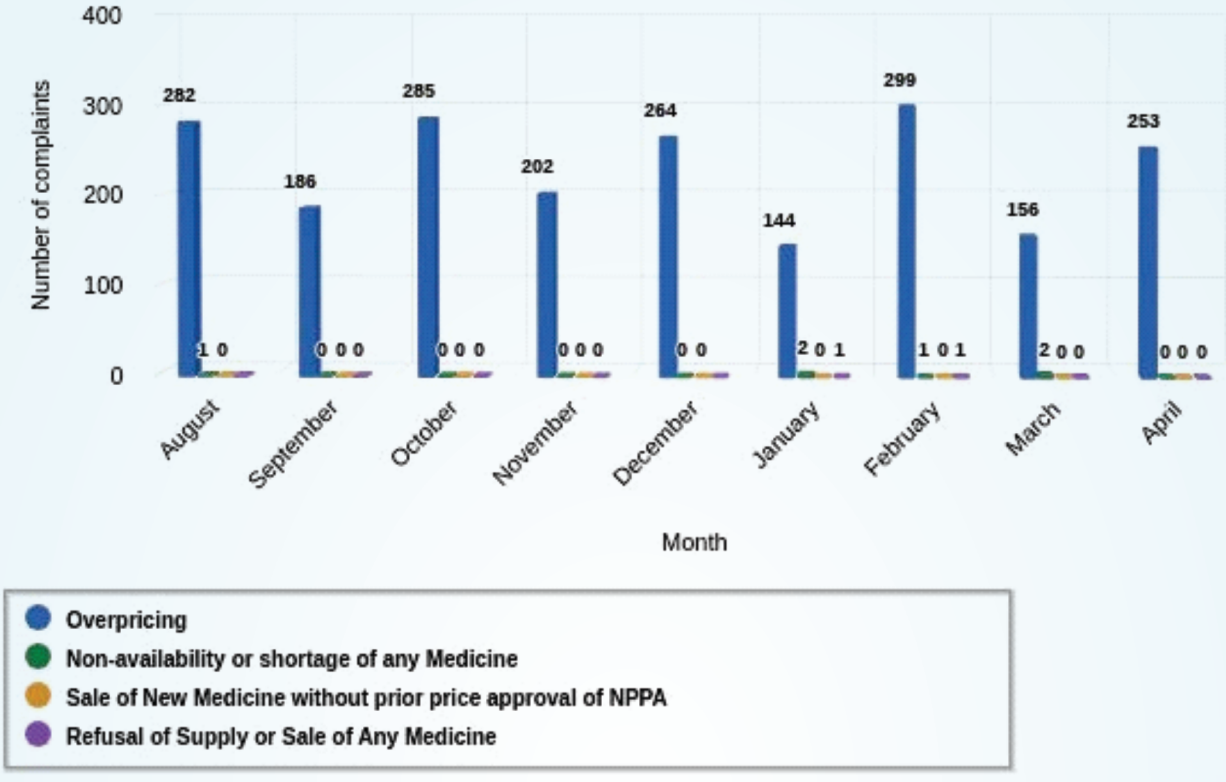


Chart 3: Number of complaints received on IPDMS/ PJS app

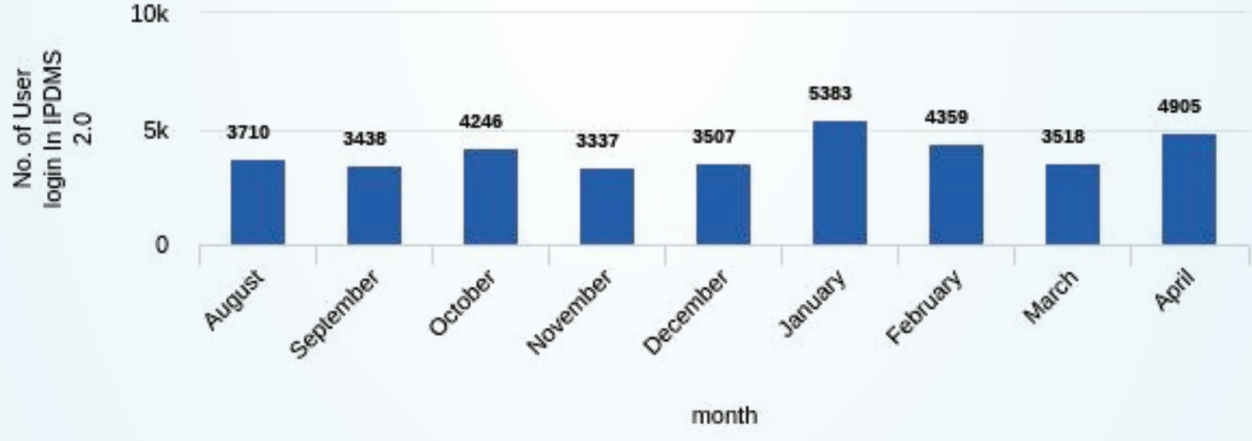


Chart 4: Number of Pharma Sahi Daam Mobile app downloads

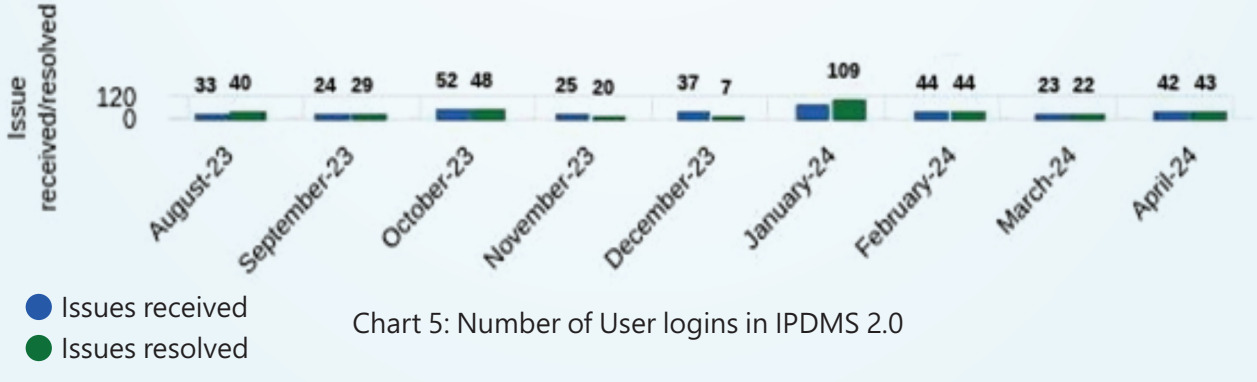


Chart 5: Number of User logins in IPDMS 2.0

FDA Approves First Treatment to Reduce Risk of Serious Heart Problems Specifically in Adults with Obesity or Overweight (March 08, 2024)

The U.S. Food and Drug Administration approved a new indication for use for Wegovy (semaglutide) injection to reduce the risk of cardiovascular death, heart attack and stroke in adults with cardiovascular disease and either obesity or overweight. Wegovy should be used in addition to a reduced calorie diet and increased physical activity. Cardiovascular disease is a group of diseases of the heart and blood vessels. Obesity or overweight affect approximately 70% of American adults. Obesity and overweight are serious health issues that increase the risk for premature death and a variety of health problems, including heart attack and stroke.

(Read more)

FDA Approves First Treatment for Patients with Liver Scarring Due to Fatty Liver Disease (March 14, 2024)

The U.S. Food and Drug Administration approved Rezdiffra (resmetirom) for the treatment of adults with noncirrhotic non-alcoholic steatohepatitis (NASH) with moderate to advanced liver scarring (fibrosis), to be used along with diet and exercise. NASH is a result of the progression of nonalcoholic fatty liver disease where liver inflammation, over time, can lead to liver scarring and liver dysfunction. NASH is often associated with other health problems such as high blood pressure and type 2 diabetes. By at least one estimate, approximately 6-8 million people in the U.S. have NASH with moderate to advanced liver scarring, with that number expected to increase. Rezdiffra is a partial activator of a thyroid hormone receptor; activation of this receptor by Rezdiffra in the liver reduces liver fat accumulation.

(Read more)

FDA Approves First Gene Therapy for Children with Metachromatic Leukodystrophy (March 18, 2024)

The U.S. Food and Drug Administration approved Lenmeldy (atidarsagene autotemcel), the first FDA-approved gene therapy indicated for the treatment of children with pre-symptomatic late infantile, pre-symptomatic early juvenile or early symptomatic early juvenile metachromatic leukodystrophy (MLD).Metachromatic leukodystrophy is a debilitating, rare genetic disease affecting the brain and nervous system. It is caused by a deficiency of an enzyme called arylsulfatase A (ARSA), leading to a buildup of sulfatides (fatty substances) in the cells. This buildup causes damage to the central and peripheral nervous system, manifesting with loss of motor and cognitive function and early death. It is estimated that MLD affects one in every 40,000 individuals in the United States. There is no cure for MLD, and treatment typically focuses on supportive care and symptom management.

(Read more)

FDA Approves New Treatment for Uncomplicated Urinary Tract Infections (April 24, 2024)

The U.S. Food and Drug Administration approved Pivya (pivmecillinam) tablets for the treatment of female adults with uncomplicated urinary tract infections (UTIs) caused by susceptible isolates of Escherichia coli, Proteus mirabilis and Staphylococcus saprophyticus. Uncomplicated UTIs are bacterial infections of the bladder in females with no structural abnormalities of their urinary tract. Approximately one-half of all women experience at least one UTI in their lifetime.

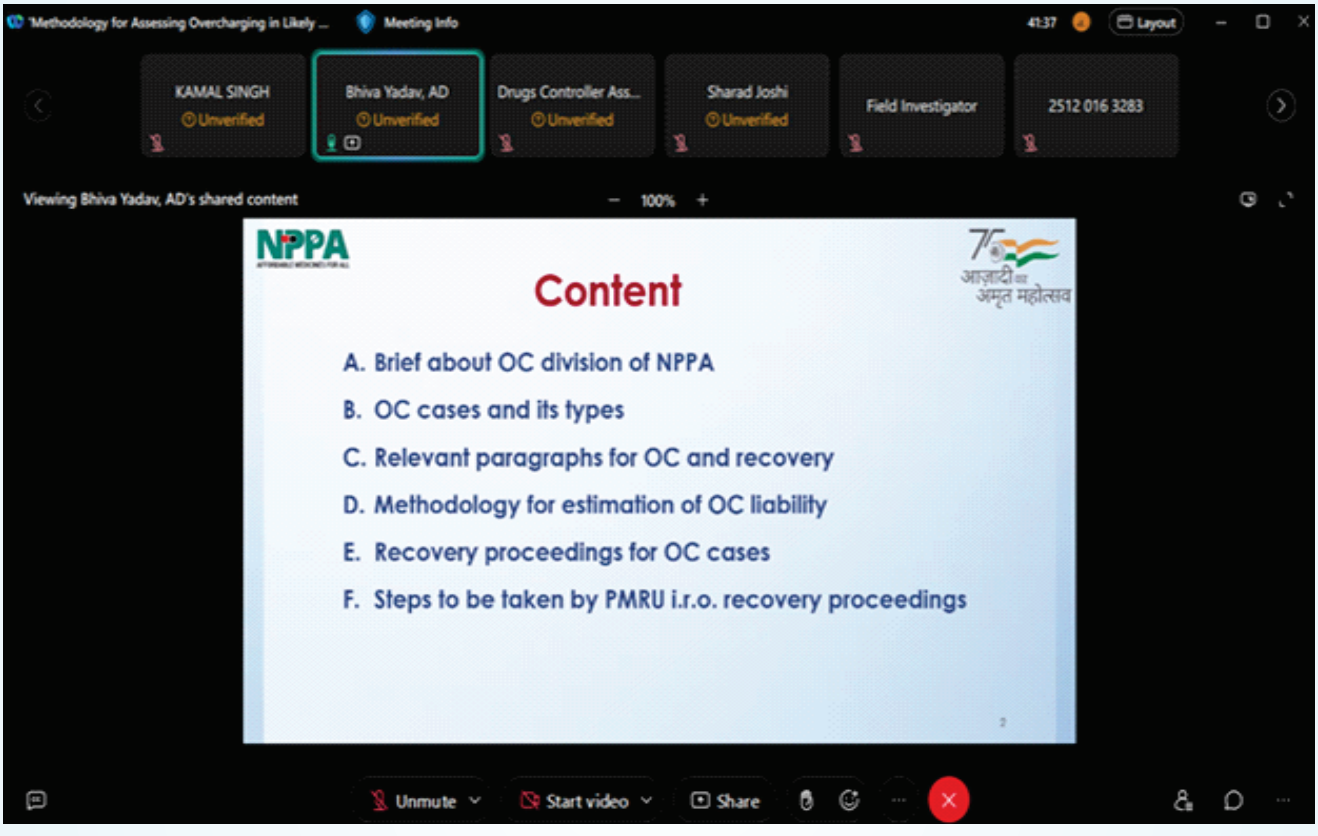
(Read more)

OTHER NEWS AND EVENTS

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

In the continuation to webinar, interactive webinar was organized by PMRU Division along with Overcharging division for Price Monitoring and Resource Units in the States/ UTs as follows:

A webinar on the topic 'Methodology for assessing overcharging in violation cases' held on 28.03.2024.



The main aim of the webinars was to provide comprehensive guidance and sharing of knowledge with PMRUs regarding Methodology for assessing overcharging in violation

State Level Events/ Seminars by PMRUs

Thirty-Seven (37) State and District level Events/ Seminars have been organized by 17 PMRUs in their respective States/ UTs viz. Puducherry, Telangana, Andhra Pradesh, Jammu & Kashmir, Kerala, Uttar Pradesh, Goa, Jharkhand, Ladakh, Meghalaya, Maharashtra, Chhattisgarh, Haryana, Punjab, Odisha, Himachal Pradesh 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:

Ladakh PMRU has organized a district level awareness program at the university of Ladakh to disseminate general awareness regarding the monitoring of prices of medicines and medical devices. PMRU also promoted initiatives such as Pharma Sahi Daam and Pharma Jaan Samadhan. During the program, approximately 140 to 150 participants were present.

OTHER NEWS AND EVENTS

During the Month of March 2024, special emphasis was given on conducting activities on International Women's Day with focus on Women Health and related issues. The major glimpses of activities are as follows:

The Puducherry State Price Monitoring and Resource Unit in association with Department of Drugs Control Puducherry has organized an event for International Women's Day on 08.03.2024 at Department of Drugs Control. Puducherry under the guidance of Member Secretary, PMRU. During the Program. PMRU along with Department of Drug Control highlighted and discussed the importance of women's empowerment in the society, women's achievements. Child abuse and health issues related to Women.'

Ladakh Price Monitoring & Resource Unit in collaboration with the Drug Regulatory Department celebrated International Women's Day on 8th March in Leh Market place with mono of "Women health and well-being such as mental and physical health and also promoted the importance of Pharma Sahi Daam and Pharma Jan Samadhan.

Mizoram PMRU in collaboration with Food & Drug Administration wing, Health & Family welfare Department organised Workshop programme as part of celebration of International Women's Day. The event was attended by around 55 staff nurses under Health & Family welfare department and staffs of Food and Drugs Administration wing, Directorate of Health Services.

FREQUENTLY ASKED QUESTIONS

1. What is IPDMS?

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. It provides a single window for submissions of all IPDMS forms as mandated under Drug Price Control Order (DPCO), 2013 & facilitates the stakeholders (Manufacturers/ Marketers/ Importers/ Public) to communicate with the National Pharma Pricing Regulator from across the country. IPDMS 2.0 will also automate the workflow of different divisions of NPPA.

2. What is Pharma Jan Samadhan and Pharma Sahi Daam web application and where can it be located?

The Pharma Jan Samadhan (PJS) is an online facility to raise complaint for Overpricing, Sale without Approval, Refusal of sale and Non-Availability of Drugs.

Pharma Sahi Daam (PSD) is an online search tool for checking MRP of all medicines and Ceiling Prices instantly. The IPDMS/ Pharma Sahi Daam and Pharma Jan Samadhan is available on the link https://nppaipdms.gov.in. The PSD and PJS portals are also available on both iOS and Android platform with the name "Pharma Sahi Daam".

3. What are the major new features in IPDMS 2.0?

- Excel feature for submitting IPDMS forms for multiple Drugs in one go
- Alerts/SMS/OTP for managing the routine tasks & monitoring
- Dashboards/MIS for information decimation and policy decisions.
- Reduction in duplicity of work/role-based access and paperless functioning of NPPA.
- The consumer interface of IPDMS i.e. Pharma Sahi Daam and Pharma Jan Samadhan is also available on mobile application.
- PSD mobile application has features like Speech recognition, Share feature, bookmarking, Complaints submission and view status, Language change etc.

4. Who is required to register on the IPDMS? What is the process of registration and form filing?

Any person who manufactures or imports or markets drugs/ medical devices for distribution or sale in the country is required to file statutory forms under DPCO, 2013. Such person is required to register on the IPDMS for filing forms. The company will have to register itself on the IPDMS website by filling the Firm registration form. After that, the company can login with valid login credentials and enter its plant and product details and submit the required IPDMS forms.

5. Where should one contact in case of any issues with IPDMS, Pharma Jan Samadhan or Pharma Sahi Daam?

Answer: In case of any technical issue, one can drop an email with proper description of the issue/s or with relevant screenshots to nppa-ipdms@gov.in. The technical team will take necessary action at the earliest to resolve the issue

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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