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

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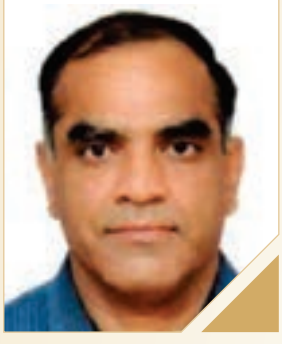


Shri Kamlesh Kumar Pant, IAS
Chairman
National Pharmaceutical Pricing Authority
Department of Pharmaceuticals
Ministry of Chemicals & Fertilizers
Government of India

It is with immense pleasure that I present to you the Seventeenth issue of the NPPA bi-monthly e-Newsletter, NPPA. 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 delighted to note that an insightful article has been contributed experts from Indian Council Of Medical Research (ICMR) on "Epidemiological perspective on emerging disease profile in India". It is an important area of study as it throws light on upcoming emerging disease profiles for the pharma industry to be aware of and align their R&D activities accordingly.

In continuation of our webinar series, Twenty Four (24) Events/ Seminars have been organized by 14 PMRUs in their respective States/ UTs viz. Puducherry, Jharkhand, Ladakh, Maharashtra, Haryana, Punjab, Arunachal Pradesh, Uttarakhand, Meghalaya, Telangana, Kerala, Jammu & Kashmir, Tripura and Uttar Pradesh PMRUs. These events were aimed for imparting awareness among people about Role of NPPA in making the Drugs affordable and available for all, Promotion and use of Pharma Sahi Daam App & IPDMS 2.0, Monitoring of prices of medicines through PMRUs.

I extend my gratitude to the NIPER and ICMR experts for their insight article 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)

EPIDEMIOLOGICAL PERSPECTIVE ON EMERGING DISEASE PROFILE IN INDIA

(By Dr Aruvi Poomali, Project Consultant (Medical), ICMR Headquarters, New Delhi;
Dr Rakesh Kumar Singh, Associate Professor, NIPER Rae Bareli;
Dr Jerin Jose Cherian, Scientist E (Med), Div. of Development Research, ICMR Headquarters, New Delhi)

The war against microbes once thought to be won, early in the 20th century, with the discovery of antibiotics, still rages on – well into the 21st century. While improved public health knowledge including improved sanitation and vector control have reduced the burden of infectious diseases in man, infectious diseases continue to infect humankind leading to significant morbidity and mortality. Around 20% of the deaths worldwide are still attributed to infectious diseases. (1,2)

An emerging infectious disease (EID) is one that has appeared and affected a population for the first time, or has existed previously but is rapidly increasing, either in terms of the number of new cases within a population, or its spread to new geographical areas. (3) The term also applies to those infections which have been reported earlier, had declined or been controlled and are now again being reported in increasing numbers. (4)

It has been reported that approximately 60% of the emerging infectious diseases are zoonotic that is transmitted between species from animals to humans (5). Zoonotic diseases are of particular importance because of their unpredictable nature, as they continue to emerge and spread across countries, and often have epidemic potential.(5) They may either be vector-borne or non-vector-borne. These diseases may be caused by helminths, fungi, protozoa, viruses or prions, bacteria, or rickettsiae, and often, these infections are caused by drug-resistant organisms.

In 2015, WHO published a list of emerging diseases needing urgent R&D. These include Crimean Congo Haemorrhagic Fever, Nipah, Middle East Respiratory Syndrome Corona virus (MERS-CoV), and Rift Valley fever. Three diseases considered serious but not included in the list were Chikungunya, Severe fever with thrombocytopenia syndrome, and Zika. (7)

The brief guide to emerging infectious diseases and zoonoses published by WHO classifies EIDs into viral, bacterial, and parasitic. Most of the viral diseases mentioned are relevant to Asia with reports from the region or have the possibility for future expansion of the geographical distribution of the disease into the region. The diseases include avian influenza, chikungunya, Crimean-Congo haemorrhagic fever, dengue, Hantavirus, Hand foot and mouth disease, Japanese encephalitis, Nipah virus, novel human corona virus, Rabies, Rift Valley Fever, and viral hepatitis. The bacterial infections relevant to the region include anthrax, botulism, brucellosis, leptospirosis, melioidosis, plague, salmonellosis, scrub typhus, and tularaemia. The three emerging parasitic diseases are taeniasis/cysticercosis, toxoplasmosis, and trichinellosis. (4)

There are many factors responsible for the occurrence of EIDs. Demographic factors like increasing population and urban overcrowding, socioeconomic factors like poor sanitation ,and rural-to-urban migration, globalization and increased international travel, changes in the way food is handled and processed are the leading causes. An overwhelmed public health infrastructure and poor infection control measures play a significant role in the establishment of the EIDs. Animal husbandry and agricultural practices put humans in close contact with animals carrying new pathogens, putting the population at high risk for emerging infectious diseases. People working close

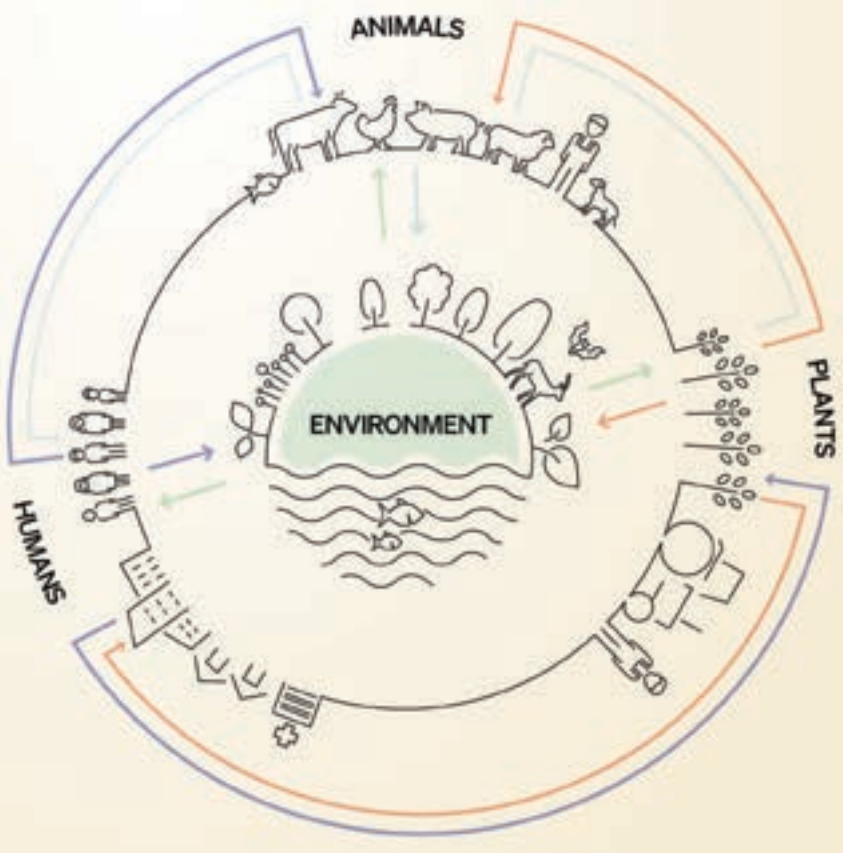
to wildlife are particularly susceptible to EIDs(2). Pockets where game meat is commonly consumed are also susceptible to exposure leading to EIDs. Environmental factors also contribute to the development of EIDs. When vector-borne, the rise of EIDs is dependent on the presence of vectors. Deforestation is said to alter the breeding and abundance of vectors and leads to increased incidence of vector-borne diseases. (6)Global warming is also said to contribute to emerging infectious diseases by affecting the vector population. Microbial capacity for adaptation and evolution and their improved ability to invade human or animal cells also contribute towards the occurrence of EIDs. Indiscriminate use of antimicrobial agents in humans as well as in animal husbandry also increases the risk of EIDs caused by drug-resistant pathogens.

Tackling emerging infectious disease outbreaks requires a multi-pronged approach and begins with community engagement, followed by testing and tracing the source, transmission dynamics studies, infection control, isolation and treatment, and ultimately vaccination to prevent the spread. A WHO report gives five strategic elements to combat emerging diseases, namely (3),

- Epidemic preparedness and rapid response
- Public health infrastructure
- Risk communication
- Research and its utilization
- Advocacy for political commitment and partnership building

However, the outbreaks often originate in remote areas making it difficult for the public health services to reach them. Good infrastructure for diagnostic facilities, collection and transport of samples at the periphery and sufficient capacity to plan, mobilize, implement and monitor control measures are important for curbing the spread of EIDs. An effective collaboration of animal and human health sectors is also essential.(5)

The pandemic that swept the world has shown that emerging infectious diseases are difficult to predict or prevent. Good surveillance measures, high degree of suspicion by front-line workers, rapid response systems, and early vaccine development and extensive vaccine coverage play an important role in early detection and management of outbreaks. Many of the emerging diseases have epidemic potential and these are under constant surveillance by the Integrated Disease Surveillance Programme (IDSP) of the National Centre for Disease Control (NCDC). These include dengue, chikungunya, Japanese encephalitis and other unusual syndromes that have not been captured in the list. Thus, emphasizing on the collaborative efforts by workers and information sharing with multi-sectoral involvement under the umbrella of "One Health" should be the path ahead to tackle these EIDs.



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News related to pricing of drugs

- Ceiling prices for 926 scheduled formulations have been fixed under DPCO, 2013 till 30th June 2024, of which 742 are from NLEM, 2022. Also, Retail prices for 2894 non-scheduled formulations have been fixed under DPCO, 2013 till 30th June 2024.
- 256 Authority meetings (overall) have been conducted of which 124 under DPCO 2013 as on 30.06.2024. The details of the recent meetings are as under:

Meeting No.	Held on	Prices Approved & Notified
255th (overall) & 123rd Meeting under DPCO 2013	10.05.2024	(i) Retail prices for 41 formulations notified vide S.O. 1990(E) & 1991(E) dated 15.05.2024. (ii) Revised Ceiling price of 6 scheduled formulations of Schedule-I (NLEM 2022) under Drugs (Prices Control) Order, 2013 vide S.O. 1992(E) dated 15.05.2024.
256th (overall) & 124th Meeting under DPCO 2013	07.06.2024	(i) Retail prices for 54 formulations notified vide S.O. 2284(E) & 2285(E) dated 14.06.2024. (ii) Ceiling price of special features of 3 scheduled formulations of Schedule-I (NLEM 2022) under Drugs (Prices Control) Order, 2013 vide S.O. 2286(E), 2289(E) & 2290(E) dated 14.06.2024.

- Details of retail prices notified for various formulations based on the decision taken in 123rd and 124th 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	39	Tablets	9.84 – 20.78
2	Analgesic & anti-inflammatory	2	Tablets	18.05 – 25.98
3	Anti-bacterial	4	Infusion/Suspension/ Eye Drops	1.90 – 2074.74
4	Anti-hypertensive	12	Tablet	4.50 – 15.96
5	Cardiovascular	6	Tablet / Capsule	2.68 – 13.84
6	Vitamins/Minerals/ Nutrients	3	Tablet/Capsule	7.82 – 15.94
7	Pain Management	3	Tablet/Spray	1.59 – 30.43
8	Anti-Infective	5	Tablet/ Suspension/Ointment	1.90 – 1569.94
9	Others	21	Capsule/Tablet/ Injection/ Suppository/Gel/ Injection/ Ointment	0.56 – 143.92

REGULATORY NEWS

➲ Ceiling prices of 926 formulations are effective as on date of which details of ceiling prices notified for various formulations under NLEM,2022 till date are as follows:

Therapeutic Category	No. of Medicines	No. of Formulations
Anti-infective Medicines	62	169
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	106	204
Unique Drugs / Formulations	**321***	**742**

*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:

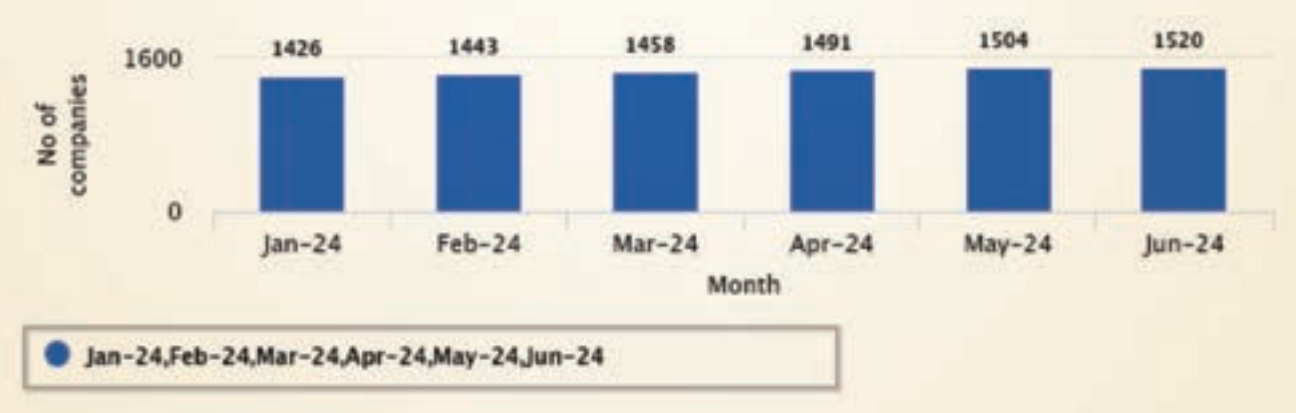


Chart1: Total number of registered companies at month end

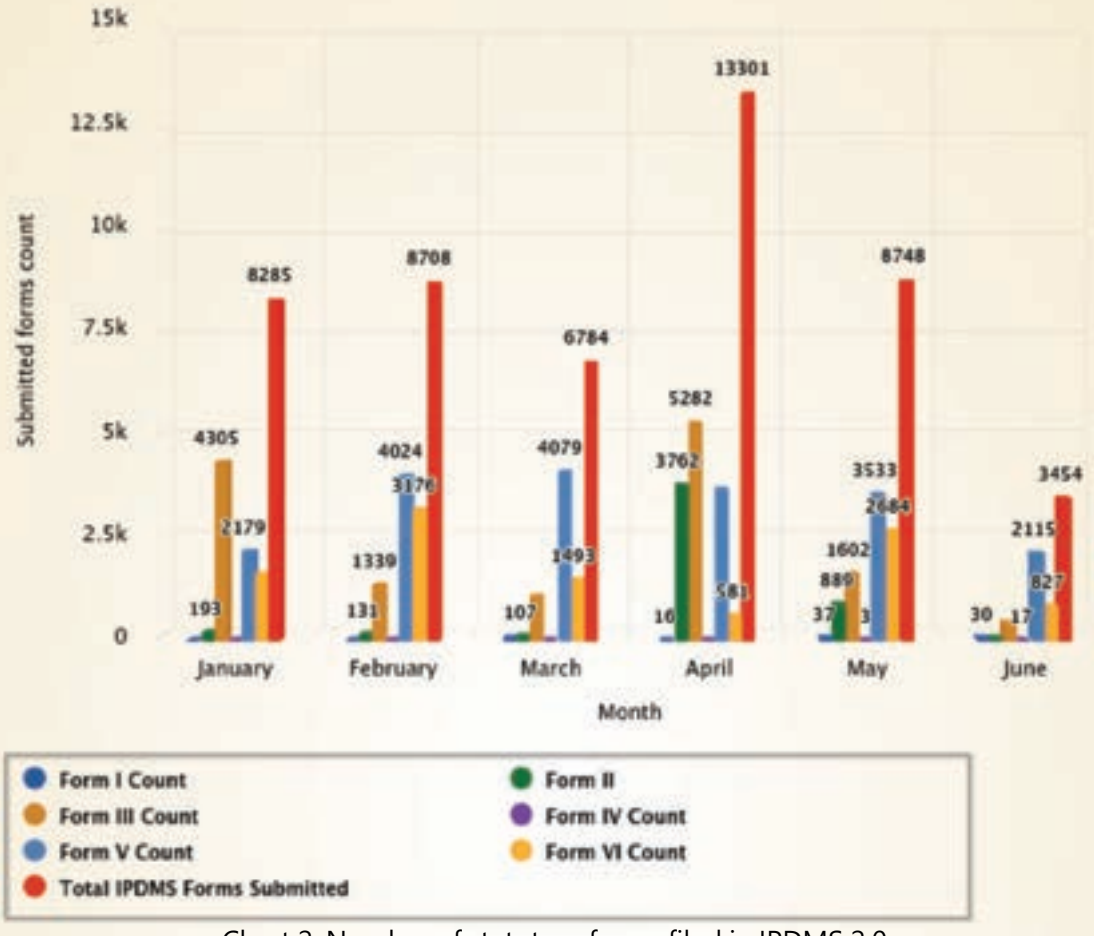


Chart 2: Number of statutory forms filed in IPDMS 2.0

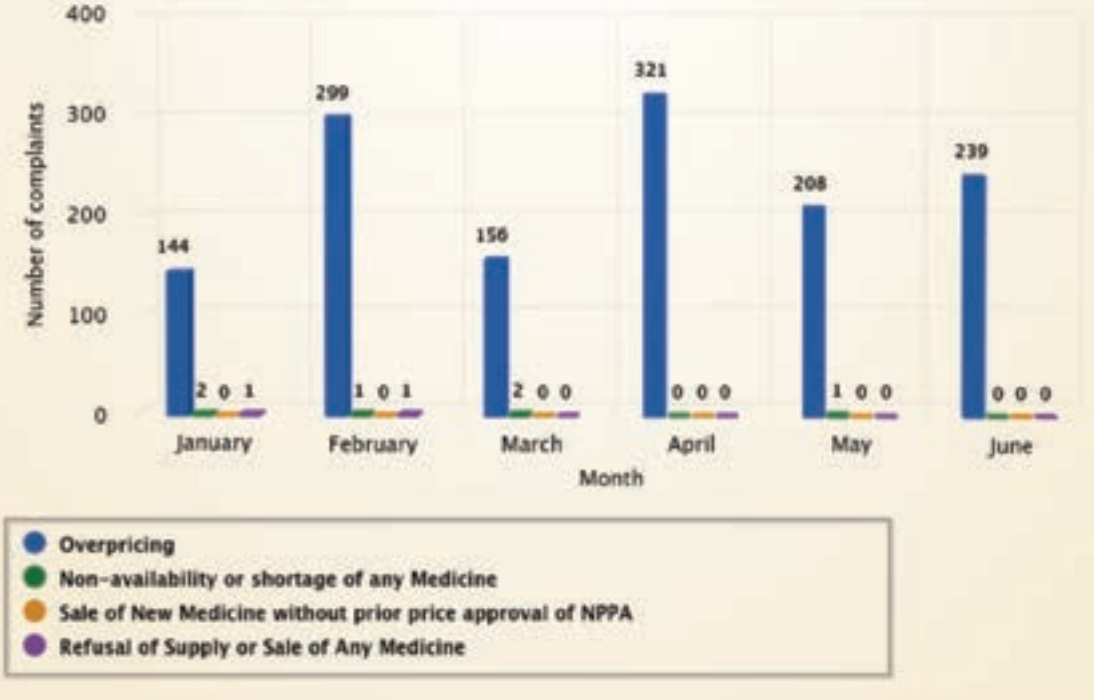


Chart 3: Number of complaints received on IPDMS/ PJS app

Chart 4: Number of Pharma Sahi Daam Mobile app downloads

Chart 5: Number of User logins in IPDMS 2.0

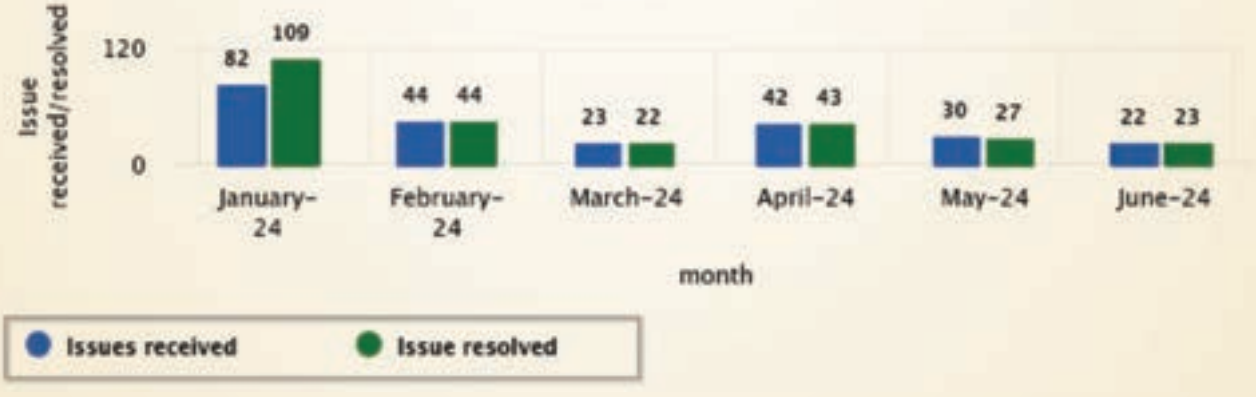


Chart 6: Number of tickets raised/ resolved at IPDMS help-desk

FDA Approves First Interchangeable Biosimilar for Two Rare Diseases (May 28, 2024)

The U.S. Food and Drug Administration approved Bkemv (eculizumab-aeeb) as the first interchangeable biosimilar to Soliris (eculizumab) to treat certain rare diseases. A disease is considered rare if it affects fewer than 200,000 people in the U.S. The conditions- PNH and aHUS are rare diseases characterized by the breakdown of red blood cells. PNH results in anemia (low red blood cells), thrombosis (blood clots), pancytopenia (low counts of red blood cells, white blood cells, and platelets) and dark urine, while aHUS results in anemia, thrombocytopenia (low platelets) and kidney failure.

(Read more)

FDA Expands Approval of Gene Therapy for Patients with Duchenne Muscular Dystrophy (June 20, 2024)

The U.S. Food and Drug Administration expanded the approval of Elevidys (delandistrogene moxeparvovec-rokl), a gene therapy for the treatment of Duchenne muscular dystrophy (DMD) for ambulatory and non-ambulatory individuals 4 years of age and older with DMD with a confirmed mutation in the DMD gene. Elevidys was previously approved under accelerated approval for ambulatory individuals 4 through 5 years of age with DMD with a confirmed mutation in the DMD gene. With today's action, Elevidys received traditional approval in ambulatory individuals 4 years of age and older with DMD with a confirmed mutation in the DMD gene, and accelerated approval in non-ambulatory individuals 4 years of age and older with DMD with a confirmed mutation in the DMD gene. In making this decision, the FDA considered the totality of the evidence, including the potential risks associated with the product, the life-threatening and debilitating nature of the disease and the urgent unmet medical need.

(Read more)

FDA Permits Marketing of First Point-of-Care Hepatitis C RNA Test (June 27, 2024)

The U.S. Food and Drug Administration granted marketing authorization to Cepheid for the Xpert HCV test and GeneXpert Xpress System, the first hepatitis C virus (HCV) test that can be used to bring diagnosis to appropriately certified point-of-care settings for individuals at risk for hepatitis C. The test may be performed in settings operating under a CLIA (Clinical Laboratory Improvement Amendments) Certificate of Waiver, such as certain substance use disorder treatment facilities, correctional facilities, syringe service programs, doctor's offices, emergency departments and urgent care clinics. Rather than requiring a sample to be sent to a central lab for testing, the test detects HCV RNA and delivers results in about an hour using a blood sample from the fingertip.

(Read more)

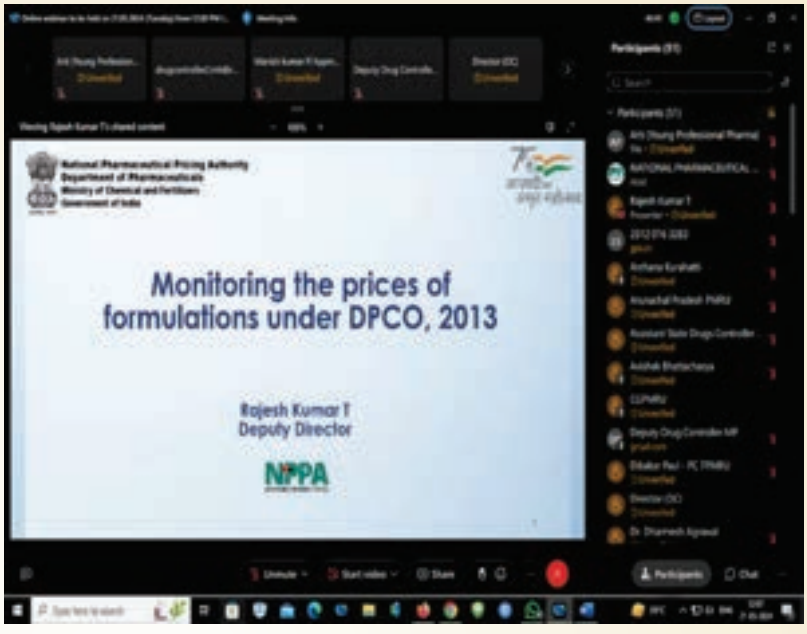
OTHER NEWS AND EVENTS

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

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

A webinar on the topic 'Monitoring the Prices of 'Scheduled and Non-scheduled formulations' held on 21.05.2024.

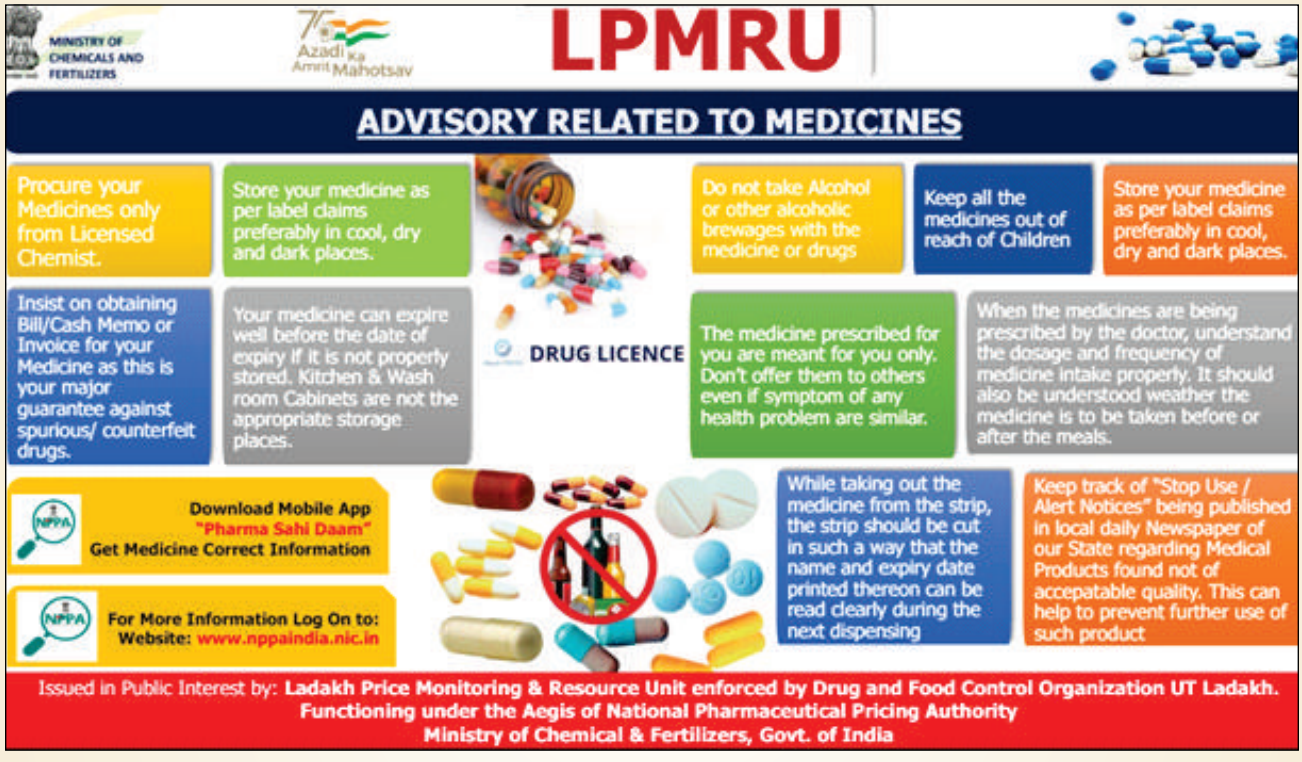
The main aim of the webinar was to provide comprehensive guidance and sharing of knowledge with PMRUs regarding Methodology for Price Monitoring activities of Scheduled and Non-scheduled formulations.



State Level Events/ Seminars by PMRUs

Twenty Four (24) Events/ Seminars have been organized by 14 PMRUs in their respective States/ UTs viz. Puducherry, Jharkhand, Ladakh, Maharashtra, Haryana, Punjab, Arunachal Pradesh, Uttarakhand, Meghalaya, Telangana, Kerala, Jammu & Kashmir, Tripura and Uttar Pradesh PMRUs. These events were aimed for imparting awareness among people about Role of NPPA in making the Drugs affordable and available for all, Promotion and use of Pharma Sahi Daam App & IPDMS 2.0, Monitoring of prices of medicines through PMRUs. Major glimpses of the activities are as follows:

PMRU Ladakh:



OTHER NEWS AND EVENTS

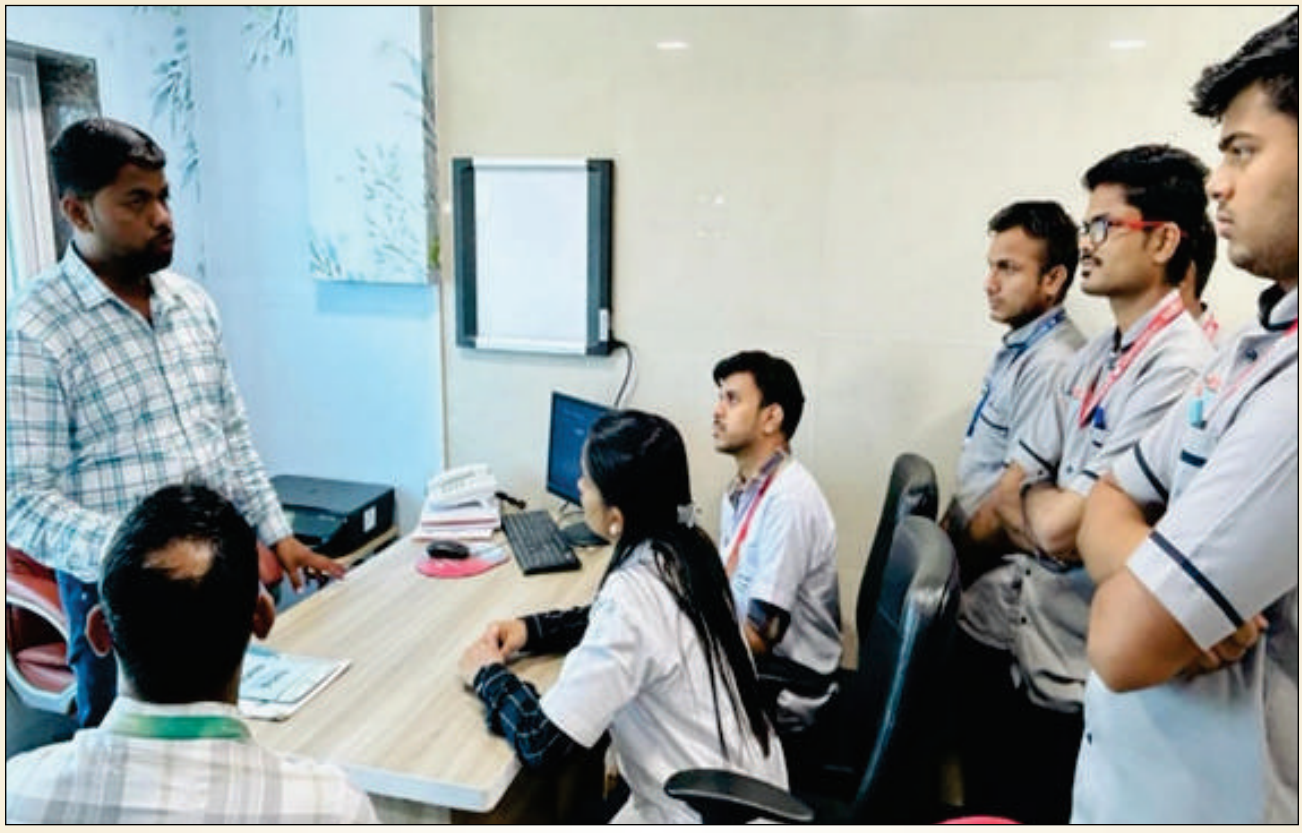
PMRU Ladakh:

PMRU Tripura:

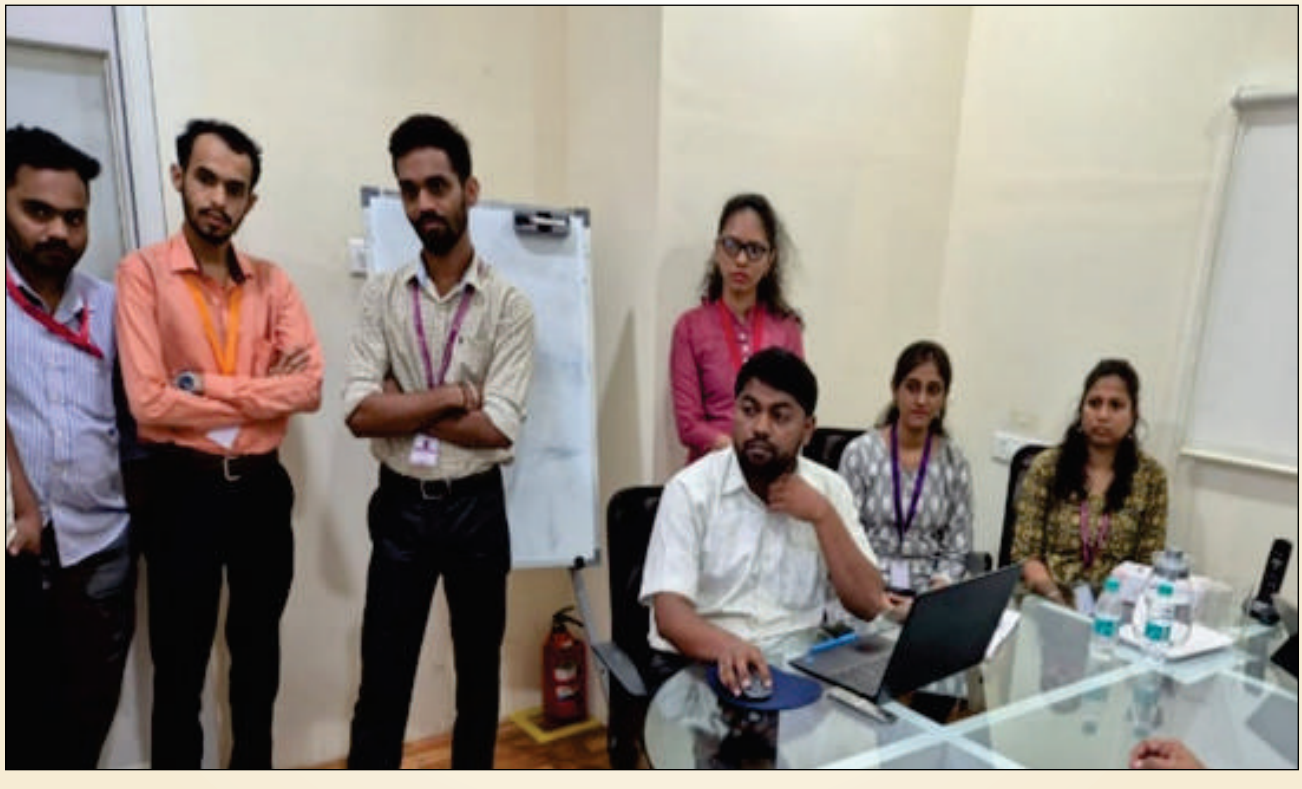
Seminar on 'Regulation of Medicine Price by NPPA & Introduction of "Pharma Sahi Daam" at I.T.I. Teliamura, Khowai, Tribue on 24-04-2024

PMRU Jharkhand:

OTHER NEWS AND EVENTS



PMRU Maharashtra:



PMRU Maharashtra:

PMRU Uttarakhand:

FREQUENTLY ASKED QUESTIONS

Question: What is the role of NPPA for price regulation of medicines?

Answer: NPPA fixes ceiling price to all drugs notified under Schedule-I of the DPCO, 2013 and monitors prices as per DPCO,2013 provisions so that drugs remain affordable.

Question: What is "Ceiling Price"?

Answer: Ceiling price of Scheduled formulations covered under National List of Essential Medicines (NLEM) are fixed under Para 4 and revised under Para 16 of DPCO 2013. MRP in such cases is Ceiling Price plus applicable taxes.

Question: Whether NPPA has any role to regulate prices of non-scheduled drugs?

Answer: The Government monitors the Maximum Retail Price (MRP) of all drugs including non-scheduled formulations to ensure that no manufacturer increases the MRP of a non scheduled drug more than ten percent of maximum retail price during the preceding twelve month and any manufacturer violating the provisions is liable to deposit the overcharged amount along with the interest. (Para 20 of DPCO 2013)

Question: Whether manufacturers have to take permission of the Government before discontinuing the manufacture of essential medicines?

Answer: As per Paragraph 21 of DPCO, 2013, manufacturers have to take permission of the Government before discontinuing the manufacture of essential medicines.

Question: What is the grievance redress mechanism related to pricing, shortage and non-availability of medicines?

Answer: The Pharma Jan Samadhan (PJS) provides the consumer with an effective and time bound grievance redress system to effectively deal with complaints related to: pricing, shortage and non-availability of medicines. Apart from the internet- based online facility, there is a consumer Help Line also, which can be used to lodge complaints.

Question: Is there any tool to check the authenticated MRP of medicine?

Answer: Yes. 'Pharma Sahi Daam' is an online search tool through which prices of scheduled / Non-Scheduled medicines can be instantly checked.

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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