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

CONTENTS

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

The journey of publishing NPPA bi-monthly e-Newsletter, the AUSHADH SANDESH began in October 2021. It is with immense pleasure that I present to you the twentieth issue of AUSHADH SANDESH. Our objective of bringing out the newsletter remains steadfast - to disseminate information that caters to the diverse interests of our stakeholders, thereby fostering informed decision-making and collaboration within the pharmaceutical and med-tech landscape.

During the course of bringing out these twenty issues, we have had the privilege of eminent experts from the government, industry, academia writing on diverse topics. For our twentieth issue, I am happy to note that article titled "Funding in Health-Related Start-ups in India and the Way Forward" has been contributed by Dr Jitendra Kumar, Managing Director, Biotechnology Innovation Research Assistance council (BIRAC)). India is poised to become a hub for health-related start-ups and investors due to its growing demand for better healthcare solutions and rapid technology adoption. To sustain growth, challenges like funding, regulation, and market adoption must be addressed. Government initiatives, such as the BioE3 policy, demonstrate proactive support for start-ups, promoting green growth, and transforming manufacturing paradigms. I extend my gratitude to Dr Jitendra Kumar for his insightful article.

In continuation of our webinar series, in November 2024 an interactive webinar on 'PMRU Module in IPDMS 2.0' was organized by PMRU Division for all Price Monitoring and Resource Units (PMRUs) established in 31 States/UTs. The main objective of above webinar was to provide step by step procedure for reporting of data/information related to PMRUs activities through IPDMS 2.0. In addition to the Webinar series, Twenty(20), IEC (Information, Education and Communication) activities have also been conducted by 9 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.

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

With best wishes

(P. Krishnamurthy)

FUNDING IN HEALTH-RELATED START-UPS IN INDIA AND THE WAY FORWARD

(By **Dr Jitendra Kumar,** Managing Director, Biotechnology Innovation Research Assistance council (BIRAC))

India presents a conducive environment for start-ups working in the domain of health and is also recognised as a promising and rapidly growing hubs for health-related start-ups. With the growing population, evolving disease burden and ever-increasing healthcare needs, India presents both opportunities and challenges. At the same time, technology, innovation, and new business models are converging to provide solutions to these challenges. Over the past few years, the healthcare start-up ecosystem in India has seen tremendous growth acting as an attractive platform for investors and entrepreneurs. However, for health-related start-ups to flourish in full spring and address the sector's deep-rooted challenges, access to funding, infrastructure, and supportive policies are crucial to address.

Current Status of Health – related Start-ups in India

India is poised to be one of the leading nations in the number of health start-ups. The country's health-tech sector is spread across different domains which includes telemedicine, diagnostics, medical devices, pharmaceuticals, wellness, fitness, biotechnology, digital health records etc. over the years the Indian healthcare start-up ecosystem has shown tremendous growth with approximately 4,000 start-ups working in the domain of health. The importance of health-related start-ups in the country has been realised during the pandemic times and the need for providing a conducive environment for them to flourish in the country. It is to note that pandemic further accelerated the demand for digital healthcare services, creating an even more fertile ground for health-tech innovations. With more than 1.4 billion population in the country the push for this sector needs priority with more focus on healthcare infrastructure, healthcare innovations for rural sector and tier II, tier III cities and technology driven solutions. In the current changing times, boost for health-related start-ups in the domain telemedicine, AI-based diagnostics, and cloud-based health data platforms is what is needed to offer the possibility to overcome different barriers and reach undeserved populations.

Available funding sources for Health-related Start-ups in India

One of the most crucial factors determining the success of health- related start-ups are large investments in the research, regulatory compliances and scaling up. Funding modalities available for health-related start - ups in India range from government sources of funding to angel investors and venture capital funding.

1. **Government sources of Funding and Regulatory Support.** Different government agencies such as ICMR, BIRAC, DBT, NITI Aayog, DST and government schemes such as Startup India, Standup India, MUDRA offer wide range of funding options to start-ups working in the domain of health. BIRAC through its different schemes such as Biotechnology Ignition Grant (BIG), Biotechnology Industry Partnership Program (BIPP), The Small Business Innovation Research Initiative (SBIRI), Promoting Academic Research Conversion to Enterprise (PACE) focusing on academic research innovation and contract research, encourage and support academia and industry collaborations for development of technologies up to

proof of concept and validation of products/ technologies towards commercialization. These specialised schemes provide funding along with technical mentorship and guidance from ideation to late stage to biotech start-ups including health related start-ups thereby stimulating technological innovation in the country. The specialized divisions in BIRAC i.e. the Regulatory Affairs & Policy Advocacy division (RAPA) and the Intellectual Property (IP) and technology management division (IPTEM) provide support to innovators in navigating the dynamic regulatory complexities in India and world and facilitating the innovators in the IP, Tech-Transfer, licensing and commercialization of products and technologies. ICMR through its investigator-initiated schemes and other collaborative projects support numerus start-ups in the domain of health and public health. The MedTech Mitra a joint initiative of ICMR, NITI Aayog and CDSCO is a one of its kind partnerships programs for facilitating the MedTech innovators in clinical validation, regulatory guidance and uptake of new products. Mission programs such as Atal Innovation Mission (AIM) under NITI Aayog aims at promoting innovation and entrepreneurship across different sectors including health. With incubation centres established across India under different government programs such as BioNEST and SPARSH centres supported by BIRAC and technology business incubators supported under DST, dedicated funds allocated for start-ups in health along with mentorship and networking opportunities for innovators a conductive ecosystem for health-related start-ups is available in the country. The National Science & Technology Entrepreneurship Development Board (NSTEDB) established in 1982 by DST supports the promotion of knowledge-driven and technology-intensive enterprises. The revamped version, National Initiative for Developing and Harnessing Innovations (NIDHI) launched in 2016 by DST enables innovators and startups to translate their ideas into successful startups since their initial phases of journey including startups in the health sectors.

2. **Seed funding, Angel Investors and Venture Capital:** It has been noted that early-stage funding plays a critical role for starts-ups to establish their foundation and initiate proof of concept studies. Angel investors play an important role via seed funding options for health-related start-ups, the investors generally offer small investments in exchange for equity along with bring valuable experience and mentorship to the start-ups. Government agencies such as BIRAC through its equity funding programs such as Sustainable Entrepreneurship and Enterprise Development fund (SEED), Launching Entrepreneurship Driven Affordable Products fund (LEAP) and Accelerating entrepreneurs (AcE) supports different health start-ups. Through the SEED support capital assistance to post PoC Startups with new and meritorious ideas, innovations and technologies is provided enabling them to achieve angel investment readiness. Further LEAP fund assists potential startups in piloting & commercializing their products & technologies acting as a catalyst enabling them to raise venture capital investment. The AcE fund termed as fund of funds aims to foster innovation and research and development by encouraging VC investment for biotech startups, SMEs including heath related startups through its AcE fund partners. Such initiatives along with funding support also provide health start-ups extensive networking and mentorship opportunities. Over the years the increasing interest from angel investors for health-related start-ups in incubators, accelerators have been promising by providing financial as well as non-financial support to the nascent business. A significant source of capital in growth stage of health startups is realised through venture capital (VC). The surge in VC backed health related startups has seen tremendous growth and benefits in the country over the years.

3. **Private equity, Corporate Funding and Strategic Partnerships:** It is seen that private equity (PE) investors plays an important role in providing support to health-related start-ups that have reached the growth stage, with larger investments flowing in as compared to VCs. The focus of PE is on more mature start-ups with a proven business model. In recent times Indian health-tech start-ups have attracted significant private equity funding from global investors such as General Atlantic etc. In the recent years a trend in the inflow of large corporations, both domestic and international to partner with health-related start-ups for technological advancement and acceleration in their growth has been witnessed. It has been observed that many pharmaceutical companies, big giants and hospitals are now engaging in partnerships or investments with start-ups in areas such as AI-based drug discovery, patient monitoring, and wellness

technology. Such strategic collaborations prove to be beneficial in health-tech start-ups with funding, distribution channels, and access to existing infrastructure.

Current challenges faced by health-related start-ups

India although presents a favourable atmosphere for the start-ups working in the domain of health, however few challenges still persist in the country in from funding to regulatory processes by the start-ups. One of the critical concerns being long regulatory and approval processes. It has been observed that due to the lengthy regulatory approvals in the country delay in time to market results in uncertainty among the investors. Further it has been noted that health sector requires substantial investments for activities such as research, regulatory compliances, long development cycles especially in the biopharma sector. Many a times high capital requirement act as a roadblock for early-stage investors with apprehensions of different uncertainties. Surveys and studies have shown that health-tech sector in India, requires significant market education. Lack of trust among consumers and healthcare professionals to adopt new technologies reduces investor confidence in new and untested areas such as AI based solutions and telemedicine. Due to excessive regulatory complexities and ethical concerns Indian investors are reluctant in taking risk for health-related start-ups, making it harder for start-ups to secure funding in the early stages of development. It is to note that along with regulatory approval/ process, funding opportunities one of the critical challenges that Indian health related startups face is the challenge of scaling up be it in terms of infrastructure, products being manufactured or availability of large GMP complaint facilities which can also be viewed in terms of emerging technologies. Addressing the challenges and streamlining processes is needed for India to flourish through its innovative potential.

Way forward

India is poised to be a top destination for health-related start-ups and investors in the coming years, given the country's increasing demand for better healthcare solutions and the rapid adoption of technology. However, sustainable solutions to challenges with respect to funding regulation and market adoption needs to be addressed for the sector's sustained growth. Newer initiatives such as BioE3 policy by the Department of Biotechnology, Government of India, which focuses on high performance biomanufacturing and bio foundry initiatives demonstrates the proactive role of the government in supporting the start-ups along with promoting green growth in the country by transforming the consumptive manufacturing paradigm to the one based on regenerative principles and also proving opportunities for scaling up the biotechnology potential of the country. With components such as enhanced public private partnerships, simplifying regulatory process and enhanced fund corpus, along with the government initiatives, the need of an hour is focus on building investor confidence, simplifying regulatory processes, strengthening support ecosystems along with attracting global investments & forging multilateral collaborations. India to emerge as a global leader in the health-tech space, emerging technologies and deep tech more innovative solutions needs to be developed and adopted. India has the potential to transform its healthcare landscape while providing lucrative opportunities for investors and entrepreneurs.

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News related to pricing of drugs

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

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 3111 (approx.) new drugs have been fixed under DPCO, 2013 till date. As on 31.12.2024, 260 Authority meetings have been conducted of which 128 have been conducted under DPCO 2013. The details of the decisions taken in the recent meeting held in December 2024 are given below:

Meeting No.	Prices Approved & Notified
260th (overall) & 128th Meeting under DPCO 2013 (held on 12.12.2024)	(i) Retail prices for 65 formulations notified vide S.O. 5493(E) dated 19.12.2024.
	(ii) Revision of Ceiling price of 7 scheduled formulations viz. based on review orders passed by of DoP. Prices notified through SO 5498 (E) dated 19.12.2024 i. Thiamine Injection 100mg/ml, ii. Clarithromycin Oral liquid 125mg/ 5ml, iii. Lignocaine 2% injection, iv. Lignocaine Topical forms 2-5%, v. Clarithromycin Tablet 250 mg, vi. Ascorbic acid Tablet 500 mg vii. Atorvastatin Tablet 10 mg
	(iii) Fixation/Refixation of ceiling price of following 13 scheduled formulations under NLEM, 2022 notified vide S.O. 5497 (E) dated 19.12.2024. i. Anti-rabies immunoglobulin Injection 150 IU/ml ii. Anti-rabies immunoglobulin As Injection 300 IU/ml iii. Measles vaccine As licensed iv. Anti-tetanus immunoglobulin As Licensed (250 IU)

Meeting No.	Prices Approved & Notified
	v. Anti-tetanus immunoglobulin As Licensed (500IU) vi. Anti-tetanus immunoglobulin As Licensed (1000IU) vii. BCG vaccine As licensed viii. Measles Rubella vaccine As licensed ix. Amphotericin B Liposomal Injection 50mg/ vial x. Amphotericin B Lipid Injection 50mg/ vial xi. Water for injection xii. Budesonide (A) + Formoterol (B) Inhalation (MDI) 400mcg (A) + 6mcg (B) xiii. Budesonide (A) + Formoterol (B) Inhalation (MDI) 200mcg (A) + 6mcg (B)

3. Details of retail prices notified for various formulations based on the decision taken in 128th 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	21	Tablet	7.46-18.21
2	Analgesic & anti-inflammatory	3	Suspension	0.73-0.92
3	Anti-bacterial	3	Tablet/Infusion	24.66-1036.60
4	Anti-hypertensive	2	Tablet	13.25-16.10
5	Cardiovascular	13	Tablet	6.32-50.00
6	Vitamins/Minerals/ Nutrients	4	Tablet/ Suspension/Drops	0.45-20.23
7	Anti-Infective	5	Tablet/Infusion/Capsule	11.51-1422.21
8	Others	14	Tablet/ Capsule Suspension/Ointment	0.83-35.64

4. Recently, Department of Pharmaceuticals (DoP) has issued 4 Review Orders for the formulations viz. Caffeine Oral Liquid 20mg/ml, Metoprolol 100mg Modified Release Tablet, Acyclovir 800mg Tablet, Methylprednisolone Injection 40mg/ml in the month of November 2024. In all these orders, decision of NPPA has been upheld by DoP.

News related to Medical Devices:

NPPA vide S.O. 4078(E) dated 15th September 2023 issued notification under Para 19 of the DPCO, 2013 regarding fixation/revision of ceiling prices of the Orthopaedic Knee Implants for Knee Replacement Systems up to 15th September 2024. This has been further extended up to 15th September 2025 vide S.O.3869(E) dated 10.09.2024.

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 January to December 2024:

Chart1: Total number of registered companies at the end of December 2024.

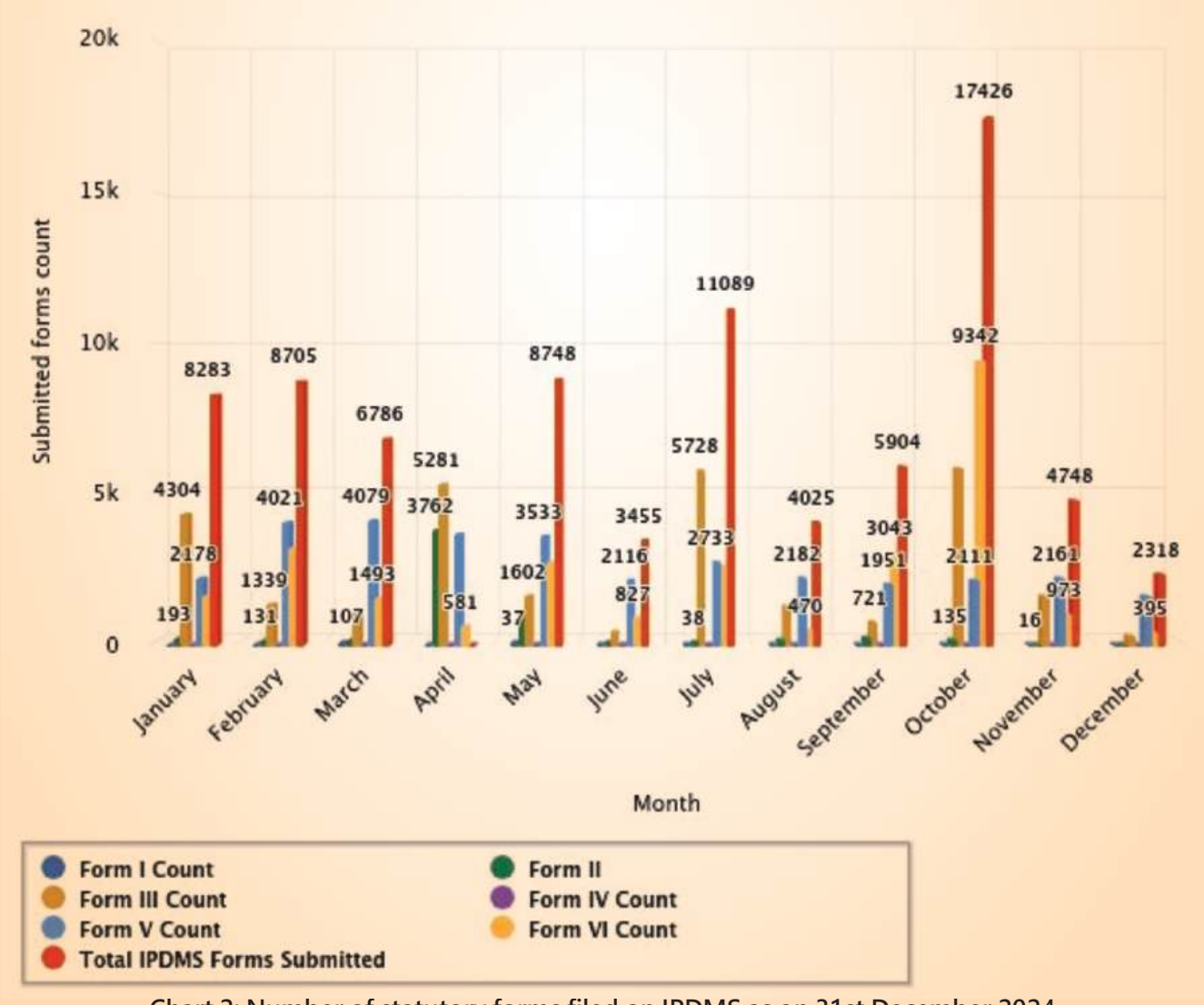


Chart 2: Number of statutory forms filed on IPDMS as on 31st December 2024

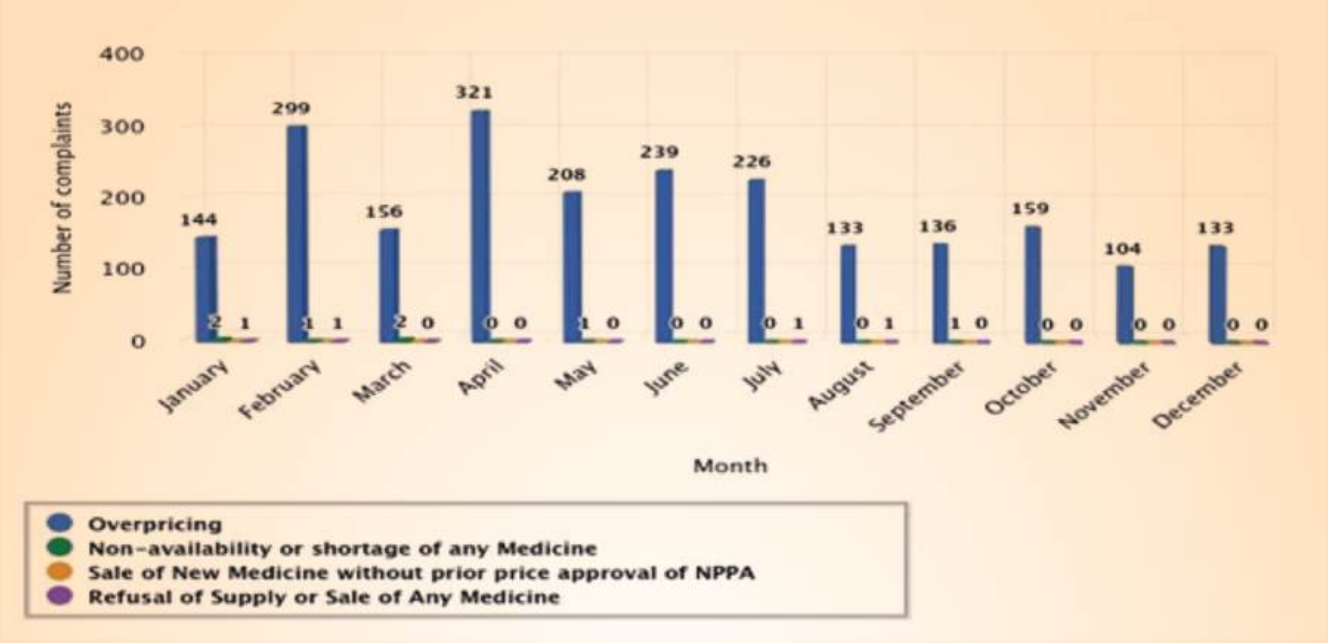


Chart 3: Number of complaints received on IPDMS/ Pharma Jan Samadhan

Chart 4: Number of Pharma Sahi Daam Mobile app downloads

Chart 5: Number of User logins in IPDMS 2.0

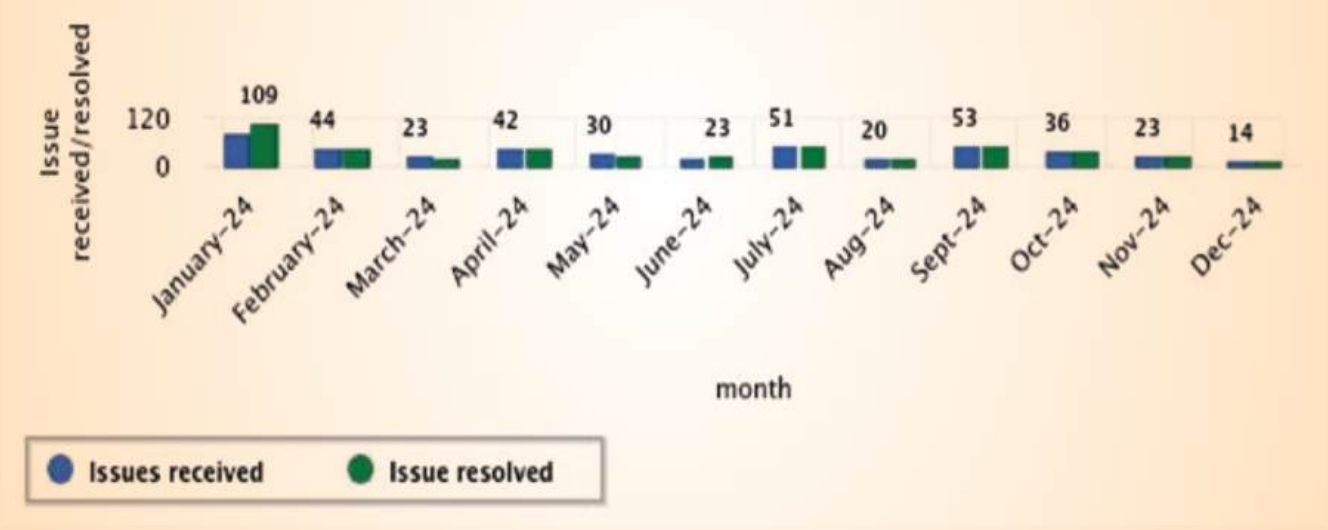
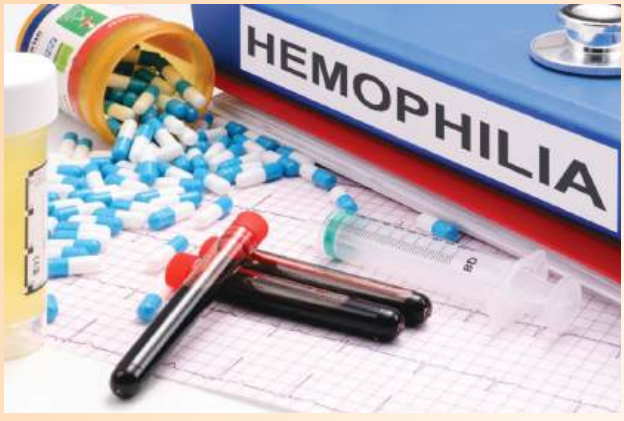


Chart 6: Number of tickets raised/ resolved at IPDMS help-desk

INTERNATIONAL NEWS

FDA Approves New Treatment for Hemophilia A or B Product is First Non-Factor and Once-Weekly Treatment for Hemophilia B (October 11, 2024)



The U.S. Food and Drug Administration approved Hympavzi (marstacimab-hncq) for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients 12 years of age and older with hemophilia A without factor VIII inhibitors or hemophilia B without factor IX inhibitors (neutralizing antibodies). Hemophilia A and hemophilia B are genetic bleeding disorders caused by a dysfunction or deficiency of coagulation factor VIII (FVIII) or IX (FIX), respectively. Patients with these hemophilia are unable to clot properly and may bleed for a longer time than normal after injury or surgery. They may also have spontaneous bleeding in muscles, joints and organs, which can be life-threatening. These bleeding episodes are typically managed by either on-demand, episodic treatment or prophylaxis using products containing FVIII or FIX, or a product that mimics a factor.

(Read more)

FDA Proposes Ending Use of Oral Phenylephrine as OTC Monograph Nasal Decongestant Active Ingredient After Extensive Review (November 07, 2024)

The U.S. Food and Drug Administration announced it is proposing to remove oral phenylephrine as an active ingredient that can be used in over-the-counter (OTC) monograph drug products for the temporary relief of nasal congestion after an agency review of the available data determined that oral phenylephrine is not

effective for this use. For now, companies may continue to market OTC monograph drug products containing oral phenylephrine as a nasal decongestant. This is a proposed order. Only a final order will affect what products can be marketed. The proposed order is based on effectiveness concerns, not on safety concerns. Currently, oral phenylephrine is widely used as a nasal decongestant active ingredient in many OTC monograph drug products. It is important to note that some products only contain oral phenylephrine as a single, active ingredient. Others contain oral phenylephrine and another active ingredient (e.g., acetaminophen or dextromethorphan), and the presence of oral phenylephrine in these medicines does not affect how other active ingredients work to treat the symptoms for which they are intended.

(Read more)

FDA Approves First Gene Therapy for Treatment of Aromatic L-amino Acid Decarboxylase Deficiency (November 14, 2024)

The U.S. Food and Drug Administration approved Kebilidi (eladocagene exuparvovec-tneq), an adeno-associated virus vector-based gene therapy indicated for the treatment of adult and paediatric patients with aromatic L-amino acid decarboxylase (AADC) deficiency. Kebilidi is the first FDA-approved gene therapy for treatment of AADC deficiency. Aromatic L-amino acid decarboxylase deficiency is a rare genetic disorder that affects the production of some neurotransmitters, which are chemical messengers that allow cells in the body's nervous system to communicate with each other. Affected individuals may experience symptoms such as delays in gross motor function (head control, sitting, standing, and walking), hypotonia (weak muscle tone), and developmental and cognitive delays.

(Read more)

FDA Approves New Treatment for Congenital Adrenal Hyperplasia(December 13, 2024)

The U.S. Food and Drug Administration approved Crenessity (crinecerfont) to be used together with glucocorticoids (steroids) to control androgen (a testosterone-like hormone) levels in adults and paediatric patients 4 years of age and older with classic congenital adrenal hyperplasia (CAH). Classic congenital adrenal hyperplasia is a rare genetic condition affecting the adrenal glands, which produce hormones such as cortisol and androgens. Patients with classic CAH do not produce enough cortisol and produce too many androgens. These patients require high doses of glucocorticoids (more than is typically needed to replace the deficient cortisol) because the glucocorticoids also help to reduce the excess levels of androgens. Crenessity works by reducing excessive adrenal androgen production, which helps reduce the amount of glucocorticoid treatment needed.

(Read more)

FDA Approves First Mesenchymal Stromal Cell Therapy to Treat Steroid-refractory Acute Graft-versus-host Disease (December 18, 2024)

Today, the U.S. Food and Drug Administration approved Ryoncil (remestemcel-L-rknd), an allogeneic (donor) bone marrow-derived mesenchymal stromal cell (MSC) therapy indicated for the treatment of steroid-refractory acute graft-versus-host disease (SR-aGVHD) in pediatric patients 2 months of age and older.Ryoncil is the first FDA-approved MSC therapy. It contains MSCs, which are a type of cell that can have various roles in the body and can differentiate into multiple other types of cells. These MSCs are isolated from the bone marrow of healthy adult human donors. Steroid-refractory acute graft-versus-host disease is a serious and life-threatening condition that can occur as a complication of allogeneic hematopoietic (blood) stem cell transplantation (allo-HSCT). In allo-HSCT, a patient receives hematopoietic stem cells from a healthy donor to replace their own stem cells and form new blood cells, a procedure often done as part of treatment for certain types of blood cancers, blood disorders or immune system disorders.

(Read more)

RETAIL PRICES OF 65 NEW DRUGS FIXED (PUBLISHED IN BUSINESS STANDARD)

Retail prices of 65 new drugs fixed

SANKET KOUL
New Delhi, 22 December

- The decision to revise the prices of the formulations was taken during the NPPA's 128th meeting on December 12
- Prices have been fixed for drugs used to treat Type 2 diabetes
- The government mentioned that makers of scheduled formulations shall revise the prices of all formulations downward not exceeding the ceiling price

The National Pharmaceutical Pricing Authority (NPPA) has fixed retail prices for 65 new drug formulations and notified ceiling price fixation of 13 formulations. The regulatory body, under the Department of Pharmaceuticals, also revised the ceiling prices of seven other drugs to include the impact of the 0.00551 per cent increase in drug prices in the National List of Essential Drugs (NLEM), based on the changes in the wholesale price index (WPI) for 2024.

The decision to revise the prices of the formulations was taken during the authority's 128th meeting on December 12. Prices have been fixed for drugs used to treat Type 2 diabetes, high cholesterol, bacterial infections, and painkillers, whereas drugs with revised ceiling prices include vaccines for rabies, tetanus, and measles, among others, according to multiple notifications from the NPPA.

The revision and fixation of retail and ceiling prices is a routine exercise undertaken by the NPPA. The drug pricing regulator is vested with the responsibility of fixing and revising the prices of pharmaceutical products, enforcing provisions of the Drug Price Control Order (DPCO), and monitoring the prices of both controlled and decontrolled drugs. In a recent government notification, retail prices of essential fixed combination drugs (FDCs) such as a combination of atorvastatin and ezetimibe tablets, used to treat high cholesterol, by reducing "bad" cholesterol (LDL) and triglyceride levels have been fixed. FDCs are drugs that contain a combination of two or more active pharmaceutical ingredients (APIs) in a single form, usually manufactured and distributed in a fixed ratio.

Other FDCs included in the list include the combinations of dispersible amoxycillin and potassium clavulanate used to treat bacterial infections such as sinusitis, and gliclazide and metformin hydrochloride, which is used to treat Type 2 diabetes. The list also includes dietary supplements such as oral cholecalciferol (Vitamin D3) tablets and antifungal itraconazole capsules.

The 20 drugs whose ceiling prices have been revised include 13 new drugs such as injectable immunoglobins for rabies, tetanus, measles, and BCG, whereas prices of the other seven drugs have been revised after review order to include WPI rate impact.

This list of seven essential formulations includes injectable version of thiamine (Vitamin B1), versions of lignocaine (local anesthetic), tablets for ascorbic acid (Vitamin C), and tablet and liquid versions of clarithromycin (antibiotic).

The government notification mentioned that manufacturers of scheduled formulations selling its branded, generic, or both versions at a price higher than the ceiling price (plus Goods and Services Tax as applicable), shall revise the prices of all such formulations downward not exceeding the ceiling price specified.

NAFITHROMYCIN: COUNTRY'S FIRST INDIGENOUS ANTIBIOTIC

Nafithromycin, was officially launched on November 20, 2024, by Union Minister Dr. Jitendra Singh. Developed by Wockhardt with support from the Biotechnology Industry Research Assistance Council (BIRAC), Nafithromycin, marketed as "Miqnaf," targets Community-Acquired Bacterial Pneumonia (CABP) caused by drug-resistant bacteria, which disproportionately affects vulnerable populations such as children, the elderly, and those with compromised immune systems.

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A Brief History of Drug Price Control in India

DR. ANIL KUMAR ANGRISH

Partial similarity of the title used in this article to 'A Brief History of Time' by Stephen W. Hawking is intentional as it attempts to present the history of drug price control in India but not in non-technical terms as Hawking's work presented the structure, origin, development, and eventual fate of the Universe.

In India, the Drugs and Cosmetics Act, 1940 regulates the import, manufacture, distribution and sale of drugs and cosmetics. Section 3(b) of the Act defines the drug that includes (i) all medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes; (ii) such substances (other than food) intended to affect the structure or any function of the human body or intended to be used for the destruction of vermin or insects which cause disease in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette; (iii) all substances intended for use as components of a drug including empty gelatin capsules; and (iv) such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette, after consultation with the Board.

This background is necessary as this forms the sphere of influence under Drug Price Control. In the wake of the Indo-Chinese War, the Drugs (Control of Prices) Order, 1963 was issued to cap drug costs. This Order was issued under the provisions of the Defence of India Act of 1915. Main aim of this Order was to make pharmaceuticals affordable and available. Pharmaceutical industry was critical of the freeze order on the ground that the prices of relevant APIs were not frozen. In 1966, a system was put in place that permitted selective increases thereby replacing total freeze. Additionally, 16 essential drugs were identified and referred to the Tariff Commission for examining the 'cost structure' and recommending 'fair selling prices.' The Drugs Prices (Display & Control) Order was notified in 1966 (NPPA full book, p.31). Manufacturers of pharmaceutical products were under obligation to obtain prior approval of the Government before increasing the prices of all formulations in their lists as on June 30, 1966. In August 1968, generic drugs were exempted from price approval.

The Drug (Prices Control) Order 1970 was issued under Section 3 of the Essential Commodities Act, 1955. This was aimed at lowering the prices of essential pharmaceuticals by limiting excessive profits. The Government of India constituted a committee under the chairmanship of Sh. Jaisukhlal Hathi, Member of Parliament, in 1974 which submitted its report titled, 'Report of the Committee on Drugs and Pharmaceutical Industry' (popularly known as Hathi Committee Report) in 1975. Out of 224 recommendations, a key recommendation was about introduction of a list of essential medicines. 44 drugs derived from synthetic sources were identified as essential drugs by the Committee, and overall 116 essential drugs were listed.

The first Drug Policy of India was formulated in March 1978. This was followed by the Drugs (Price Control) Order, 1979 under which bulk drugs as well as formulations were classified as scheduled and non-scheduled. For scheduled formulations (about 4,000 in number), retail price was to be determined by using 'mark-ups' over material and other costs. In contrast to this, maximum selling prices of regulated bulk drugs (347 in number) was to be determined by taking into consideration stipulated rates of return on net worth/capital employed.

Due to different mark-ups, pharmaceutical business entities curtailed production in those categories which offered lower allowable mark-ups. In this background, a committee – Kelkar Committee (named after Sh. Vijay Kelkar) was constituted in 1984 which recommended the reduction in the number of drugs under price control. This was followed by the Drug Policy, 1986 and DPCO, 1987. Under DPCO, 1987 the number of regulated bulk drugs came down to 142. Two key arguments, i.e., India becoming one of the cheapest drug makers in the world since the early 1980s, and the rate of increase of drug prices being lower than general price level, formed the basis for reduction in the number of drugs under price control.

Economic reforms of 1991 resulted into modification of the Drug Policy of 1986. In 1995, new DPCO was announced under which just 74 bulk drugs remained under price control. The criteria applied included market competition and annual turnover. In 1997, the National Pharmaceutical Pricing Authority (NPPA) was formed and the task of price fixation, revision and other related matters for bulk drugs and formulations were transferred to NPPA which used to be dealt by the Bureau of Industrial Costs & Prices (BICP) earlier.

In March, 1999 the Government constituted a Drug Price Control Review Committee (DPCRC) to review the existing drug price control mechanism and to suggest alternate models, if any, with a view to reducing the rigours of price control where they had become counter-productive.

On December 7, 2012 the National Pharmaceutical Pricing Policy (NPPP, 2012) was announced. The National List of Essential Medicines (NLEM) – 2011 and the Report of Task Force headed by Dr. Pronab Sen formed the basis of NPPP, 2012. Task Force headed by Dr. Sen had the mandate to "Explore Options other than Price Control for Achieving the Objectives of Making Available Life-saving Drugs at Reasonable Prices."

By 2005, the number of bulk drugs under price control came down to 74. It was realized that the DPCO, 1995 overly focused on the bulk drugs and affected the bulk drug manufacturers so several bulk drugs went out of production due to such price controls. Another major development during this period was related to shift from process patent regime to product patent regime due to obligations under TRIPS.

Post NPPP, 2012 the DPCO, 2013 was issued which adopted 'market-based approach' as against 'cost-based approach' followed earlier. It should be seen in the light of the Task Force headed by Dr. Sen which had recommended that price regulations should be applied only to formulations and not to upstream products (e.g., bulk drugs). Further, it was recommended that the ceiling prices of regulated drugs should normally not be based on cost of production, but on readily monitorable market-based benchmarks. Recommendation to the government was to announce the ceiling price of all formulations based on 354 drugs (APIs and fixed-dose combinations) contained in the National List of Essential Medicines (NLEM), 2003.

Formulations listed in Schedule-I of the DPCO, 2013 were defined as scheduled formulations (Section 2(1)(zb) of the DPCO, 2013) and those not included in Schedule-I were termed non-scheduled formulations. Ceiling prices of scheduled medicines are revised annually on the basis of Wholesale Price Index (WPI) (all commodities for preceding calendar year by the National Pharmaceutical Pricing Authority (NPPA), on or before April 1 of every year. For non-scheduled formulation whether branded or generic, as per para 20 of the DPCO, 2013, no manufacturers can increase Maximum Retail Price by more than 10% of MRP during preceding 12 months.

Schedule-I of DPCO, 2013 was amended through adoption of NLEM, 2015 that consisted 377 medicines. By July 2021 the NPPA had fixed ceiling prices of 355 medicines and 882 formulations for medicines under NLEM, 2015 and the number went up to 890 scheduled formulations of medicines by June 30, 2022. Additionally, the NPPA had fixed retail price (applicable only to the applicant manufacturing/marketing companies) of 2,023 new drugs under DPCO, 2013 by June 30, 2022 and this number went up to 2,607 by December 29, 2023. The NPPA had also fixed ceiling prices of Stents (February 2017), Knee Implants (August, 2017), and capped trade margin on selected 42 anti-cancer drugs (February, 2019). By December 29, 2023 the NPPA had fixed the ceiling prices of 915 formulations comprising 700 formulations under NLEM 2022 and 215 formulations under NLEM 2015 and ceiling prices of 131 anti-cancer formulations were effective. Due to the fixation of ceiling prices of scheduled formulations listed in NLEM 2022 alone, the consumers saved Rs. 3,388 crore.

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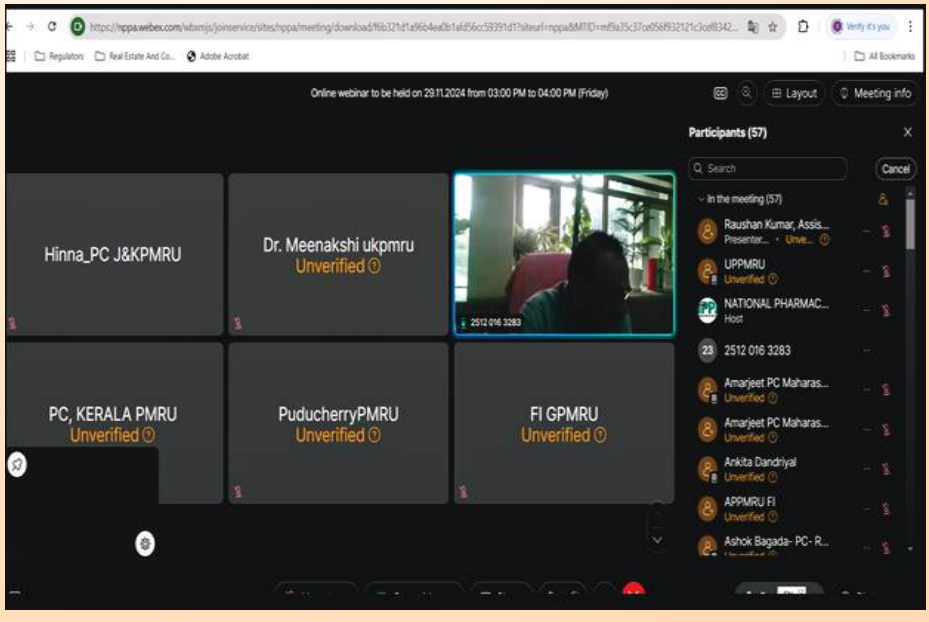
DISCLAIMER: Views are personal and do not represent the views of the Institute.

WEBINARS FOR PRICE MONITORING AND RESOURCE UNITS IN THE SATES/ UTs

In the continuation to the webinar series, an interactive webinar was organized by PMRU Division for Price Monitoring and Resource Units (PMRUs) established in 31 States/UTs.

The main objective of above webinar was to provide step by step procedure for reporting of data/information related to PMRUs activities through IPDMS 2.0 (held on 29.11.2024).



OTHER NEWS AND EVENTS

A. IEC (INFORMATION, EDUCATION AND COMMUNICATION) ACTIVITIES BY PMRUs

During the reporting month of November and December 2024, twenty (20) IEC activities have been conducted by 09 PMRUs in their respective States/ UTs viz., Maharashtra, Meghalaya, Kerala, Jammu & Kashmir, Tripura, Goa, KIHT, Haryana and Punjab 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.

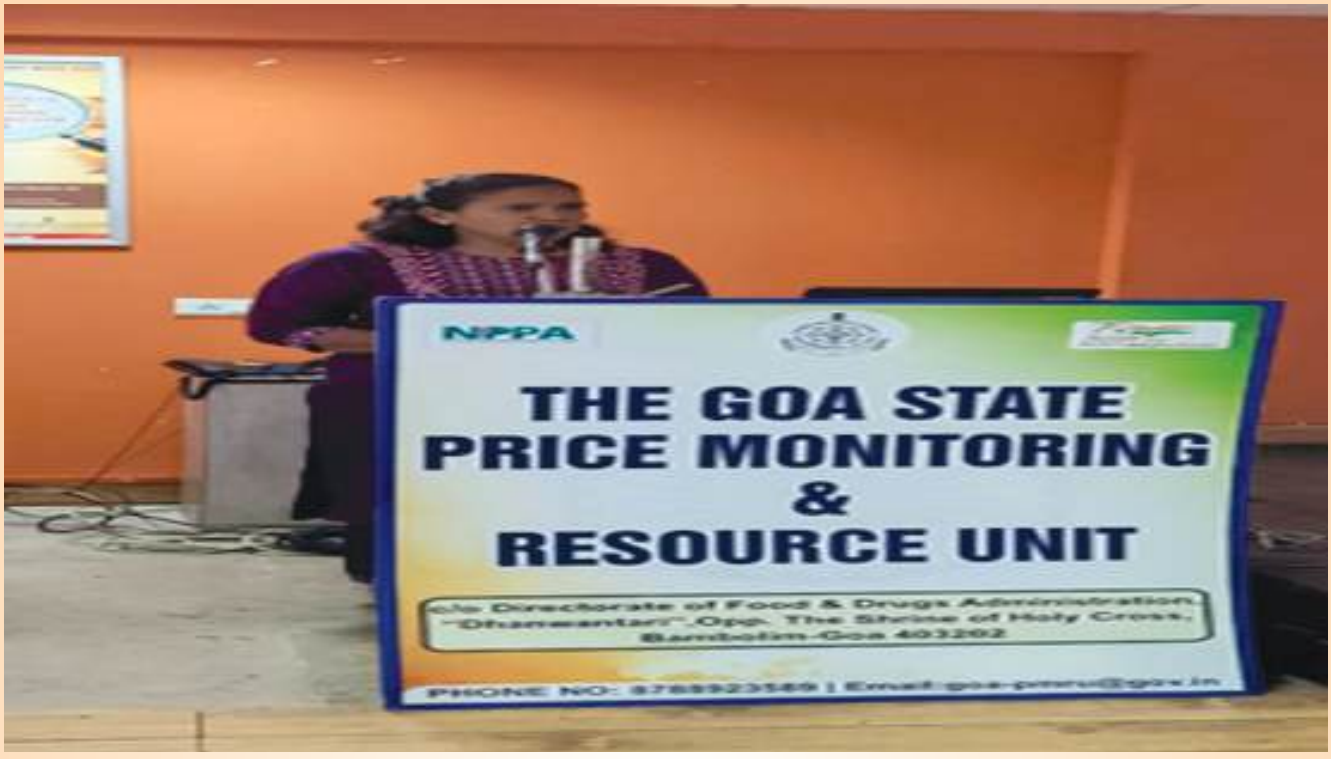
PMRU Kerala:

PMRU Tripura:

PMRU Meghalaya:

OTHER NEWS AND EVENTS

PMRU Goa:



MONITORING OF OVERCHARGING CASES

Price Monitoring and Resource Unit (PMRU) play an important role in monitoring the prices of Scheduled and Non-Scheduled formulations in their respective States/UTs. In view of above, (16) PMRUs have reported One Hundred and Ninety-One (191) likely violation cases through IPDMS 2.0 during November and December 2024.

FREQUENTLY ASKED QUESTIONS

What is HMPV?

Human Metapneumovirus (HMPV) is a respiratory virus that can cause infections in the upper and lower respiratory tracts, including colds, bronchitis, and pneumonia. It primarily affects children, older adults, and those with weakened immune systems.

How is HMPV transmitted?

HMPV is spread through respiratory droplets when an infected person coughs, sneezes, or talks. It can also be transmitted by touching surfaces contaminated with the virus and then touching the face.

What are the symptoms of HMPV infection?

Symptoms can vary but typically include: Cough, Fever, Runny nose, Shortness of breath, Wheezing Sore throat. In severe cases, it may lead to pneumonia or bronchiolitis, especially in vulnerable populations.

How is HMPV diagnosed?

HMPV can be diagnosed through laboratory tests, including PCR (polymerase chain reaction) tests, which detect the virus in respiratory samples such as throat or nasal swabs.

Is there a vaccine for HMPV?

Currently, there is no specific vaccine available for HMPV. Researchers are working on developing vaccines, but for now, preventive measures focus on hygiene and avoiding close contact with infected individuals.

How is HMPV treated?

There is no specific antiviral treatment for HMPV. Supportive care, such as rest, fluids, and fever reducers, can help manage symptoms. In severe cases, hospitalization may be required for oxygen therapy or ventilation.

Can HMPV cause severe illness?

Yes, while many people recover with mild symptoms, HMPV can cause severe illness, particularly in young children, the elderly, and people with weakened immune systems. Complications like pneumonia or bronchiolitis can occur in these groups.

How can I prevent HMPV infection?

Wash hands frequently with soap and water. Avoid close contact with sick individuals. Cover your mouth and nose when coughing or sneezing. Clean commonly touched surfaces regularly.

Is HMPV the same as COVID-19 or flu?

No, HMPV is a different virus from COVID-19 and the flu. It is important to differentiate between these infections through testing, as the treatment and management may differ.

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
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सभी के लिए वहनीय दवाईयाँ

NATIONAL PHARMACEUTICAL PRICING AUTHORITY

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