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 affairs and events 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

सत्यमेव जयते

From CHAIRMAN'S DESK

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

It is with great pleasure that I bring to you the twelfth issue of the NPPA bi-monthly e-Newsletter. This issue carries an article on "MSME and Innovation" by Dr Viranchi Shah, National President, Indian Drug Manufacturers Association (IDMA). I hope you would find it interesting and informative as it highlights the role of Indian SMEs in addressing some niche untouched areas including India specific diseases, India specific natural resources and India specific healthcare solutions.

The Department of Pharmaceuticals, Government of India organized 'India MedTech Expo 2023' from 17th – 19th August in Gandhinagar, Gujarat with the aim to showcase India's journey and opportunities in the sector. The event was inaugurated by Shri Bhupendrabhai Patel, the Hon'ble Chief Minister of Gujarat, Dr. Mansukh Mandaviya, the Hon'ble Minister of Health and Family Welfare and Chemicals and Fertilizers, Government of India along with other dignitaries. The Coffee Table Book (CTB) titled **"Serving Humanity: The Indian Pharmaceutical Sector" सर्वेभवन्तुसुखिनःसर्वेसन्तुनिरामयाः** was also unveiled during the inaugural of the 'India MedTech Expo 2023'. The CTB showcases the inspiring story of growth of Indian pharmaceutical industry from its humble beginning.

NPPA also participated in the 'India MedTech Expo 2023' and NPPA stall was visited by around 250 visitors including G20 foreign delegates. The visitors were apprised about the role of NPPA and the various initiatives taken to ensure availability and affordability of essential medicines.

Integrated Pharmaceutical Database Management System (IPDMS) 2.0, an upgraded version of IPDMS was launched last year in the month of August 2022. IPDMS 2.0 is an integrated responsive cloud-based application and this edition of e-newsletter highlights the progress in registration of companies, filing of forms, etc., in the IPDMS. The editorial team has also included some FAQs on the Medical Devices in this edition for the ease of understanding of all the stakeholders.

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

With best wishes

(Kamlesh Kumar Pant)

MSME AND INNOVATION

Dr Viranchi Shah, National President IDMA

"Carill", a brand of a SME startup in 1980's in India, introduced effervescent salts in multiple flavors, for the first time in the world. It was done way ahead of the global leader, and emerged out of the idea of making the administration of effervescent granules pleasant for the patient. A small, yet, significant innovation that resulted into better patient acceptance."Painless Diclofenac Injection" is another example of innovation, of the then Indian SME, now a large company; that questioned as to why the administration of a painkiller injection should be painful in the first place. This thought resulted in the world's first painless diclofenac injection.

Many Fixed Drug Combinations (FDCs) sold in the market have emanated from some out-of-the box thinking by Indian companies- including many from the SME sector. Over the years the regulatory systems also have become more complex, making it more challenging to get regulatory approvals for innovations in the Pharma space.

India never had the dearth of talent for innovation. But, innovation is like an embryo; it needs a womb to grow. It demands an umbilical cord that constantly pours in resources, which are needed to

support the innovation drive. The resources include money, infrastructure, regulatory support and IPR resources to name a few. It also demands an ecosystem that helps the concept evolve into a marketable innovation through the intervention of industry and market players.

A successful research ecosystem demands a complete biome comprising of Venture Capitalists, Academic centers, IPR experts, Researchers and Industry. In the context of the Indian SMEs, the NIPERs and other acclaimed Centers of Excellence can collaborate to provide the much needed research pool that can understand the industry gap and work out innovative solutions. Successful innovation globally has emerged from such collaborations between industry and research institutes. Involvement of IPR experts augments success in capturing the innovations in form of good patent applications, so that ample protection can be availed for the hard work that is done. Incentives can be given to the industry to bring international experts to be a part of their drug development program. This experience would be just like the IPL that transformed the Indian cricket by bringing in international players. Collaboration between SMEs and large companies is another area of interest, especially where SMEs work to conceptualize a solution and bring it to the proof of concept stage, while the large organizations take the innovation to the market after extensive clinical trials and commercialize on a large scale with their marketing arms. Joint research and development alliances between SMEs and larger companies allow for the pooling of resources and expertise to tackle complex healthcare challenges.

Honorable Health Minister Dr. Mansukh Mandaviya ji has always encouraged the industry to shift its focus from Volume to Value. Moving from volume leadership to value leadership requires to reset our focus on value added products, which could be developed through research and innovation. As we move through the Amrit Kaal, we need to do manthan to churn out the best ideas that will lead us to better healthcare solutions for the world. Focusing on innovation is one proven way to develop value added products and services that will ultimately fill the gaps and improve healthcare outcomes. The recent G20 Health Minister's summit was focused on the theme of Vasudhaiva Kutumbakam. We speak of One World- One Health. It demonstrates the massive opportunity we have as a Nation to cater to the healthcare needs of the whole world. All-in-all, there is a huge opportunity, and those SMEs who can differentiate from the rest, can excel, and create value.

Indian SMEs have a unique opportunity in addressing some niche untouched areas. These include India specific diseases, India specific natural resources and India specific healthcare solutions. India needs India specific innovation, where SMEs could play a major role. These areas as seldom focused by large companies or MNCs, leave a great opportunity to the Indian SMEs.

India specific diseases like Chikungunya, TB and others could be of interest to SMEs. These are mostly seen in the Indian sub-continent. Global players may not be too interested in focusing on these ailments as they have a limited market size owing to small patient pool that too in Low & Middle income nations in South Asia. Such areas offer a great opportunity for Indian researchers, especially in the MSME sector.

ARTICLE BY EXPERT

India has vast natural resources. Ayurveda has demonstrated medicinal use of many plants and minerals. However, a lot can be done in identifying the use of our natural assets in modern diseases. This would require renewed evidence based research on these plants and national resources, finding newer uses or finding their applications in modern diseases. Turmeric formulations had gained a lot of momentum in the West during and post covid, garnering a huge market share among wellness products. Ispaghula is another plant of interest cultivated only in India. Indian SMEs may take up research on the modern use of these plants.

In the same way, India is perhaps the only country in the world that grows and cultivates Opium legally, and uses it for medicinal purposes. However, we haven't seen any significant research in India on this plant. We can work to identify certain opium derivatives that many not be addictive, yet have the same medicinal effect. Can we work to identify ways of improving crop with higher content of actives in our opium? There can be many areas of interest for research in these areas, and SMEs can play a significant role in such research work.

Recognizing the importance of promoting research in Pharmaceuticals, the Department of Pharmaceuticals (DoP) has formulated a scheme called PRIP (Promotion of Research in Pharma and MedTech Sector). This scheme has dedicated funds to support innovation by SMEs. The PRIP is an interesting scheme to support research in the Indian Pharma sector. If the funded research is successful commercially, the company must return the money as royalty, and if the research fails, the money is written off. It brings together the Large Pharma companies, the SMEs, researchers and marketers on one platform. PRIP opens up an opportunity to 125 MSMEs. These startups or MSMEs can research from problem identification to proof of concept, for which they get funded. The journey further, is both capital intensive and requires mature infrastructure and ecosystem, will be undertaken by larger corporate to whom the research may be of interest. The PRIP is all set to ignite the innovation race in the Indian Pharma, and the SMEs will have a window to capture this opportunity.

SMEs are a crucial component of India's pharmaceutical industry, contributing to a significant portion of APIs and formulation development and manufacturing, bolstering the country's position as a global pharmaceutical powerhouse. Focus and push driving innovation in this sector can create wonders, literally. Despite facing challenges, these smaller enterprises continue to thrive and make significant contributions to the healthcare sector. By fostering collaboration between SMEs and academic institutes like NIPERs, as also with larger pharmaceutical companies and providing targeted support and incentives, the Indian government can further bolster innovation in the industry and ensure affordable and accessible healthcare for millions of people worldwide. The success of SMEs in the pharmaceutical sector serves as an inspiring example of how innovation can flourish even under resource constraints, and their continued growth promises to shape the future of healthcare in India and beyond.

News related to pricing of drugs

- Ceiling prices for 691 scheduled formulations (National List of Essential Medicines, 2022) and Retail prices for 2494 non-scheduled formulations have been fixed under DPCO, 2013 till August 2023.
- As on end of August 2023, overall 247th Authority meetings have been conducted of which 115th are under DPCO 2013. The details of the recent meetings are given as below:

Meeting No.	Held on	Prices Approved & Notified
246th (overall) & 114th Meeting under DPCO 2013	19.06.2023	(i) Retail prices for 51 formulations notified vide SO. 2821(E) dated 28.06.2023.
		(ii) Ceiling prices for 02 formulations notified vide S.O. 2822(E) dated 28.06.2023.
247th(overall) & 115th Meeting under DPCO 2013	31.07.2023	(i) Retail prices for 44 formulations notified vide SO. 3560(E) dated 08.08.2023.
		(ii) Exemption for 1 formulation notified under Section 32 vide S.O. 3561(E) dated 08.08.2023.

- Details of retail prices notified for various formulations based on the decision taken in 114th & 115th 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	64	Tablets	8.90 – 20.67
2	Anti-biotics	2	Tablet/Injection	25.69 – 162.11
3	Anti-bacterial	3	Drop / Suspension	2.05 – 6.09
4	Antihypertensive	3	Tablet	10.12 – 13.12
5	Anti-depressant	2	Capsule	14.53 – 15.81
6	Cardiovascular	1	Tablet	17.96
7	Anti-Infection	7	Tablet	8.99 – 90.28
8	Pain management	1	Gel	4.08
9	Anti-pyretic & Analgesics	3	Tablet / Drop/Syrup	1.21 – 8.38
10	Others	9	Capsule / Tablet/ Injection / Sachet	0.89 – 13.39

➲ Details of ceiling prices notified for various formulations under NLEM, 2022are as follows:

Therapeutic Category	No. of Medicines	No. of Formulations
Anti-infective Medicines	61	160
Anticancer Medicines	55	105
Neurological Disorder Medicines	18	59
Psychiatric Disorder Medicines	14	39
CardiovascularMedicines	25	58
HIV Management Medicines	17	20
Analgesics, Antipyretics, Non-steroidal Anti-inflammatory Drugs (NSAIDs)	10	23
Hormones, other Endocrine Medicines and Contraceptives	23	43
Others	102	184
Total	**307***	**691**

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

➲ Exemption under para 32 of DPCO,2013 was granted to M/s Troikaa Pharmaceuticals Limited, in respect of the formulation "Paracetamol Injection (Intramuscular) 250mg/ml, 2ml in 115th Authority meeting dated 31.07.2023 which was notified vide S.O. 3561 (E) dated 08.08.2023.

Launch of Scheme for Promotion of Research and Innovation in Pharma MedTech Sector (PRIP).

The Department of Pharmaceuticals has announced the Scheme for Promotion of Research and Innovation in Pharma MedTech Sector (PRIP). The scheme would have a financial outlay of Rs 5,000 crore, over a period of 5 years from financial year 2023-24 to 2027-28.

Read more

IPDMS 2.0:

Integrated Pharmaceutical Database Management System (IPDMS), an integrated responsive cloud-based application has a system for online information collection and processing to monitor and regulate the prices of medicines and medical devices. The upgraded IPDMS 2.0 was launched on 29th August, 2022 charts given below present the progress for the last six months:

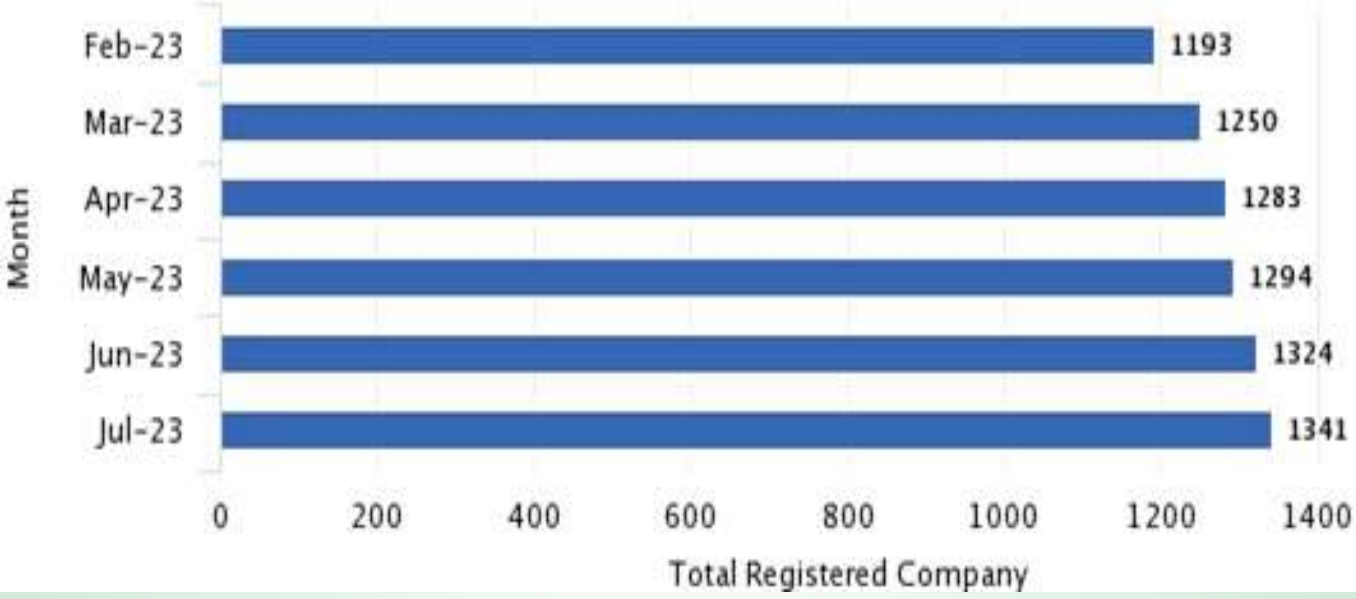


Chart 1: Total number of registered companies

Chart 2: Number of statutory forms filed on IPDMS

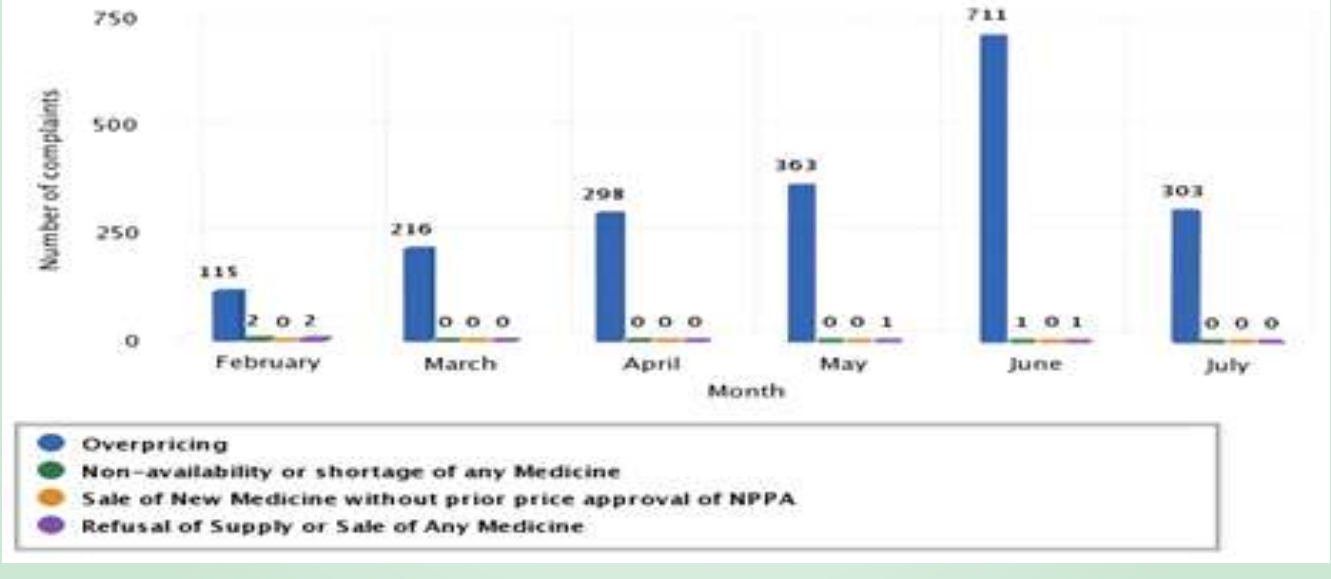


Chart 3: Number of complaints received on IPDMS/Pharma Jan Samadhan (PJS) app

Chart 4: Number of Pharma Sahi Daam app downloads

Chart 5: Number of User logins in IPDMS 2.0

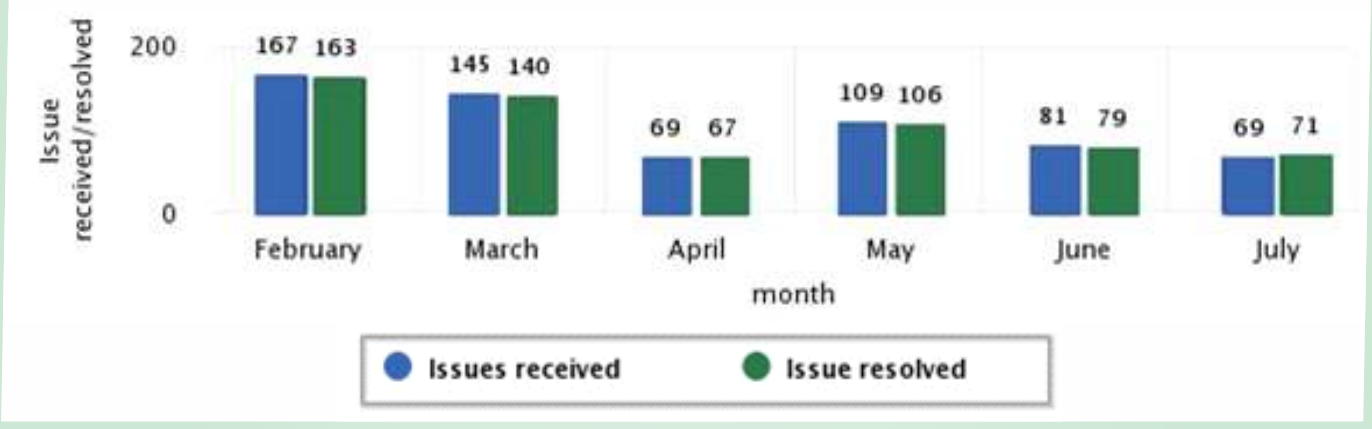


Chart 6: Number of tickets raised/ resolved at IPDMS helpdesk

FDA Approves New Class of Medicines to Treat Paediatric Type 2 Diabetes (June 20, 2023)

The U.S. Food and Drug Administration (US FDA)approved Jardiance (Empagliflozin) and Synjardy (Empagliflozin and Metformin hydrochloride) as addition to diet and exercise to improve blood sugar control in children 10 years and older with type 2 diabetes. These approvals provide a new class of medicines taken by mouth to treat paediatric type 2 diabetes. Metformin, the only other oral therapy available for the treatment of children with type 2 diabetes, was first approved for paediatric use in 2000.

Type 2 diabetes, the most common form of diabetes, is a chronic and progressive condition in which the body does not make or use insulin normally, leading to high levels of glucose (sugar) in the blood.

Read more

FDA Approves First Gene Therapy for Treatment of Certain Patients with Duchene Muscular Dystrophy (June 22, 2023)

U.S. FDA approved Elevidys, the first gene therapy for the treatment of paediatric patients 4 through 5 years of age with Duchene muscular dystrophy (DMD) with a confirmed mutation in the DMD gene who do not have a pre-existing medical reason preventing treatment with this therapy.

Duchene muscular dystrophy is a rare and serious genetic condition which worsens over time, leading to weakness and wasting away of the body's muscles. The disease occurs due to a defective gene that results in absence of dystrophin, a protein that helps keep the body's muscle cells intact. DMD

mainly affects males and in rare cases may affect females.

Read more

FDA Approves First Gene Therapy for Adults with Severe Haemophilia A (June 29, 2023)

U.S. FDA approved Roctavian, an Adeno-associated virus vector-based gene therapy for the treatment of adults with severe haemophilia A without pre-existing antibodies to adeno-associated virus serotype 5 detected by an FDA-approved test.

Haemophilia A is a rare genetic bleeding disorder that occurs due to a mutation on the gene which produces factor VIII (FVIII), a protein that enables blood to clot. The disorder primarily affects males. This deficiency in FVIII causes affected individuals to have uncontrolled bleeding and bleed longer than people who do not have the condition. The frequency and severity of bleeding episodes depends on how much FVIII protein a person produces. Severe haemophilia A is characterized by especially low levels of FVIII (less than 1% in the blood) and represents about 60% of all cases.

Read more

INTERNATIONAL NEWS

FDA Approves New Drug to Prevent RSV in Babies and Toddlers (July 17, 2023)

U.S. FDA approved Beyfortus (nirsevimab-alip) for the prevention of Respiratory Syncytial Virus (RSV) lower respiratory tract disease in neonates and infants born during or entering their first RSV season, and in children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season.

RSV is a virus that causes acute respiratory infection in individuals of all age groups. While most infants and young children experience mild, cold-like symptoms, some infants, especially with their first infection, develop lower respiratory tract disease such as pneumonia and bronchiolitis (swelling of the small airway passages in the lungs), that often leads to an emergency department or physician office visit. Premature infants, and those with chronic lung disease of prematurity or significant congenital heart disease, are at highest risk for severe RSV disease. Approximately 1% to 3% of children under 12 months of age in the United States are hospitalized each year due to RSV, according to the American Academy of Paediatrics.

Read more

FDA Approves Second Over-the-Counter Naloxone Nasal Spray Product (July 28, 2023)

U.S. FDA approved RiVive, 3 milligram (mg) Naloxone hydrochloride nasal spray for over-the-counter (OTC), non-prescription use for the emergency treatment of known or suspected opioid overdose. This is the second non-prescription Naloxone product the agency has approved, helping increase consumer access to Naloxone without a prescription. The timeline for availability and the price of this non-prescription product will be determined by the manufacturer.

Drug overdose persists as a major public health issue in the United States. In the 12-month period ending in February 2023, more than 105,000 reported fatal overdoses occurred which were primarily driven by synthetic opioids like illicit fentanyl. Naloxone is a medication that rapidly reverses the effects of opioid overdose and is the standard treatment for opioid overdose. The approval of Revive nasal spray for non-prescription use was supported by data from a study submitted by the manufacturer that showed similar levels of Revive reach the bloodstream as an approved prescription naloxone product.

Read more

FDA Approves First Oral Treatment for Postpartum Depression (August 04, 2023)

The U.S. FDA approved Zurzuvae (Zuranolone), the first oral medication indicated to treat postpartum depression (PPD) in adults. PPD is a major depressive episode that typically occurs after childbirth but can also begin during the later stages of pregnancy. Until now, treatment for PPD was only available as an IV injection given by a health care provider in certain health care facilities. Postpartum depression is a serious and potentially life-threatening condition in which women experience sadness, guilt, worthlessness-even, in severe cases, thoughts of harming themselves or their child.

Read more

India MedTech Expo 2023 event on Medical Devices sector from 17th - 19th August at Helipad Exhibition Centre, Gandhinagar, Gujarat

Department of Pharmaceuticals, Government of India organized 'India MedTech Expo 2023', a large-scale event on Medical Devices sector from 17th – 19th August at Gandhinagar, Gujarat with the aim to showcase India's journey and opportunities in the MedTech sector. The main objective of the event was to bring together industry, academia, research institutions, investors, state governments, MedTech parks and the Government bureaucrats for taking the Pharma sector on a forward growth trajectory.

The event was inaugurated by Shri Bhupendrabhai Patel, the Hon'ble Chief Minister

of Gujarat, Dr. Mansukh Mandaviya, the Hon'ble Minister of Health and Family Welfare and Chemicals and Fertilizers, Government of India in presence of Dr. V.K. Paul, Member, Niti Aayog, Secretary Pharma, Ms. S. Aparna, Chairman NPPA, Shri K.K. Pant, Chairman, NPPA along with other dignitaries. The dignitaries also unveiled the coffee table book on India's pharmaceutical sector on the occasion.

Dr. V. K. Paul emphasised, 'The Indian MedTech sector has accelerated its growth and excellence and is now on a trajectory to rapidly grow globally in terms of quantity, quality, and reach.'

Ms. S Aparna, Secretary, DoP highlighted that 'the medical devices sector is one of the fastest-growing segments today. Recognising the potential of this sector, the Central Government has launched several schemes to boost the industry for domestic manufacturing of medical devices.

Dr. Mandaviya noted that 'India's start-up ecosystem in the medical devices sector is diverse and vibrant, with more than 250 organizations engaged in innovating to solve critical health-related problems.

Union Minister of Health and Family Welfare and Chemicals and Fertilizers, Dr Mansukh Mandaviya accompanied the G-20 Ministers and delegates to the India Medtech Expo 2023, India's first medical technology expo. Dr Bharati Pravin Pawar and Prof S P Singh Baghel, Union Ministers of State for Health and Family Welfare and Dr V K Paul, Member (Health), NITI Aayog were also present. The delegates took a round of the Exhibition halls and visited various pavilions in the expo such as the Future Pavilion, Startups Pavilion and R&D Pavilion. They also enquired about the medical devices and technologies on display and interacted with the exhibitors.

Read More

NPPA's participation in India MedTech Expo 2023

NPPA participated in the 'India Medtech Expo 2023' from 17.08.2023 to 19.08.2023 wherein NPPA stall displayed various creatives on NPPA functions, IPDMS, Pharma Sahi Daam, Pharma Jan Samadhan and PMRU's were displayed. Awareness was created by displaying creatives, running TVCs on LED screen, distributing brochures and providing information through interaction/ discussion with people.

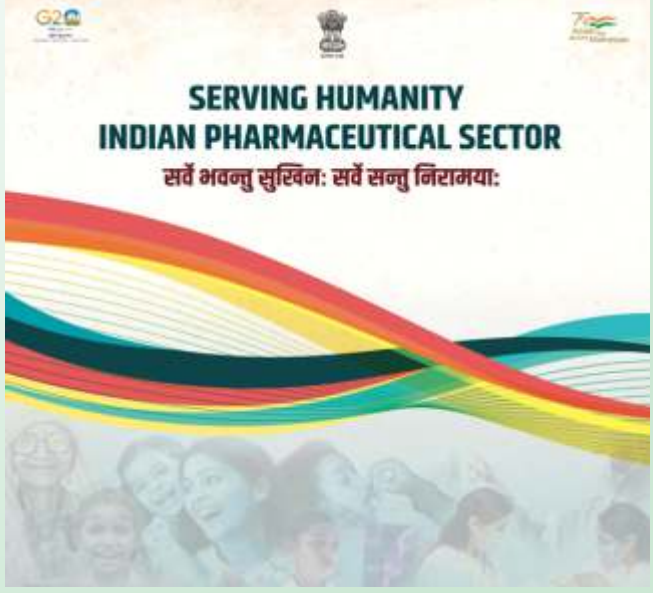
During the campaign, awareness was generated to the visitors including the Doctors, Govt. Officials, Pharmaceutical/ Medical Device manufacturer/ Marketers, Pharma Students, Start-ups and common people about Pharmaceutical Pricing, Functions of NPPA, Pharma Sahi Daam Mobile App and IPDMS 2.0. More than 250 people were covered during the campaign.

OTHER NEWS AND EVENTS

Release of Coffee Table book

The Department of Pharmaceuticals, Government of India has brought out a Coffee Table Book (CTB) titled "Serving Humanity: The Indian Pharmaceutical Sector" सर्वेभवन्तुसुखिनःसर्वेसन्तुनिरामयाः showcasing the inspiring story of growth of Indian pharmaceutical industry from its humble beginning. It was also unveiled at the inaugural event of the 'India Medtech Expo 2023'.

The Coffee Table Book showcases the story of India becoming "Pharmacy of the world". It throws light on the visionaries from the past to future whose collective efforts have transformed the generic drug industry into a vital cornerstone of modern healthcare. The book serves as a testament to the tireless efforts and unwavering dedication of countless individuals who have contributed to the development, accessibility, and success of the sector.



Webinar on Deposit of Interest earned on unspent balance in CNA Bank Account through Bharatkosh- PFMS

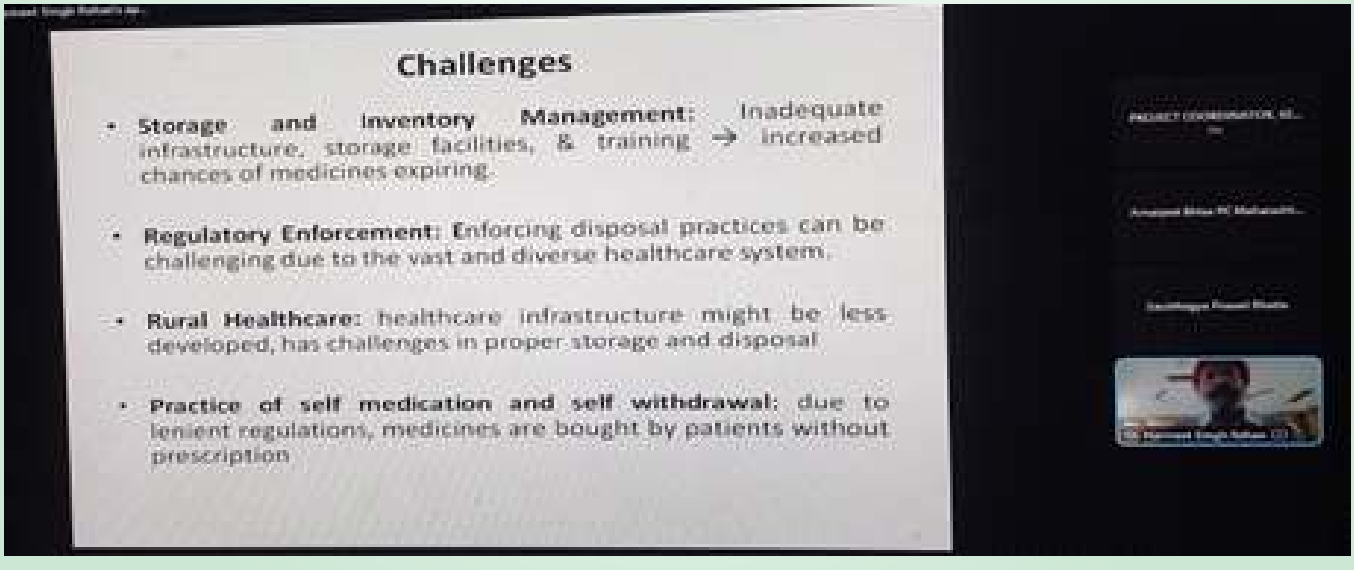
In the Run-up of India @ 75, 'Azadi ka Amrit Mahotsava', NPPA organized a webinar with PMRUs on 'Deposit of Interest earned on unspent balance in CNA Bank Account through Bharatkosh-PFMS' on 28th July 2023. The main aim of webinar was to provide guidance and sharing of knowledge with PMRUs. The PMRUs in the State/ UTs have actively participated in the webinar.

Webinar on Management of expiry/ near expiry medicines

In the Run-up of India @ 75, 'Azadi ka Amrit Mahotsava', NPPA organized a webinar with PMRUs on 'How to handle medicines nearing expiry date or already expired' on 14th August 2023. The main aim of webinar was to provide guidance and sharing of knowledge with PMRUs to ensure the safe and responsible disposal of expiry/ near expiry medicines. In the webinar Dr. Rehan, Director, Professor and Head, Department of Pharmacology, Lady Hardinge Medical College and Associated Hospital, apprized about:

- Factors contributing to high prevalence of expired drugs
- Types of Pharmaceutical waste
- Hazards of unused/ expired medicines
- Challenges in handling expiry/ near expiry medicines
- Strategies to reduce wastage of medicines
- Methods for safe disposal of medicines

The PMRUs in the State/ UTs have actively participated in the webinar.



OTHER NEWS AND EVENTS

State Level Events/ Seminars by PMRUs

In the run up of India @75 'Azadi ka Amrit Mahotsava', six (6) State level Events/ Seminars have been organized by PMRUs in their respective States/ UTs viz. Tripura, Jammu & Kashmir, Madhya Pradesh, Ladakh, Karnataka and Goa on the topic of 'Fixation of Ceiling Prices under NLEM 2022- Ensuring Affordability'. These seminars 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.

Seminar organized by PMRU Karnataka on "Health and wellness" on 11.08.2023

Seminar organized by PMRU J&K on 'Fixation of Ceiling Prices under NLEM 2022 - Ensuring Affordability' on 17.07.2023

Seminar organized by PMRU Tripura on "Fixation of Ceiling Prices under NLEM-2022" on 28.06.2023

Seminar organized by PMRU Ladhak on "Fixation of Ceiling Prices under NLEM-2022" on 25.07.2023

आरोग्य, औषध विषयक राज्यस्तरीय कार्यक्रमास प्रतिसाद

पणजी : पुढारी वृत्तसेवा

राज्य अन्न आणि औषधे खाते, राज्य प्राइस मॉनिटरिंग अँड रिसोर्स युनिट व नॅशनल फार्मास्युटिकल प्राइसिंग (पीएमआरयूच्या) ऑथॉरिटीच्या सहकार्याने, अन्न आणि औषधे खाते येथे स्थित भारत सरकारच्या रसायन आणि खते मंत्रालयाच्या फार्मास्युटिकल्स विभागाच्या अंतर्गत, आझादी का अमृत महोत्सवानिमित्त पणजी सिरीला येथे एक दिवसीय राज्यस्तरीय कार्यक्रमास उत्स्फूर्त प्रतिसाद मिळाला. 'नॅशनल लिस्ट ऑफ इसेन्शियल मेडिसिन-२०२२ अंतर्गत जनतेला वाजवी किमती निश्चित करणे,

पणजी : कार्यक्रमाचे उद्घाटन करताना आरोग्य सचिव अरुण कुमार मिश्रा. सोबत ज्योती सरदेसाई, महाबीर सैनी व मान्यवर.

परवडणारी क्षमता आणि आरोग्य आणि निरोगीपणाची खात्री करणे आदी विषयांवर या कार्यक्रमात चर्चा झाली.

कार्यक्रमाचे उद्घाटन आरोग्य सचिव, आयएएस अरुण कुमार मिश्रा,

Seminar organized by PMRU Goa on "State Level Programme on Health and Medicines" on 11.08.2023

FREQUENTLY ASKED QUESTIONS

➲ **What is a"Medical Device"?Are there any price controls on medical devices?**

Ans. All devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals are medical devices.

Examples include implants like stents, surgical items like sutures, In-Vitro Diagnostics like HIV test kit, mechanical contraceptives like condoms, medical equipment like patient monitors, Laboratory instruments, patient aid software etc.

All Medical devices are covered under the definition of Drugs and the prices of all drugs are regulated by Drugs (Prices Control) Order, 2013.

➲ What are the price controls on medical devices?

Ans. National List on Essential Medicines (NLEM 2015) covers four medical devices namely (i) Cardiac Stents, (ii) Drug-Eluting Stents, (iii) Condoms, and (iv) Intra Uterine Device (Cu-T). These are called Scheduled Drugs and their ceiling prices are fixed by NPPA.

All other medical devices are non-scheduled drugs for which prices are not fixed by NPPA except in certain cases. However, under Para 20 of the DPCO, 2013, NPPA monitors that the manufacturers and importers do not increase the MRP by more than ten percent in a year.

➲ Are there any cases where prices are fixed by NPPA for non-scheduled medical devices?

Ans NPPA has fixed the prices of non-scheduled medical devices in the following cases:

a) Ceiling Price fixation for Knee Implants in August, 2017.

b) The trade margin of six medical devices used in Covid management was capped at 70% in 2021.

Feedback and Complaint Redressal

Grievance Redressal

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

Information Dissemination

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

Collaboration with State Governments

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

NPPA
AFFORDABLE MEDICINES FOR ALL
सभी के लिए वहनीय दवाईयाँ

NATIONAL PHARMACEUTICAL PRICING AUTHORITY

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