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 as amended vide S.O. th 701(E) dated 10 March, 2016 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.

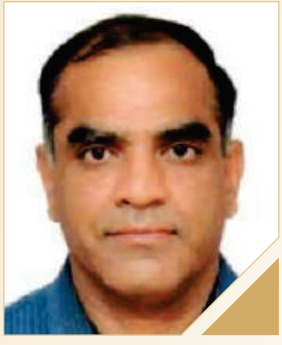
DISCLAIMER:

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**

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 Eleventh issue of the NPPA bi-monthly e-Newsletter. This issue carries an expert article on " Biosimilars- The emerging wave for the Indian pharma sector" by Shri Sudarshan Jain, Secretary General IPA. I hope you would find it interesting as it highlights the role India can play in leading the revolution in biosimilars.

On 16th May 2023, NPPA and DoP organised a workshop to review the working of DPCO, 2013 and National Pharmaceutical Pricing Policy, 2012. The workshop saw active participation from the industry stakeholders where the insights provided after ten-year implementation of DPCO,2013 were discussed. The workshop had separate sessions on Pharma, Medical Devices and NPPP, 2012.

As you are aware, National List of Essential Medicines, 2022 was incorporated in the Schedule-I of DPCO, 2013 and accordingly, NPPA had refixed the Ceiling Prices of Scheduled Drugs. Till date, NPPA has fixed/refixed the Ceiling Prices of 691 formulations, which has resulted in reduction in the MRP of the drugs. This issue contains details about the Ceiling Prices and Retail Prices fixed by NPPA.

This time, the editorial team has included some insights on best PMRU/SDC practices on the enforcement activities. In this issue, we carry information on the best practice introduced by SDC, Gujarat. Further details on the initiative "XLN- Xtended Licensing & Laboratory Node" a web based IT solution, https://xln.gujarat.gov.in/MainPage.aspx are there in the newsletter. I am also happy to share that NPPA has expanded its reach to one more States i.e. Assam in the month of June 2023 by setting up Price Monitoring and Resource Units (PMRUs), taking the total tally of PMRUs to 29 States/UTs.

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

With best wishes

(Kamlesh Kumar Pant)

BIOSIMILARS – THE EMERGING WAVE FOR THE INDIAN PHARMA SECTOR

By **Sudarshan Jain**
Secretary General, Indian Pharmaceutical Alliance

The Indian pharmaceutical industry has played a significant role in shaping global health outcomes. During the COVID-19 pandemic, India ensured an uninterrupted supply of medicines to the world thereby asserting its position globally. Today, India is the 3rd largest supplier of medicines in the world with 20% of the generics volume share. India supplies 60% of global vaccine demand and is a major supplier of drugs for AIDS. Over 80% of the antiretroviral drugs used globally to combat AIDS are now supplied by Indian pharma companies. The industry has helped lower the treatment cost of life-threatening diseases like AIDS, Hepatitis C and Leukaemia by 95% and provides affordable medicines and is rightly known as the "Pharmacy of the World". Going forward, biosimilars will play an important role to tackle the changing disease burden.

Biosimilars – Tackling the change in disease burden

Over the past 30 years, there is a significant change in the disease profile from Communicable to Non-Communicable Diseases (NCDs) globally. NCDs like Cancer and Diabetes and Musculoskeletal Diseases now represent more than 60% of the global disease burden with 10 million and 6.7 million deaths per year, due to Cancer and Diabetes respectively, impacting patients in both advanced and emerging markets.

Biologics are evolving as the standard of care to treat NCDs such as Diabetes and Breast Cancer. The global biologics market accounts for 1/3rd of the pharma market; with the US representing the largest share. The biologics market is expected to grow to USD 650+ bn by 2027. While biologics are typically more

expensive than small-molecule treatments, the launch of biosimilars is likely to expand the market with reduced prices making them more accessible.

Biosimilars are affordable versions of biologics that can address the affordability and access challenges while ensuring the same treatment outcomes. The global biosimilar market has grown to $ 19 Bn (from 5x times in the last 5 years) in 2022 and is expected to grow to $ 56 Bn by 2027. There is an opportunity for the biosimilars market as more than 55+ blockbuster drugs lose exclusivity by 2032. There is a second wave of biosimilars from 2022-26 representing a $ 85 bn opportunity in the near term.

India – potential to lead the biosimilar revolution

Biosimilar is the next wave that will fuel the Indian pharma industry. India has a flourishing biosimilar ecosystem compared to other countries. The first biosimilar was approved and marketed in India in 2000 for Hepatitis B. In comparison, the first biosimilar approved in Europe was in 2006 while the US gave its approval for its first biosimilar in 2015.

Today India has over 100 approved biosimilars in the domestic market which is more than any other country. The market penetration of biosimilars is expected to increase quickly in the coming years due to rising demand and cost-effective manufacturing capabilities. A sizeable pool of highly trained scientific and technical manpower is also propelling the rapid growth of the segment. Several Indian pharma companies have already had their products authorised by regulatory agencies in India, Europe, and the U.S.

The introduction of the Indian Government's guidelines for Biosimilars in 2012 paved the way for increased investment in this sector. These guidelines established a regulatory framework for the development, evaluation, and approval of biosimilars, ensuring the quality, safety, and efficacy of these products. The guidelines also provided clarity on the data requirements for demonstrating similarity to the reference biological drugs.

Globally, the regulatory landscape is evolving across markets to favour biosimilars and reduce the time and cost of development. The market is seeing intense competition and this along with the increasing discounting will require cost competitiveness to ensure sustainable returns. The companies are looking at strategic initiatives for vertical integration and scale for developing cost competitiveness.

Conclusion

The Indian pharmaceutical industry has the advantage of scale and reach. The emergence of biosimilars in the Indian pharmaceutical industry has opened up new avenues for growth and innovation. With supportive regulations and a skilled workforce, Indian companies are actively developing and commercializing biosimilars for various therapeutic areas. Over the past decade, India has seen the largest number of approved biosimilars that are serving the needs of patients globally. While the reimbursement system has to be created for the accessibility of biosimilar products for the patients as treatment will be expensive compared to small molecules. Furthermore, market development is required for creating awareness among doctors regarding modern forms of treatment. It will be important for India to work towards regulatory harmonisation between different markets of the world to improve faster access to biosimilars.

As the industry's product portfolio shifts towards more complex products, the demand for highly skilled personnel for manufacturing of these products will also increase at an unprecedented pace. Concerted efforts are required to build infrastructure, upskill talent and explore strategic global collaboration for manufacturing biosimilars and increase global adoption. Biosimilar has the potential to fuel the Indian pharma industry and meet the unmet needs of patients globally. As these companies continue to build their capabilities and expand their global footprint, biosimilars have the potential to transform healthcare by increasing access to affordable biologic treatments.

REGULATORY NEWS

News related to pricing of drugs

- Ceiling prices for 689 scheduled formulations (National List of Essential Medicines, 2022) and Retail prices for 2399 non-scheduled formulations have been notified under DPCO, 2013 till 25th June 2023.
- As on 15th June, 2023, 245th Authority meetings have been conducted of which 113th are under DPCO 2013. The details of the recent meetings are given as below:

Meeting No.	Held on	Prices Approved & Notified
244th (overall) & 112th Meeting under DPCO 2013	01.05.2023	(i) Retail prices for 15 formulations notified vide SO. 2123(E) dated 04.05.2023. (ii) Ceiling prices for 20formulations notified vide S.O. 2124(E) &2125(E) dated 04.05.2023.
245th (overall) & 113th Meeting under DPCO 2013	26.05.2023	(i) Retail prices for 23 formulations notified vide SO. 2539(E) dated 08.06.2023.
		(ii) Ceiling prices for 18formulations notified vide S.O. 2540(E) 2541(E) &2542(E) dated 08.06.2023.

- Details of retail prices notified for various formulations based on the decision taken in 112th & 113th Authority Meetings are as follows:

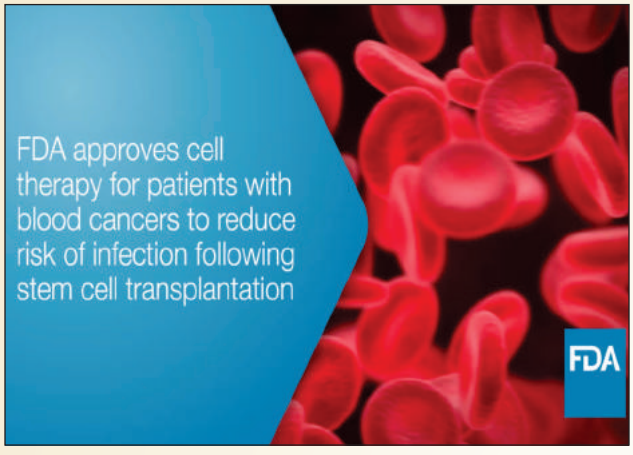
S. No.	Therapeutic group	Total Number	Type of formulation	Retail Price fixed Range (Rs.) (Excl. GST) per tablet/per ml
(1)	(2)	(3)	(4)	(5)
1	Anti-biotics	3	Tablet/Injection	2.08 – 178.39
2	Anti-bacterial	4	Drop / Injection	0.72 – 5.80
3	Antihypertensive	7	Tablet	9.82–17.96
4	Cardiovascular	2	Tablet / Capsule	8.34–13.22
5	Anti-Infection	2	Infusion/Tablet	3.75 – 4.42
6	Pain management	4	Tablet/Spray	1.77–20.51
7	Vitamins	1	Tablet	18.36
8	Others	15	Capsule/Tablet/Injection/ Infusion	0.88 – 56.20

➲ Details of ceiling prices notified for various formulations based on the decision taken in 112th & 113th Authority Meetings are as follows:

Therapeutic Category	No. of Medicines	No. of Formulations
Anti bacterial	41	118
Medicines used in the Management of HIV	23	27
Analgesics, Antipyretics, Non-steroidal Anti-inflammatory Drugs (NSAIDs), Medicines used to treat Gout and Disease Modifying Agents used in Rheumatoid Disorders	11	30
Anti-cancer agents including Immunosuppressives and Medicines used in Palliative Care	48	83
Cardiovascular Medicines	24	56
Medicines used in Neurological Disorders	18	62
Medicines used in treatment of Psychiatric Disorders	14	39
Ophthalmological Medicines	12	15
Others	131	259
Grand Total	**322**	**689**

INTERNATIONAL NEWS

FDA Approves Cell Therapy for Patients with Blood Cancers to Reduce Risk of Infection Following Stem Cell Transplantation (April 17, 2023)



The U.S. Food and Drug Administration approved Omisirge (omidubicel-onlv), a substantially modified allogeneic (donor) cord blood-based cell therapy to quicken the recovery of neutrophils (a subset of white blood cells) in the body and reduce the risk of infection. The product is intended for use in adults and pediatric patients 12 years and older with blood cancers planned for umbilical cord blood transplantation following a myeloablative conditioning regimen (treatment such as radiation or chemotherapy).

Stem cell transplantation is a common treatment for blood cancers. It involves putting healthy stem cells into the body to help restore the normal production and function of blood cells. One source of healthy stem cells is umbilical cord blood. Generally, before receiving this kind of transplant, the patient will undergo a course of treatments to remove their own stem cells and prepare the body for the new stem cells. This process may include undergoing therapies such as radiation or chemotherapy, both of which may weaken an individual's immune system. As a result, a frequent and serious risk of this treatment is the occurrence of severe and sometimes deadly infections.

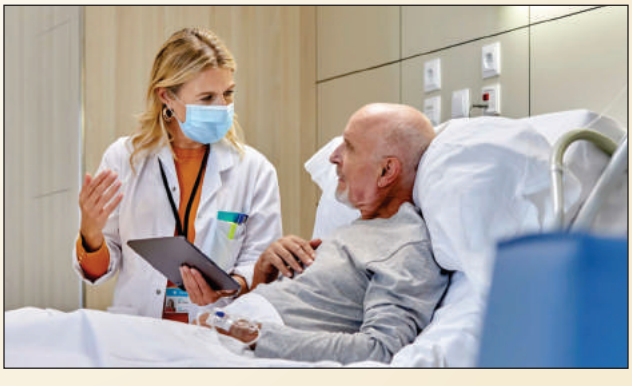
Read more

Coronavirus (COVID-19) Update: FDA Authorizes Changes to Simplify Use of Bivalent mRNA COVID-19 Vaccines (April 18, 2023)

Today, the U.S. Food and Drug Administration amended the emergency use authorizations (EUAs) of the Moderna and Pfizer-BioNTech COVID-19 bivalent mRNA vaccines to simplify the vaccination schedule for most individuals. This action includes authorizing the current bivalent vaccines (original and omicron BA.4/BA.5 strains) to be used for all doses administered to individuals 6 months of age and older, including for an additional dose or doses for certain populations. The monovalent Moderna and Pfizer-BioNTech COVID-19 vaccines are no longer authorized for use in the United States.

Read more

FDA Approves First Orally Administered Fecal Microbiota Product for the Prevention of Recurrence of Clostridioides difficile Infection (April 26, 2023)



Today, the U.S. Food and Drug Administration approved Vowst, the first fecal microbiota product that is taken orally. Vowst is approved for the prevention of recurrence of Clostridioides difficile (C. difficile) infection (CDI) in individuals 18 years of age and older, following antibacterial treatment for recurrent CDI. CDI, caused by the bacterium C. difficile, is one of the most common healthcare-associated infections in the United States and is associated with 15,000 to 30,000 deaths annually. The human intestinal tract contains millions of microorganisms, often referred to as the "gut flora," or "gut microbiome." Certain situations, such as taking antibiotics to treat an infection, may change the balance of microorganisms in the gut, allowing C. difficile to multiply and release toxins causing diarrhea, abdominal pain and fever, and in some cases, organ failure and death. Other risk factors that can increase the risk of CDI include age over 65 years, hospitalization, nursing home residency, a weakened immune system and/or a previous history of CDI.

Read more

FDA Conditionally Approves First Drug for Anemia in Cats with Chronic Kidney Disease (May 01, 2023)

Today, the U.S. Food and Drug Administration conditionally approved Varenzin-CA1 (molidustat oral suspension), the first drug for the control of nonregenerative anemia associated with chronic kidney disease (CKD) in cats. Nonregenerative anemia can be a fatal condition because the cat's bone marrow is not able to produce enough red blood cells to replace the older or damaged red blood cells that are naturally removed from the blood, resulting in the inability for oxygen to be carried from the lungs throughout the body. CKD is a disease that requires day-to-day management in cats, and nonregenerative anemia is a complication that often contributes to death or euthanasia of affected cats due to poor quality of life. Cats can develop CKD at any age, but it is frequently diagnosed in older cats. It can be triggered by other diseases or malformation of the kidneys, bacterial or viral infections, kidney inflammation and associated damage (glomerulonephritis), cancers, or a build-up of protein in the kidney (amyloidosis). Cats with CKD develop nonregenerative anemia when their kidneys produce less of a hormone called erythropoietin, which helps the bone marrow produce red blood cells.

Read more

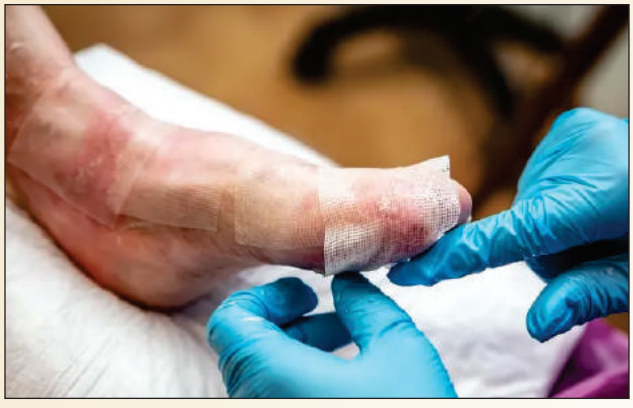
FDA Approves First Respiratory Syncytial Virus (RSV) Vaccine (May 03, 2023)

Today, the U.S. Food and Drug Administration approved Arexvy, the first respiratory syncytial virus (RSV) vaccine approved for use in the United States. Arexvy is approved for the prevention of lower respiratory tract disease caused by RSV in individuals 60 years of age and older. RSV is a highly contagious virus that causes infections of the lungs and breathing passages in individuals of all age groups. RSV circulation is seasonal, typically starting during the fall and peaking in the winter.

Read more

INTERNATIONAL NEWS

FDA Approves First Topical Gene Therapy for Treatment of Wounds in Patients with Dystrophic Epidermolysis Bullosa (May 19, 2023)



Today, the U.S. Food and Drug Administration approved Vyjuvek, a herpes-simplex virus type 1 (HSV-1) vector-based gene therapy, for the treatment of wounds in patients 6 months of age and older with dystrophic epidermolysis bullosa (DEB) with mutation(s) in the collagen type VII alpha 1 chain (COL7A1) gene. "DEB is a genetic disorder that affects the connective tissue in the skin and nails and results from mutation(s) in the COL7A1 gene. This gene encodes type VII collagen (COL7), which is an essential protein that helps strengthen and stabilize the outer and middle layers of the skin. When COL7A1 is deficient, skin layers can separate, causing painful and debilitating blisters and wounds. DEB usually presents itself at birth and is divided into two major types depending on the inheritance pattern: recessive dystrophic epidermolysis bullosa (RDEB) and dominant dystrophic epidermolysis bullosa (DDEB).

Read more

FDA Approves First Oral Antiviral for Treatment of COVID-19 in Adults (May 25, 2023)

Today, the U.S. Food and Drug Administration approved the oral antiviral Paxlovid (nirmatrelvir tablets and ritonavir tablets, co-packaged for oral use) for the treatment of mild-to-moderate COVID-19 in adults who are at high risk for progression to severe COVID-19, including hospitalization or death. Paxlovid is the fourth drug-and first oral antiviral pill-approved by the FDA to treat COVID-19 in adults. Paxlovid manufactured and packaged under the emergency use authorization (EUA) and distributed by the U.S. Department of Health and Human Services will continue to be available to ensure continued access for adults, as well as treatment of eligible children ages 12-18 who are not covered by today's approval. Paxlovid is not approved or authorized for use as a pre-exposure or post-exposure prophylaxis for prevention of COVID-19.

Read more

FDA Permits Marketing of First COVID-19 At-Home Test Using Traditional Premarket Review Process (June 06, 2023)

Today, the U.S. Food and Drug Administration granted marketing authorization for the Cue COVID-19 Molecular Test. The product is a molecular nucleic acid amplification test (NAAT) that is intended to detect genetic material from SARS-CoV-2 virus present in nasal swabs from adults with signs and symptoms of upper respiratory infection. This test is the first at-home over-the-counter (OTC) test for COVID-19 to be granted marketing authorization using a traditional premarket review pathway and the first ever at-home test authorized using a traditional premarket review pathway for any respiratory illness. The Cue COVID-19 Molecular Test consists of a single-use Cue COVID-19 test cartridge, a single-use Cue sample wand (nasal swab), and the Cue cartridge reader (sold separately). The test also uses the Cue Health app, which displays results when the test is complete. The reusable, battery-operated Cue Cartridge Reader runs the Cue Test Cartridge and communicates results directly to the app in about 20 minutes. In a study reviewed by the FDA, this test correctly identified 98.7% of negative and 92.9% of positive samples in individuals with signs and symptoms of upper respiratory infection.

Read more

Workshop on Review of working of DPCO 2013 and NPPP 2012

NPPA in coordination with DoP organized an interactive workshop under the chairmanship of Dr V.K. Paul, Member(Health), NITI Aayog on 16.05.2023 with the representatives of Pharmaceutical and Medical Device Associations on "Review of working of DPCO, 2013 and NPPP, 2012". In the workshop, point related to Pharma, Medical Device and NPPP 2012 were discussed with the representatives of Pharmaceutical and Medical Device Associations. About 100 industry stakeholders participated in this workshop.

Visit of NPPA officers for Preparation Coffee Table Book

NPPA officers visited NIPER Mohali, Pharmaceutical's hubs at Baddi in Himachal Pradesh, Hyderabad and Ahmedabad for information/photograph gathering for preparation of Coffee table Book on Show casing the Growth of Indian Pharma generics in India and interacted with NIPER faculty and State Drug Controllers and Key pharmaceutical manufacturing units in selected states.

OTHER NEWS AND EVENTS

राजभाषा हिंदी में सराहनीय कार्य निष्पादन के लिए राजभाषा शील्ड वितरण

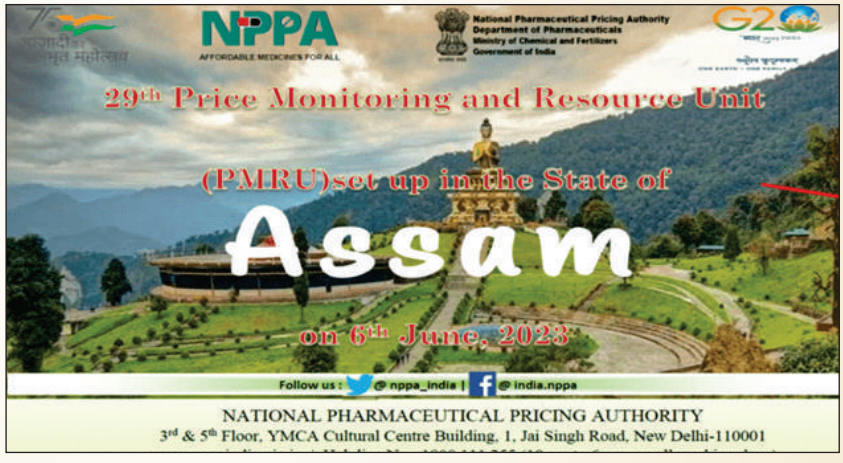
रसायन एवं उर्वरक मंत्रालय की दिनांक 30 मई, 2023 को आयोजित सलाहकार समिति की बैठक में राजभाषा हिंदी के प्रयोग के प्रति प्रोत्साहन एवं हिंदी के प्रयोग के क्षेत्र में उत्तरोत्तर प्रगति के लिए राष्ट्रीय औषध मूल्य निर्धारण प्राधिकरण कार्यालय को माननीय रसायन एवं उर्वरक मंत्री के हाथों राजभाषा शील्ड प्राप्त करने का गौरव प्राप्त हुआ।

Participation of Member Secretary, NPPA in the study visit of Committee on Petition, Rajya sabha at Kolkata from 6-7 June, 2023

Celebration of International Yoga Day 2023 in NPPA on 21st June 2023

8th International Conference on Pharmaceuticals & Medical Devices Industry held on 26th & 27th May 2023 at New Delhi

NPPA sets up Price Monitoring and Resource Unit (PMRU) in the State of Assam in June, 2023



NPPA under Consumer Awareness, Publicity and Price Monitoring (CAPPM) Scheme has set up Price Monitoring and Resource Unit (PMRU) in the State of Assam in June, 2023. NPPA has so far set-up PMRUs in 29 States/UTs. The 29th PMRU was established in the State of Assam on 08th June 2023. Now, NPPA has its presence in the States/ UTs viz. Kerala, Gujarat, Odisha, Rajasthan, Punjab, Haryana, Tripura, Nagaland, Uttar Pradesh, Andhra Pradesh, Mizoram, Jammu & Kashmir, Karnataka, Telangana, Maharashtra, Goa, Madhya Pradesh, Chhattisgarh, Jharkhand, Puducherry, West Bengal, Ladakh, Himachal Pradesh, Bihar, Uttarakhand, Meghalaya, Arunachal Pradesh, Chandigarh and Assam. This will help NPPA to trickle down the benefits of DPCO, 2013 at grass-root level with the help of PMRU to ensure that consumer at large is benefited.

Webinar on Monitoring Framework of Drugs – DPCO 2013

In the Run-up of India @ 75, 'Azadi ka Amrit Mahotsava' NPPA organized an interactive webinar with PMRUs on 'Monitoring Framework of Drugs – DPCO 2013' on 30th May 2023. The main aim of webinars were to provide guidance and sharing of knowledge with PMRUs regarding:

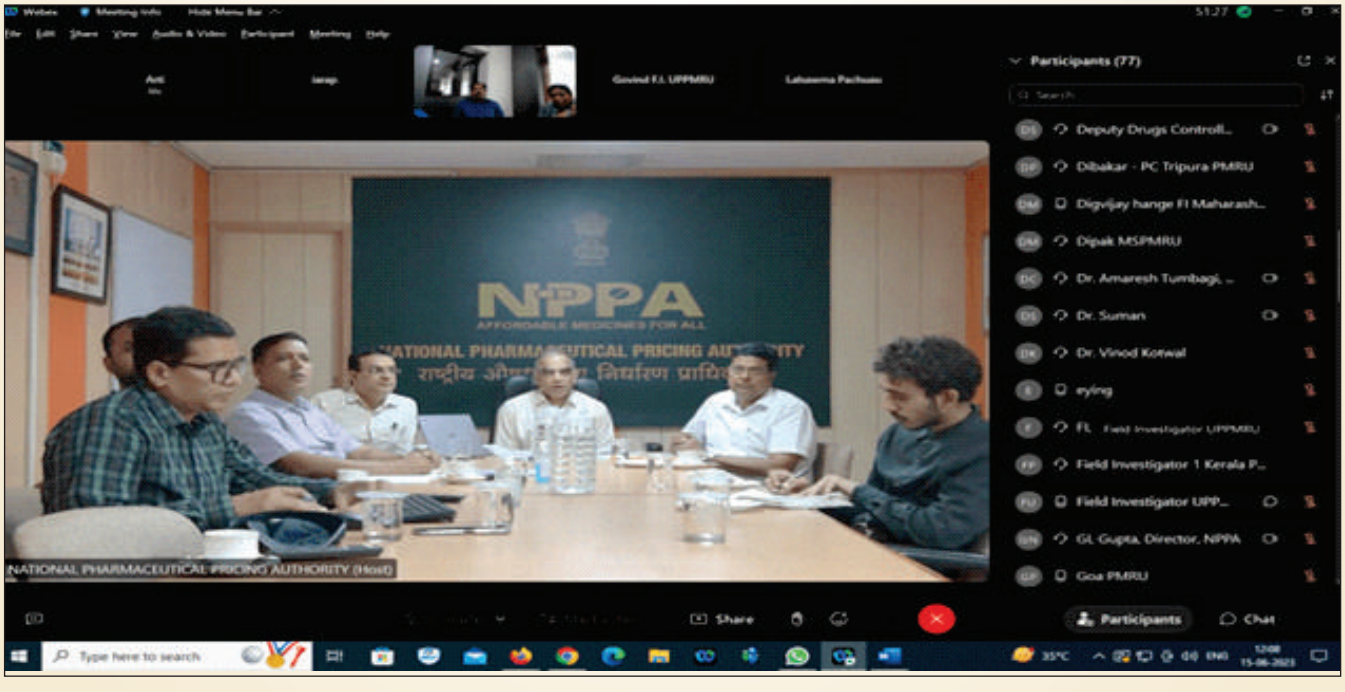
- Types of price violations and their applicable para's as per DPCO, 2013
- Methods of monitoring of different violations of scheduled and non-scheduled formulations.
- Process of initiation action in case detection of Violations
- Disposal of violation cases.

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

OTHER NEWS AND EVENTS

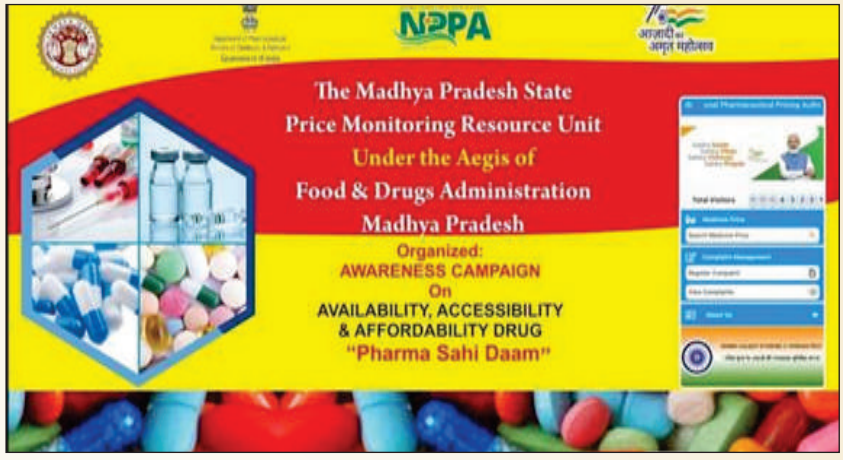
Rendezvous with PMRUs by Chairman, NPPA

National Pharmaceutical Pricing Authority (NPPA) organised a review meeting with PMRUs on 15th June, 2023 through video conferencing under the Chairpersonship of Chairman NPPA Shri Kamlesh Kumar Pant, IAS, to discuss and review of progress of PMRUs. The representatives of 29 PMRUs participated in the meeting. Necessary guidance on various points were provided in order to increase the performance of the PMRU states.



Awareness program organized by PMRU Madhya Pradesh

'Madhya Pradesh Price Monitoring Resource Unit' organized an awareness program on 'Price Monitoring and Regulations Under the provisions of DPCO, 2013' and 'Pharma Sahi Daam' App at Barwani, District of Madhya Pradesh to make people aware about medicines through education and publicity to counter the common perception that quality medicine is available only with high prices only and to use of Pharma Sahi Daam App to know the right prices of the medicine.



Awareness program organized by PMRU Maharashtra

'Maharashtra State Price Monitoring and Resource Unit' on 28.04.2023 organized an awareness program in Civil Hospital at 'Beed' District of Maharashtra wherein patients, consumers and hospital staffs were made aware about the use and benefits of Pharma Sahi Daam App of NPPA.

Awareness program organized by PMRU Chhattisgarh

'The Chhattisgarh State Pharmaceutical Price Monitoring & Resource Unit' on 03.05.2023 organized an awareness program at Marine Drive Raipur, Chhattisgarh wherein PMRU guided the local population about affordability and availability of essential medicines and benefit of using Pharma Sahi Daam Mobile App and Pharma Jan Samadhan.

OTHER NEWS AND EVENTS

Seminars organized by PMRU Tripura

'Tripura State Pharmaceutical Price Monitoring and Resource Unit' in the Run up of India @75 organized seminar on 01.05.20223 and 27.05.2023 on **"Regulation of Medicine Price by NPPA & Introduction of Pharma Sahi Daam App"** at Teliamura and Agartala, Tripura. The whole concept of the these awareness programs were to create awareness about the activities of National Pharmaceutical Pricing Authority, its price monitoring & drug price control mechanism and objectives and role of PMRU, use of Pharma Sahi Daam App for the benefits of consumers and Affordability and Availability of Essential Drugs.

In the seminar, more than 100 participants participated including Officials from Drug Control Department, Graduating students of B. Pharma and their faculty members and Members of Tripura Press Club.

Xtended Licensing, Laboratory & Legal Node (XLN): An Effective Tool for e-Governance in fields of Drugs and Cosmetics Regulation

Food & Drug Control Administration (FDCA), Gujarat regulates the Sales & Manufacturing aspects related to Food, Drugs & Cosmetics FDCA is the authority responsible for issuing licenses to stake holders for Manufacturing and Sales of pharmaceutical and related products i.e. manufacturers of drugs, wholesalers, retailers, stockiest, C&F agents etc. The enforcement mission targets to fulfill the objective of making available the safe and effective medicines by ensuring that the menace of manufacture of spurious /substandard drugs is eradicated. For the enforcement activities it is vital to have immediate and accurate access to information as well as there is a need to communicate effectively and quickly with the stake holders. Prior to the initiative of implementation of software, SMS alerts etc the enforcement task was dependent on manual means of actions and communications. The initiative "XLN- Xtended Licensing & Laboratory Node" is a web based IT solution, **https://xln.gujarat.gov.in/MainPage.aspx** , with data stored in the central server. The introduction of the new system has strengthened the enforcement function. It has helped to bring harmonization, speed, accuracy, effectiveness, accountability and transparency in functions related to G2G, G2C and G2B and to attain & maintain FDCA's leadership in drug regulations in India.

Food & Drug Control Administration (FDCA), Gujarat regulates the Sales & Manufacturing aspects related to Food, Drugs & Cosmetics. FDCA head office is located in Gandhinagar and has 25 circle offices in various districts across the state. The jurisdiction of some of the circle offices is beyond one district. Each circle office is headed by an Asst. Commissioner and assisted by Drug Inspectors / Sr. Drug Inspectors for the field duties. Some of the key responsibilities of FDCA are:

Issuance of licenses: FDCA is the authority responsible for issuing licenses to stake holders for Manufacturing and Sales of pharmaceutical and related products i.e. manufacturers of drugs, wholesalers, retailers, stockiest, C&F agents etc.

Enforcement: It includes monitoring of the quality of drugs manufactured or coming from other states. For the monitoring purpose each drugs inspector/Sr. Drugs Inspector has to draw drugs samples on regular basis. Drugs inspectors have to sent these samples for analysis to the government drugs testing laboratory located at Vadodara,

Gujarat. On the basis of test results samples declared as of Standard Quality or Not of Standard Quality. Moreover, based on the test results different types of punitive actions are entertained against the manufacturer. The enforcement mission targets to fulfill the objective of making available the safe and effective medicines by ensuring that the menace of manufacture of spurious /substandard drugs is eradicated. For the enforcement activities it is vital to have immediate and accurate access to information as well as there is a need to communicate effectively and quickly with the stake holders. Prior to the initiative of implementation of software, SMS alerts etc the enforcement task was dependent on manual means of actions and communications. The introduction of the new system has strengthened the enforcement function.

Laboratory Management: Ensure Collection of Samples to analyzing them and lessen the time for the communication of the results with drug officers & conveying Sub Standard Drugs information to various stake holder

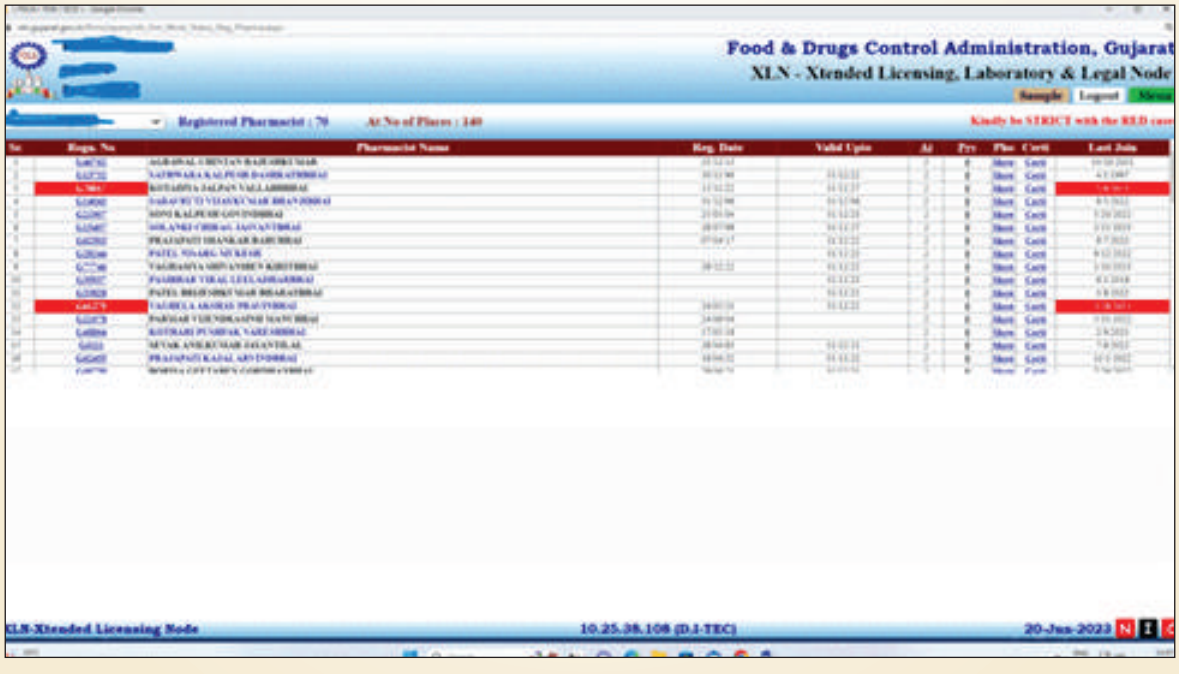
Challenges in the Enforcement

FDCA has been entrusted to ensure availability of quality medicines through licensed pharmacies and wholesalers by Health & Family Welfare Department of Government of Gujarat and thereby to promote & protect public health in the Gujarat state having population of more than 62 million.
The Sales licensing procedure is decentralized and prior to the initiative, it was carried out manually and lacked harmonization in all Circle Offices. Because of this some of the challenges areas identified were:

Multiple illegal enrollments: It was noticed that some Pharmacists had illegally enrolled their names in multiple pharmacies in different districts. During a drive conducted for verification of Pharmacists in pharmacies in the State, it was observed that there was the absence of Pharmacists in various pharmacies and subsequently licenses of such pharmacies were cancelled by the FDCA.

Tedious licensing procedure: The procedure for issue of sales license was tedious and time consuming. Right from the collection of application form to the issuance of the sales license, the applicant had to visit the circle office several times. There was no harmonization of procedures in all circle offices.

Disconnect because of distance: There was kind of disconnect between the head office and circle offices. (i) The information related to sales licenses granted, suspended, cancelled, pharmacists etc. was not readily available with head office and



hence effective monitoring of the working of the circle offices was difficult. (ii) The details of samples drawn by Drug Inspectors & Senior Drug Inspectors were not immediately available to Head Office. (iii) Difficulty in compilation and retrieval of information asked for by Parliament & citizens under the Right to Information (RTI) Act.

Procedural delays: The administrative procedure for "Not of Standard Quality" (NSQ) report was lengthy. After receipt of NSQ test report from laboratory, it took more than two months to convey the information to dealers, and by the time the NSQ information reached the dealers, most of stock was consumed and effective recall was not possible and the very objective of FDCA to protect public health was not being met.

No information access to public: No system for public to access the information related to pharmacies, NSQ drugs, Blood Banks, availability of blood etc.

Thus FDCA proposed a web based information technology solution to the problem which resulted into the current initiative – Xtended Licensing & Laboratory Node (XLN).

Objectives of Xtended Licensing, Laboratory & Legal Node (XLN)

The initiative "XLN- Xtended Licensing & Laboratory Node" is a web based IT solution, **https://xln.gujarat.gov.in/MainPage.aspx** , with data stored in the central server. It evolved to the current features over a period of time XLN's implementation which was initiated on 1st January 2007 with the following objectives:

a) Standardization of procedures & bringing about transparency in administration.

b) Effectively monitor the circle offices through this online IT application.

c) Ensure that a pharmacist does not illegally enroll his name in multiple pharmacies in different districts - The software restricts him to one pharmacy only at a particular point of time.

d) Reduce the number of personal visits to the circle offices by the applicant for expediting the decision on their application and to reduce their hardship.

e) Details of samples drawn by Drug Inspectors & Senior Drug Inspectors and test reports needed be made available to Head Office immediately.

f) Ensure quick & effective recall of NSQ medicines through mass messaging (SMS).

g) Provide a seamless link between FDCA, Food & Drug Laboratory (FDL), Gujarat State Pharmacy Council and the Gujarat Medical Services Corporation Ltd. (GMSCL).

h) To provide information in public domain, regarding medical stores / wholesalers and Blood Banks operating in Gujarat State.

Strategies for implementation of Initiative -XLN

Under the leadership and guidance of FDCA Commissioner, FDCA team & NIC Team discussed various aspects of the FDCA functions in several brainstorming sessions and worked out a plan for development of **XLN- Xtended Licensing & Laboratory Node.**

i. Several workshops were held with all Assistant Commissioners & Drugs Inspectors to demonstrate the software and to get their feed back.

ii. FDCA Commissioner ensured computer access in circle offices with the Gujarat State Wide Area Network **(GSWAN)** / internet connectivity.

iii. FDCA team constantly monitored all circle offices to ensure that the details of more than 30,000 licenses issued before 1st January 2007 were keyed in the software to generate database, and the sales licenses issued after 1st January 2007 were issued only through the software.

iv. FDCA team also constantly monitored all circle offices to ensure that details of each and every sample drawn by Drug Inspectors & Senior Drug Inspectors are keyed in and necessary forms are generated through the software.

v. NIC Team looked into the system requirements, its analysis, database designing, the development part & other technical aspects.

BEST PRACTICES FROM PMRU/SDC GUJARAT

Stakeholders of XLN are : All circle offices of FDCA, FDCA's Head Office, Food & Drug Laboratory (FDL), Gujarat Medical Services Corporation Ltd. (earlier known as Central Medical Stores Organization - CMSO) (Government of Gujarat's central drug purchasing & distributing agency to all Government hospitals & dispensaries), Gujarat State Pharmacy Council, Pharmacies (Retailers) and Wholesalers of drugs, Blood Banks and most importantly citizens.

Benefits to Government (G2G):-

i. XLN interlinks FDCA, GMSCL, Drug laboratory and Pharmacy Council for co-ordination and monitoring.

ii. Display of real time ranking of all Circle Offices on the basis of their performances.

iii. Real time statistical reports becoming available.

iv. Drug laboratory can immediately view the sample data entered by Drug Inspectors..

v. The test result entered by the laboratory can be immediately viewed by the concerned circle offices, Head office of FDCA and GMSCL.

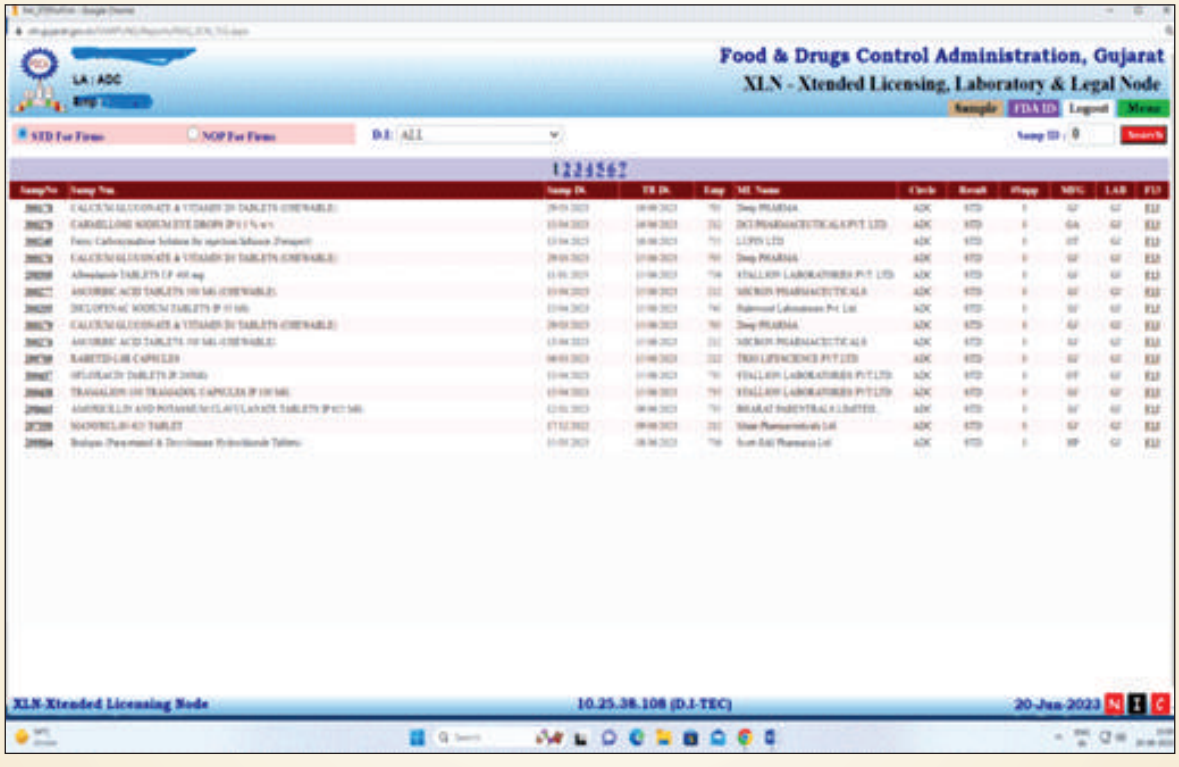
vi. Drug Inspectors are alerted to initiate prompt action in various cases like:

a. 24 hours Pharmacy operating without 3 Registered Pharmacists.

b. Pharmacy operating without a mandatory Registered Pharmacist.

c. Firms "NOT INSPECTED" since last 1 year.

d. Firms whose Renewal is due in coming month.



e. Pharmacist at multiple locations within Gujarat.

vii. Administrative uniformity, accuracy, speed, transparency and instant accessibility of information through XLN helped to increase performances of circle offices. During year 2005 to 2011, number of disposal of applications increased from 6103 to 10827 and no. of raids increased from 4 to 22.

viii. As XLN is replicated by other seven states, access to their databases on – drug inspectors, sales licensee etc.

ix. Maintains the history of all data.

5.2. Benefits to citizen (G2C):-

i. Citizen can locate nearby Pharmacies.

ii. Information about 24 Hours functional Pharmacy is available.

iii. Information about all NSQ Drug Samples.

iv. Citizen can also verify whether the drug purchased has been declared as NSQ by Government Drug Laboratory or not.

v. Information about upcoming Blood Donation Camps, availability of Blood Bags of each Blood Group and Blood Component with the Blood Banks

Impacts of XLN initiative:

XLN has enhanced trust, confidence and image of FDCA for better regulation and public services among all stakeholders including citizens. XLN received appreciation for better public services at several conclaves and published in various print media. **"To make public Services efficient and corruption free",** Government of Gujarat rewards its various departments for their exemplary initiatives. During March 2012, Dr. H.G. Koshia Commissioner, FDCA, Gujarat was awarded the first award under above category for the FDCA, Gujarat's initiative of **XLN.** XLN initiative received "CSI IT Excellence Runner up award" from the Computer Society of India, a premier computer society association operating since more than 50 years in India. Government of India conferred "National e-Governance Gold Award 2012-2013 for Exemplary Re-Use of ICT based solution" on FDCA and Dr. H.G. Koshia, Commissioner, FDCA for XLN initiative. XLN received an e-India Award 2013 & Certificate of Excellence for Government initiative in Healthcare.

Thus, XLN has further strengthened the position of FDCA, Gujarat as leading State Drug department in the country.

Thus, XLN has helped to bring harmonization, speed, accuracy, effectiveness, accountability and transparency in functions related to G2G, G2C and G2B and to attain & maintain FDCA's leadership in drug regulations in India.

➢ **What is CAPPM Scheme?**

Ans. Consumer Awareness & Publicity and Price Monitoring (CAPPM) a central sector scheme implemented by National Pharmaceutical Pricing Authority (NPPA), Department of Pharmaceuticals (DoP), to create general awareness about the availability of medicines, prices of medicines, ceiling prices of medicines fixed by the Government, precaution to be taken while purchasing medicines. The scheme has two components:

I. Assistance for setting up Price Monitoring Resource Units (PMRUs) in State/UTs

II. Advertising and Publicity

➢ **What is Price Monitoring Resource Units (PMRUs)?**

Ans. Price Monitoring Resource Units (PMRUs) are registered societies in the States/ UTs under the supervision of State Health and Drug Control Department. PMRUs are the key collaborating partners of NPPA with information gathering mechanism at the grass roots levels. They are expected to monitor price movement of scheduled/ non-scheduled formulations, ensuring availability of medicines and to create public awareness so that benefits of the Drug Price Control Orders (DPCOs) trickle down to the grassroots levels. Also, PMRUs are expected to provide necessary technical assistance to the State Drug Controllers and NPPA.

➢ **What are the Categories of States/ UTs for setting up the PMRUs ?**

Ans. For the purpose of providing grants and staffing PMRUs have been categorized in three (3) categories as mentioned below:

Category I – States/ UTs having population of more than 3% of total population;

Category II – States/ UTs having population of less than 3% but more than 1% of total population; and

Category III – States/ UTs having population of less than 1% of total population.

➢ **What is the grant given to PMRU under CAPPM Scheme ?**

Ans. PMRUs are fully funded by NPPA under CAPPM. The provision of Grants to PMRUs is divided into two parts, viz., Non-Recurring (for Capital expenditure) and Recurring grants (operating expenses). The as detailed hereunder:

	Non-Recurring Grant	Recurring Grant
Category I	₹7 lakh	₹55 lakh
Category II	₹5 lakh	₹49 lakh
Category III	₹ 3 lakh	₹ 42 lakh

The grant for Non-Recurring (for Capital expenditure) is provided only once after setting up of a New PMRU in the State/ UT for purchase of basic infrastructure assets to start functioning while Recurring grant is provided to PMRU for performing their day to day activities.

- **What is the method of release of funds to PMRU under CAPPM Scheme?**

Ans. In the first year, 90% of the non-recurring expenses and six months advance for recurring expenses would be released as first instalment to the selected States/ UTs. The remaining non-recurring expenses and recurring expenses for the next six months will be released as second instalment on the basis of actual expenditure of first six months of funds received as first instalment subject to submission of Utilization certificate and as revised guidelines for flow of funds issued by Department of Expenditure, Ministry of Finance as per the O.M. dated 9th March, 2022.

- **How many PMRUs have been set-up in the States/ Uts?**

Ans. Twenty-nine (29) Price Monitoring and Resource Unit (PMRU) have been set up in the States till date, viz., Kerala, Gujarat, Odisha, Rajasthan, Punjab, Haryana, Tripura, Nagaland, Uttar Pradesh, Andhra Pradesh, Mizoram, Jammu & Kashmir, Karnataka, Telangana, Maharashtra, Goa, Madhya Pradesh, Chhattisgarh, Jharkhand, Puducherry, West Bengal, Ladakh, Himachal Pradesh, Bihar, Uttarakhand, Meghalaya, Arunachal Pradesh, Chandigarh and Assam. Setting up of PMRUs in the other States is in progress.

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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