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**

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From CHAIRMAN'S DESK

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

I would like to wish all the readers a very Happy New Year 2023 as we bring to you the eighth issue of the NPPA bi-monthly e-Newsletter.

NPPA strives to strike a balance between the interests of the consumers and the Pharma Industry within the ambit of the DPCOs notified from time to time.

This edition of the e-newsletter contains an article penned by Dr. Harmeet Singh Rehan, Director Professor & Head, Department of Pharmacology, LHMC, New Delhi on **"Improper Disposal of Expired Pharmaceuticals May Pose a Serious Threat to the Environment".** He highlights that improper disposal of expired pharmaceuticals including disposal in unsecured landfill may pose a serious threat directly or indirect to the environment leading to affect the public health. Hence, this activity should be carried out with due care following the laid down guidelines/protocols.

A webinar on the topic "Tracking the drugs: Ensuring last mile availability" was organized by NPPA in hybrid mode on 30.11.2022, under the Chairmanship of Dr. V. K. Paul, Member (Health), NITI Aayog. During the panel discussion, panelists highlighted the various facets that touch upon this important area including the complexity of the pharmaceutical supply chain across manufacturers, distributors and retailers. They also focused on the need for standardization of data elements; inter-operability and a systems approach. In this issue we present to you the highlights of the panel discussion.

I also happy to inform that a number of IEC activities were carried out by the PMRUs. This issue highlights the IEC activities conducted by PMRUs of West Bengal, Karnataka, Ladakh and Goa.

As you all are aware that NPPA has recently implemented IPDMS 2.0. This issue contains some brief FAQs on IPDMS 2.0 and the Pharma Sahi Daam mobile application.

The Newsletter would help stakeholders stay up-to-date with the latest information on government policies and programmes, upcoming events and progress of projects.

NPPA wishes good health to all its readers; stay safe, stay healthy and follow all COVID appropriate behaviour.

(Kamlesh Kumar Pant)

IMPORTANCE OF PROPER DISPOSAL OF EXPIRED PHARMACEUTICALS

(Dr. Harmeet Singh Rehan, Director Professor & Head, Department of Pharmacology, LHMC, New Delhi)

Medicines have been a boon for the betterment of human health and wellbeing when used either for diagnosis, cure or prevention of diseases. Though medicines use is always expected to have beneficial effects, they are also associated with undesired adverse effects at therapeutic and toxicity doses. The process of drug development, both in preclinical and clinical stages, is primarily focused on safety of the patient and to ensure that it is environmentally friendly. Every New Chemical Entity (NCE) undergoes – preclinical testing (acute, sub-chronic, chronic toxicity studies) and first-in-human, 0,1 & 3 phases of clinical trials before the market authorisation. Recently, drug development has also attracted the attention of the industry to safeguard the environment from the deleterious effect of NCEs and their metabolites by innovating readily biodegradable NCEs. Despite these measures there have been a few cases where improper use or disposal of medicines has led to harmful effects on the environment, ranging from contamination of drinking water leading to disruption of lifecycle of aquatic animals to life threatening consequences to humans. Local Civic authorities in India have recommended STP/ETPs as mandatory to have in healthcare facility with more than ten beds.

The scavenging of the carcass of animals who were administered diclofenac before their death led to decline in vultures' population in the Indian subcontinent, (1) suggesting NCEs found safe for one species may not be necessarily safe for others. Further, extensive use of tetracycline in pig farms in Japan (2) and in poultry led to the exposure of the environment to antibiotics and contributed to antimicrobial resistance (AMR) posing (3) risk to human health globally (4).

To understand adverse impact of medicines and their metabolites on the environment, a new term **Ecopharmacovigilance** has been coined. It is defined as science and activities concerning detection, assessment, understanding and prevention of adverse effects/other problems related to the presence of pharmaceuticals in the environment which affect both human and other animal species. Apart from the effluent by pharmaceutical industry, improper disposal of expired and unused drugs is another growing challenge to the environment.

Consequences of improper disposal of expired and unused medicines

Improper disposal of expired pharmaceuticals including disposal in unsecured landfill may pose a serious threat directly or indirect to the environment leading to affect the public health. Some of the health risks of improper disposal of expired/unused medicines are:

- Contamination of drinking water through leachate from landfill entering an aquifer, surface water or drinking water system.
- Non-biodegradable antibiotics, anti-neoplastics (anti-cancer) and disinfectants should not be disposed of into the sewage system as they may kill bacteria which are necessary for the treatment of the sewage and may precipitate the development of AMR.
- Antineoplastics should not be flushed into watercourses as they may damage aquatic life or contaminate drinking water. The utilization of such contaminated water by the human especially the pregnant women may pose serious consequences to the foetus.
- Large quantities of disinfectants should not be discharged into a sewerage system or watercourse but can be introduced if well diluted, as it may adversely impact the micro flora of the sewage.

- Burning pharmaceuticals at sub-ideal temperatures with inadequate emission standards i.e. open container may result in release of toxic pollutants into the air.\
- Inefficient sorting and disposal of expired/unused medicines may allow drugs to be used beyond their expiry date which may not be desirable for the general public.

Methods of medicinal Waste segregation and disposal

1. **Health and safety of work teams:** All workers/volunteers must wear appropriate protective equipment including gloves and mask, and overalls and boots when appropriate.

o Masks should be worn when tablets or capsules are being crushed and when there is a risk of powder being liberated.

o Overalls and boots when chance of exposure or quantity tablets or capsules to be crushed is higher.

2. **Sorting:** The objective of sorting is to separate the pharmaceuticals into different categories to enable selecting appropriate disposal method. Segregated temporary storage areas or receptacles must be made available for each sorted category.

- **Sorting process**

i. identifying each item

ii. making a decision on whether it is usable

   a. if found usable, leaving packaging intact

   b. if not usable, sort them accordingly to the optimal method of disposal.

- **Optimum conditions for sorting**

i. Sorting should be done in the open or in a well-ventilated structure, as close as possible to the stockpile in an orderly way, with all sorted material clearly labelled and separated at all times.

- **Packing of sorted medicines**

i. Once sorted, the pharmaceuticals should be carefully packed into steel drums or into containers such as sturdy cardboard boxes, with the contents clearly indicated on the outside of the containers.

- **Sorting categories**

i. **Pharmaceuticals and other materials which are still usable**

The first step in dealing with stockpiles of collected medicines is removing medicines which are still usable. They are

a. **Non-pharmaceutical useful materials:** Dressings, clothing, laboratory glassware, etc. can be either by the institution or recycled.

b. **Useful pharmaceuticals:** Pharmaceuticals having their expiry date more than six months are considered useful and should be separated out and consider immediately for donation.

ii. **Expired or unwanted pharmaceuticals**

These medicines should never be used and should always be considered as pharmaceutical waste.

A. **Special disposal method is needed for:**

   a. Controlled substances such as narcotics, psychotropic substances etc.

   b. Anti-infective substances Antineoplastics

   c. Antiseptics and disinfectants

B. **All other pharmaceuticals**

   a. Solids, semi-solids and powders e.g., tablets, capsules, granules, powders for injection, mixtures, creams, lotions, gels, suppositories etc.

   b. Liquids e.g., solutions, suspensions, syrups etc.

   c. Aerosol canisters e.g., Propellant-driven sprays and inhalers

C. **Recyclable materials** - Waste paper, cloth, packing materials, glass bottles and wood materials etc.

Appeal to the public

- Do not improperly discard/ dispose of unused medicines.
- Donate good quality of medicines.
- When pharmaceuticals pass their expiry-date they do not automatically become hazardous, they may simply become less efficacious with passage of time and may also develop a different adverse drug reaction profile.
- Most pharmaceuticals are relatively harmless to the environment; they do not present a serious threat to the public or environment unless handled recklessly.

There are non-profit establishments like Mediflo, which are engaged in the pursuit of reducing pharmaceutical waste. They undertake activities like collecting medicines from households, sorting them at a segregation facility at the Department of Pharmacology, LHMC, New Delhi, and lastly disposing expired medicines as per WHO norms. Good quality medicines having an expiry date of more than 6 months are deemed usable and provided to those in needs through charitable dispensaries/clinics/hospitals at no cost. Such an initiative has been modeled on pre-existing drug take back programs from around the world that have proven successful in ensuring safe medication disposal.

References

1. https://doi.org/10.1111/j.0021-8901.2004.00954.x
2. https://doi.org/10.1292%2Fjvms.20-0436
3. https://doi.org/10.1186/s12917-020-02488-z
4. Antimicrobial resistance (who.int)

News related to pricing of drugs

- Ceiling prices for 890 scheduled formulations (National List of Essential Medicines, 2015) and Retail prices for 2186 non-scheduled formulations have been fixed under DPCO, 2013 till 30th November, 2022.
- As on 30th November, 2022, 236 Authority meetings have been conducted of which, 104 meetings are under DPCO 2013. The details of recent meetings are given as below:

Meeting No.	Held on	Retail Prices Approved & Notified
235 (overall) & 103 Meeting under DPCO 2013	10.11.2022	40 Formulations & notified vide SO. 5388(E) dated 18.11.2022
236 (overall) & 104 Meeting under DPCO 2013	23.11.2022	1 Formulation & notified vide SO. 5511 (E) dated 28.11.2022

- Details of retail prices notified for various formulations based on the decision taken in 103rd & 104th 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	15	Tablet	9.66 - 30.70
2	Antihypertensive	6	Tablet	11.41–18.77
3	Antibiotic	2	Suspension	168.43
4	Hypertension	3	Tablet	9.51 – 10.88
5	Cardiovascular	2	Tablet	50.71
6	Pain management	6	Tablet/ suspension/Spray	0.41 – 4.15
7	Antineoplastic	1	Injection	12420.28
8	Others	6	Tablet/Injection/ Vitamins/ Sachet	9.05– 51.19

- Revised Schedule-I of DPCO, 2013 (i.e. National List of Essential Medicines, 2022) notified by Department of Pharmaceuticals (DoP) vide SO No. 5249 (E) dated 11.11.2022. The number of formulations covered in revised Schedule – I are as follows:

S. No.	Particulars	Number of formulations
1.	Approximate number of formulations	954 (388 Medicines)
2.	Duplicate formulations under various sections	135
3.	Unique formulations, including a) Formulations of newly added drugs b) Formulations continued from NLEM, 2015 drugs	 56 (included in unique) 763 (approx.)
4.	**Total**	**819 (approx.)**

FDA Approves First Drug That Can Delay Onset of Type 1 Diabetes (November 17, 2022)

The U.S. Food and Drug Administration approved Tzield (teplizumab-mzwv) injection to delay the onset of stage 3 type 1 diabetes in adults and pediatric patients 8 years and older who currently have stage 2 type 1 diabetes.

Type 1 diabetes is a disease that occurs when the immune system attacks and destroys the cells that make insulin. People with a type 1 diabetes diagnosis have increased glucose that requires insulin shots (or wearing an insulin pump) to survive and must check their blood sugar levels regularly throughout the day.

Tzield binds to certain immune system cells and delays progression to stage 3 type 1 diabetes. Tzield may deactivate the immune cells that attack insulin-producing cells, while increasing the proportion of cells that help moderate the immune response. Tzield is administered by intravenous infusion once daily for 14 consecutive days.

Read more

FDA Approves First Gene Therapy to Treat Adults with Hemophilia B (November 22, 2022)

The U.S. Food and Drug Administration approved Hemgenix (etranacogenedezaparvovec), an adeno-associated virus vector-based gene therapy for the treatment of adults with Hemophilia B (congenital Factor IX deficiency) who currently use Factor IX prophylaxis therapy, or have current or historical life-threatening hemorrhage, or have repeated, serious spontaneous bleeding episodes.

Hemgenix is a one-time gene therapy product given as a single dose by IV infusion. Hemgenix consists of a viral vector carrying a gene for clotting Factor IX. The gene is expressed in the liver to produce Factor IX protein, to increase blood levels of Factor IX and thereby limit bleeding episodes.

The FDA granted approval of Hemgenix to CSL Behring LLC.

Read more

FDA Warns Seven Companies for Selling Dietary Supplements with Claims to Treat Cardiovascular Disease (November 17, 2022)

The U.S. Food and Drug Administration issued warning letters to seven companies for illegally selling dietary supplements that claim to cure, treat, mitigate or prevent cardiovascular disease or related conditions, such as atherosclerosis, stroke or heart failure, in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

The FDA is urging consumers not to use these or

similar products because they have not been evaluated by the FDA to be safe or effective for their intended use and may be harmful.

The warning letters were issued to: Essential Elements (Scale Media Inc.); Calroy Health Sciences LLC; Iwi; BergaMet North America LLC; Healthy Trends Worldwide LLC (Golden After 50); Chambers' Apothecary; and Anabolic Laboratories, LLC.

Read more

FDA Authorizes Updated (Bivalent) COVID-19 Vaccines for Children Down to 6 Months of Age (December 08, 2022)

The U.S. Food and Drug Administration amended the emergency use authorizations (EUAs) of the updated (bivalent) Moderna and Pfizer-BioNTech COVID-19 vaccines to include use in children down to 6 months of age.

The Moderna and Pfizer-BioNTech bivalent COVID-19 vaccines include an mRNA component corresponding to the original strain to provide an immune response that is broadly protective against COVID-19 and an mRNA component corresponding to the omicron variant BA.4 and BA.5 lineages to provide better protection against COVID-19 caused by the omicron variant.

The safety of a single booster dose of the Moderna COVID-19 Vaccine, Bivalent for children 6 months through 5 years of age is supported by safety data from a clinical study which evaluated a booster dose of Moderna's investigational bivalent COVID-19 vaccine (original and omicron BA.1), safety data from clinical trials which evaluated primary and booster vaccination with the monovalent Moderna COVID-19 Vaccine, and postmarketing safety data with the monovalent Moderna COVID-19 Vaccine and Moderna COVID-19 Vaccine, Bivalent.

Read more

FDA Approves New HIV Drug for Adults with Limited Treatment Options (December 22, 2022)

The U.S. Food and Drug Administration approved Sunlenca (lenacapavir), a new type of antiretroviral medication for adult patients living with human immunodeficiency virus type 1 (HIV-1), whose HIV infections cannot be successfully treated with other available treatments due to resistance, intolerance, or safety considerations. After the starting dose is completed, Sunlenca is administered as subcutaneous (under the skin) injections once every six months, allowing convenient dosing for patients.

Sunlenca is the first of a new class of drugs called capsid inhibitors to be FDA-approved for treating HIV-1. Sunlenca works by blocking the HIV-1 virus' protein shell (the capsid), thereby interfering with multiple essential steps of the viral lifecycle. Sunlenca's starting dose is given as oral tablets and subcutaneous injections, followed by maintenance injections every six months; Sunlenca is given in combination with other antiretroviral(s)

Read more

WEBINAR ON "TRACKING THE DRUGS: ENSURING LAST MILE AVAILABILITY"

A webinar on the topic **"Tracking the drugs: Ensuring last mile availability"** was organised in hybrid mode on 30.11.2022, under the Chairmanship of Dr. V. K. Paul, Member (Health), NITI Aayog. The Guest of Honour of the webinar was Ms. S. Aparna Secretary, Department of Pharmaceuticals. About 340 participants attended the webinar from Pharma Association, Industry Representatives, Consumer Groups, Students, related departments and Price Monitoring Resource Units of States/ UTs etc.

Shri Kamlesh Kumar Pant, Chairman, NPPA in his welcome address, while welcoming the participants to the webinar, highlighted the need to have a system in place, which tracks the stocks of medicines in the supply chain on a real-time basis. It was pointed out that NPPA was constituted in 1997 with the mandate to ensure availability and accessibility of medicines at affordable prices. During the COVID pandemic in the country, NPPA played an active role in addressing the exigencies arising out of pandemic and undertook necessary measures to ensure continued availability of life saving essential medicines throughout the country.

NPPA had greater interaction with Industry, manufacturers; Retailer associations; State Drug Controllers (SDCs); District administration etc., to ensure that supply chains were not compromised. One of the major roles of NPPA is to constantly monitor the availability of drugs, identify shortages, if any, and to take remedial steps. However, at that time, there was no institutional mechanism to get data on a daily or weekly basis. Hence, it is desirable to have a system in place, which tracks the stocks of medicines in the supply chain on a real-time basis. This will help in proactive monitoring of availability of stocks, to verify complaints/ references of non-availability of drugs and to map stocks with shortage locations in case of crisis situations.

Speaking on the occasion, Ms. S. Aparna, Secretary, Department of Pharmaceuticals, thanked Dr. Paul for playing the role of a friend, philosopher, guide and his mature guidance in effective response of India to the COVID pandemic as chair of the Empowered Group. In its efforts to ensure continuous supply of COVID management drugs, DoP was greatly helped by the State/UT Governments, and supported by Manufacturers/ AIOCD/ Market database agencies. Tracking supplies was a huge collective effort and a lot of man-hours were spent on it. It was done in a crisis situation, however, there needs to be a systematic approach to achieve this goal of tracking and

ensuring availability of drugs till the last mile. Data availability is the 1st step. There are around 8900 PMBJP outlets which covers only 1% of the retail network. Majority of the retail coverage is through the private sector and there is the need to build the ability to track and fill this gap. Need to have scalable database of drug availability and data should be:

- Updated
- Accurate
- Granular
- Authentic source
- With GIS capability

Having such a system will lead to better deployment and equitably efficient distribution of drugs and also curb anti-social activities.

Panel Discussion

The panel discussion was moderated by Shri Himanshu Agrawal, AVP, Invest India and had experts drawn from various fields i.e., Dr. Somani, Drug Controller General of India (DCGI); Shri Sudarshan Jain, Secretary General, IPA; Shri Amit Backliwal, CMD, Pharmasoftech AWACS; and Shri Swaminathan, CEO GS1, India. Shri Himanshu Agrawal, the moderator for the panel discussion explained the

- During the panel discussion, panellists highlighted the various facets that touch upon this important area including the complexity of the pharmaceutical supply chain across manufacturers, distributors and retailers. They also focused on the need for standardization of data elements; inter-operability and a systems approach. Few examples of country best practices in this area were also shared by the panellists.

- Dr. V. G. Somani, DCGI also highlighted the fact that CDSCO was trying since 2015 to have a system that tracks last mile availability of drugs. He further highlighted that basic point is related to data collection that is authentic. The recent notification on introduction of barcodes on APIs and top 300 brands will cover around 60% of the market. The system has to be implemented w.e.f. December 2022 in case of APIs and for top 300 brands by August 2023. Initial response of API manufacturers was one of confusion but subsequently it changed to acceptance. The intent is to put in place simple and technology agnostic authentication system and then tracking can be built over it. The focus is more on consumer empowerment.

- Shri Sudarshan Jain, Secretary General, IPA highlighted the fact that Indian pharma industry is third largest in the world in terms of volume and is catering to not only the need of India but across the globe. However, it was emphasized that the pharma distribution chain is complex and different from other products. The complexity of the distribution chain poses problems but the industry is committed to have such a system that gives retail level visibility.

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- Shri Amit Backliwal, CMD, Pharmasoftech AWACS while giving an overview of the sector that has around 10,000 pharma companies, 65,000 – 70,000 Distributors, 9.5 lakh retailers/pharmacies; data is an issue. The data being maintained by different entities does not speak to each other as there is no standardization of data. To illustrate the point, he said Crocin can be written in 10 different ways. Hence, standardization of data elements would be the pre-requisite for tracking and traceability system.

- Shri Swaminathan, CEO GS1 India highlighted that unique identity is required to have 'One version of tracking'. The principle of harmonization of codes will have to follow. Traceability can be one up or one down and there has to be a centralized platform. With IT penetration, it is easy to capture transaction data. He also informed that a track ability system has been implemented in Turkey. He also informed about the EU Falsified Medicines Directive (2011/62/EU) (FMD) which was adopted in 2011 and introduced new harmonised measures to ensure that medicines in the European Union (EU) are safe and that trade in medicines is properly controlled. Measures put in place include: obligatory safety features – a unique identifier and an anti-tampering device - on the outer packaging of medicines; strengthened record-keeping requirements for wholesale distributors, etc. He opined that Thinking can be big but start can be small. Also, he observed that such a system can be run by a neutral party and not vested.

WEBINAR ON AWARENESS WORKSHOP ORGANIZED BY PMRU WEST BENGAL

Price Monitoring & Resource Society West Bengal Unit (PMRSWBU) and Department of Health & Family Welfare have jointly organized one-day State level Awareness workshop on 30th November 2022 at Biswa Bangla Convention Centre, Kolkata. The Workshop was organised covering Inauguration Session followed by Technical Session-1 and Technical Session 2 (Panel Discussion).

Inaugural Session, was graced by Smt. Chandrima Bhattacharya (Minister of State in the dept. of Health and family welfare, Government of WB), Sh. Tapan Kanti Rudra, IAS, Sh. Narayan Swaroop Nigam, IAS – (Secretary Health, & Chairman-PMRS-WBU), Sh. Ratan Kumar Khatwani (Joint Director, Legal Division and CAPPM, NPPA) and other dignitaries from State Government and eminent representative from Pharma Industries and associations.

In the Technical Session presentation was given by Sh. Tapan Kanti Rudra, IAS, Sh. Ratan Kumar Khatwani, Joint Director, NPPA and others.

In the Technical Session II, there was a Panel Discussion on "Monitoring of Prices and Availability of Medicines, Medical Devices – Challenges and Opportunities". In the Panel Discussion, the panellist was Sh. Tapan Kanti Rudra (IAS), Sh. Ratan Kumar Khatwani (Joint Director, Legal Division and CAPPM, NPPA), Representatives Consumer Affairs, NGOs and Industry & Trade.

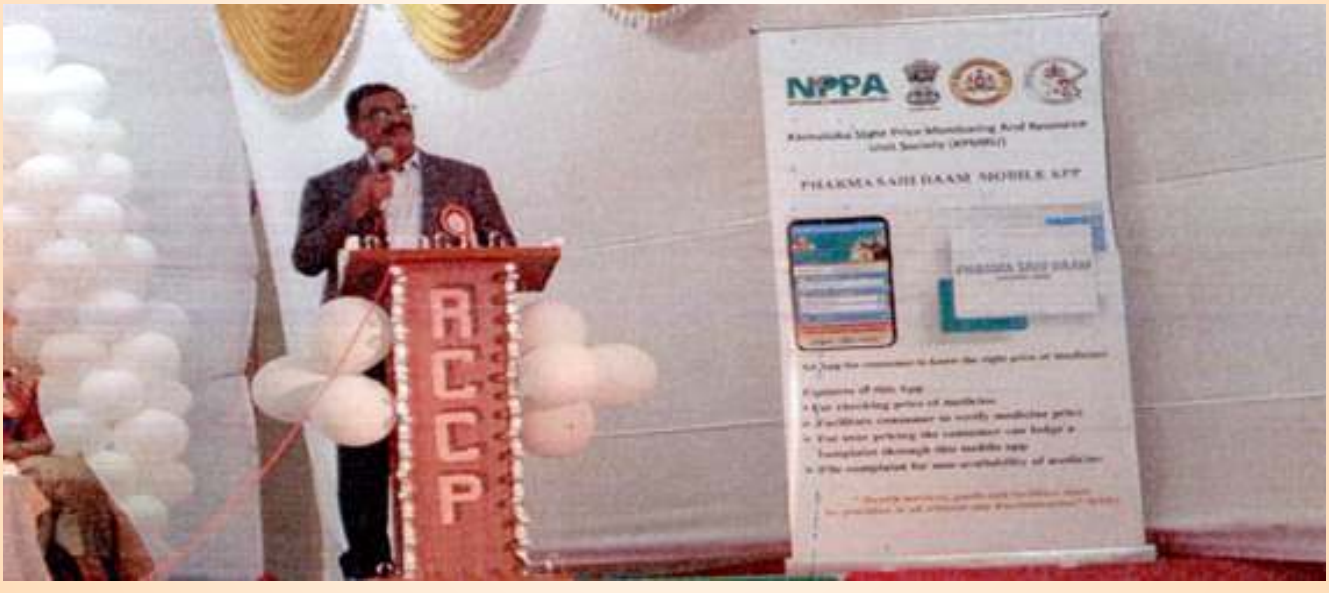
The workshop was attended by approx. 250 participants, in which officials from the state drug controller office, NGOs and industry experts mark their presence and honour this event. The workshop was very successful.

IEC (INFORMATION EDUCATION AND COMMUNICATION) ACTIVITIES ORGANIZED BY PMRU KARNATAKA

Karnataka State Price Monitoring Resource Unit (KPMRU) and Drugs Control department have jointly organized an Awareness program on 20.10.2022 on 'Pharma Sahi Daam Mobile App and Affordability and Availability of Essential Drugs' the occasion of 'Utsah 2K22' at Rani Chennamma College and RML College of Pharmacy, Belgaum, Karnataka. The objective of the webinar was disseminating awareness on use of Pharma Sahi Daam App for the benefits of consumers and Affordability and Availability of Essential Drugs.

An awareness program on "Activities of NPPA and various provisions of DPCO' was also organised nm 19.11.2022 in Bengaluru. The awareness programs were aimed to create awareness about the activities of National Pharmaceutical Pricing Authority, its price monitoring & drug price control mechanism and objectives and role of KPMRU. The brief information of Production linked incentive (PLI) scheme of DoP for promotion of domestic manufacturing of critical key starting materials (KSM)/ Drug intermediates and Active Pharmaceutical Ingredients (APIs) in the country, scheme for promotion of Bulk Drug Parks and Medical Device Parks in the country were also discussed in the session.

More than 500 participants form Drug Control Department, Pharma Industries and B-Pharma and M-Pharma students have participated in these awareness programs.



IEC (INFORMATION EDUCATION AND COMMUNICATION) ACTIVITIES ORGANIZED BY PMRU LADAKH

Ladakh Price Monitoring Resource Unit (LPMRU) along with Drug regulatory department UT Ladakh conducted various Awareness-cum-workshops/ training, interactive sessions with the various Stakeholders viz. Chemist and pharmaceutical distributors, Register pharmacist with Ladakh Pharmacy Council, Medical Assistants students of the Degree colleges, officials of the various health institutions Government Nurses, Government Medical assistants, lecturers/ teachers, Civil societies, women help group, women organization etc. and the Government Pharmacist within town area of District Leh and Kargil and far-flung areas of different blocks regarding following topics:

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- Role of the NPPA and price monitoring w.r.t fixation/revised of the medicines and medical devices.
- The important of medicines its usage, storage/ preservation, prescriptions etc. and to ensure other related important points to be seen while purchasing and taking the medicine.
- Lunching of "Pharma Jaan Samadan" and "Pharma Sahi Daam" application in the interest of the general public and its usage.
- Violations or complaints regarding the issues related to the price of medicine/ medical devices, non-availability/ shortage of medicines / medical devices.
- Availability, Accessibility, Affordability and Quality of the medicines/ medical devices
- Pradhan Mantri Bhartiya Janaushadhi Pariyaojana (PMBJP)

More than 700 participants from different professions have actively participated in these programs.

IEC (INFORMATION EDUCATION AND COMMUNICATION) ACTIVITIES ORGANIZED BY PMRU GOA

Goa State Price Monitoring Resource Unit in coordination with Directorate of Food & Drug Administration has carried out various IEC activities for awareness as mentioned below:

Sr. No.	Date	IEC Activities
1	Nov.-2022	Distribution of IEC material (leaflets) on 'Affordable medicines for all' to Institutes, Banks, Health Centres and Panchayat etc.
2	Dec.-.2022	Awareness program at Taluka level on 'Promotion of affordable generic medicines' through Pradhanmantri Bharatiya Janaushadhi Pariyojna (PMBJP)

IEC ACTIVITIES ORGANISED BY OTHER PMRUS ARE AS UNDER:

UP PMRU: Project Co-Ordinator, UP PMRU Participated in the talk on दवा की सही कीमत एवं उपलब्धता organised by Indian Science Communicators Group on 29.12.2023 as part of a Lecture Series on Facebook.

(ii) Uttar Pradesh State Drugs Control Department on 21.12.22 organized Round Table Discussion on Investment Opportunities in Uttar Pradesh Pharmaceutical & Medical Device Sector. On this occasion Uttar Pradesh PMRU also had a talk of awareness about the continuous contribution of NPPA to make Essential and Life Saving Drugs Available Affordable and Accessible for All, Various Surveys, Price Monitoring done by UP PMRU and also Importance of Digital platforms like IPDMS 2.0 and Pharma Sahi Daam App.

MP PMRU: MP PMRU organised a workshop/ training programme on the Role of NPPA in Drug

pricing and ensuring Availability and Affordability of essential medicines on 27.12.2022.

Kerala PMRU: Kerala State Pharmaceutical Price Monitoring & Resource Unit and Kerala State Drugs Control department jointly organised an awareness program on the topic " NPPA as Drug price regulator in ensuring Affordability of essential medicines " & " Regulatory insights on drug misuse" at John Enoch College of Pharmacy, Trivandrum on 20.12.2022. The concept of the program was to create a general awareness about NPPA, its price Monitoring & drug price control mechanism, DPCO, NLEM and activities of Kerala State PMRU society. Videos of Pharma Sahi Daam app, Live projection of Pharma Sahi Daam app and introduction of Pharma Jan Samadhan app were the highlights of the session. Drug misuse, drug abuse and role of pharmacist in preventing drug abuse were also discussed in the session.

(ii) Awareness program on the topic " Emergence of NPPA as Drug price regulator in Pharma sector" & " Spread Awareness, Stop Resistance - Regulatory Measures for Anti- Microbial Resistance" was organised on 16.12.2022 at AJ College of Pharmacy, Trivandrum.

Tripura PMRU: State level seminar was organised by Tripura PMRU on 08.12.2022 in the presence of Secretary, H&F Welfare Department, Govt. Of Tripura & Director of Health Services, H&F Welfare Department, Govt. Of Tripura.

Haryana PMRU: Haryana PMRU conducted a Workshop on 11.11.22 on IEC Activities including (i) Compliance of DPCO, 2013 (Under PMRU) (ii) Use of 'Sathi' application to curb the misuse of Habit forming drugs as intoxicants. (iii) To curb the illegal sale of MTP Kits. (iv) Sale of drugs by Registered Pharmacists only (v) Sale of scheduled drugs against prescription of RMPs only. In addition to this a District level Educational Seminar was also organised on 20.11.2022 on working of PMRU viz Availability, accessibility and affordability of essential medicines; Monitoring the notified prices of medicines; detection of violation of the provisions of DPCO (revised from time to time); pricing compliance and ensuring availability of medicines; Collection of test samples of medicines at the retail market for monitoring of notified prices and detection of violation of the DPCO, Price Compliance and ensuring availability of medicines.

Punjab PMRU: Punjab PMRU has organized events on the topic on "Affordability & Availability of Essential Drugs" in the various Districts of Punjab. These events were aimed at creating awareness among the public regarding the prices of Drugs and Medical Devices and also told them about the Pharma Sahi Daam App for checking the price of medicines as well as about the toll-free no of Punjab PMRU 1800-180-2414 and email punjab.pmru@gmail.com for any queries/ information/complaints. Along with this, awareness about the basic functioning of NPPA, DPCO 2013 & PMRU was also carried out.

J&K PMRU: (i) A district level awareness programme was held at Rajori in PWD conference Hall on 10.11.22 on "Availability, accessibility and affordability of medicines for all". Event was graced by Sh. Vikas Kundal (IAS) DC Rajori and Principal GMC Rajori Dr. Amarjeet Singh Bhatia, State Drugs Controller Lotika Khajuria , and Senior Officers of Drug and Food Control Organization. The event was attended by pharma trade members, general public & media. Handoutr's were distributed among the participants.

(ii) A district level awareness programme was also held at Dak Banglow, Sopore on 16.11.2022 on "Availability, accessibility and affordability of medicines for all."

Awareness at SMRC, V. M. Salgaocar Hospital, North Goa by Goa PMRU

FREQUENTLY ASKED QUESTIONS

1. What is IPDMS?

Integrated Pharmaceutical Database Management System (IPDMS) is an integrated responsive cloud-based application. It is a system for online information collection, processing and communication portal to monitor and regulate the prices of medicines and medical devices, to ensure availability and affordability of drugs and medical devices in the country.

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

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

The Pharma Jan Samadhan (PJS) is an online facility to raise complaint for Overpricing, Sale without Approval, Refusal of sale and Non-Availability of Drugs. Pharma Sahi Daam (PSD) is an online search tool for checking MRP of all medicines and Ceiling Prices instantly.

The IPDMS/ Pharma Sahi Daam and Pharma Jan Samadhan is available on the link https://nppaipdms.gov.in. The PSD and PJS portals are also available on both iOS and Android platform with the name "Pharma Sahi Daam".

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

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

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

Any person who manufactures or imports or markets drugs/ medical devices for distribution or sale in the country is required to file statutory forms under DPCO, 2013. Such person is required to register on the IPDMS for filing forms.

The company will have to register itself on the IPDMS website by filling the Firm registration form. After that, the company can login with valid login credentials and enter its plant and product details and submit the required IPDMS forms.

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

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

Feedback and Complaint Redressal

Grievance Redressal

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

Information Dissemination

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

Collaboration with State Governments

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

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www.nppaindia.nic.in | Helpline No.: 1800 111 255 (10 am to 6 pm on working hours)