





AUSHADH SANDESH

Vol.-XIII | OCTOBER, 2023

A Bi-monthly e-Newsletter



CONTENTS

S.No.	Description	Page No.
1	From Chairman's Desk	1
2	Article By Experts	2
3	Regulatory News	7
4	International News	10
5	Events and News	12
6	FAQs	18

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 11th November, 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.

EDITORIAL BOARD

Dr Vinod Kotwal, Member Secretary Shri Sanjay Kumar, Adviser Shri G. L. Gupta, Director Shri Pallav Kumar Chittej, Deputy Director

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



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

From CHAIRMAN'S DESK

It is with great pleasure that I bring to you the thirteenth issue of the NPPA bi-monthly e-Newsletter. This issue carries an expert article on "Changes in Disease Profile – Patient awareness and Action" by Dr Amita Bali Vohra, Deputy Director General, Dte.GHS, MoHFW; Dr Rupali Roy, Assistant Director General, Dte.GHS, MoHFW; Dr Sumit Kumar Kansotia, CMO-NFSG, Dte.GHS, MoHFW. I hope you would find it interesting as it highlights to stay informed about changes in disease profiles and take proactive steps to protect our health as most of the problems can be either prevented or be cured in time. Disease profiles means the characteristics symptoms, spread of infection, disease severity, self-limiting disease or not, precautions, and complications associated (if any) with a particular disease.

In the run up of India @75 'Azadi ka Amrit Mahotsava', eleven (11) State level Events/ Seminars have been organized by PMRUs in their respective States/ UTs viz. Puducherry, Goa, Jharkhand, Karnataka, Madhya Pradesh, Maharashtra, Chhattisgarh, Jammu & Kashmir, Kerala, Uttar Pradesh and Uttarakhand. These events 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.

This edition of e-newsletter also highlights Swachhata Hi Seva' (SHS) Campaign NPPA in co-ordination with PMRUs in the States/ UTs have conducted 'Swachhata Hi Seva' (SHS) i.e. preparatory phase campaign from 15th September – 1st October 2023 to raise awareness about cleanliness and sanitation. Massive cleanliness drives were conducted by PMRUs in the States/ UTs at Office premises as well as public places as was envisaged by SHS.

Further, Like every year, this year too use of Hindi /promotion fortnight was successfully organized in the office of National Pharmaceutical Pricing Authority. During this event, various competitions were organized in which regular members of the office as well as contractual and outsourced staff participated enthusiastically. In the closing ceremony of the event, prizes and certificates were presented to all the winners by the Chairman, National Pharmaceutical Pricing Authority.

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

With best wishes

(Kamlesh Kumar Pant)

NA

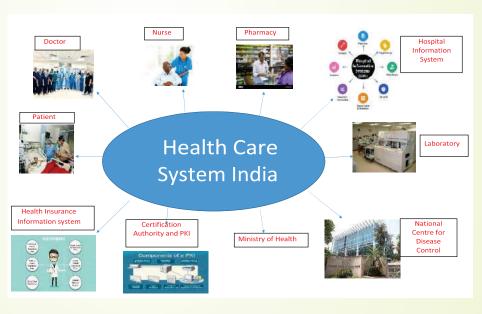
CHANGES IN DISEASE PROFILE – PATIENT AWARENESS AND ACTION

Authors: Dr Amita Bali Vohra, Deputy Director General, Dte.GHS, MoHFW; Dr Rupali Roy, Assistant Director General, Dte.GHS, MoHFW; Dr Sumit Kumar Kansotia, CMO-NFSG, Dte.GHS, MoHFW.

In the past 2-3 decades, the Healthcare system of India is becoming challenging because of emerging new diseases and an increased prevalence of non-communicable diseases. The COVID 19 too threw up new challenges.

The demographic and epidemiological transition is also an important cause factors for increasing dual burden of communicable and non-communicable diseases in India (1). As per Center for Disease Control and Prevention [CDC], there are four modifiable risk factors the principal contributors to chronic disease, associated disability, and premature death: lack of physical activity; poor nutrition; tobacco use; and excessive alcohol consumption (4). Disease burden is further exacerbated by rapid unplanned urbanization, globalization of unhealthy lifestyles and ageing population. Changes of disease profile directly affect overall health care budgets, employee productivity, and economy as a whole. So, if the community may work on risk factors, then much illness and suffering (morbidity) and early death (mortality) can be avoided or prevented.

It is crucial for us to stay informed about changes in disease profiles and take proactive steps to protect our health as most of the problems can be either prevented or be cured in time. Disease profiles means the characteristics symptoms, spread of infection, disease severity, self-limiting disease or not, precautions, and complications associated (if any) with a particular disease. These profiles do not always remain the same, because they depend on many factors, like changes in lifestyle,



environmental factors, antimicrobial resistance and due to the emergence of new pathogens (Bacteria and Viruses)(5). The understanding of these changes is very important for patients, as it can affect their health and well-being.

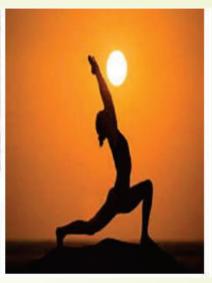
Actions to be Taken by Patients:-

1. Maintain Healthy Lifestyle Habits:-

Many diseases are affected by lifestyle factors, such as diet, exercise, and tobacco or alcohol consumption. As disease profiles change due to lifestyle, persons should be aware of their lifestyles to reduce their risk of developing these illnesses.







- (1) Eat a balanced diet rich in fruits, vegetables (high fiber diet), whole grains, proteins, and healthy fats.
- (2) Do regular physical activity to maintain a healthy weight.
- (3) Avoid smoking and limit alcohol consumption, maintain good hygiene, like regular hand washing and safe food handling etc.
- (4) Healthy eating is also promoted by various means through FSSAI. There is 'Eat Right India' movement, project 'safe and nutritious food' and 'Aaj se thoda kum' awareness activities.

Fit India movement, launched in August 2019, by Ministry of Youth Affairs and Sports on National Sports Day aims to make fitness an integral part of the daily life of every Indian citizen.

Lifestyle modifications have a significant role in disease prevention and management, so it is essential to have a healthy lifestyle.

2. Awareness about Vaccination:-

Vaccination is one of the most effective tools in preventing certain diseases. Community should be aware about vaccination for various age group. Healthcare provider (like PHC's/CHC's health staff) may help them in vaccinations within their communities to maintain herd immunity and protect vulnerable populations (like young children, pregnant woman, and old aged person).





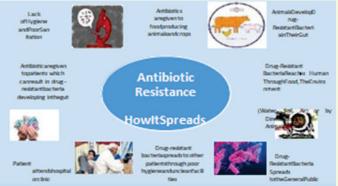


The COVID-19 pandemic has highlighted the importance of vaccines in controlling the spread of infectious diseases. Patients should take interest in getting vaccinated and promoting vaccine uptake in their communities. As disease profiles changes, new vaccines may become available in market for the benefits of patients.

3. Awareness about Judicious use of Antimicrobials: -

- Resistance to Antimicrobials has emerged as one of the biggest public health challenges of present times, threatening the ability to treat several infectious diseases and undoing much of the advances in healthcare made in the last few decades.
- It is very important to be aware about the judicious use of Antimicrobials because indiscriminate use of these medicines creates antimicrobial resistance.
- Educational and awareness initiatives are urgently needed for the end users on responsible use of Anti Microbials.





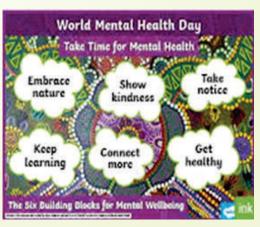
4. Gain access to Health Screenings including Mental Health Screening:-

- Screening for diseases such as cancer, diabetes, and heart disease are essential for early detection and treatment. The National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS) was launched in 2010 with focus on strengthening infrastructure, human resource development, health promotion, early diagnosis, management, and referral.
- Mental health conditions are also part of the evolving disease profile landscape. The stresses of modern life, especially in the context of the COVID-19 pandemic, have highlighted the importance of mental health. Mental health is an integral component of overall well-being and addressing it proactively can

lead to a healthier and more fulfilling life.

➤ Patients should be aware of their own mental health and seek help when needed like access mental health resources and support services if experiencing symptoms of anxiety, depression, or other mental health conditions.





- Be part of regular health check-ups and screenings based on age, gender, family history, and risk factors. Follow through with recommended screenings and adhere to any follow-up recommendations provided by healthcare professionals.
- Early detection can significantly improve the prognosis of many diseases, making regular health screenings a vital aspect of proactive healthcare.







- 5. Be part of Community Health Awareness Activities: -
- Diseases often impact communities, and community involvement plays a vital role in disease prevention and management. Patients can take several actions to foster community involvement.
- Support local healthcare initiatives, such as health fairs, blood drives, and educational workshops.
- Encourage neighbours, friends, and family members to stay informed and take preventive measures.
- Community engagement is a powerful tool in promoting overall health and reducing disease risks at the population level.
- 6. Appropriate use of Assistive Technologies: -
- > Patients may explore digital health apps and wearable devices that can track and monitor health metrics.
- Take advantage of telemedicine options for remote consultations with healthcare providers.







Conclusions:

Health promotion addresses behavioral risk factors such as tobacco use, obesity, diet, and physical inactivity, as well as the areas of mental health, injury prevention, drug abuse control, alcohol control, health behavior related to HIV, and sexual health. It is advised to eat a balanced diet rich in fruits, vegetables, whole grains, proteins, and healthy fats. Do regular physical activities and maintain a healthy weight. Avoid smoking and

limit alcohol consumption, maintain good hygiene, like regular hand washing and safe food handling etc.

References:

- 1. Debasis Barik and Perianayagam Arokiasamy. Rising Health Expenditure Due to Non-Communicable Diseases in India: An Outlook. Front Public Health. 2016;4: 268
- 2. Directorate General Health Services, Ministry of Health
- 3. National Centre for disease control
- 4. Harald Schmidt. Chapter 5, Chronic Disease Prevention and Health Promotion. Public Health Ethics: Cases Spanning the Globe
- 5. https://www.who.int/news-room/fact-sheets/detail/NCDs
- 6. Wei He, Xueyin Zhao, Zhiying Yang, Yan Min, Yi-Hsuan Wu, et al. Changes in lifestyles and depressive symptom among patients with chronic diseases duringCOVID-19lockdown.Open access Published: 06 July 2022



News related to pricing of drugs

- Ceiling prices for 691 scheduled formulations (National List of Essential Medicines, 2022) and Retail prices for 2474 non-scheduled formulations have been fixed under DPCO, 2013 till 30th October 2023.
- As on 13th October, 249 Authority meetings have been conducted of which 117 are under DPCO 2013. The details of the recent meetings are given as below:

Meeting No.	Held on	Retail Prices Approved & Notified
248th(overall) & 116th Meeting under DPCO 2013	06.09.2023	(i) Retail prices for 51 formulations notified vide SO. 4076(E) dated 15.09.2023.
249th (overall) & 117th Meeting under DPCO 2013	13.10.2023	(i) Retail prices for 29 formulations notified vide SO. 4660(E) dated 25.10.2023.

Details of retail prices notified for various formulations based on the decision taken in 116th & 117th 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	46	Tablets	8.97-19.00
2	Anti-biotics	2	Tablet	55.23-151.98
3	Antihypertensive	3	Tablet/Suspension	13.05 – 105.25
4	Cardiovascular	2	Tablet / Capsule	13.22-14.23
5	Anti-pyretic & Analgesics	2	Tablet / Infusion	2.63 – 3.91
6	Vitamins & Minerals	3	Tablets	8.58-10.37
7	Others	22	Capsule / Tablet / Injection / Drops/Gel	0.52-66.50

- Exemption under Para 32 (i) & (ii) of DPCO 2013 granted to M/s Cadila Pharmaceuticals Limited for their product Cholecalciferol Aqueous Injection 6,00,000 IU/2ml (Vitmain D3 Injection)"
- Exemption granted under para 32 (i) of DPCO 2013 to M/s Panacea Biotec Limited for their product EasyfourPol (DTwP-Hib-IPV) Vaccine.



News related to pricing of Medical devices

- NPPA vide notification S.O.4078(E) dated 15.09.2023 issued notifications under Para 19 of the DPCO,2013 regarding fixation/revision of ceiling prices of the Orthopedic Knee Implants for Knee Replacement System. It has been decided that the Orthopedic Knee Implants may be monitored as per the provisions of Paragraph 20(1) of the DPCO, 2013. This order shall be applicable for the period of one year from 16th September 2023(i.e., up to 15th September 2024).
- NPPA vide OM dated 10th Oct 2023 issued clarification regarding increase in the price of Orthopedic Knee Implants w.r.t notification no. S.O.4078(E) dated 15th September 2023. The clarification states that w.e.f 16th September 2023, the manufacturer/importers of knee implants can avail an increase in Maximum Retail Prices (MRP) of Knee Implants up to 10% of MRP during the preceding 12 months.

REGULATORY NEWS

IPDMS 2.0:

Integrated Pharmaceutical Database Management System (IPDMS) is an integrated responsive cloud-based application. It is a system for online information collection, processing and communication portal to monitor and regulate the prices of medicines and medical devices, to ensure availability and affordability of drugs and medical devices in the country. The upgraded IPDMS 2.0 was launched on 29th August, 2022 and the below charts showcase the statistics for the last snix months:



Chart 1: Total number of registered companies at month end

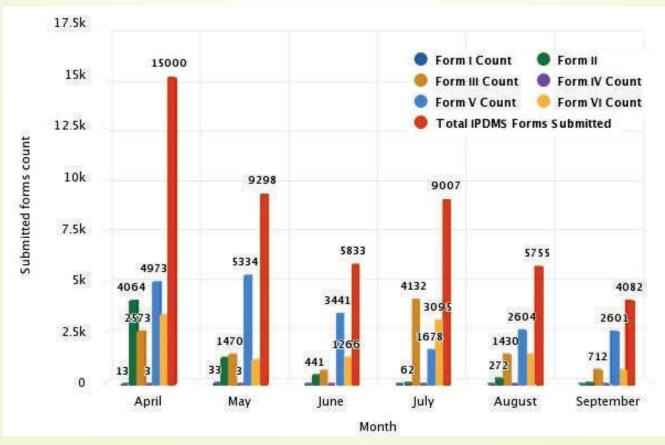


Chart 2: Number of statutory forms filed on IPDMS

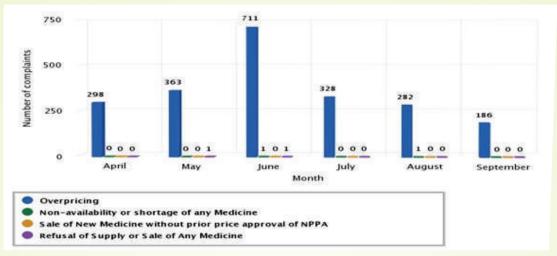


Chart 3: Number of complaints received on IPDMS/ PJS app



Chart 4: Number of Pharma Sahi Daam Mobile app downloads

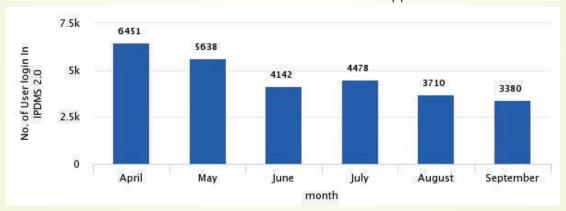


Chart 5: Number of User logins in IPDMS 2.0



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

INTERNATIONAL NEWS

FDA Approves First Vaccine for Pregnant Individuals to Prevent RSV in Infants (August 21, 2023)



The U.S. Food and Drug Administration approved Abrysvo (Respiratory Syncytial Virus Vaccine), the first vaccine approved for use in pregnant individuals to prevent lower respiratory tract disease (LRTD) and severe LRTD caused by respiratory syncytial virus (RSV) in infants from birth through 6 months of age. RSV is a highly contagious virus that causes respiratory infections in individuals of all age groups. It is the most frequent cause of lower respiratory tract illness in infants worldwide.

Read more

FDA Approves First Biosimilar to Treat Multiple Sclerosis (August 24, 2023)



The U.S. Food and Drug Administration approved Tyruko (natalizumab-sztn), the first biosimilar to Tysabri (natalizumab) injection for the treatment of adults with relapsing forms of multiple sclerosis (MS). Tyruko, like Tysabri, is also indicated for inducing and maintaining clinical response and remission in adult patients with moderately to

severely active Crohn's Disease (CD) with evidence of inflammation who have had an inadequate response to, or are unable to tolerate, conventional CD therapies and inhibitors of TNF- α (tumor necrosis factor, a substance in your body that causes inflammation.

Read more

FDA Launches Pilot Program to Help Further Accelerate Development of Rare Disease Therapies (September 29, 2023)



The U.S. Food and Drug Administration is taking steps to help further accelerate the development of novel drug and biological products for rare diseases. The agency is announcing the opportunity for a limited number of sponsors to participate in a pilot program allowing for more frequent communication with FDA staff to provide a mechanism for addressing clinical development issues. Selected participants of the Support for clinical Trials Advancing Rare disease Therapeutics (START) Pilot Program will be able to obtain frequent advice and regular ad-hoc communication with FDA staff to address productspecific development issues, including, but not limited to, clinical study design, choice of control group and fine-tuning the choice of patient population.

Read more

FDA Authorizes Updated Novavax COVID-19 Vaccine Formulated to Better Protect Against Currently Circulating Variants (October 03, 2023)

The U.S. Food and Drug Administration amended the emergency use authorization (EUA) of the Novavax COVID-19 Vaccine, Adjuvanted for use in individuals 12 years of age and older to include the

INTERNATIONAL NEWS



2023-2024 formula. Individuals 12 years of age and older previously vaccinated with a COVID-19 vaccine (and who have not already been vaccinated with a recently updated mRNA COVID-19 vaccine) are eligible to receive one dose and unvaccinated individuals receive two doses. The updated vaccine addresses currently circulating variants to provide better protection against serious consequences of COVID-19, including hospitalization and death. Consistent with the totality of the evidence and input from the FDA's expert advisors, the Novavax COVID-19 Vaccine, Adjuvanted, a monovalent vaccine, has been updated to include the spike protein from the SARS-CoV-2 omicron variant lineage XBB.1.5 (2023-2024 formula).

Read more

FDA Takes Steps to Advance the Development of Novel Therapies for Stimulant Use Disorders (October 04, 2023)



The U.S. Food and Drug Administration published a new draft guidance to assist sponsors in

developing treatments for stimulant use disorders. The guidance, Stimulant Use Disorders: Developing Drugs for Treatment, when finalized, will be the first to provide the FDA's current thinking on the overall development program and clinical trial design to develop drugs and biologics to support treatment of moderate to severe cocaine use disorder, methamphetamine use disorder and prescription stimulant use disorder. The draft guidance contains recommendations regarding clinical trial design related to evaluating stimulant use disorder treatments.

Read more

EMA recommends non-renewal of authorisation of multiple myeloma medicine Blenrep (15/09/2023)

EMA's human medicines committee (CHMP) has recommended not renewing the conditional marketing authorisation for Blenrep (belantamab mafodotin), a medicine used to treat multiple myeloma (a cancer of the bone marrow). Blenrep is given to adults who have received at least four previous treatments and whose disease does not respond to certain other types of cancer treatment, and whose cancer has worsened since receiving the last treatment.

Read more

EMA alerts EU patients and healthcare professionals to reports of falsified Ozempic pens (18/10/2023)

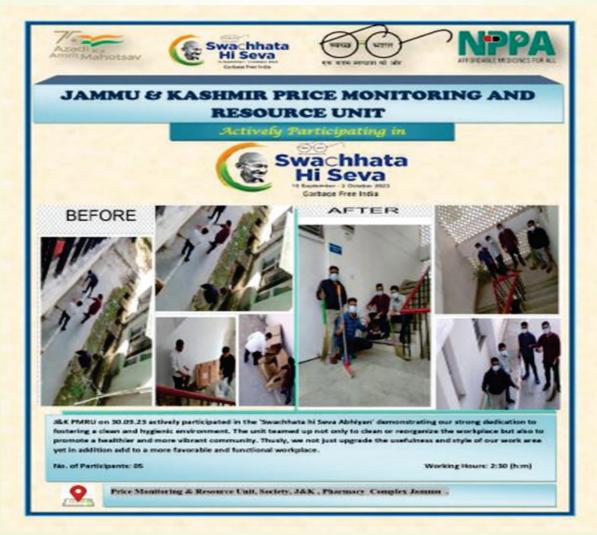
The European Medicines Agency has been notified by relevant national competent authorities that pre-filled pens falsely labelled as the diabetes medicine Ozempic (semaglutide, 1 mg, solution for injection) have been identified at wholesalers in the EU and the UK. The pens, with labels in German, originated from wholesalers in Austria and Germany. The pens have batch numbers, 2D barcodes and unique serial numbers from genuine Ozempic packs. In the EU, each medicine pack has a unique 2D barcode and serial number so that it can be tracked in an EU-wide electronic system.

Read more

SWACHHATA HI SEVA' (SHS) CAMPAIGN:

NPPA in co-ordination with PMRUs in the States/ UTs have conducted 'Swachhata Hi Seva' (SHS) i.e. preparatory phase campaign from 15th September – 1st October 2023 to raise awareness about cleanliness and sanitation. Massive cleanliness drives were conducted by PMRUs in the States/UTs at Office premises as well as public places as was envisaged by SHS. The details of Swachhata activities along with photos of before the activity/after the activity, No. of people participated and Location (the building/premises name) were uploaded on the SHS Portal. PMRUs have devoted 373 hours of shramdan for carrying out the Swachhata activities at Offices, Government Colleges, Temple, Places near Hospitals, nearby Gardens, Housing Complexes etc.





SWACHHATA SPECIAL CAMPAIGN 3.0

NPPA in co-ordination with PMRUs in the States/ UTs have conducted 'Swachhata Special Campaign 3.0' from 02nd October 2023 to 31st October 2023. The main focus areas of the Campaign included space management, disposal of scrap/waste materials, cleanliness drives, plantation, disinfection, beautification of public places.

During the campaign period from 02 – 31st October 2023, sixty-eight (68) various activities were accomplished i.e., cleanliness drives, plantation, beautification and other innovative activities to exemplify the importance of team efforts with emphasis upon Jan Bhagidari (803 Persons), Swachhata and Shramdaan (1341 Devoted Hours) at different public places like colleges/schools, Parks, water tanks, Roads, Drug Control offices, Testing & Research Laboratories etc.

The campaign is envisaged as a milestone whereby PMRUs have demonstrated strong commitment towards organized team effort to foster a clean and hygienic environment and workplace.





J&K PMRU staff on 14:10.23 actively participated in the "Swatchta Hi Seya 3.0 Campaign" at a public park, Dalgate Sringar from 10:30 am to 12:00 pm demonstrating our strong dedication to fostering a clean and hygienic environment. No. of Participants; 06

BEFORE





JBK PMRU staff on 14.10.23 actively participated in the "Swacchta Hi Seva 3.0 Campaign" at a public park. Dalgate Srinagar from 10:30 am to 12:00 pm demonstrating our strong dedication to fostering a clean and hygienic environment.







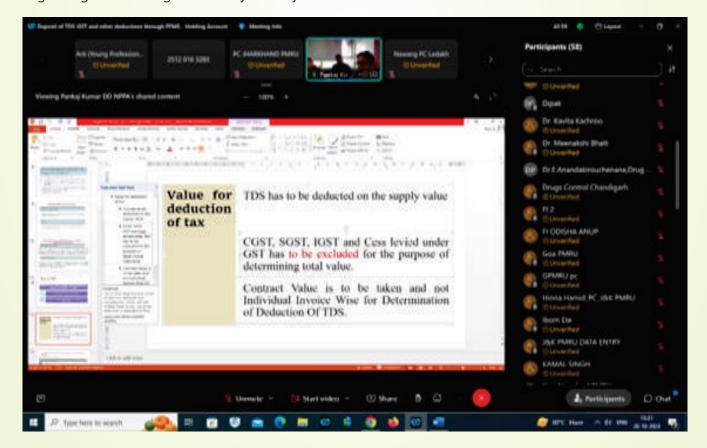


WEBINARS FOR PRICE MONITORING AND RESOURCE UNITS IN THE SATES/ Uts

In the continuation to webinar series, two (2) interactive webinars were organized by NPPA for Price Monitoring and Resource Units in the Sates/ UTs as mentioned below:

Date	Webinar		
26.09.2023	Webinar on 'Activities to be performed by PMRUs'		
26.10.2023	Webinar on deposit of TDS-GST and other deductions through PFMS – Holding Account		

The main aim of these webinars were to provide guidance and sharing of knowledge with PMRUs regarding conducting of Weekly Survey and Submission of Report, Collection/ purchase of test samples of medicines, monitoring of price movement of scheduled/ non-scheduled formulations and reporting of likely violation cases through IPDMS, Incurring of Expenditure through PFMS and maintenance of records/ supporting documents, Organising Meetings (Executive Committee Meeting & Governing Body Meeting) and Submission of Monthly report including Static and dynamic report, Reporting and submission of data/ information / reports to NPPA through IPDMS Software, Necessity of deduction of TDS-GST/IT, Deposit of TDS-GST/IT and other deductions through PFMS – Holding Account.



STATE LEVEL EVENTS/ SEMINARS BY PMRUs

In the run up of India @75 'Azadi ka Amrit Mahotsava', eleven (11) State level Events/ Seminars have been organized by PMRUs in their respective States/ UTs viz. Puducherry, Goa, Jharkhand, Karnataka, Madhya Pradesh, Maharashtra, Chhattisgarh, Jammu & Kashmir, Kerala, Uttar Pradesh and Uttarakhand. These events 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.











हिंदी पखवाड़ा, 2023 आयोजन

प्रत्येक वर्ष की भांति इस वर्ष भी राष्ट्रीय औषध मूल्य निर्धारण प्राधिकरण कार्यालय में हिंदी प्रयोग/प्रोत्साहन पखवाड़े का सफल आयोजन किया गया। इस आयोजन के दौरान विभिन्न प्रतियोगिताएं आयोजित की गईं जिसमें कार्यालय के नियमित सदस्यों के साथ-साथ संविदात्मक एवं आउटसोर्स स्टाफ ने भी बढ़-चढ़ कर भागीदारी की। इस आयोजन के समापन समारोह में अध्यक्ष, राष्ट्रीय औषध मूल्य निर्धारण प्राधिकरण के हाथों सभी विजेताओं को पुरस्कार और प्रमाण-पत्र प्रदान किए गए। इसी कार्यक्रम में हिंदी प्रोत्साहन योजना एवं स्वच्छता पखवाड़ा प्रतियोगिताओं के विजेताओं को भी पुरस्कार प्रदान किए गए।









Question: What is the "Drugs (Prices Control) Order, 2013 (DPCO, 2013)"?

Answer:

The Drugs (Prices Control) Order, 2013 is an order issued by the Government of India under Section 3 of Essential Commodities Act, 1955 to, inter-alia, ensure maintaining supplies of drugs or for securing their equitable distribution and availability at fair prices. The Order, inter-alia, provides the list of Scheduled (controlled) drugs, procedures for fixation of prices of drugs, control on increase in MRP of all drugs, method of implementation of prices fixed by Government, recovery of overcharged amount with interest and penalty in case of contravention of provisions etc.

Question: Are all the drugs marketed in the country under price

control?

Answer:

NPPA fixes the ceiling price of formulation listed in Schedule I of DPCO, 2013 as per Para 4 of DPCO, 2013. NLEM 2015 which was notified as Schedule I of DPCO, 2013 contains 966 scheduled drug formulations (including formulations as per explanation 1 to Schedule - I of DPCO 2013) spread across 31 therapeutic groups. NPPA also fixes the ceiling prices of formulations listed under Explanation-I to Schedule -I of DPCO 2013. NPPA fixes the retail price of medicine based on the Form-I application received from the manufacturing/ marketing companies. The notified retail prices are applicable only to the applicant manufacturing/ marketing companies. Further, Companies also cannot sell non-scheduled formulation (other than those appearing in Schedule I of DPCO, 2013) at a price which is more than 10% higher than the MRP of the preceding twelve months.

Question: What happens if a manufacturer sells a drug with MRP above the price allowed under DPCO, 2013?

Answer:

Selling a medicine at an MRP which is higher than the notified ceiling price/retail price plus applicable local taxes is a violation of DPCO, 2013 and the manufacturers are, inter- alia, liable to deposit the overcharged amount along with interest and penalty thereon. In case of non-deposit, the amount can be recovered as arrears of land revenue. Similar action is taken whenever companies are found selling non-scheduled formulations having an MRP which is more than 10% higher than the MRP of the preceding twelve months.





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.



NATIONAL PHARMACEUTICAL PRICING AUTHORITY

3rd / 5th Floor, YMCA Cultural Center Building 1, Jai Singh Road, New Delhi, India www.nppaindia.nic.in | Helpline No.: 1800 111 255 (10 am to 6 pm on working hours)