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 affairs and events related to Pharmaceutical industry and the NPPA. This newsletter has been curated purely for informative purposes and do not reflect the official policy or position of NPPA. This newsletter is not intended to be used for any commercial/official purposes.

You can also give your suggestions/ feedback at: monitoring-nppa@gov.in

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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 am happy to bring to you the sixth 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.

NPPA is expanding its physical presence outside Delhi, through the Price Monitoring and Research Units (PMRUs) at State/UT levels, for strengthening monitoring and public awareness. There is a proactive attempt to synergise with the office of the Drug Controller General of India and State Drug Controllers for data collection, surveillance and monitoring of drugs. During last two months NPPA has expanded its reach in two more states of Uttrakhand and Bihar through setting up of PMRU's, taking total tally to 25 States/UTs.

NPPA administers 'Pharma Sahi Dam' and 'Pharma Jan Samadhan' platforms for information on medicine prices and registering public grievances respectively. The web based Integrated Public Database Management System (IPDMS) ver. 2.0 has been launched during the Silver Jubilee celebration of NPPA by Union Minister of Chemical and Fertilizers, Dr. Mansukh Mandaviya. Further, information on enhanced features of IPDMS 2.0 & Pharma Sahi Dam 2.0 will be carried in our next issue.

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)

JUDICIOUS USE OF MEDICINES

By: **Shri Manmohan Sachdeva,** Advisor (Cost) NPPA

As per the Economic Survey, 2021-22, Indian Pharmaceutical industry ranks third in the world in pharmaceutical production by volume. During 2020-21, total pharma export was US$ 24.4 Bn against the total pharma import of US$7.0 Bn, thereby generating trade surplus of US$17.5 Bn. India is the largest supplier of generic medicines with a 20 percent share in the global supply. Price competitiveness and good quality has enabled Indian medicines producers to be dominant players in the world market, thereby making the country the "Pharmacy of the world".

According to health experts in India, India's pharmaceutical industry has played a "crucial role" during the COVID-19 pandemic and the country has cemented its position as a "dependable nation" when it comes to health crises. The country's pharmaceutical market, which has been playing a key role in the global pharmaceuticals industry, was estimated at $42 billion domestically in 2021 and is projected to expand to $120 billion by 2030. India ranks third worldwide for pharmaceutical production by volume and exports pharmaceuticals to more than 200 countries and territories. The share of 'made in India' medicines in the Indian pharma market is now a robust 80% from the previous 5% in 1969. The pharma industry in India contributes more than 20% by volume of the global generics market and 62% of the worldwide demand for vaccines,"

The most widely self-medicated substances are over-the-counter (OTC) drugs and dietary supplements, which are used to treat common health issues at home.

Analgesics such as various non-steroidal anti-inflammatory drugs (NSAID) and acetaminophen are the most frequently-used drug groups for self-medication practices. The NSAIDs include commonly used drugs such as ibuprofen, diclofenac, aspirin, etc.

Although NSAIDs relieve pain, their irrational use may cause many prominent adverse drug reactions (ADRs) such as heartburn, upper gastrointestinal (GI) complications ranging from dyspeptic symptoms to life-threatening complicated stomach ulcers, cardiovascular side effects,gastro duodenal (GD) damage, tendency towards bleeding, hepatic and renal issues. Continued use of NSAIDs for pain relief as mono therapy or in combination with other drugs over long periods of time are associated with the development of slowly progressive kidney diseases.(Annales Pharmaceutiques Françaises (2021) 79, 275-285)

Some of the risks associated with self-medication include incorrect self-diagnosis and choice of therapy, severe adverse drug reactions, failure to recognize warnings and precautions, failure to recognize that the same active substance is already being taken under a different name, incorrect route of administration, inadequate or excessive dosage, risk of dependence and abuse, storage in incorrect conditions or beyond the

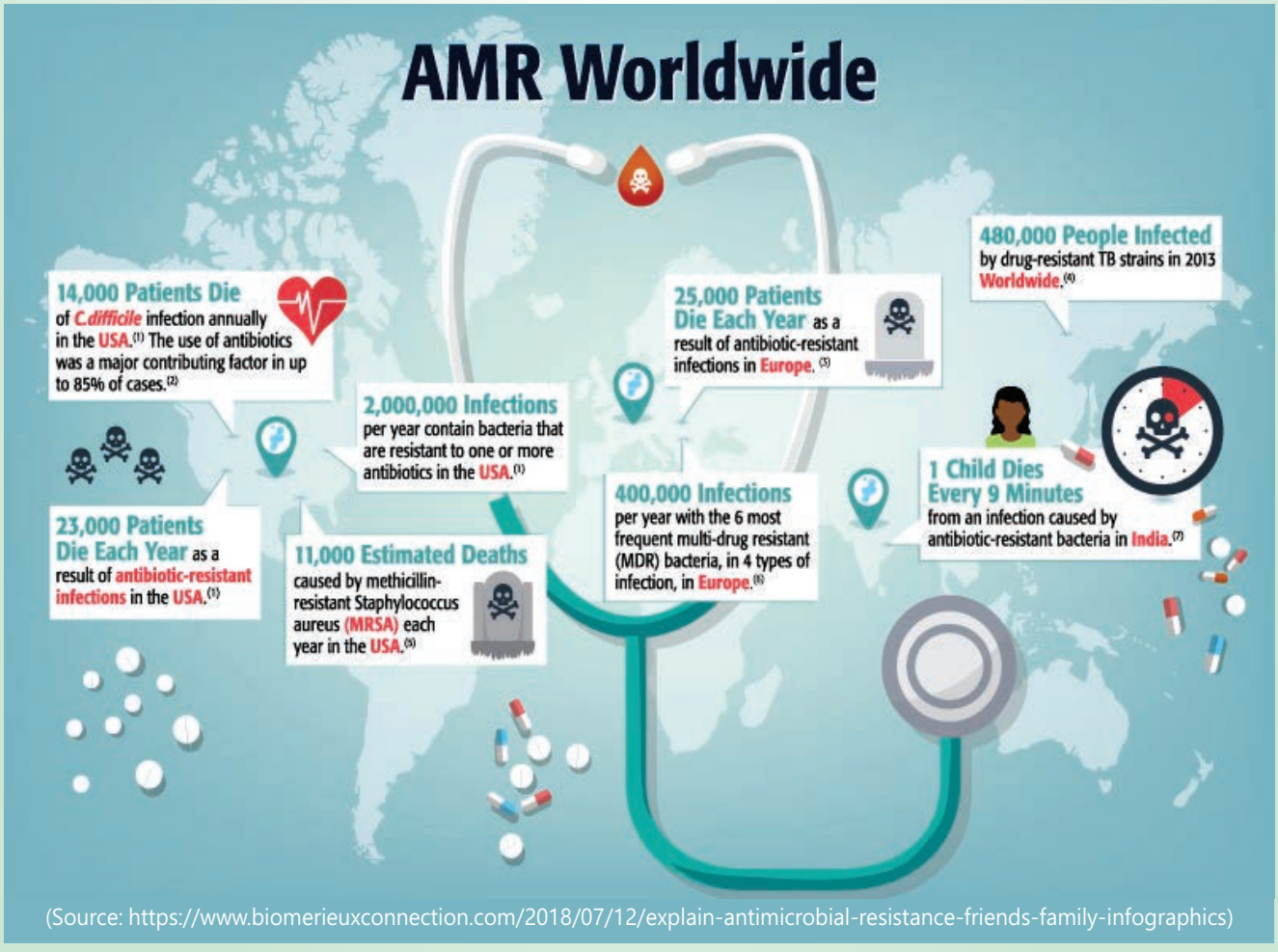
recommended shelf life, etc. Further, from wider perspective, improper self-medication could result in an increase in drug induced disease and in wasteful public expenditure.

Dispensing medicines without prescription by registered medical personnel which are required to be given on prescription only is classified as a mis conduct by pharmacy practice regulation 2015 in India. The Drug and Cosmetic Act, 1945 also state that Schedule "H" drugs are required to be dispensed to any person over prescription only and has described the practice of dispensing without prescription as illegal.

Despite being prescription drugs, antibiotics are also commonly available over-the-counter (OTC) at retail pharmacies and antimicrobial (AMR) is being considered as a public health concern.

Given its importance for human health, the Government of India has developed a National Action Plan on Antimicrobial Resistance (NAP-AMR) 2017–2021. Strengthening the knowledge and evidence base through surveillance of AMR is one of the five key strategies of this action plan. The Indian Council of Medical Research (ICMR) has established an Antimicrobial Resistance Surveillance & Research Network (AMRSN) across selected hospitals in India, focusing on drug resistance among pathogens of human importance.

By 2050, the Welcome Trust predicts that resistant infections will be the number one cause of death globally, with an estimated 10 million attributable deaths per year. Considering the limited number of new antimicrobial agents in the pharmaceutical pipeline, we could be faced with challenges that far exceed the current major global illnesses such as HIV, tuberculosis and malaria.

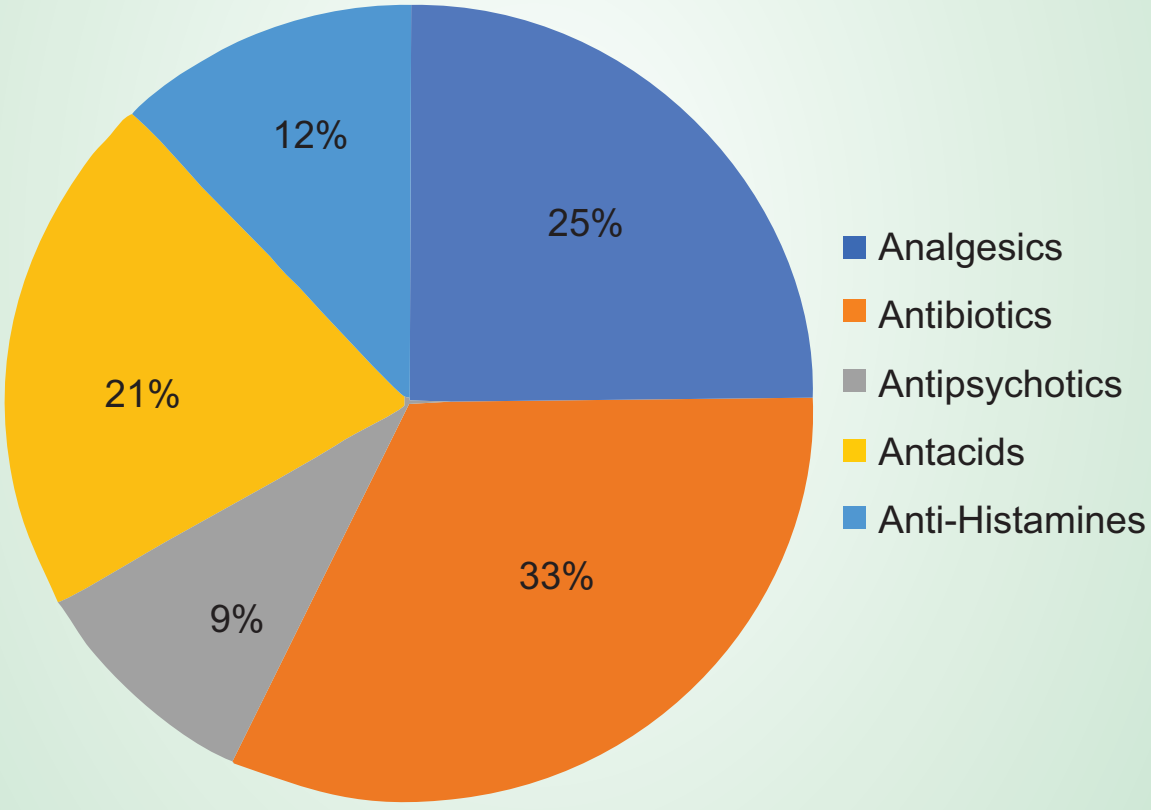


(Source: https://www.biomerieuxconnection.com/2018/07/12/explain-antimicrobial-resistance-friends-family-infographics)

Conclusion :

A comprehensive strategy which is well aligned with activities under the National Action Plan-AMR, including stewardship efforts targeting pharmacists and evidence-based targeted awareness campaigns for all stakeholders, may required to curb the inappropriate use of antibiotics. In addition, the improvement in the quality of healthcare facilities with easy access, law enforcement, and control regulations regarding the inappropriate use of antibiotics closely collaborating with public awareness about antibiotic resistance may help in addressing the challenge of self medication. Since many patients get knowledge about drugs from the previous prescriptions, physicians should limit unneeded prescriptions of antibiotics. Pharmacists should also be encouraged to educate patients and rationalize antibiotic use by strictly stopping antibiotic sales without an authorized prescription by physicians. In addition, initiatives like AMR Industry Alliances (AMRIA) Antibiotic Manufacturing Standards (AMS) will help to reduce the risk from antibiotic manufacturing efforts.

FIGURE 1: DRUGS COMMONLY DISPENSED WITHOUT PRESCRIPTION



News related to pricing of drugs

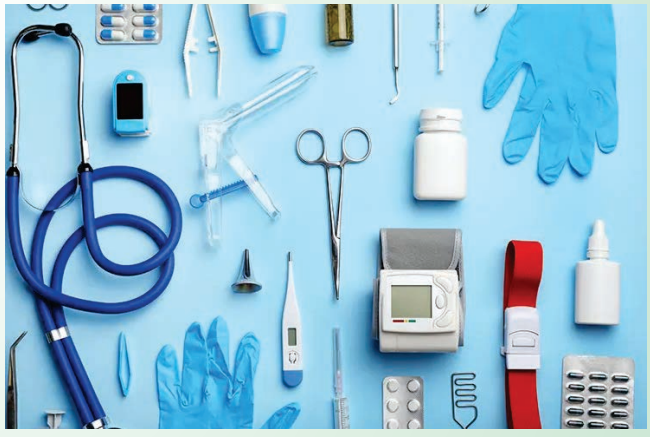
- Ceiling prices for 890 scheduled formulations (National List of Essential Medicines, 2015) and Retail prices for 2023 non-scheduled formulations have been fixed under DPCO, 2013 till 31st July, 2022.
- As on 31st July, 2022, over all 231st Authority meetings have been conducted and out of which 99 are under DPCO 2013. The 231st (Overall) and the 99th meeting of the Authority under DPCO 2013 was held on 28.06.2022.
- Retail price for 84 formulations were fixed during 99th Authority Meeting held on 28.06.2022 and notified vide SO. 2981(E) dated 30.06.2022.

Details of retail prices notified for various formulations based on the decision taken in 99th 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	50	Tablet	6.75–21.56
2	Antipyretic	2	Tablet/ Suspension	0.33–2.88
3	Cardio Vascular	3	Tablet	9.76 – 17.33
4	Anti-bacterial	4	Suspension/ Injection	3.40-168.43
5	Anti-Ulcerand Prokinetic	2	Capsule/ Suspension	1.76 – 10.83
6	Pain Analgesic	2	Tablet/ Injection	13.85–20.72
7	Hypertension	3	Tablet	9.92-12.77
8	Others	18	Tablet/ Capsule/ Suspension/ Gel/Injection	0.70– 34.03

News related to pricing of Medical devices

- NPPA, vide notification S.O 2983 dated 30th June 2022 has extended the notification for capping the trade margin of Oxygen Concentrator at first point of sale (price to distributor) up to 31st December 2022 or till further order, whichever is earlier. The Prices of Oxygen Concentrators shall be monitored under Para 20 of the DPCO, 2013 subject to maintenance of Trade Margin.
- NPPA, vide notification S.O 3534(E) dated 29th July 2022 has extended the notification for capping the trade margin of five medical devices, namely, (i) Pulse Oximeter, (ii) Blood Pressure Monitoring Machine, (iii) Nebulizer, (iv) Digital Thermometer, and (v) Glucometer at first point of sale up to 31st December 2022 or till further order, whichever is earlier. The Prices of these medical devices shall be monitored under Para 20 of the DPCO, 2013 subject to maintenance of Trade Margin.



INTERNATIONAL NEWS

FDA Authorizes Emergency Use of JYNNEOS Vaccine to Increase Vaccine Supply (August 05, 2022)

The U.S. Food and Drug Administration issued an emergency use authorization (EUA) for the JYNNEOS, the Modified Vaccinia Ankara (MVA) vaccine to allow healthcare providers to use the vaccine by intradermal injection for individuals 18 years of age and older who are determined to be at high risk for monkeypox infection.

JYNNEOS Vaccine will increase the total number of doses available for use by up to five-fold. The EUA also allows for use of the vaccine in individuals younger than 18 years of age determined to be at high risk of monkeypox infection; in these individuals, JYNNEOS is administered by subcutaneous injection.

The FDA considered the available JYNNEOS safety and immune response data in adults as well as the historical data with use of live vaccinia virus smallpox vaccine in pediatric populations.

Read more

FDA Denies Authorization to Market JUUL Products (June 23, 2022)

The U.S. Food and Drug Administration issued marketing denial orders (MDOs) to JUUL Labs Inc. for all of their products currently marketed in the United States. As a result, the company must stop selling and distributing these products. In addition, those currently on the U.S. market must be

removed, or risk enforcement action. The products include the JUUL device and four types of JUUL pods: Virginia tobacco flavored pods at nicotine concentrations of 5.0% and 3.0% and menthol flavored pods at nicotine concentrations of 5.0% and 3.0%. Retailers should contact JUUL with any questions about products in their inventory.

"The action is further progress on the FDA's commitment to ensuring that all e-cigarette and electronic nicotine delivery system products currently being marketed to consumers meet FDA public health standards".

"The agency has dedicated significant resources to review products from the companies that account for most of the U.S. market. FDA recognizes these make up a significant part of the available products and many have played a disproportionate role in the rise in youth vaping."

To date, the FDA has not received clinical information to suggest an immediate hazard associated with the use of the JUUL device or JUULpods. However, the MDOs issued today reflect FDA's determination that there is insufficient evidence to assess the potential toxicological risks of using the JUUL products. The FDA recommends against modifying or adding substances to tobacco products. JUUL users are encouraged to report any unexpected health problems or product problems to the FDA through the Safety Reporting Portal and to seek medical attention as necessary.

Read more

FDA Approves First Targeted Therapy for HER2-Low Breast Cancer (August 05, 2022)

The U.S. Food and Drug Administration approved Enhertu (fam-trastuzumab-deruxtecan-nxki), an IV infusion for the treatment of patients with unresectable (unable to be removed) or metastatic (spread to other parts of the body) HER2-low breast cancer. This is the first approved therapy targeted to patients with the HER2-low breast cancer subtype, which is a newly defined subset of HER2-negative breast cancer.

As part of the Administration's Cancer Moonshot program, Enhertu's approval further illustrates how the FDA's efforts align with the Cancer Moonshot goals of targeting the right treatments to the right patients, speeding progress against the most deadly and rare cancers, and learning from the experience of all patients.

The approval highlights the FDA's commitment to be at the forefront of scientific advances, making targeted cancer treatment options available for more patients, "Having therapies that are specially tailored to each patient's cancer subtype is a priority to ensure access to safe and innovative treatments."

Read more

FDA Authorizes Emergency Use of Novavax COVID-19 Vaccine, Adjuvanted (July 13, 2022)

The U.S. Food and Drug Administration issued an emergency use authorization (EUA) for the Novavax COVID-19 Vaccine, Adjuvanted for the prevention of COVID-19 caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older.

"Authorizing an additional COVID-19 vaccine expands the available vaccine options for the prevention of COVID-19, including the most severe outcomes that can occur such as hospitalization and death"

The FDA has determined that the Novavax COVID-19 Vaccine, Adjuvanted has met the statutory criteria for issuance of a EUA. The data support that the known and potential benefits of the vaccine outweigh its known and potential risks in people 18 years of age and older, and that this vaccine may be effective in preventing COVID-19. In making this determination, the FDA can assure the public and medical community that a thorough analysis and evaluation of the available safety and effectiveness data and manufacturing information have been conducted.

Read more

FDA Recommends Inclusion of Omicron BA.4/5 Component for COVID-19 Vaccine Booster Doses (June 30, 2022)

The U.S. Food and Drug Administration's independent experts on the Vaccines and Related Biological Products Advisory Committee met to publicly discuss whether a change to the current vaccine strain composition of COVID-19 vaccines for booster doses is necessary for the 2022 fall and winter seasons.

The COVID-19 vaccines that the FDA has approved and authorized for emergency use have made a tremendous difference to public health and have saved countless lives in the U.S. and globally. However, SARS-CoV-2, the virus that causes COVID-19, has evolved significantly, with recent surges around the world associated with the rapid spread of highly transmissible variants such as omicron.

Read more

SILVER JUBILEE CELEBRATIONS OF NATIONAL PHARMACEUTICAL PRICING AUTHORITY ON 29.08.2022

- Union Minister of Chemical and Fertilizers, Dr. Mansukh Mandaviya addressed the Silver Jubilee Celebrations of National Pharmaceutical Pricing Authority (NPPA), on 29.08.2022. Shri Bhagwanth Khuba, Minister of State for Chemicals & Fertilizers and New & Renewable Energy graced the occasion as guest of honour.

- Addressing the event, Dr Mandaviya congratulated NPPA for working more as a facilitator, not merely as a regulator. He highlighted their noteworthy contribution towards ensuring availability and affordability of medicines in the last 25 years.

- The Union Minister also praised the Indian Industries for continuously producing quality products. He urged them to produce medicines and bring innovative research with the goal of ensuring good health and well-being of the people, not only for commercial purpose.

- Dr Mandaviya assured Indian pharma companies of continuous support from the govt. He highlighted the PLI 1 and PLI 2

schemes for the industries, which has helped in bringing about indigenous manufacturing of many critical APIs in the country. He also recalled the positive contribution of Indian pharma companies during the Covid crisis and highlighted the importance of cooperation and collaboration between the govt and industry in bringing quality healthcare to the masses

- Shri Bhagwanth Khuba praised NPPA for being in service of the country and the Pharma sector successfully for the last 25 years. He stated that "NPPA ensures availability of

affordable medicines without harming the interests of the industry". He also expressed his optimism that with the launch of the two applications today, NPPA is expected to further carry on its work in a smooth and efficient manner in the coming years".

- At the inaugural session, Integrated Pharmaceutical Database Management System 2.0 (IPDMS 2.0) and Pharma Sahi Daam 2.0 App were launched

- IPDMS 2.0 is an integrated responsive cloud-based application developed by NPPA with technical support from Centre for Advance Computing (C-DAC). It is envisaged to optimize synergies in operations in order to promote Government's thrust on 'Ease of Doing Business' as it would provide a single window for submissions of various forms as mandated under Drug Price Control Order (DPCO), 2013. It would also enable paperless functioning of NPPA and facilitate the stakeholders to connect with National Pharma Pricing Regulator from across the country.

- Pharma Sahi Daam 2.0 App will have updated features like speech recognition; availability in Hindi and English; share button and bookmarking medicines. This version of Pharma Sahi Daam also has facility for launching complaints by consumer through the consumer complaint handling module. The App will be available in both iOS and Android versions.

- A publication titled 'An overview of Drug Pricing @ NPPA 25 year Odyssey' was also launched at the inaugural session. The publication chronicles not only the 25 year journey of NPPA but also highlights the evolution of the drug regulatory system in the country with special emphasis on pricing regulation.

- Earlier, Shri Kamlesh Pant, Chairman, NPPA had delivered the welcome address. Ms S Aparna, Secretary, Department of Pharmaceuticals, and Dr. Vinod Kotwal, Member Secretary, NPPA were present in the event.

- Stakeholders from the pharmaceutical and MedTech devices industry, Central and State Governments, Price Monitoring and Resource Units, Civil Society, patient advocacy groups, Pharmaceutical Research and Academic Institutions, Think-Tanks and media representatives from all over the country were also present on the occasion. In total about 600 participents were presents in this event.

INFORMATION EDUCATION AND COMMUNICATION (IEC) ACTIVITIES BY NPPA AND PMRUS

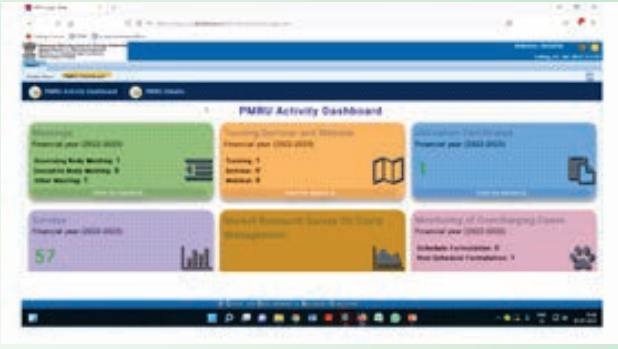
- NPPA sets up 25th PMRU in the State of Uttarakhand in July, 2022
- NPPA under Consumer Awareness, Publicity and Price Monitoring (CAPPM) Scheme has so far set-up Price Monitoring and Resource Units (PMRU) in 25 States/UTs. Now, NPPA has its presence in following states/UTs viz. Kerala, Gujarat, Odisha, 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 and Uttarakhand. 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.

IEC ACTIVITIES

- In the Run-up of India @ 75, 'Bharat ka Amrit Mahotsava' during the months of June and July 2022, three (3) webinars were conducted by NPPA with different PMRUs mentioned as bellow:

Date	Webinar
13.06.2022	Webinar on Guidance on Functioning of New PMRUs
01.07.2022	Webinar on submission of data and reports online through IPDMS
15.07.2022	Webinar on Sample Purchase Reporting by PMRUs

- The main aim of these webinars were to provide guidance to PMRUs on various activities to be performed by PMRUs, training on IPDMS Software to enable PMRUs to use/ operate the new IPDMS software effectively and training on the procedure to be followed for sample purchase, its' documentation, analysis, preparation and submission of reports



Awareness Program organized by PMRU Kerala on 3rd August, 2022

- Kerala State Pharmaceutical Price Monitoring & Resource Unit Society (KSPMRU) and Drugs Control department has jointly organized an Awareness program on "Role of NPPA in Drug Price Control Mechanism" & "Regulations enforced by Drugs Control Department. At a Glance" on 03rd August 2022 at Trivandrum. A total of 80 participants including Faculties & Students of pharmacy colleges of Trivandrum district & Enforcement officers from Drugs Control Department attended the event.
- The whole concept of the program was to create awareness about the National Pharmaceutical Pricing Authority, its price monitoring & drug price control mechanism & activities of KSPMRU society. The Regulations enforced by Drugs Control department was also discussed in the session. The awareness program aided in providing a common platform to discuss & update the knowledge with respect to the NPPA & its mandate, DPCO, PMRU &regulatory enforcement of Drugs Control department in the State.

KERALA STATE PMRU SOCIETY - REPORT OF AWARENESS PROGRAM

The details of major top selling subgroups, which have vanished from the market, are as follows:

Row Labels	MAT VAL JUL 18	MAT VAL JUL 22
CEFIXIME + AZITHROMYCIN	157.09	0.00
SOFOSBUVIR + LEDIPASVIR	147.08	2.65
BOTULINUM TOXIN	58.57	4.98
CEFUROXIME + LINEZOLID	53.76	-
CEFIXIME + ORNIDAZOLE	48.73	0.16
CEFPODOXIME + AZITHROMYCIN	45.17	0.49
CEFIXIME + LINEZOLID	39.81	0.00
TINIDAZOLE + NORFLOXACIN + LACTOBACILLUS	32.46	0.03
NOSCAPINE + CHLORPHENIRAMINE	32.08	-
SILYMARIN + URSODEOXYCHOLIC ACID	26.79	0.88
OXYTETRACYCLINE	24.62	4.05
GUAIFENESIN + DEXTROMETHORPHAN + PHENYLEPHRINE	23.81	0.03
NORFLOXACIN + METRONIDAZOLE	21.47	0.65
INTERFERONS, BETA	20.05	0.32
PRESERVED HUMAN SERUM	19.85	0.64

The details of major Subgroups, whose Sales was minimal some years back but seen high growth, are as follows:

Row Labels	MAT VAL JUL 18	MAT VAL JUL 22
EMPAGLIFLOZIN + LINAGLIPTIN	1.37	274.73
REMDESIVIR	-	148.54
FAVIPIRAVIR	-	147.60
BRIVARACETAM	-	118.56
CEFTAZIDIME + AVIBACTAM	-	110.01
MONTELUKAST + BILASTINE	-	107.84
TOFACITINIB	-	100.98
EMPAGLIFLOZIN + METFORMIN	1.95	97.76
DOLUTEGRAVIR + EMTRICITABINE + TENOFOVIR ALAFENAMIDE	-	92.60
NINTEDANIB	1.64	87.60
BILASTINE	-	86.57
CASIRIVIMAB + IMDEVIMAB	-	84.82
REMOGLIFLOZIN	-	78.87
REMOGLIFLOZIN + VILDAGLIPTIN	-	78.22
MEBEVERINE + CHLORDIAZEPOXIDE	7.75	67.43

FREQUENTLY ASKED QUESTIONS

➲ **Question 1 : What is the role of NPPA in ensuring availability of medicines?**

Answer: NPPA was constituted to ensure availability and accessibility of medicines at affordable prices. The Government of India Resolution dated 29th August, 1997, inter-alia, mentions "to monitor the availability of drugs, identify shortages, if any, and to take remedial steps" as one of the functions of NPPA.

The availability of medicines is regularly monitored by the NPPA mainly through Drugs Control Administration of State Governments. Whenever shortage is reported through any source, NPPA takes remedial steps for ensuring availability of drugs.

➲ **Question 2 : What can a Consumer /Patient do if he is unable to find a medicine in the market?**

Answer: Consumer can file a complaint through Pharma Jan Samadhan (PJS) portal available on the website of NPPA ie. www.nppaindia.nic.in as well as Pharma Sahi Daam mobile application. Besides, the complaint can also be emailed at monitoring-nppa@gov.in or the complainant can call on Toll-free helpline no. 1800-111-255.

➲ **Question 3 : How are the above complaints dealt by NPPA?**

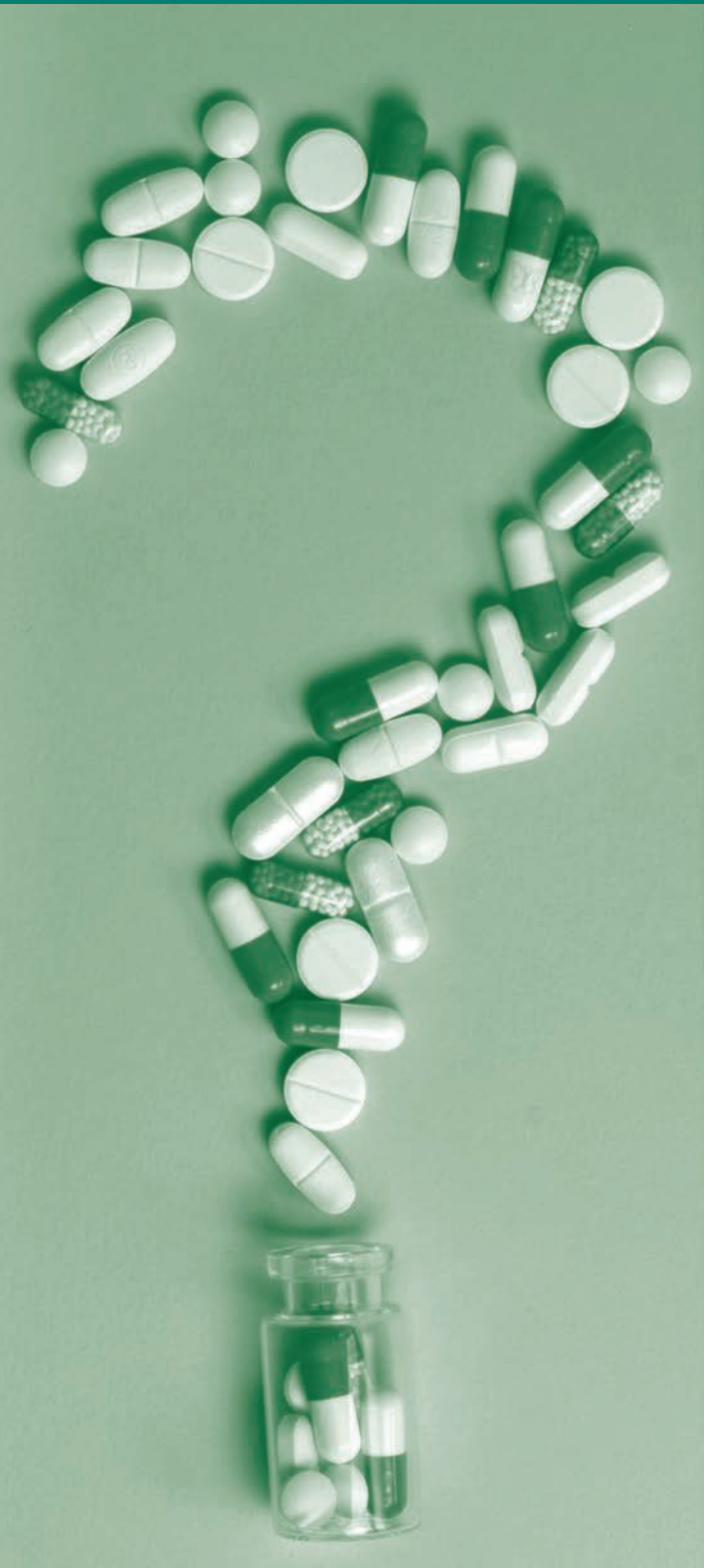
Answer: The manufacturers/marketers of drugs are directed to make the drug available in affected area. Further, the reasons for such shortages are also sought form the company besides, the production/ Sales/import details to check if there is a demand-supply mismatch.

If any issues in import, production or supply are highlighted by the companies, the same are taken up with the concerned agencies for quick resolution so as to ensure timely availability of drugs.

➲ **Question 4 : Can a manufacturer discontinue manufacturing imports of scheduled / non-scheduled formulations?**

Answer: As per Para 21(2) of DPCO, 2013, any manufacturer intending to discontinue any scheduled formulation from the market, shall issue a public notice and also intimate the Government in Form-IV at least six months prior to the intended date of discontinuation.

Further, in case of scheduled as well as non-scheduled drugs, NPPA can direct any manufacturer to increase the production and ensure availability in the market under Para 3 of DPCO, 2013.



Feedback and Complaint Redressal

Grievance Redressal

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

Information Dissemination

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

Collaboration with State Governments

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

NPPA
AFFORDABLE MEDICINES FOR ALL
सभी के लिए वहनीय दवाईयाँ

NATIONAL PHARMACEUTICAL PRICING AUTHORITY

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