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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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.

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सत्यमेव जयते

# From CHAIRMAN'S DESK

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

It is with great pleasure that I bring to you the tenth issue of the NPPA bi-monthly e-Newsletter. In these ten issues we have had experts covering wide ranging topics like National List of Essential Medicines, India's contribution to affordable health care innovations to tracing and tracking of availability of medicines. It has been an enriching experience for us bringing the e-newsletter to you.

Continuing in the same tradition of bringing relevant topics to your attention, this issue contains article on "Health Technology Assessment (HTA) in India: Implications for value-based pricing for drugs and devices" written by Prof. Shankar Prinja & Ms. Jyoti Dixit from PGIMER, Chandigarh. The article very lucidly explains that HTA approach, involving setting of a threshold price that reflects the maximum amount that should be paid for a drug based on the additional health benefits which it provides, relative to an existing treatment. It provides insights on the role which HTA can play in Drug Pricing at National and Global Level.

As you all are aware, National List of Essential Medicines, 2022 was incorporated in the Schedule-I of DPCO, 2013 and accordingly, NPPA had refixed the Ceiling Prices of Scheduled Drugs. Since the last issue of e-newsletter, NPPA has fixed/ refixed the Ceiling Prices of 651 formulations, which has resulted in reduction in the MRP of the drugs. This issue contains details about the Ceiling Prices and Retail Prices fixed by NPPA.

This time, the editorial team has included some insights on the growth of the pharmaceutical sector, top pharma products and companies and their year-on-year growth.

I am also happy to share that NPPA has expanded its reach in two more States/UTs i.e. Arunachal Pradesh and Union Territory of Chandigarh in the month of March 2023 by setting up Price Monitoring and Resource Units (PMRUs), taking the total tally of PMRUs to 28 States/UTs.

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

With best wishes

**(Kamlesh Kumar Pant)**

# HEALTH TECHNOLOGY ASSESSMENT IN INDIA: IMPLICATIONS FOR VALUE-BASED PRICING FOR DRUGS AND DEVICES

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## Overview

According to the World Health Organization (WHO), the global spending on medicines was estimated at around US$ 1.48 trillion in 2022 [1]. This represents about 16.4% of the total global health expenditure. In high-income countries, the share of medicines in health care expenditures ranges from 15% to 25% [2], while in low- and middle-income countries (LMICs), it is around 26% to 63% [3]. Thus, medicines are a significant contributor to health care expenditure.

Recent evidence from India shows the share of medicines in total out-of-pocket expenditure (OOPE) was 29.1% among inpatients and 60.3% among outpatients [4] and hence the medicines significantly contribute to OOPE, which results in additional financial burden for households. Approximately 11.2 % of households in India experience catastrophic health expenditures due to OOPE on medicines alone [5]. This can also push the households into poverty.

Therefore, any policy initiative or aspiration for universal health coverage (UHC) must address the issue of medicine costs. This could include strategies such as price regulation, increasing access to low-cost generic medicines, and improving the efficiency of the supply chain for medicines to deliver free medicines in public healthcare facilities. Additionally, measures to improve the affordability of medicines for low-income households, such as subsidies or insurance schemes, could also help reduce the

burden of OOPE on medicines.

### Context and Stakeholders

Broadly, policy strategies cited above to control medicine cost can be addressed by action of 2 key stakeholders – payers and regulators. In the context of developed countries which have large coverage of tax-funded or social insurance programs, the role of payer is extremely important given the size of the market that it controls. For instance, in the United Kingdom, the National Health Service (NHS) provides a wide range of healthcare services, including prescription medicines to all residents of the country, with no charge at the point of use [6]. Another example is of Thailand wherein the National Health Security Office (NHSO) provides UHC through a tax-funded system. The NHSO covers both inpatient and outpatient care, including prescription medicines, and has contributed to a significant reduction in out-of-pocket healthcare spending for Thai citizens. As of 2020, the NHSO covered approximately 48 million people, or around 71% of the population [7].

In Indian context, the coverage of publicly funded health insurance was 10% in 2013 [8]. Due to expansion of Ayushman Bharat Pradhan Mantri Jan Aarogya Yojana (AB PM-JAY), the coverage has increased to 15.4% in 2023 [9]. As on 2023 too, the coverage is far from being universal. In this scenario, there are 2 options - firstly, introducing free drug delivery initiatives in public facilities or low cost generic drugs at public hospitals through Pradhan Mantri Jan Aushadhi Kendras [10]. However, the public sector contributes to only 30.1% and 42% of outpatient care and inpatient care respectively [3]. In view of this, a large section of population is catered to by private sector, and thus continues to incur OOPE for medicines at the private pharmacies. In this scenario, the role of regulator, i.e. National Pharmaceutical Pricing Authority (NPPA) becomes extremely important [11].

### Drug Pricing at National and Global Level: Role of HTA

The NPPA is empowered under the Drug Price Control Order (DPCO) to fix and regulate the prices of essential drugs in the country [11]. The pricing of drugs under the DPCO has been revised several times (2003, 2011, 2015, 2022 and 2023) since the release of first National list of essential medicines (NLEM) in 1996, so as to include more drugs under price control. Through DPCO-2013, the NPPA capped the prices of 890 formulations under NLEM, 2015. Under NLEM, 2022 as on 31.03.2023, NPPA has fixed/ re-fixed the ceiling prices of 651 formulations. Over the years, the methodology for price regulation has also evolved. The method of fixing price was changed in DPCO-2013 from cost-based price (CBP), which was in practice since 1979, to market-based price (MBP). In CBP method, the retail price was fixed based on material and conversion costs, packaging material costs and packaging charges, along with maximum allowable post-manufacturing and excise duty. The NPPA currently uses a MBP strategy to determine the ceiling prices of scheduled medicines in India. The ceiling price is calculated based on the average market price for all brands selling a particular drug with more than 1 per cent of market share and further adds a national retailer margin of 16 per cent to it. Such a practice is grounded on the assumption of a competitive drug market. The DPCO, which was initially limited to regulating the prices of essential medicines, has been expanded over the years to include non-essential medicines, medical devices, and other healthcare products. The maximum retail price of non-scheduled drugs cannot exceed more than 10% in one year time.

Several countries globally have resorted to using health technology assessment (HTA) and value-based pricing (VBP) methods to set drug prices. HTA involves analysing the costs and benefits of a new drug compared to existing treatments, and assessing its value for money. This approach involves setting a threshold price that reflects the maximum amount that should be paid for a drug based on the additional health benefits which it provides, relative to an existing treatment. This threshold price can be determined by evaluating the incremental clinical benefits and incremental cost of a new drug compared to the existing treatments. In the case of new medicines that offer minimal additional health benefits, the prices

should be capped such that any higher price reflects the additional individual and societal value that it creates in terms of quality-adjusted life years (QALYs).

Many countries across the world, including Canada, United Kingdom and Australia, use HTA and VBP for their procurement decisions [13-14], while others like Germany and France use it for regulatory decisions [15-16]. The methodology of HTA and VBP vary across different countries, with some countries using direct price negotiations or reference pricing, while others set prices based on cost-effectiveness ratios or budget impact analysis. Price negotiations allow the government to exert greater control over drug prices and ensure that they are affordable for patients.

Common approaches used for drug pricing in different countries are enlisted in Table 1. There are some key lessons from global experiences. First, Germany shows that it is possible to combine a market-oriented pricing policy with value-based pricing methods and external reference pricing. Second, incorporating cost-effectiveness analyses does not restrict access to certain drugs or interventions. Third, innovation can be rewarded in a number of ways by integrating assessments of therapeutic value and added therapeutic value into the drug pricing system. Fourth, external reference prices can provide helpful information, even if it is not used directly to set prices. Fifth, distinct price controls can be used for generics versus branded drugs, as in Australia where generics are subject to therapeutic reference pricing. All these approaches offer valuable lessons.

The HTA system is India is still in its early stages, and there is a need to strengthen its implementation and uptake. In 2018, the Department of Health Research (DHR), under the Ministry of Health and Family Welfare in India, has created a new ecosystem for the HTA -The Health Technology Assessment in India (HTAIn) [17]. Several HTA studies, commissioned by the HTAIn, have led to uptake in policy decisions [18-20]. A recent study undertaken by Post Graduate Institute of Medical Education and Research, Chandigarh evaluating the value-based pricing for several anticancer drugs in India was commissioned by DHR [21]. The study found that most of the drugs which came under price regulation are not cost-effective at their current prices [22]. The study also recommended various levels of further reduction in prices to make the price reflect the additional value of these drugs. For example, a 78% reduction in market price and 72% reduction in the reimbursement rate for Fulvestrant monotherapy were recommended to make it a cost-effective treatment option in the Indian context [23].

The National Health Authority (NHA) has shown the way for adoption of HTA evidence in decisions around health benefit packages (HBPs) inclusion and it's pricing under the Pradhan Mantri Jan Arogya Yojana (PM-JAY). This has also resulted in significant cost savings to the healthcare system. For example, revisions in HBP of Trastuzumab and radiotherapy for breast cancer have been estimated to potentially save ₹ 426 crore and 50-100 crore respectively per year. [24-25].

To facilitate the process of uptake of HTA evidence, the NHA has established a dedicated unit, called the Health Financing and Technology Assessment (HeFTA) unit [26]. To streamline the process of early adoption of new drug and technology, the NHA has also created a portal on its website for accepting new technology applications, including medicines. This portal can be used by pharmaceutical companies and other technology providers to submit their products for consideration. The portal can also be used by healthcare professionals, patients, and other stakeholders to provide input and feedback on the technology under review.

**Way forward for NPPA**

One way forward is to adopt a threshold pricing approach for determining the value based price of drugs. Integrating HTA in the entire course of drug development can also ensure that decisions made about drug pricing are informed by a comprehensive understanding of the drug's clinical value. This approach is known as a life-cycle approach to HTA. By adopting this approach, HTA would be used from the earliest stages of drug development, to evaluate the potential value of new drugs before they are approved for use. During the pre-approval phase, HTA can help identify the

most promising drugs and provide guidance on how to design clinical trials to effectively demonstrate the drugs' clinical value. Once a drug is approved and enters the market, HTA can be used to continuously evaluate its clinical value and provide guidance on pricing. Using HTA, drug's price over time can be adjusted to reflect changes in its clinical value or market competition.

In addition to the cost and clinical value of new drugs/technologies, it is important to consider the other positive externalities of a new drug. For example, in the context of antibiotics, economic models need to account not only for clinical effectiveness of patient, but the positive effect on reducing infection transmission. A study by Mortan et al (2019) found that the health gain derived from avoided infections (33,178 QALYs) at population level surpassed the health gain accruing to patients (12,442 QALYs) [27]. In addition, it is important to quantify the value of an antibiotic at population level to account for their value which may put lesser strain on antimicrobial resistance (AMR). Similarly, a drug with narrow spectrum may also reduce AMR. If such elements are not taken into account in economic evaluation, there is a risk that antibiotics are under-valued, that the decision to reimburse an antibiotic based on its value is misinformed and that pharmaceutical companies do not receive an appropriate reward for their antibiotic research and development efforts [28].

Given the rise in burden of infectious diseases across the globe, such alternate value frameworks addressing the issue of externalities associated with use of antibiotics and other drugs, will help in reducing the pressure on existing drugs and the propensity to develop antimicrobial resistance (AMR) will also get diminished.

## Conclusion

Overall, HTA provides information on clinical effectiveness, safety, cost-effectiveness, social and ethical implications (such as impact of equity etc.) of drugs and healthcare technologies. This can be useful for multiple stakeholders like a regulator (NPPA) and payer (NHA). The effectiveness component of HTA can be used to consider inclusion of drug in the essential medicine list. To conclude, we recommend a strong role for HTA to be considered, by policymakers while determining health insurance benefit packages and their prices, by clinicians while framing standard treatment guidelines, and by regulatory agencies, while setting prices. Together, these will enhance the value of healthcare in India.

**Table 1: Common Approaches for drug pricing used in different countries :**

| Country | External reference pricing | Therapeutic / Internal reference pricing | Added value/ Innovation | Cost-effectiveness analysis | Performance/ risk sharing agreements | Cost-plus pricing | Tendering and Negotiations | Price maintenance premium |
|---|---|---|---|---|---|---|---|---|
| United Kingdom | | ✓ | ✓ | ✓ | | | | |
| Australia | | ✓ | ✓ | ✓ | ✓ | | ✓ | |
| Germany | ✓ | ✓ | ✓ | ✓ | ✓ | | | |
| France | ✓ | | ✓ | ✓ | ✓ | | | |
| Japan | ✓ | | ✓ | ✓ | | ✓ | | ✓ |
| Thailand | | ✓ | | ✓ | ✓ | | | |
| Bangladesh | | | | | | ✓ | ✓ | |
| China | ✓ | ✓ | | | | | ✓ | |
| Hong Kong | | | | | | | ✓ | ✓ |
| Vietnam | ✓ | | | | | ✓ | ✓ | |
| Indonesia | | | | | | ✓ | ✓ | |
| India | | | | | | ✓ | ✓ | ✓ |

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## News related to pricing of drugs

- Ceiling prices for 651 scheduled formulations (National List of Essential Medicines, 2022) and Retail prices for 2361 non-scheduled formulations have been fixed under DPCO, 2013 till 30th April 2023.
- As on 30th April, 2023, 243 Authority meetings have been conducted of which 111 are under DPCO 2013. The details of the recent meetings are given as below:

| Meeting No. | Held on | Prices Approved & Notified |
|---|---|---|
| 241 (overall) & 109 Meeting under DPCO 2013 | 21.02.2023 | (i) Retail prices for 74 formulations notified vide SO. 878(E) dated 24.02.2023.<br>(ii) Ceiling prices for 81 formulations notified vide S.O. 879(E) &880(E) dated 24.02.2023. |
| 242 (overall) & 110 Meeting under DPCO 2013 | 23.03.2023 | (i) Retail prices for 25 formulations notified vide SO. 1434(E) dated 27.03.2023 |
| 243 (overall) & 111 Meeting under DPCO 2013 | 29.03.2023 | (i) Ceiling prices for 170 formulations notified vide S.O. 1577(E) 1578(E) 1579(E) & 1581(E) dated 31.03.2023 |

- Details of 99 retail prices notified for various formulations based on the decision taken in 109th, 110th & 111th 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 | 40 | Tablet | 6.57 – 29.29 |
| 2 | Anti-Cancer | 2 | Injection | 5866.76 - 15522.32 |
| 3 | Allergic rhinitis | 7 | Tablet / Injection | 0.86 – 15.39 |
| 4 | Antihypertensive | 17 | Tablet | 8.34 – 12.83 |
| 5 | Anti-Infection | 6 | Capsule / Infusion/Tablet | 3.90 – 34.68 |
| 6 | Cardiovascular | 5 | Tablet | 6.19 – 13.72 |
| 7 | Vitamins | 1 | Tablet | 1.88 |
| 8 | Others | 21 | Capsule/Tablet/Injection/ Infusion/Sachet | 0.55 – 3773.31 |
| | **Total** | **99** | | |

- Details of ceiling prices notified for various formulations based on the decision taken in 109th, 110th & 111th Authority Meetings are as follows:

| Therapeutic Category | No. of Medicines | No. of Formulations |
|---|---|---|
| Anti bacterial | 38 | 109 |
| Medicines used in the Management of HIV | 23 | 26 |
| Analgesics, Antipyretics, Non-steroidal Anti-inflammatory Drugs (NSAIDs), Medicines used to treat Gout and Disease Modifying Agents used in Rheumatoid Disorders | 11 | 28 |
| Anti-cancer agents including Immunosuppressives and | 48 | 82 |
| Medicines used in Palliative Care | | |
| Cardiovascular Medicines | 24 | 56 |
| Medicines used in Neurological Disorders | 17 | 60 |
| Medicines used in treatment of Psychiatric Disorders | 14 | 34 |
| Ophthalmological Medicines | 11 | 14 |
| Others | 125 | 242 |
| **Grand Total** | **311** | **651** |

- Ceiling prices for total 905 formulations (Fixed under NLEM, 2022 and earlier NLEMs) revised w.e.f. 01.04.2023 on the basis of WPI @12.1218% in pursuance to Para 16(1) of DPCO, 2013.

## News related to pricing of Medical devices

- NPPA vide S.O. 2161(E) dated 3rd June 2021 issued notification under Para 19 of the DPCO, 2013 regarding capping the trade margin of **Oxygen Concentrators** at first point of sale (price to distributor) for fixation of Maximum Retail Price of the product up to 31st March 2023. This has been further extended up to 30th June 2023 vide **S.O. 1519(E) dated 29th March 2023.**
- NPPA vide S.O. 2808(E) dated 13th July 2021 issued notification under Para 19 of the DPCO, 2013 regarding 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 (price to distributor) for fixation of Maximum Retail Price of the product up to 31st March 2023. This has been further extended up to 30th June 2023 vide **S.O. 1518(E) dated 29th March 2023.**
- NPPA vide **S.O. 1520(E) dated 29th March, 2023,** has revised the ceiling price of a scheduled formulation/drug i.e. **Hormone releasing IUDs**
- NPPA vide **S.O. 1572(E) dated 31st March 2023,** has revised the ceiling prices of Coronary Stents, which includes **Bare metal Stents, Drug Eluting Stents and Bioresorbable Vascular Scaffold(BVS)/ Biodegradable stents** after considering the WPI @ 12.1218% for the year 2022 over 2021 in accordance with Para 16(2) of the DPCO, 2013, read with Para 13(2) of the DPCO, 2013.

## National Medical Devices Policy, 2023

The Union Cabinet, chaired by the Hon'ble Prime Minister Shri Narendra Modi, approved the National Medical Devices Policy, 2023 on 26th April 2023.


The medical devices sector in India is an essential and integral constituent of the Indian healthcare sector. The Indian medical devices sector's contribution has become even more prominent as India supported the domestic and global battle against COVID-19 pandemic through the large scale production of medical devices & diagnostic kits, such as Ventilators, Rapid Antigen Test kits, Real-Rime Reverse Transcription Polymerase Chain Reaction (RT-PCR) kits, Infrared (IR) Thermometers, Personal Protective Equipment(PPE) Kits & N-95 masks.

The medical devices sector in India is a sunrise sector which is growing at a fast pace. The market size of the medical devices sector in India is estimated to be $11 billion (approximately, ₹ 90,000 Cr) in 2020 and its share in the global medical device market is estimated to be 1.5%. The Indian medical devices sector is on a growth track and has an enormous potential to become self-reliant and to contribute towards the goal of universal health care. The Government of India has already initiated implementation of PLI Scheme for medical devices and support for setting up of 4 Medical devices Parks in the States of Himachal Pradesh, Madhya Pradesh, Tamil Nadu and Uttar Pradesh. Under the PLI scheme for Medical Devices, till now, a total of 26 projects have been approved, with a committed investment of Rs.1206 Cr and out of this, so far, an investment of Rs.714 Cr has been achieved. Under the PLI scheme, total of 14 projects producing 37 products have been commissioned and domestic manufacturing of high-end medical devices has started which include Linear Accelerator, MRI Scan, CT-Scan, Mammogram, C-Arm, MRI Coils, high end X-ray tubes, etc. Remaining 12 products will be commissioned in near future. Five projects out of total 26 projects have been approved recently, under Category B, for domestic manufacturing of 87 products / product components.

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# INTERNATIONAL NEWS

**FDA Authorizes First Over-the-Counter At-Home Test to Detect Both Influenza and COVID-19 Viruses (February 24, 2023 )**

The U.S. Food and Drug Administration issued an emergency use authorization (EUA) for the first over-the-counter (OTC) at-home diagnostic test that can differentiate and detect influenza A and B, commonly known as the flu, and SARS-CoV-2, the virus that causes COVID-19. The Lucira COVID-19 & Flu Home Test is a single-use at-home test kit that provides results from self-collected nasal swab samples in roughly 30 minutes.


In individuals with symptoms, the Lucira COVID-19 & Flu Home Test correctly identified 99.3% of negative and 90% of positive Influenza A samples, 100% of negative and 88.3% of positive COVID-19 samples and 99.9% of negative Influenza B samples. As with all rapid diagnostic tests, there is a risk of false positive and false negative results. Individuals who test positive for either flu or COVID-19 should take appropriate precautions to avoid spreading the virus and should seek follow-up care with their physician or healthcare provider as additional testing may be necessary. The collective impact of COVID-19, flu and RSV underscore the importance of diagnostic tests for respiratory viruses, and the FDA recognizes the benefits that home testing can provide.

**Read more**

**FDA Takes Action to Restrict Unlawful Import of Xylazine (February 28, 2023 )**

The U.S. Food and Drug Administration announced that it has taken action to restrict the unlawful entry of xylazine active pharmaceutical ingredients and finished dosage form drug products into the country to address a growing public health concern. This


action aims to prevent the drug from entering the U.S. market for illicit purposes, while maintaining availability for its legitimate uses in animals. Veterinarians legitimately use drug products containing xylazine to sedate large animals such as horses and deer, but it is not safe for use in people and may cause serious and life-threatening side effects. Xylazine is not an opioid, it is dangerous because it can depress breathing, blood pressure, heart rate and body temperature to critical levels. Additionally, people who inject drugs containing xylazine can develop severe skin wounds and patches of dead and rotting tissue that easily become infected and, if left untreated, may lead to amputation.

**Read more**

**FDA Authorizes Bivalent Pfizer-BioNTech COVID-19 Vaccine as Booster Dose for Certain Children 6 Months through 4 Years of Age (March 14, 2023 )**

The U.S. Food and Drug Administration amended the emergency use authorization (EUA) of the Pfizer-BioNTech COVID-19 Vaccine, Bivalent to provide for a single booster dose of the vaccine in children 6 months through 4 years of age at least 2 months after completion of primary vaccination with three doses of the monovalent (single strain) Pfizer-BioNTech COVID-19 Vaccine.

**Read more**

**FDA Issues Draft Guidance Aimed at Improving Oncology Clinical Trials for Accelerated Approval (March 24, 2023)**

The U.S. Food and Drug Administration issued draft guidance, Clinical Trial Considerations to Support Accelerated Approval of Oncology Therapeutics, regarding clinical trial design considerations to support accelerated approval applications. The accelerated approval pathway is commonly used for approval of oncology drugs in part due to the serious and life-threatening nature of cancer and because of available intermediate clinical endpoints likely to predict clinical benefit.

Specifically, the draft guidance addresses the design, conduct and analysis of data through two randomized clinical trial approaches – conducting two separate randomized controlled clinical trials or using one trial for both accelerated approval and to verify clinical benefit. The draft guidance also provides considerations for sponsors to determine the adequacy of single-arm studies to support an application.

**Read more**

**FDA Approves First Over-the-Counter Naloxone Nasal Spray (March 29, 2023 )**

The U.S. Food and Drug Administration approved Narcan, 4 milligram (mg) Naloxone hydrochloride nasal spray for over-the-counter (OTC), non-prescription, and use – the first Naloxone product approved for use without a prescription. Naloxone is a medication that rapidly reverses the effects of opioid overdose and is the standard treatment for opioid overdose. Today's action paves the way for the life-saving medication to reverse an opioid overdose to be sold directly to consumers in places like drug stores, convenience stores, grocery stores and gas stations, as well as online. Other

formulations and dosages of Naloxone will remain available by prescription only. Drug overdose persists as a major public health issue in the United States, with more than 101,750 reported fatal overdoses occurring in the 12-month period ending in October 2022, primarily driven by synthetic opioids like illicit fentanyl.

Narcan nasal spray was first approved by the FDA in 2015 as a prescription drug. In accordance with a process to change the status of a drug from prescription to non-prescription, the manufacturer provided data demonstrating that the drug is safe and effective for use as directed in its proposed labelling. The approval of OTC Narcan nasal spray will require a change in the labelling for the currently approved 4 mg generic Naloxone nasal spray products that rely on Narcan as their reference listed drug product. The FDA granted the OTC approval of Narcan to Emergent BioSolutions.

**Read more**

**FDA Commissioner and Chief Scientist Announce Decision to Withdraw Approval of Makena (April 06, 2023 )**

The U.S. Food and Drug Administration announced the final decision to withdraw approval of Makena-a drug that had been approved under the accelerated approval pathway. This drug was approved to reduce the risk of preterm birth in women pregnant with one baby who have a history of spontaneous preterm birth. The decision was issued jointly by the FDA Commissioner and Chief Scientist. Effective today, Makena and its generics are no longer approved and cannot lawfully be distributed in interstate commerce.The decision issued today by the FDA Commissioner and Chief Scientist outlines their rationale and also recognizes the crucial need to develop treatments to reduce the serious risks associated with preterm birth.

**Read more**

# OTHER NEWS AND EVENTS

## NPPA sets up Price Monitoring and Resource Unit (PMRU) in the State of Arunachal Pradesh and Union Territory of Chandigarh in March, 2023

NPPA under Consumer Awareness, Publicity and Price Monitoring (CAPPM) Scheme has set up Price Monitoring and Resource Unit (PMRU) in the State of Arunachal Pradesh and Union Territory of Chandigarh in March, 2023. NPPA has so far set-up PMRUs in 28 States/UTs. The 28th PMRU was established in the Union Territory of Chandigarh on 27th March 2023. Now, NPPA has its presence in the States/ UTs of Kerala, Gujarat, Odisha, Rajasthan, Punjab, Haryana, Tripura, Nagaland, Uttar Pradesh, Andhra Pradesh, Mizoram, Jammu & Kashmir, Karnataka, Telangana, Maharashtra, Goa, Madhya Pradesh, Chhattisgarh, Jharkhand, Puducherry, West Bengal, Ladakh, Himachal Pradesh, Bihar, Uttarakhand, Meghalaya, Arunachal Pradesh and Chandigarh.


## Webinars for Price Monitoring and Resource Units in the Sates/ UTs

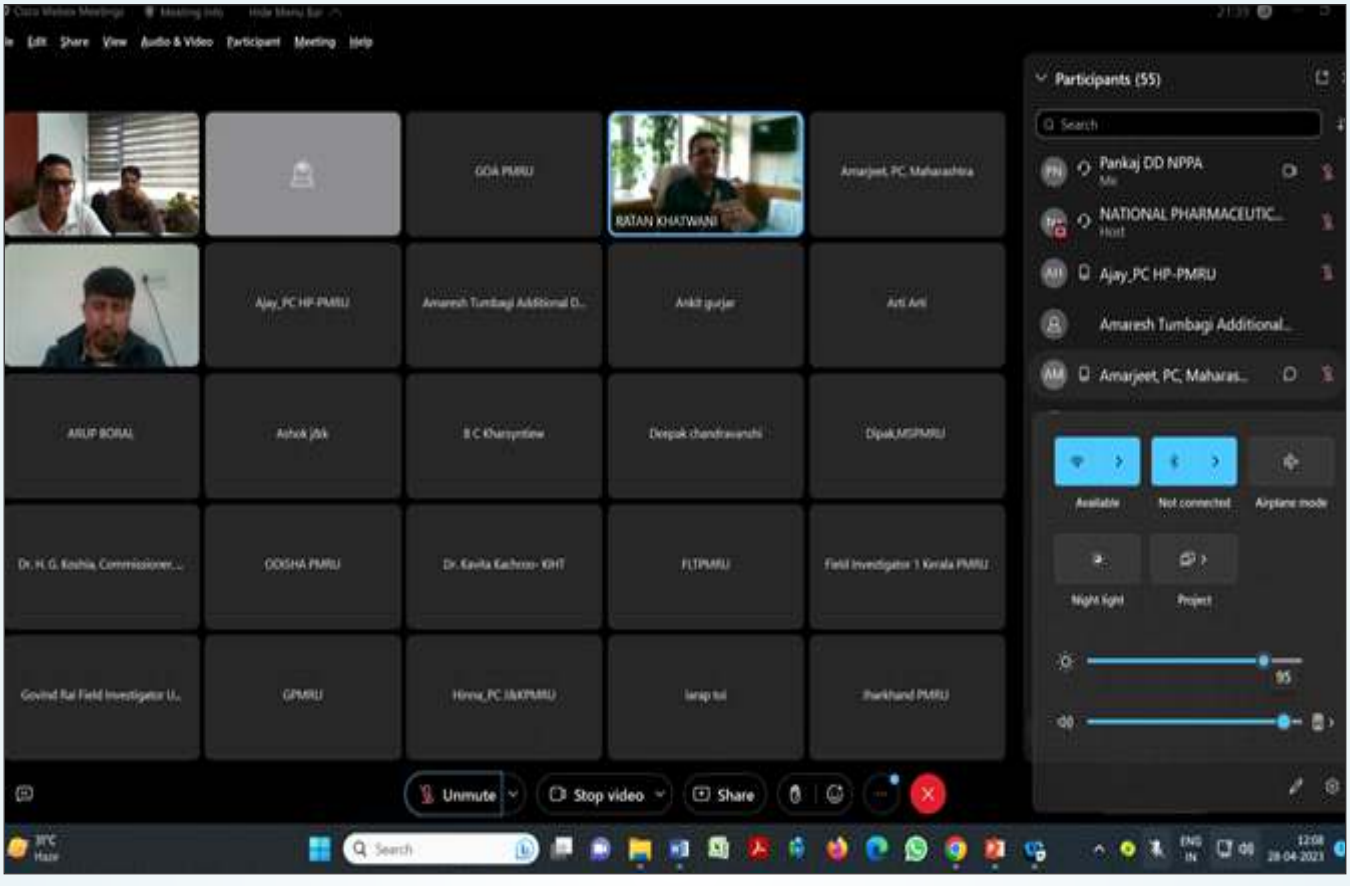
In the Run-up of India @ 75, 'Azadi ka Amrit Mahotsava' during the months of March and April 2023, two (2) interactive webinars were organized by NPPA for Price Monitoring and Resource Units in the Sates/ UTs as mentioned below:

| Sr. No. | Date | Webinar |
|---|---|---|
| 1 | 28.03.2023 | Guidance on effective reporting through IPDMS Software |
| 2 | 28.04.2023 | NLEM-2022 and Activities to be undertaken by PMRUs |

The main aim of these webinars was to provide guidance and sharing of knowledge with PMRUs regarding:

- Guidance on reporting of activities/ data/ reports through IPDMS 2.0 Software to enable PMRUs to use/ operate the new IPDMS software effectively
- Changes brought about in the National List of Essential Medicine (NLEM) 2022
- Monitoring of price movement of scheduled/ non-scheduled formulations and reporting of likely violation cases through IPDMS
- Collection/ purchase of test samples of medicines, procedure to be followed for sample purchase, its' documentation, analysis, preparation and submission of reports.
- Organising Meetings (Executive Committee Meeting & Governing Body Meeting) and Submission of Monthly report including Static and dynamic report
- Conducting of Weekly Survey and Submission of Report

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




## Awareness program organized by PMRU Madhya Pradesh

PMRU Madhya Pradesh has organized an awareness campaign on 'Accessibility, Availability and Affordability of drugs and Pharma Sahi Daam app during Khelo India Youth 2022 Festival at Madhya Pradesh Academy Water Sports Upper Lake where Water Sports activities going on from till 2nd - 3rd February 2023.

# OTHER NEWS AND EVENTS

## Awareness program organized by PMRU Andhra Pradesh (KIHT)

PMRU KIHT has organized a one day awareness program on dated 17th March 2023, at Vishwanath Institute of Pharmaceutical Sciences, Vishakhapatnam. The thought behind the awareness program was to highlight the functioning of PMRU, the benefits of Pharma Sahi Dam mobile application and the role of National Pharmaceutical Pricing Authority (NPPA). The program was well attended by all stakeholders from Pharma industry, Pharmacy professionals, research scholars, academic staff and consumers.

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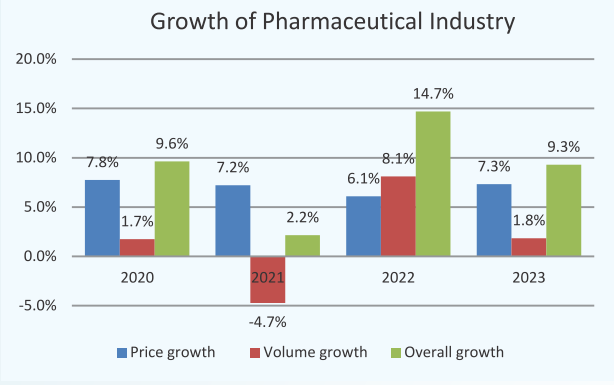
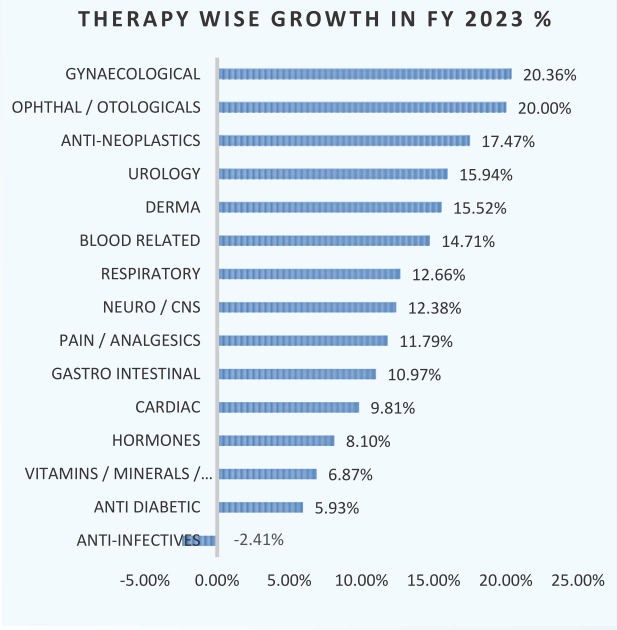
## IEC activities conducted by PMRU Ladakh

PMRU Ladakh in collaboration with 'Drug and Food Control department' organised an event on the occasion of 'Jan Aushadhi Diwas' on 2nd March in which the consumers and institutional pharmacists were made aware about the Jan Aushadhi quality generic medicines available at different centres across the country and at Leh and Kargil Jan Aushadhi centers at affordable prices. They were also briefed about the Pharma Sahi Dam and Pharma Jan Samadan app.

The pharmaceutical sector has witnessed a year-on-year growth ranging from 9.3% to 14.7% in the last four years, except for the FY 2020-21 where the growth was only 2.2%.

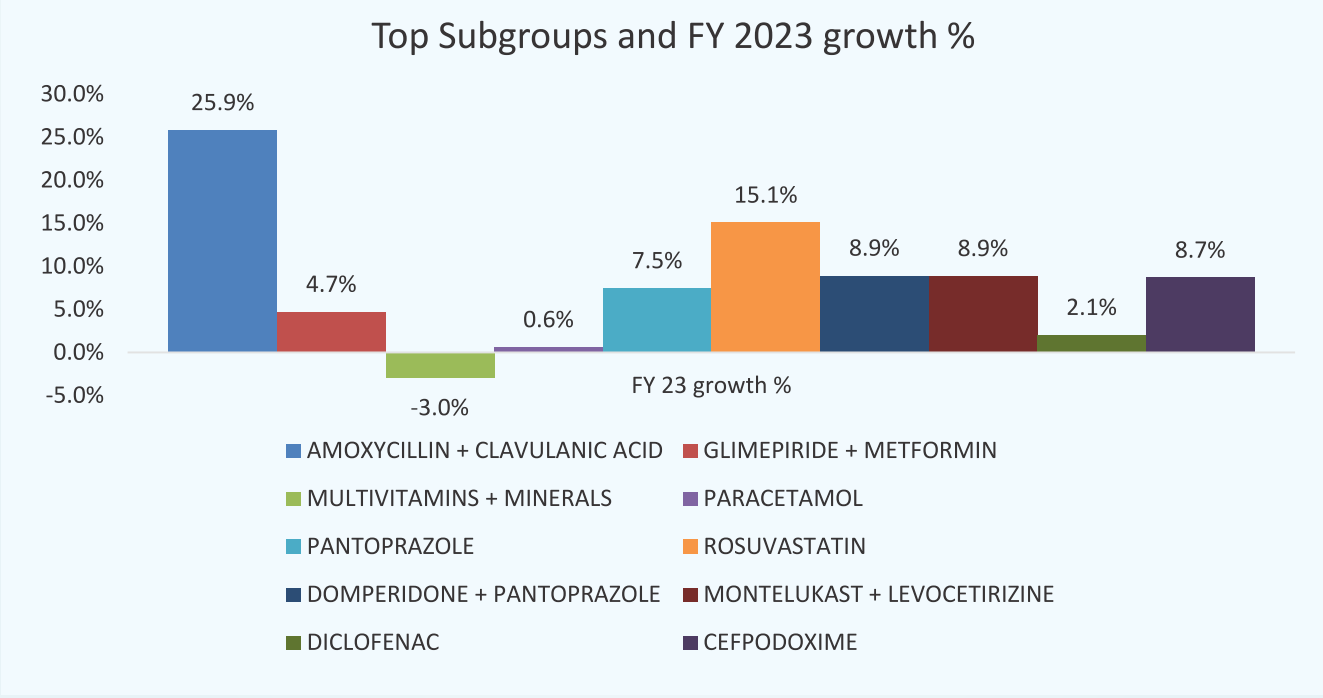



The therapeutic group wise growth during the FY 2022-23 over the last financial year in % terms are as follows:




It may be seen that Gynaecological and ophthalmological products have a growth of over 20% whereas Anti-infectives have seen a decline of 2.41%.

The top ten pharmaceutical companies, mother brands and subgroups and their year-on-year growth in % for the FY 2022-23 are as follows:




# FREQUENTLY ASKED QUESTIONS

**1. What are the enabling provisions for overcharging under DPCO,2013?**

NPPA monitoring the prices of scheduled as well as non-scheduled medicines under DPCO, 2013 and takes action against companies as per the provisions of DPCO, 2013.

a. In case of scheduled formulation, as per Para 14(2), "Where any manufacturer sells a scheduled formulation at a price higher than the ceiling price (plus local taxes as applicable) fixed and notified by the Government, such manufacturers shall be liable to deposit the overcharged amount along with interest thereon from the date of such overcharging."

b. In case of non-scheduled formulation, as per Para 20(1), "no manufacturer increases the maximum retail price of a drug more than ten percent of maximum retail price during preceding twelve months and where the increase is beyond ten percent of maximum retail price, it shall reduce the same to the level of ten percent of maximum retail price for next twelve months."In case of violation, "The manufacturer shall be liable to deposit the overcharged amount along with interest thereon from the date of increase in price in addition to the penalty."

c. Further, in case launching the new drug without price approval from NPPA, as per Para 15(5), "Where existing manufacturer of scheduled formulation fails to apply for prior approval of the price of the new drug in Form-I, such manufacturer shall be liable to deposit the overcharged amount over and above such price fixed and notified by the Government, if any, along with interest thereon from the date of launch of the new drug, in addition to the penalty."

2. What are the various stages involved in overcharging process?

The various stages in the process are as follows:

a) Upon identification of violation of DPCO related to overcharging, preliminary noticeis issued to the manufacturer, directing them to explain the reasons of non-compliance and to submit batch wide details of production/ sales of said formulation. If no satisfactory response is received, the case is considered to be prima facie established and fit for issuance of Show Cause notice.

b) The cases which are considered to be prima facie established are considered fit for issuance of Show Cause Notice. In such cases, Show Cause Notices are issued to the defaulting Pharmaceutical Companies seeking explanation and the CA/CMA certified quantitative data (in case not already submitted) of the subject formulations.

c) Upon establishment of overcharging, the overcharged amount is calculated based on data submitted by them, or market-based data available (Pharmatrac) in case default in submission of quantitative data. Upon finalisation of the overcharged amount, Demand Notices are issued to the manufacturer, directing them to deposit the overcharged amount along with interest and penalty, as the case may be.

d) If the company fails to deposit the amount mentioned in the Demand Notice within the time limit provided in demand notice, the case is referred to the concerned District Collector for recovery of demanded amount from the manufacturer as arrears of Land Revenue.

# 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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