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

Vol.-V | JUNE, 2022

A Bi-monthly e-Newsletter

दवा वही
दाम सही

Committed Towards Accessibility, Availability & Affordability of Medicines for All

CONTENTS

S.No.	Description	Page No.
1.	From Chairman's Desk	1
2.	Article by Pharma Expert	2-4
3.	Regulatory News	5
4.	International News	6-7
5.	Other News and Events	8-9
6.	Know Your Sector	10
7.	FAQs	11

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.

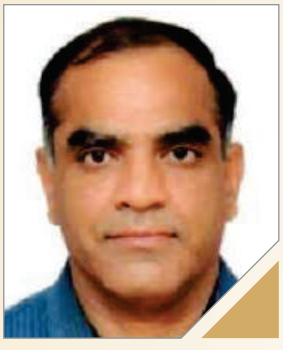
c. **Market Based Pricing:** The ceiling prices of medicines are fixed on Market Based Pricing (MBP) methodology.

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

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 fifth 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. In the 99th meeting of the Authority held under DPCO, 2013 retail prices for 85 new drugs were fixed. These drugs fall broadly in the therapeutic category of anti-diabetic and cardio-vascular drugs and will lead to reduction in their prices benefitting the consumers.

At the same time, 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 is under development and will shortly be implemented with enhanced features and easy user interface. As in every issue, in this segment of FAQs we discuss about discontinuation of scheduled formulations from the market as per provisions of DPCO, 2013.

The reach of NPPA through Price Monitoring and Resource Units (PMRUs) is expanding and during the month of June, 2022, new PMRU has been set up in the State of Bihar. With this the total number of PMRUs set-up in the States/UTs in the country till date has gone up to Twenty-Four (24).

NPPA will complete 25 years of its existence in August this year and series of events are planned to commemorate the silver jubilee celebrations. Details of the same will be shared shortly.

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

(Kamlesh Kumar Pant)

NEED FOR INDIA TO BE AT THE INTERNATIONAL HTA PLATFORM

Pramil Tiwari, M.Pharm., Ph.D.
Prof & Head, Deptt of Pharmacy Practice,
National Institute of Pharmaceutical Education and Research (NIPER), SAS Nagar, Punjab, India

Health technology assessment (HTA) plays a vital role in advancing health systems throughout the world. This multidisciplinary process uses explicit methods to determine the value of a health technology at different points in its lifecycle. The goal of HTA is to inform decision-making in order to promote an equitable, efficient, and high-quality health system. HTA is necessary to assess the safety and effectiveness of new health technology or intervention.

A health technology can be an intervention developed to prevent, diagnose, or treat medical conditions; promote health; provide rehabilitation; or organize healthcare delivery. The intervention can be a test, device, medicine, vaccine, procedure, program, or system.

Stakeholders are the individuals, organizations or communities that have direct interest in the process and result of a health technology assessment. These could be consumer, clinician, policy maker, researcher, research funding agency, insurance companies and pharmaceutical manufacturers.

If one tries to look at the HTA mechanisms in the southeast Asian region, there are HTA boards in many countries. The countries of the south east Asian region have approximately 2.04 billion population – of this, India has a contribution of 1.38 billion in the population pool. The most populated country after India is Indonesia (273.524 million), Bangladesh (164.68 million) and the least populated country is Maldives (541 thousand).

Several contries have adopted policies to achieve a ahigh level of universal health coverage. The variation in Universal Health coverage among the countries of southeast Asian region is huge. South Korea has almost achieved their universal health coverage which is 80% followed by Thailand (75%), Myanmar (60%). Countries like Nepal and Timor Leste have relatively poor coverage- below 50%.

Lately, India is moving toward universal health coverage with the aim to provide financial protection and to minimize out of pocket expenditure of the population so taking decision on investing in cost effective health technology is critical in improving population health and health equity and also due to limited health budget to cover or include new health technologies into benefit package decision makers or policy makers are confuse to decide adaptation of which health technology provide maximum benefits. Decisions for allocation of health resources at both the national and state level are predominantly made on the basis of consensus opinion from expert committees. The concept of Health technology assessment provides a globally accepted and structured approach to synthesising evidence for cost and clinical effectiveness alongside ethical and equity considerations to form the basis for evidence-based priority setting and policy decisions.

With the aim of establishing HTA in India, the government of India- in 2017- has established the Medical Technology Assessment Board (MTAB). The MTAB aims to uplift the process and finalize the development of standardized cost-effective interventions that will reduce –

1. The cost and variation in patient care
2. The Expenditure on medical equipment
3. The overall cost of patient care
4. Overall cost of medical treatment
5. Out of pocket expenditure of patient

It streamlines the medical reimbursement procedures and serves as an important tool in prioritizing national health spending and help achieve universal health coverage.

Indian healthcare delivery system: India's healthcare system is complex, and is a mix of both, public and private entities. The quality of healthcare available in India ranges from globally acclaimed hospitals to poorly maintained facilities that provide quality of care which has scope for improvement. Currently 1.3% of total GDP is spent on public health which by 2025 is set to increase by 2.5%.

High household out of pocket expenditure (OoP) 62.67% among Indian population includes doctors' consultation fees, diagnostic tests, cost of medicines and medical appliances, and hospitalization costs. The extensive OOP spending toward healthcare results in financial hardship, which is a situation when 40% of household's income is spent on healthcare. The achievement of universal health coverage (UHC) in India, which aims to provide equal access to quality medical care to all citizens, including access to new pharmaceutical products launched worldwide, and at the same time does not result in financial hardships is crucial. This would also result in OoP going down.

To reduce the OoP healthcare spending and thereby achieve UHC, the Government of India and different State Governments have implemented various health schemes, with a varying degree of success in reducing OoP expenditure.

While multiple efforts are taking place to advance the Health technology Assessment, the author believes that India needs to showcase itself at the internstional platform emphatically. One such platform is the "Health Technology Assessment International" (HTAi). The association "Health Technology Assessment International" (HTAi) is the global, non-profit, scientific and professional society for all those who produce, use or encounter health technology assessment (HTA). HTAi is a member-driven organization representing 82 organizations and over 2,500 individual members from 65 countries around the world. As expected, the stakeholders of HTAi are policy makers, researchers, pharmaceutical industry, academia, health service providers, agencies involved in delivery of healthcare and patients.

ARTICLE BY PHARMA EXPERTS

The first HTAi Annual Meeting was held in 2003 in Canmore, Alberta, Canada and the last one in June 2022. HTAi's Annual Meetings are key international gatherings for sharing the latest research, advancing discussions in policy and methods, and building global networks around HTA. The annual meetings bring together over 1,000 researchers, policymakers, industry, academia, health service providers, agencies and patients/consumers from around the world. They provide an arena for these groups to share information and best practices, from cutting-edge technologies to system development in order to advance healthcare India need to participate at such international platform and leverage the exchange of ideas and knowledge. Such exchange will be beneficial towards achieving universal health coverage.

News related to pricing of drugs

- Ceiling prices for 890 scheduled formulations (National List of Essential Medicines, 2015) and Retail prices for 1939 non scheduled formulations have been fixed under DPCO, 2013 till 31st May, 2022.
- As on 31st May, 2022, 230 Authority meetings have been conducted of which 98 meetings are under DPCO 2013. During May, 2022, the 229th (overall) & 97th Meeting under DPCO 2013 was conducted on 06.05.2022 and 230th (Overall) & 98th meeting of the Authority under DPCO 2013 was conducted on 24.05.2022.
- Retail price for 66 formulations were fixed during 97th Authority Meeting held on 06.05.2022 and notified vide SO. 2164(E) dated 09.05.2022.
- Retail prices of 56 formulations were fixed during 96th Authority Meeting held on 24.03.2022 of which retail prices of 38 formulations were notified vide SO 1782 (E) dated 12.04.2022 and SO No. 1833 (E) dated 18.04.2022. The remaining 18 formulations were notified vide SO. 2165(E) dated 09.05.2022 after due deliberation in the 97th meeting.
- Details of retail prices notified for various formulations based on the decision taken in 96th & 97th Authority Meetings are as follows:

S. No.	Therapeutic group	Total Number	Type of formulation	Retail Price Fixed Range (Rs.)
(1)	(2)	(3)	(4)	(5)
1	Anti Diabetic	50	Tablet	6.75 – 20.03
2	Antihypertensive	3	Tablet	9.49 – 10.55
3	Cardio Vascular	5	Tablet	4.68 – 17.17
4	Anti Ulcerant and Proton Pump Inhibitor	4	Capsule	9.21 – 10.17
5	Pain Analgesic	6	Tablet/Gel/ Spray/Patch	2.69 – 19.20
6	Eye Drop	3	Drop	49.04 – 123.68
7	Others	13	Tablet/ Infusion/ Injection	0.51 – 30.74

- During the 98th meeting of the Authority under DPCO 2013, the prices of oxygen concentrator regulated through Trade margin Rationalization was extended upto 30.06.2022 or until further orders whichever is earlier.

News related to pricing of Medical devices

- NPPA vide S.O. 2161 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 upto 30th Nov 2021. This has been further extended upto 30th June 2022 vide S.O. 2465(E) dated 30th May 2022.
- A meeting was held on 20.05.2022 through Video Conferencing under the Chairmanship of Member Secretary, NPPA to elicit the views of stakeholders and their recommendations on the implementation of Trade Margin Rationalization (TMR) on non-scheduled medical devices.
- The India Medical Devices CEO's Roundtable meeting was held under the chair of Hon'ble Minister of Chemicals and Fertilizers on 25.04.2022 during 7th edition of India Pharma and India Medical Devices 2022 (25-277 April 2022). Hon'ble MoS, M/oC&F, Member, Health, NITI Aayog, Secretary, DoPand seniorofficials of stakeholder departments / regulators viz, DoP, NPPA, DoHFW, CDSCO, GeM, DPIIT and other departments participated in the Round Table.

FDA Authorizes Moderna and Pfizer-BioNTech COVID-19 Vaccines for Children Down to 6 Months of Age (17th June, 2022)

The U.S. Food and Drug Administration authorized emergency use of the Moderna COVID-19 Vaccine and the Pfizer-BioNTech COVID-19 Vaccine for the prevention of COVID-19 to include use in children down to 6 months of age.

- For the Moderna COVID-19 Vaccine, the FDA amended the emergency use authorization (EUA) to include use of the vaccine in individuals 6 months through 17 years of age. The vaccine had been authorized for use in adults 18 years of age and older.
- For the Pfizer-BioNTech COVID-19 Vaccine, the FDA amended the EUA to include use of the vaccine in individuals 6 months through 4 years of age. The vaccine had been authorized for use in individuals 5 years of age and older.

Read more

FDA Approves First Systemic Treatment for Alopecia Areata (13th June, 2022)

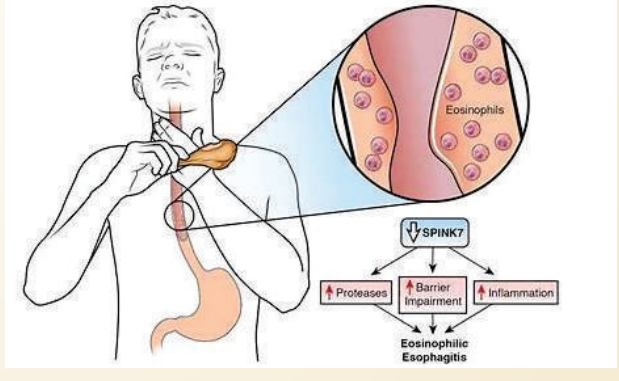
The U.S. Food and Drug Administration approved Olumiant (baricitinib) oral tablets to treat adult patients with severe alopecia areata, a disorder that often appears as patchy baldness and affects more than 300,000 people in the U.S. each year. This action marks the first FDA approval of a systemic treatment (i.e. treats the entire body rather than a specific location) for alopecia areata.

"Access to safe and effective treatment options is crucial for the significant number of Americans affected by severe alopecia," said Kendall Marcus, M.D., director of the Division of Dermatology and Dentistry in the FDA's Center for Drug Evaluation and Research. "Today's approval will help fulfill a significant unmet need for patients with severe alopecia areata."

Alopecia areata, commonly referred to as just alopecia, is an autoimmune disorder in which the body attacks its own hair follicles, causing hair to fall out, often in clumps. Olumiant is a Janus kinase (JAK) inhibitor which blocks the activity of one or more of a specific family of enzymes, interfering with the pathway that leads to inflammation.

Read more

FDA Approves First Treatment for Eosinophilic Esophagitis, a Chronic Immune Disorder (20th May, 2022)



The U.S. Food and Drug Administration approved Dupixent (dupilumab) to treat eosinophilic esophagitis (EoE) in adults and pediatric patients 12 years and older weighing at least 40 kilograms (which is about 88 pounds). This action marks the

first FDA approval of a treatment for EoE.

"As researchers and clinicians have gained knowledge about eosinophilic esophagitis in recent years, more cases of the disorder have been recognized and diagnosed in the U.S.," said Jessica Lee, M.D., director of the Division of Gastroenterology in the FDA's Center for Drug Evaluation and Research. "Today's approval will fulfill an important unmet need for the increasing number of patients with eosinophilic esophagitis."

EoE is a chronic inflammatory disorder in which eosinophils, a type of white blood cell, are found in the tissue of the esophagus. In adults and adolescent patients with EoE, common symptoms include difficulty swallowing, difficulty eating, and food getting stuck in the esophagus. Dupixent is a monoclonal antibody that acts to inhibit part of the inflammatory pathway.

Read more

Global regulators work towards strengthening collaboration on observational research beyond COVID-19 pandemic (20th June 2022)

Lessons learned from international collaboration on observational research during the pandemic were highlighted during the latest global regulatory workshop on COVID-19 observational studies and real-world data. The workshop, organised under the umbrella of the International Coalition of Medicines Regulatory Authorities (ICMRA), was co-chaired by Health Canada and the European Medicines Agency (EMA) and took place on 20 May 2022. The main findings of the workshop are summarised in a report.

International regulators are working together to enhance global capabilities for observational research in the context of the COVID-19 pandemic and beyond. Real-world evidence generated from observational research is critical to understanding the safety and effectiveness of medicines when used in clinical practice for the prevention and treatment of COVID-19.

Read more

EMA recommends withdrawal of marketing authorisation for amfepramone medicines (10th June, 2022)

EMA's safety committee (PRAC) has recommended the withdrawal of EU marketing authorisations for amfepramone obesity medicines.

The recommendation follows a review which found that measures to restrict the use of these medicines for safety reasons have not been sufficiently effective. It found that the medicines were being used for longer than the recommended maximum period of 3 months, thereby potentially increasing the risk of serious side effects, such as pulmonary arterial hypertension (high blood pressure in the arteries of the lungs) and dependency. The medicines were also being used in patients with a history of heart disease or psychiatric disorders, increasing their risk of heart and psychiatric problems. In addition, there was evidence of use during pregnancy, which could pose risks to the unborn baby.

Read more

Top 300 drug brands to now have QR codes on label

The Union government has introduced quick response (QR) codes to ensure authenticity and traceability of 300 common drug brands, including analgesics, vitamins, diabetic, and hypertension medicines, among others.

The Union Ministry of Health has made amendments to the Drugs Rules, 1945, to implement this. In March, the ministry had asked the department of pharmaceuticals (DoP) to shortlist 300 drug brands that can be included for implementation of mandatory QR codes. The National Pharmaceutical Pricing Authority (NPPA) had identified the list of 300 drugs, which include widely used medicines, such as painkillers, contraceptives, vitamins, blood-sugar, and hypertension medicines.

Popular brands, such as Dolo, Allegra, Asthalin, Augmentin, Saridon, Limcee, Calpol, Corex, Thyronorm, Unwanted 72, were identified. These high-selling brands have been shortlisted based on their moving annual turnover (MAT) value.

In the draft notification issued on June 14, the ministry said the manufacturers of the formulation products will print or affix bar code or QR code on its primary packaging label and on the secondary package label that store data or information legible with software application to facilitate authentication.

The stored data or information will include unique product identification code, proper and generic name of the drug, brand name, name and address of the manufacturer, batch number, date of manufacturing, date of expiry, and manufacturing licence number. SOHINI DAS

महंगी दवाई पर कड़ाई

भास्कर ब्रेकिंग

प्रशांत गुप्ता | रायपुर

कोरोनाकाल में जिन दवाइयों की मांग आई, उनमें जमकर ब्लैकमार्केटिंग हुई। प्रदेश में ओवररेट की शिकायतें इतनी ज्यादा थीं कि ड्रग कंट्रोलर जांच ही नहीं कर पाए। अब प्रदेश कोरोना से उबर चुका है और सरकारी तंत्र ने दवाइयों की कालाबाजारी और ओवररेट पर काबू करने की तगड़ी तैयारी की है। प्रदेश में दवाइयों के मूल्य नियंत्रण के लिए पूरी तरह से स्वतंत्र एजेंसी प्राइज मानिटरिंग रिसोर्स यूनिट (पीएमआरयू) का गठन कर लिया गया है। यह यूनिट केंद्र की एजेंसी नेशनल प्राइस कंट्रोल अथॉरिटी (एनपीपीए) के निर्देश पर बनाई गई है। आम लोग किसी भी दवा का रेट एमआरपी से अधिक रहने, स्टॉक होने के बावजूद नहीं देने या एमआरपी से छेड़छाड़ की शिकायत सीधे पीएमआरयू से करेंगे। यह यूनिट अधिकतम् दो माह में प्रदेश में एक्टिव हो जाएगी। इससे पहले ही शिकायत के लिए टोल फ्री नंबर, शिकायत पोर्टल और ई-मेल एड्रेस भी जारी कर दिए जाएंगे।

फिलहाल 29 राज्यों और 9 केंद्र शासित प्रदेशों में दवाओं के ओवररेट पर निगरानी के लिए सिर्फ एनपीपीए ही थी। राज्यों में केवल ड्रग कंट्रोलर विभाग है, जिसके इंस्पेक्टर शिकायत पर सैंपल लेकर कार्रवाई करते हैं। इसमें स्टाफ काफी कम है, इसलिए हर शिकायत का निराकरण नहीं हो पाता। इसलिए राज्यस्तरीय एजेंसी के गठन का फॉर्मूला निकाला गया। छत्तीसगढ़ में इस संबंध में कार्रवाई तेज है।

Also, a news article was published in front page of Dainik Bhaskar, Chhattisgarh newspaper regarding PMRU and its functions.

प्रदेश में कालाबाजारी-ओवररेट की शिकायत के लिए जारी होगा टोल-फ्री नंबर, मेल आईडी

क्योंकि कोई भूला नहीं है... 900 का रेमडेसिविर इंजेक्शन 25-30 हजार में बिका था

कोरोनाकाल में कुछ दवाइयों की ऐसी ब्लैकमार्केटिंग की गई, जिसे लोग भूल नहीं पाएंगे। सबसे ज्यादा कालाबाजारी रेमडेसिविर इंजेक्शन की हुई। इसकी मूल कीमत प्रति इंजेक्शन 900 रुपए है, लेकिन यह कोरोनाकाल में जरूरत के दौर में 30-30 हजार रुपए में बिका। छह इंजेक्शनों का डोज जरूरतमंदों ने दो-दो लाख रुपए में भी खरीदा। यही हाल उन टैबलेट्स का भी रहा, जिन्हें कोरोना से इलाज में थोड़ा कारगर माना गया था। फ्लू के इंजेक्शन की कीमत भी अधिक वसूली गई। पीएमआरयू सदस्यों के मुताबिक इसे पूरी तरह रोकने का दावा तो नहीं है, लेकिन कालाबाजारियों में डर रहेगा।

फैक्ट फाइल

- प्रदेश में 14000 दवा दुकानदार, हर माह 500 करोड़ का कारोबार
- यहां से ओड़िशा, मध्यप्रदेश, झारखंड, महाराष्ट्र में भी दवा सप्लाई

पीएमआरयू की टीम में

पीएमआरयू में खाद्य एवं औषधि प्रशासन विभाग के नियंत्रक को अध्यक्ष नामित किया गया है। सहायक औषधि नियंत्रक सदस्य हैं। दवा विक्रेताओं की तरफ से एक सदस्य नामित किया गया है। एक नोडल अधिकारी हैं। इनके अतिरिक्त 5 फील्ड अफसर नियुक्त होंगे।

ग्राहक बनकर करेंगे जांच

छत्तीसगढ़ पीएमआरयू के सदस्य अविनाश अग्रवाल ने बताया कि यूनिट में सोसाइटी सदस्यों के अतिरिक्त ऐसा स्टाफ भी नियुक्त किया जा रहा है, जो दवा दुकानों में ग्राहक बनकर जांच करेगा। ये दवाएं खरीदकर एमआरपी से मिलान करेंगे। अंतर आया तो तुरंत कार्रवाई करेंगे।

पीएमआरयू को दवा निर्माता पर भी कार्रवाई का अधिकार

दवा की कीमतों पर निगरानी के लिए पीएमआरयू का गठन कर लिया है। स्टाफ की भर्ती इसी महीने हो जाएगी। इस यूनिट को सीधे दवा निर्माता के विरुद्ध कार्रवाई के अधिकार दिए गए हैं।

-कमलकांत पाटनवार, नोडल अधिकारी-पीएमआरयू

Observance of 8th International Day of Yoga on 21.6.2022 in NPPA

- NPPA celebrated the International Day of Yoga on 21.6.2022 in the lawn of YMCA's Tourist Hostel. All the employees including contractual staffs (YP/Consultat/DEO/drivers etc) participated in this program and performed various asanas (yoga postures) for one hour.

- A yoga instructor demonstrated different types yoga postures and explained the benefit of each yoga asana. He also explained that how yoga can be helpful to keep a balance between the body and the mind. At the end of the demonstration, Chairman, NPPA also explained the physical and mental health benefits of yoga. He emphasized that yoga should be part of day to day activity and we should practice it regularly to reduce levels of stress and prevent lifestyle diseases.

- For promotion of yoga, banners mentioning International Day of Yoga were displayed around the building and T-shirts/yoga mat with prints of IDY2022 were distributed to all the employees including contractual staff.

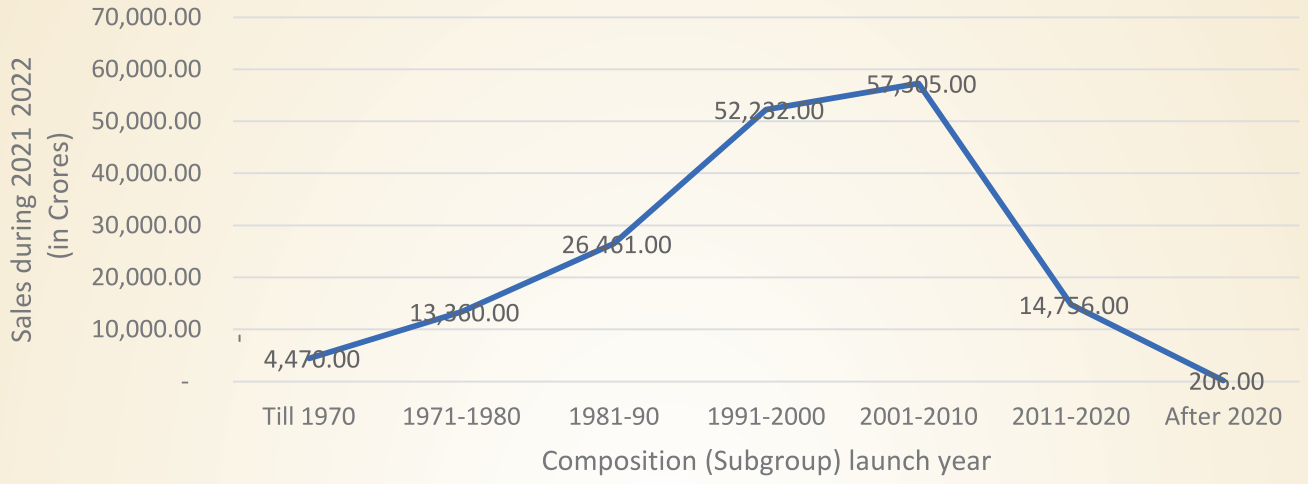
Information Education and Communication (IEC) Activities by NPPA and PMRUs

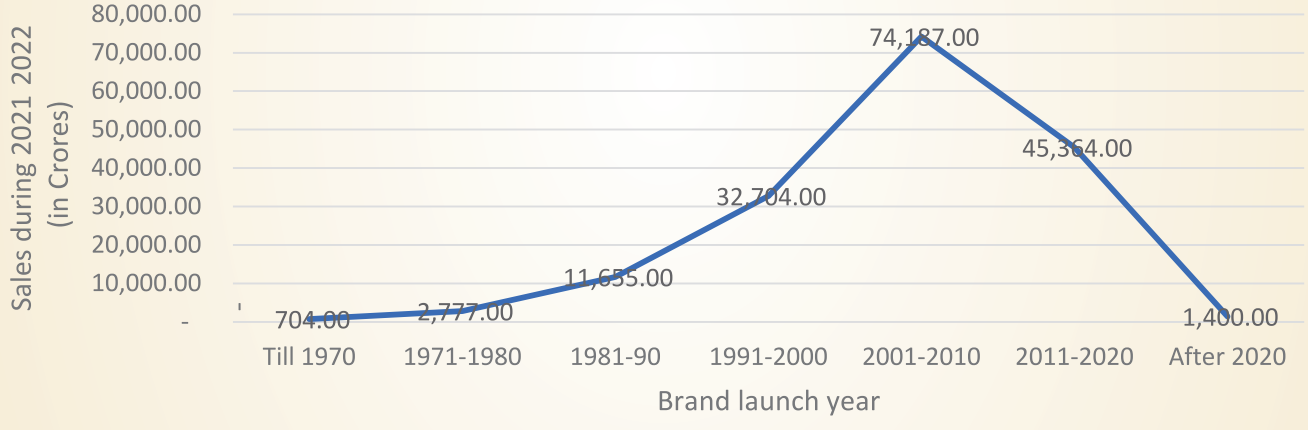
NPPA had organized a one-day webinar on 12.05.2022, on "Expenditure Booking in PFMS and UC Generation". The main aim of this webinar was to provide training to PMRU staff for booking their expenditure details in PFMS and how to generate Utilization Certificate.

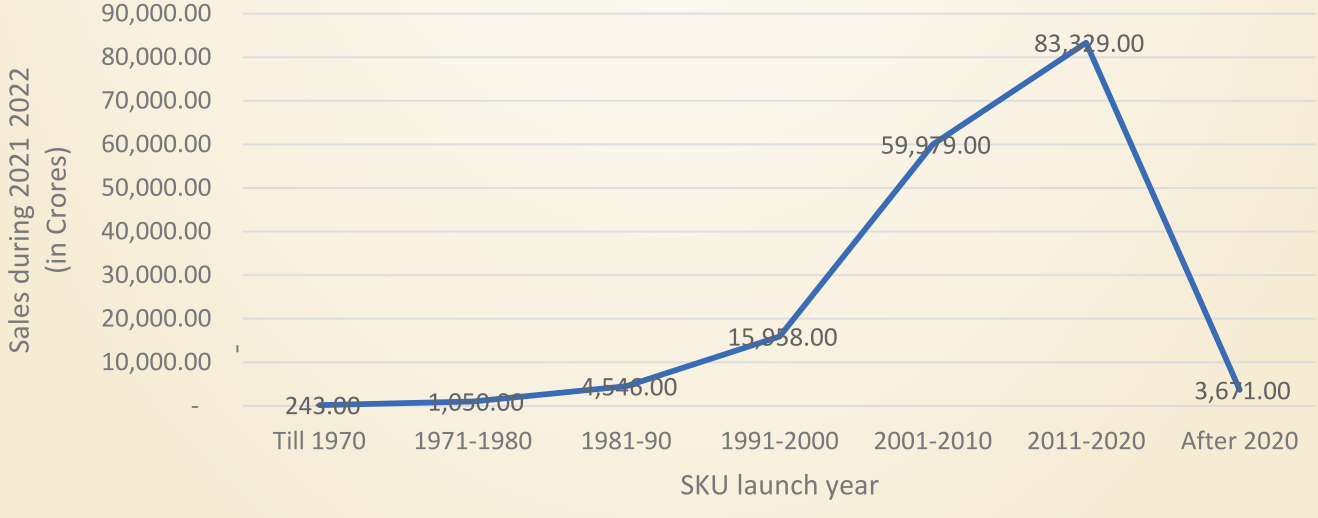
Further, a seminar was conducted at Lajpat Bhawan, Kanpur District on 20.05.2022 by PMRU, Uttar Pradesh. The seminar was attended by Drug Controlling and Licensing Authority, Uttar Pradesh/ Member Secretary, PMRU, U.P., Drug Control Officer, Head Quarter, Assistant Commissioner of Drug & Drug Control Officer, Kanpur Division, Medicine Retailer and Whole Sellers of Kanpur, Drug Manufacturers and Various other professionals. The seminar was attended and reported by several News agencies in newspapers and social media.

INDUSTRY TRENDS

The below tables indicate the bifurcation of the Annual sales value during 2021-2022 of the pharmaceutical industry, which is around Rs. 1,68,791 Crores, based on the launch year of the composition, brands and SKUs







FREQUENTLY ASKED QUESTIONS

- **Can a company stop the production/ sale of medicines if it is non-profitable?**

  Any company intending to discontinue any scheduled drug from the market shall issue a public notice and also intimate the Government, at least six months prior to the intended date of discontinuation. However, in case of non-scheduled drugs, the companies can change their product portfolio.

- **What action would be taken on such intimations filed with the Government?**

  NPPA examines all discontinuation intimations in accordance with discontinuation guidelines dated 14-08-2020. The said guidelines are available on NPPA website.

- **What if a discontinuation intimation is not in public interest and it may lead to non-availability of essential medicines drugs?**

  The Government may, in public interest, direct the manufacturer of the scheduled drugs to continue with required level of production or import for a period of one year from the intended date of such discontinuation.

  In case further continued production/ sale is considered necessary in public interest, the Government may direct the applicant to maintain/ increase the production by invoking Para 3 of DPCO, 2013.

- **What are the penal provisions for violations of directions given by NPPA?**

  Any violation of directions issued under Para 3 or 21 of DPCO, 2013 is punishable under Section 7 of the Essential Commodities Act, 1955, which provides for imprisonment and fine.

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

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)

Follow us: @nppa_india @india.nppa