आज़ादी का अमृत महोत्सव

NATIONAL PHARMACEUTICAL PRICING AUTHORITY
DEPARTMENT OF PHARMACEUTICALS
MINISTRY OF CHEMICALS & FERTILIZERS
GOVERNMENT OF INDIA

NPPA
AFFORDABLE MEDICINES FOR ALL
सभी के लिए वहनीय दवाईयाँ

AUSHADH SANDESH

Vol.-I | OCTOBER, 2021

A Bi-monthly e-Newsletter

Committed Towards Accessibility, Availability & Affordability of Medicines for All

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. 701(E) dated 10th 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.

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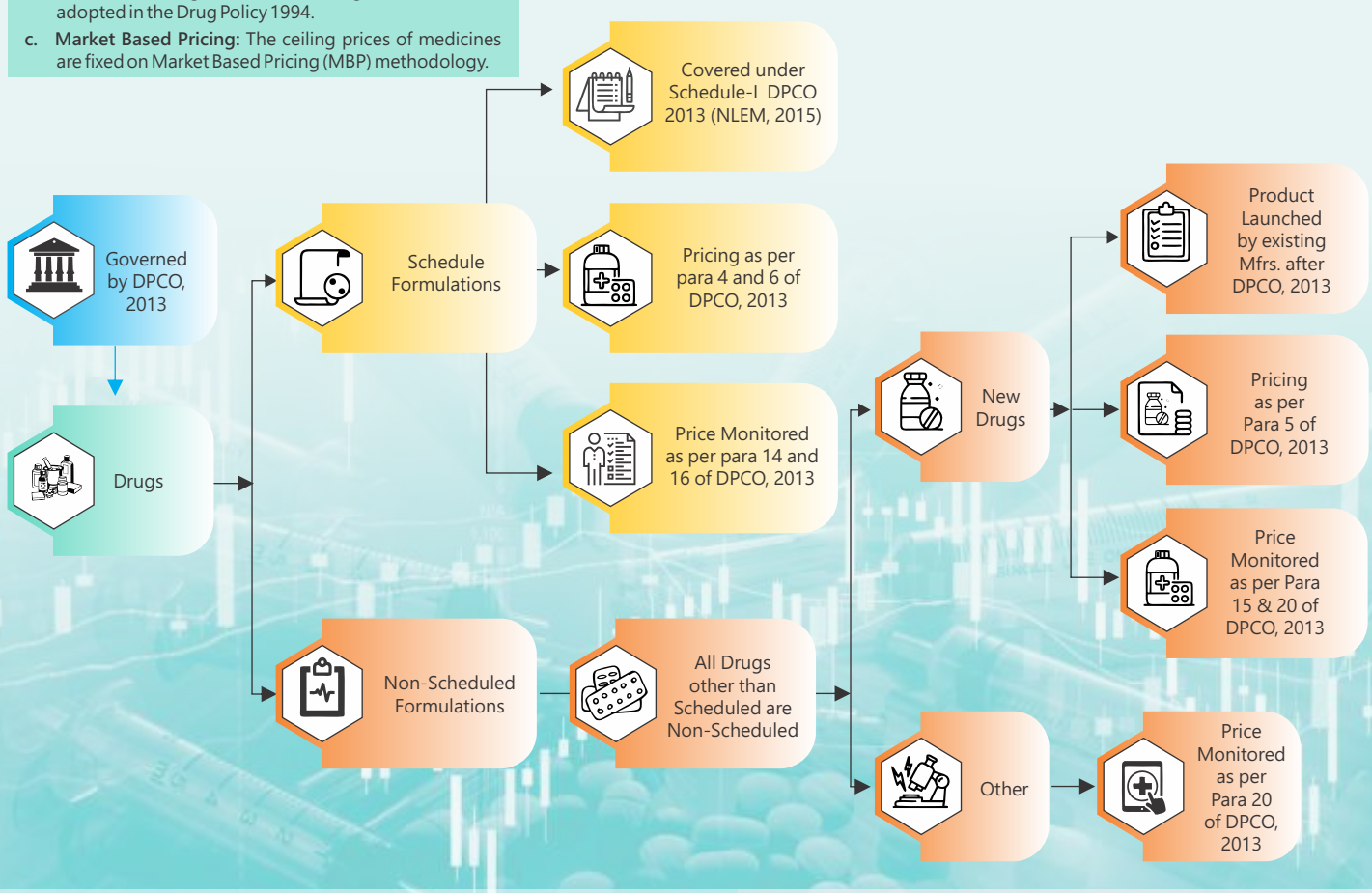
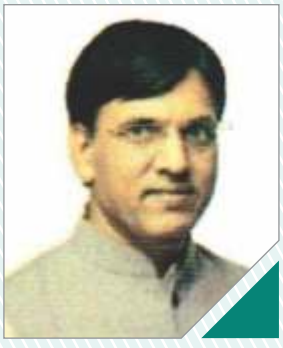


DISCLAIMER:
This is an initiative by NPPA to report current events and affairs related to Pharmaceutical industry and the NPPA. This newsletter has been curated purely for informative purposes and do not reflect the official policy or position of NPPA. This newsletter is not intended to be used for any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

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

MESSAGE

सत्यमेव जयते



Dr. Mansukh Mandaviya
Minister for Health & Family Welfare
and Chemicals & Fertilizers
Government of India

I am happy to note that the National Pharmaceutical Pricing Authority (NPPA) is bringing out a bi-monthly e-Newsletter.

The launch of this Newsletter is timely and much needed to disseminate the work being done by NPPA and also informs about the government policies in the Pharmaceutical sector including the good work being done both by the government as well as the private sector.

NPPA provides the price regulatory framework for all the drugs notified under Schedule-I of the DPCO, 2013 as well as the non-scheduled drugs so that they remain affordable to the public.

NPPA's role as a regulator is to work towards a Healthy Nation by making medicines accessible and affordable while creating an enabling environment for the sector as a whole. NPPA invites the cooperation of all stakeholders in this endeavour.

I am sure that the Newsletter will prove to be a wonderful platform for communication to all the stakeholders. On this occasion, I would like to extend my appreciation to Team NPPA for this initiative.

(Dr. Mansukh Mandaviya)

MESSAGE

सत्यमेव जयते

Shri Bhagwanth Khuba
Minister of State for
Chemicals & Fertilizers and
New & Renewable Energy
Government of India

It gives me immense pleasure to bring to you the first edition of the bi-monthly e-Newsletter brought out by the National Pharmaceutical Pricing Authority (NPPA) under my Ministry. I am sure the Newsletter would help the stakeholders to stay abreast with the latest information on NPPA work, government policies, and upcoming events.

NPPA has taken various steps to ensure the affordability of drugs and medical devices throughout the country. All these endeavours call for an effective platform to quickly reach out to the stakeholders in disseminating new initiatives, governmental policies and the e-Newsletter is a step in the right direction.

I am confident; it would serve as one of the important medium for disseminating information among the stakeholders especially amongst manufacturers, consumers, youth and entrepreneurs across the country.

I extend my compliments to Shri Kamlesh Kumar Pant, IAS, Chairman and his team at NPPA for bringing out the first edition of the bi-monthly e-Newsletter.

I take this opportunity to extend my best wishes to the stakeholders and readers.

(Bhagwanth Khuba)

Dated : 26th October, 2021

MESSAGE

सत्यमेव जयते

Professor K. VijayRaghavan
Principal Scientific Adviser
to the Govt. of India

I take great pleasure in launching the first bi-monthly e-Newsletter of National Pharmaceutical Pricing Authority (NPPA), which is both important and timely.

Besides fulfilling its primary role of ensuring affordability of drugs, NPPA has been at the forefront in dealing with issues related to availability of drugs, especially during the Covid-19 waves when availability of drugs was of grave concern.

In this edition, the multi-faceted efforts of NPPA in various areas like affordability and availability of drugs; stories of their translation to benefit of common people and key macro indicators for pharmaceutical industry is being presented in a comprehensive manner, which is both informative and easy, to read.

I must compliment the Chairman, NPPA and his team for this initiative and encourage the editorial board in their endeavour.

K. VijayRaghavan

(K. VijayRaghavan)

Dated : 25th October, 2021

MESSAGE

सत्यमेव जयते

Ms. S. Aparna
Secretary
Department of Pharmaceuticals
Ministry of Chemicals & Fertilizers
Government of India

It gives me immense pleasure to introduce the first edition of the bi-monthly e-Newsletter, published by the National Pharmaceutical Pricing Authority (NPPA). The e-Newsletter is an outcome of the endeavour to inform and educate stakeholders about the latest regulatory initiative of NPPA, policies of the government and current developments regarding the pharma sector etc.

In addition to its core function of regulating prices, NPPA has taken a number of steps to ensure the availability of essential drugs during the COVID-19 pandemic in the country. NPPA and CDSCO worked in close coordination under the overall guidance of Department of Pharmaceuticals and actively monitored the equitable distribution of drugs required for COVID 19 treatment to address the supply gaps and stabilize the demand. This was achieved through proactive engagement with the state government, manufacturers/ importers; Industry Associations across all segments of the sector including retail; State Drug Controllers (SDCs) etc. NPPA continues to work tirelessly and systematically to ensure availability of drugs through the pandemic.

I am confident that this e-Newsletter would serve as a useful platform for showcasing the best practices, latest developments and success stories in the pharma sector. I commend the effort and talent that has gone into this initiative.

I encourage the team in their endeavour and wish you a happy reading.

Aparna

(S. Aparna)

Dated : 26th October, 2021

CHAIRMAN'S DESK

सत्यमेव जयते

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 first 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. For the first time, NPPA is expanding its physical presence outside Delhi, through the Price Monitoring and Resource 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.

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.

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)

Dated: 27th October, 2021

National List of Essential Medicines (NLEM): Important tool for accessibility and affordability of quality medicine in India

Gupta YK[1] Pahuja M[2,] Mathur K[2], Bhargava B[3]

[1]Former Dean (Academics), and Head, Department of Pharmacology, AIIMS, New Delhi, Vice Chairman, Standing National Committee on Medicines, GOI, Principal Advisor India Strategy Development – Global Antibiotics Research and Development Partnership (GARDP)

[2]Scientist, Division of Basic Medical Sciences, Indian Council of Medical Research, New Delhi

[3]Secretary to the Government of India, Department of Health Research, Ministry of Health & Family Welfare and Director General, Indian Council of Medical Research, New Delhi and Chairman Standing National Committee on Medicines, Government of India

Introduction

High investments in drug discovery, production, and marketing lead to high cost of medicines. Globally, there is an increase in cost of healthcare services and low- and middle-income nations, in particular are under pressure to devise policies for affordable medicines accessible to their citizens. The affordability of medicine is measured in terms of an unskilled worker's daily wage that can be spent on health care, specifically drugs. It is a challenge for the governments to provide quality and affordable health-care services while also keeping (public) health-care spending capped.

A sizable segment of the Indian populace pays for their health care out of their own pocket. Thus, the need of limited number of carefully selected essential medicines become obligatory, which aid in better medicine management (because the medicine number is manageable), improved access to medicines, and cost effectiveness.

What is National List of Essential Medicines (NLEM)?

Essential Medicines are those that satisfy the priority health care needs of any population, based on efficacy, safety, quality, and total cost of the treatment. The aim behind formulating essential medicine list (EML) is to ensure that these medicines are available in adequate amounts, in appropriate dosage forms and strengths with assured quality. The Indian National List of Essential Medicine (NLEM) is also characterized by these features and is basically a list of medicines that are safe, efficacious, collectively address the majority of the public health concerns of India and are cost effective.

NLEM is further intended to promote rational use of medicines. The NLEM was first published in India in the year 1996 and included 279 medicines. Later, it was revised in the year 2003, 2011, and 2015 and now in 2021.

Furthermore, drugs are also classified based on their essentiality and need for being stocked in a primary, secondary, or tertiary care facility. The drugs that are included are single medicines and not a fixed-dose combination unless the combination is rational and has a proven benefit (such as, the combination has proven to be advantageous over individual ingredients administered separately, in terms of increasing efficacy, reducing adverse events, and/or improving compliance). Finally, the drug should be licensed in India and be aligned with the disease's current treatment guidelines.

Balance of affordability and essentiality in NLEM

There may be situations where certain medicines or formulations may have some advantage over others in similar class, but the high cost differential may not merit their inclusion in NLEM. As a corollary, there may also be a situation where a medicine/ formulation are included in NLEM despite it being more expensive as it has significant advantage of safety and/or efficacy. However, considering the socioeconomic conditions, the less expensive, other formulation may also find a place in the list.

Hierarchical Healthcare Structure in India

In India, the health care system is categorized as a three-tier system with primary, secondary and tertiary levels having different health care concerns and medicine requirements. While a primary health care level setup may require medicines prescribed in an outpatient setup like basic antibiotics, analgesics and anti-inflammatory drugs; a tertiary level setup might need more medicines administered through parenteral routes, medicines for critical care settings, for specialized treatments like organ transplantation and for inpatient setup. Thus, the essentiality of medicines also depends upon the hierarchy of the health care system, and hence there is need to stratify the recommendation for inclusion of medicines at:

(P) = Primary care facility; (S) = Secondary care facility and (T) = Tertiary care facility

Various purposes that can be served by National List of Essential Medicines

- Promote the rational use of medicines
- Guide safe and effective treatment of priority disease conditions of a population and optimize the available health resources of the country.
- It can also serve as a guiding document for:
  - State governments to prepare their list of essential medicines
  - Developing Standard Treatment Guidelines
  - Help in preparing hospital formularies
  - Procurement and supply of medicines in the public sector as well as private sector hospitals
  - Reimbursement of cost of pharmaceutical products by employers
  - Reimbursement by insurance companies
- Identifying the 'MUST KNOW' domain for the teaching and training of health care professionals (medical, dental, pharmacy and nursing).

The process of revision of NLEM

Ministry of Health & Family Welfare (MoHFW), Government of India, constituted Standing National Committee on Medicines (SNCM) under the chairmanship of Prof. Balram Bhargava, Secretary, Department of Health Research (DHR) and Director General, Indian Council of Medical Research (ICMR), and Prof. Y.K. Gupta, Formerly Head, Department of Pharmacology and Dean, All India Institute of Medical Sciences (AIIMS), New Delhi as its Vice Chairman. The notification provided the list of experts of different disciplines from across the country with a provision that the chairman may consult other experts as and where required. The revision process of NLEM included following steps:

PROCESS OF REVISION OF NLEM 2021

Consulting various source documents of medicines

- NLEM2021and 2015
- WHO EML 2019 and EMLc 2019
- National Formulation of India 2016
- National Health Programmes
- Standard Treatment Workflows, Treatment guidelines of association, and professional bodies
- Newsletters of Pharmacovigilance Programme of India

Stakeholders' meetings with officials from:

Ministry of Health and Family Welfare, Ministry of AYUSH, Department of Consumer Affairs, Department of Pharmaceuticals, NPPA, CDSCO, IPC, NGOs, pharmaceutical industry associations and patent groups

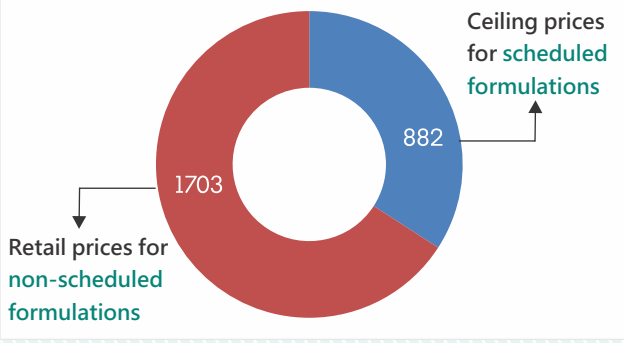
Nationwide consultations to review the recommendations of all subject experts meetings, deliberations on the submissions of NGOs, pharmaceutical associations, patient groups and other stakeholders.

SNCM's vision for revision of NLEM: The way forward

Globally as well as in India, the therapeutics and pharmaceutical landscape have changed rapidly with the advent of newer technologies and incremental innovations. Continuous and critical analysis of such technologies is warranted in the form of standardized and validated Health Technology Assessment (HTA) protocols and it is recommended that this be taken up on priority as part of SNCM activity. Indian healthcare ecosystem is cost sensitive due to minimal insurance coverage and lesser public spending on healthcare. NLEM, 2021 was released in September, 2021 and one of the cornerstones of SNCM is to identify drugs/medicines of public importance so as to improve their accessibility through suitable executive interventions. Such identification needless to say is a dynamic process, based on regular accrual of country specific data and is subject to continuous refinement. Analysis of associated factors that affect cost (such as cost of therapy, cost of ADRs, cost of diagnostic tests, loss of wages, hospital admission costs, cost of travel etc) have to be taken in cognizance and incorporated into pharmacoeconomics decision making process.

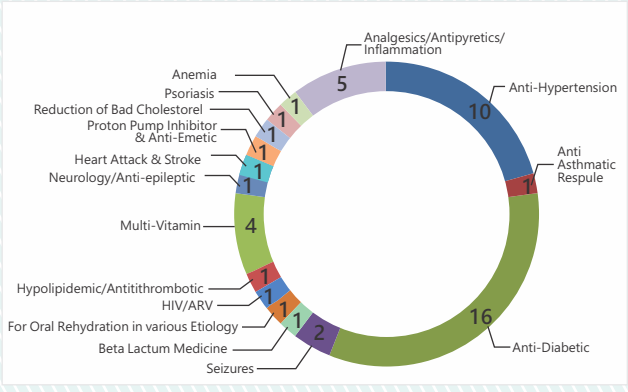
NEWS RELATED TO PRICING OF DRUGS

Ceiling prices for 882 scheduled formulations (National List of Essential Medicines, 2015) and Retail prices for 1703 non-scheduled formulations have been fixed under DPCO, 2013 till 25th September 2021.



As on 08.09.2021, over all 224 Authority meetings have been conducted, 92 of which are under DPCO 2013. The 223rd (Overall) and the 91st meeting of the Authority was held on 29.07.2021.

Retail prices of 25 and 23 new drugs for various Pharmaceutical companies were fixed in the 91st and 92nd meeting of the Authority held in July & September 2021 under DPCO 2013 respectively.



Details of Prices fixed for various formulations in 91st and 92nd Authority Meetings are given in Table No.1.

Table No. 1

S. No.	Therapeutic group	Total Number	Type of formulation	Retail Price fixed (Rs. Per unit)	Range (Rs.)
1	Anti-Hypertension	10	Tablet		5.00-13.39
2	Anti asthmatic respule	1	Respule	17.79	
3	Anti-Diabetic	16	Tablet		6.25-11.17
4	Seizures	2	Tablet		91.56-148.72
5	Beta Lactum Medicine	1	Tablet	21.97	
6	For oral rehydration in various etiology	1	Solution	0.15	
7	HIV/ARV	1	Tablet	59.8	
8	Hypolipidemic/ Antithrombotic	1	Capsule	16.55	
9	Muti-Vitamin	4	Tablet		5.36-17.12
10	Neurology/ Anti-epileptic	1	Injection	91.56	
11	heart attack and stroke	1	Capsule	19.64	
12	Proton Pump inhibitor and Anti-Emetic	1	Tablet	10.00	
13	Reduction of bad Cholestorel	1	Tablet	33.14	
14	Psoriasis	1	Gel (per gram)	13.21	
15	Anemia associated with cancer and cancer chemotherapy, HIV infected patients on Zidovudirie, adult surgery patients in an autologous pre-donation program and peri-surgery patients without antologous blood donation	1	Pack	2054.82	
16	Analgesics / Antipyretics/ Inflammation	2	Tablet		2.81-33
		2	Syrup	295.58	0.64 per ml 295.58 per 100 ml pack
		1	Gel (per gram)	2.70	

Table No. 2

Drug	Extended Till	Effective Order
Heparin Injection 5000IU/ml and 1000IU/ ml	31.03.2022 or until further order whichever is earlier	S.O. No. 2151(E) dated 30.06.2020
Liquid Medical Oxygen (LMO) and Oxygen Inhalation (Medicinal gas) in cylinder	31.12.2021 or until further order, whichever is earlier	S.O. No. 1335(E) dated 25.03.2021
Orthopaedic Knee Implants for Knee Replacement System	15.09.2022	S.O. 3670(E) dated 10.09.2021

During the 92nd meeting of the Authority under DPCO 2013, the prices of above items (Table No. 2) were also extended in public interest.

NEWS RELATED TO PRICING OF MEDICAL DEVICES

The National Pharmaceutical Pricing Authority (NPPA), with an aim to regulate the prices of medical devices, essential for diagnostic purposes, in general and specifically for COVID-19 management, had issued Gazette Notification No. 2808 (E) dated 13th July 2021 which capped Trade Margin at Price to Distributor (PTD) at 70% for medical devices, namely, Pulse Oximeter, Blood Pressure Monitoring Machine, Nebulizer, Digital Thermometer, and Glucometer. The maximum retail prices (MRPs) are capped with the Trade Margin Rationalisation (TMR) for 5 Medical Devices.

The notification mandates to fix the Maximum Retail Price (MRP) as per the specified formula: "Maximum Retail Price = Price to Distributor (PTD) + (PTD x TM) + Applicable GST, Where TM = Trade Margin not exceeding 70%."

NPPA vide OM dated 14th July 2021 directed manufacturers / importers of these medical devices to submit revised MRPs of their products, in pursuance to the aforesaid Notification. Based on the data provided, the downward revision of MRP has been reported by imported and domestic brands across all the categories. The details are given in Table No. 3.

Earlier, NPPA notified price regulation for Oxygen Concentrators through Trade Margin Rationalization Approach on 03rd June 2021.

Impact:

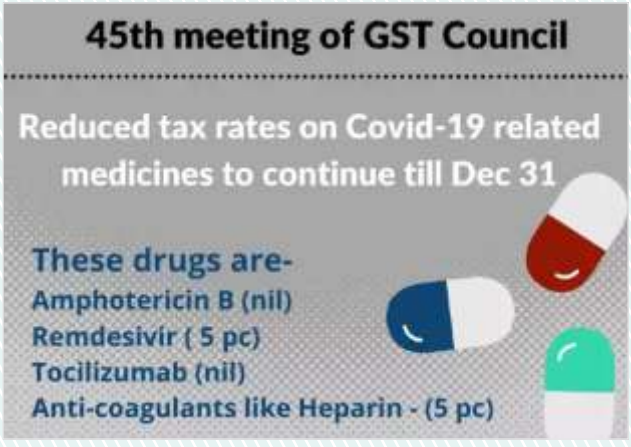
- Price reduction in 70 out of 252 products observed.
- MRP reduced up to 54% (up to Rs. 54,337).
- Pricing of Oxygen Concentrators did not adversely impact domestic production.
- No disruption in supplies were observed.

Table No. 3 : Impact of TMR on Prices of Medical Devices

DATA REPORTED BY MANUFACTURERS AND IMPORTERS					
Sl. No	Classification Wise	No of Product Reported after the Notification	No of Brands reported Downward revision of MRP	Decrease in MRP (Rs)	Decrease in MRP (%)
(1)	(2)	(3)	(4)	(5)	(6)
1	Pulse Oximeter	277	137 (90%)	12 - 295 375	1% - 89%
2	Blood Pressure Monitoring Machine	329	306 (93%)	20 - 38776	1% - 83%
3	Glucometer	105	84 (80%)	30 - 2250	1% - 98%
4	Digital Thermometer	164	148 (90%)	8 - 44775	1% - 89%
5	Nebulizer	257	244 (95%)	56 - 6165	1% - 83%
	Total	1132	1033 (91%)		

OTHER RELATED NEWS

GST council has decided to extend the concessional rates on drugs used in COVID-19



treatment till December 31, 2021. The council has decided that no tax will be levied on medicines like the monoclonal antibody Tocilzumab and Amphotericin B, used for treating Black Fungus.

Read more

India achieves the major milestone of 'one billion' vaccinations

Addressing the nation, the Prime Minister lauded the difficult but remarkable feat of administering 100 crore vaccine doses.. He attributed this achievement to the dedication of 130 crore countrymen and said this success is the success of India and the success of every countryman. He said 100 crore vaccinations are not just a figure, but a reflection of the strength of the country, it is the creation of a new chapter of history. This is a picture of a new India that sets difficult goals and knows how to achieve them.

Read more

INTERNATIONAL NEWS

ECDC and EMA highlight considerations for additional and booster doses of COVID-19 vaccines

As per the Press release dated 2nd September, 2021, EMA has stated that based on current evidence, there is no urgent need for the administration of booster doses of vaccines to fully vaccinated individuals in the general population, according to a technical report issued yesterday by the European Centre for Disease Prevention and Control (ECDC). The report also notes that additional doses should already be considered for people with severely weakened immune systems as part of their primary vaccination.

Read more

INCB, UNODC and WHO Joint Statement on Access to Controlled Medicines in Emergencies (WHO press release dated 8th September 2021)

United Nations Office on Drugs and Crime

UNODC

Access to controlled medicines in humanitarian emergencies remains constrained: Recognizing World Humanitarian Day 2021, the International Narcotics Control Board (INCB), the United Nations Office on Drugs and Crime (UNODC) and the World Health Organization (WHO) once again call on governments to facilitate access to medicines containing controlled substances in emergency settings, including during pandemics and the increasing number of climate-related disasters.

Read more

Stories from the field: How vaccines can help to prevent antibiotic resistance - Zimbabwe's response to drug-resistant outbreaks of typhoid and cholera. (WHO release dated 11 September 2021)

Antibiotic resistance is a natural phenomenon that happens when bacteria develop the ability to defeat the drugs designed to kill them. The germs change over time, no longer responding to medicines thus making infections harder, and sometimes impossible, to treat. This, in turn, results in higher health care costs for both individuals and governments. "Preventing and controlling antibiotic resistance calls for a multi-pronged approach, of which vaccines is one", says Dr Stanley Midzi, WHO Health Systems Strengthening Advisor.

Read more

First monoclonal antibody treatment for COVID-19 approved for use in the UK

As per the Press release dated 20th August 2021, the Medicines and Healthcare products Regulatory Agency (MHRA) has given approval for the first monoclonal antibody treatment for the prevention and treatment of COVID-19 in the UK.

Read more

FDA approves new treatment for Pompe disease

As per press release dated 06th August 2021, the U.S. Food and Drug Administration approved Nexviazyme (avalglucosidase alfa-ngpt) for intravenous infusion to treat patients 1 year of age and older with late-onset Pompe disease. Patients with Pompe disease have an enzyme deficiency that leads to the accumulation of a complex sugar, called glycogen, in skeletal and heart muscles, which cause muscle weakness and premature death from respiratory or heart failure.

Read more

COVID MANAGEMENT RELATED INITIATIVES OF NPPA

NPPA has taken a number of steps to ensure the availability of medicines throughout the country in response to COVID-19. Some of them are as under:

- To address the supply gaps and stabilize the demand for Remdesivir, Tocilizumab and Amphotericin, NPPA monitored equitable distribution of these drugs as per allocation given by DoP, in close coordination with nodal officer of the State/UT governments and Liaison officers of the manufacturers

- Taken various steps to ensure the availability of life saving essential drugs like Hydroxychloroquine, Paracetamol, Anti-Tuberculosis drugs, Anti-diabetic drugs, Cardiac drugs, anti-cancer drugs etc.

- Extended ceiling price of Liquid Medical Oxygen (LMO) & Medical Oxygen Gas (in cylinders) and Heparin up to 31.12.2021 and 31.03.2022 respectively or till further order.

- To facilitate availability and ensure affordability of selected medical devices, NPPA capped the trade margin for Oxygen Concentrators at 70% on Price to Distributor (PTD) level vide notification dated 3rdJune 2021 and on Pulse Oximeter, Glucometer, BP Monitor, Nebulizer and Digital Thermometer vide notification dated 13th July, 2021.

- Setting up a Control Room (Helpline No.-1800111255/ Email: monitoring-nppa@gov.in) to receive complaints on availability on medicines and to undertake efforts to address the issues promptly by coordinating with the State authorities, manufacturers, marketers and their associations.

EVENTS

PMRU, Goa celebrated World Pharmacist day

Indian Pharmaceutical Association, Goa State Branch in association with Directorate of Food and Drugs Admin and Goa College of Pharmacy, celebrated World Pharmacist Day on 25.9.21 at Goa College of Pharmacy, Panaji. Health Minister, Govt of Goa Shri Vishwajit Rane was the Chief Guest.

Dr Vinod Kotwal, Member Secretary, National Pharmaceutical Pricing Authority Govt of India, was the special guest on this occasion.

Guest lecture on availability, affordability and a acessibility of drugs was presented by Shweta Dessai, Deputy Director, FDA.

Knowledge Sharing Events

NPPA in the run-up to India @75 Azadi Ka Amrit Mahotsav organised a series of Webinars during FY 2021-22 in coordination with Price Monitoring and Resource Units (PMRUs).

S. No.	Topic of the Webinar	Date on which held
1.	Making Medicines Affordable, Available and Accessible for All	7th April 2021
2.	Role of PMRUs during COVID 2.0 with special focus on consumer redress	23rd June 2021
3.	Training webinar on Expenditure Advance Transfer (EAT) Module of PFMS	9th July 2021
4.	Trade Margin Rationalisation of Oxygen Concentrators and other 5 Medical Devices	30th July 2021
5.	Price monitoring of drugs including medical devices under the provisions of DPCO, 2013	26th August 2021
6	Survey on Availability of Covid Management Drugs	30th September, 2021

September 2021

Cankids - Kidscan - National Society for Change for Childhood Cancer in India is a National NGO working across the entire spectrum of Childhood Cancer Care, partnering with 116 childhood cancer treating hospitals in 47 cities and 23 States of India. It has 15 Access2Care State projects covering 94% of the total incidence of childhood cancer in India, and MOUs with 3 State Governments as knowledge and technical partner for childhood cancer. Its YANA - you are not alone umbrella program aims to ensure best treatment, care, and support for children with cancer and their families in India.

Access2Care also means ensuring availability, affordability and quality of drugs, diagnostics, and therapies for treatment of cancer affected children.

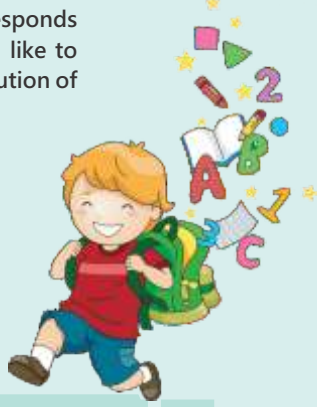
We have written letters to National Pharmaceutical Pricing Authority (NPPA), Department of Pharmaceuticals and Drug Controller General of India (DCGI) on August 16, 2021, regarding shortage of five molecules, essential for childhood cancer treatment. The shortages would impact treatment of children in India suffering from Hodgkin lymphoma, Bone and soft tissue Sarcomas, Retinoblastoma, Neuroblastoma, Germ Cell Tumours, and Wilms Tumour.

NPPA acted immediately and worked closely with us and the pharma industry to resolve the problem. Within few days of writing to NPPA, we got calls from pharmaceuticals companies assuring us of availability of the drugs. The officers from NPPA worked with us closely to overcome the shortage of drugs.

On behalf of children with cancer and their families and the WHO GICC- India Responds Working Group on Availability, Affordability & Quality. Team Cankids would like to extend our sincere gratitude to NPPA officers for helping us with a timely resolution of shortage of drugs for children with cancer.

Warm Regards

Poonam Bagai, Ex IRAS 1984
Cancer Survivor & Patient Advocate
Founder Chairperson, Cankids Kidscan
Vice Chairperson, Pallium India



www.cankids-india.org

PRICE MONITORING AND RESOURCE UNITS (PMRUs)

To fulfill its role as a national regulator, NPPA is required to collect, compile/ create and analyze "market based data". The attainment of such task by NPPA would be possible only with necessary support from the States / UTs through the Price Monitoring and Resource Units (PMRUs).

NPPA, under 'Consumer Awareness Publicity and Price Monitoring' (CAPPM) scheme, provides assistance to State/ UTs governments to set-up 'Price Monitoring and Resource Units' (PMRUs) under the direct supervision of the State Drug Controller for increasing outreach of NPPA. PMRUs will be the key collaborating partners of NPPA with information gathering mechanism at the grassroots level.

So far, PMRUs have been set up in nineteen (19) 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 and Jharkhand.

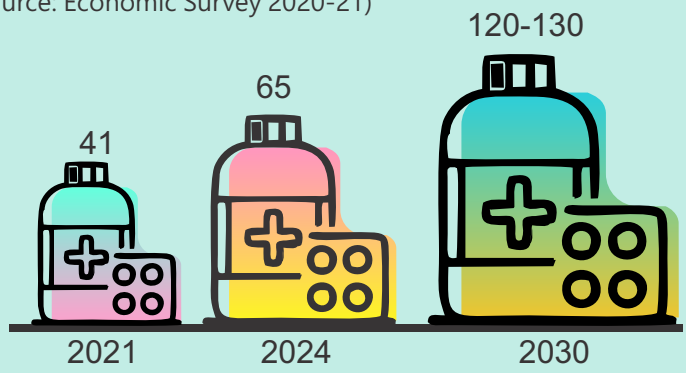
PMRUs function is to provide necessary technical assistance to the State Drug Controllers and NPPA in monitoring of compliance with notified prices, monitoring price trends, collection and compilation of market based data, collect test samples of medicines, conduct training, seminars and workshops etc.

PMRUs undertake activities related to creating general awareness about the availability of medicines, prices of medicines, ceiling prices of medicines fixed by GoI, precaution to be taken while purchasing of medicines, functioning of NPPA, etc. In addition to this, PMRUs are undertaking weekly availability surveys of COVID management drugs since May 2021.

Size of Pharma Industry

(Source: Economic Survey 2020-21)

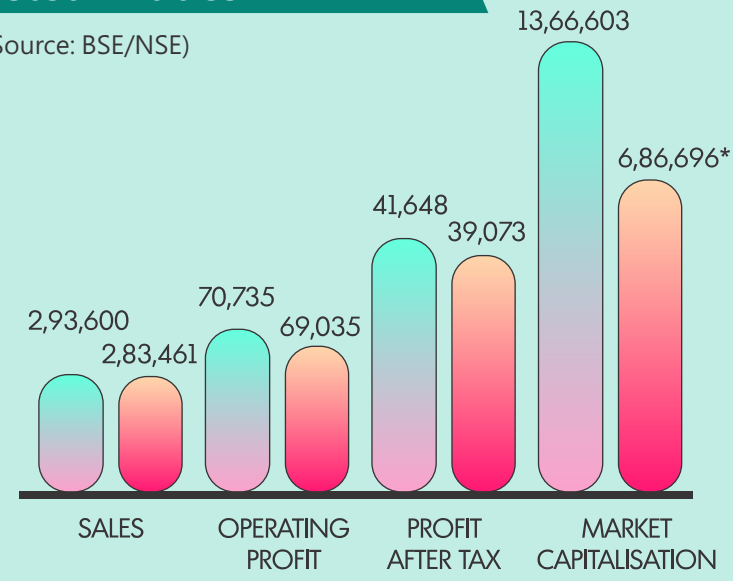
(Amount in $ Billions)



Financial Indicators of Listed Entities

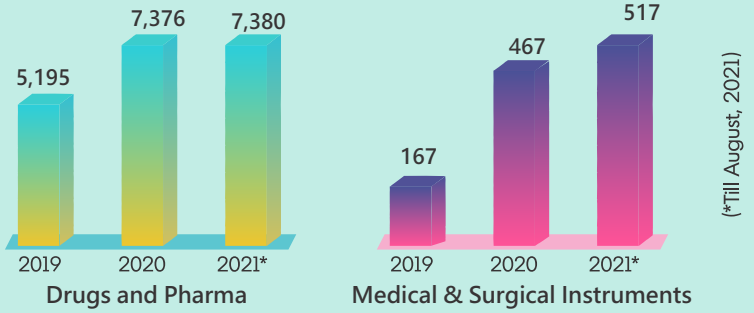
(Source: BSE/NSE)

(in ₹ Crores)



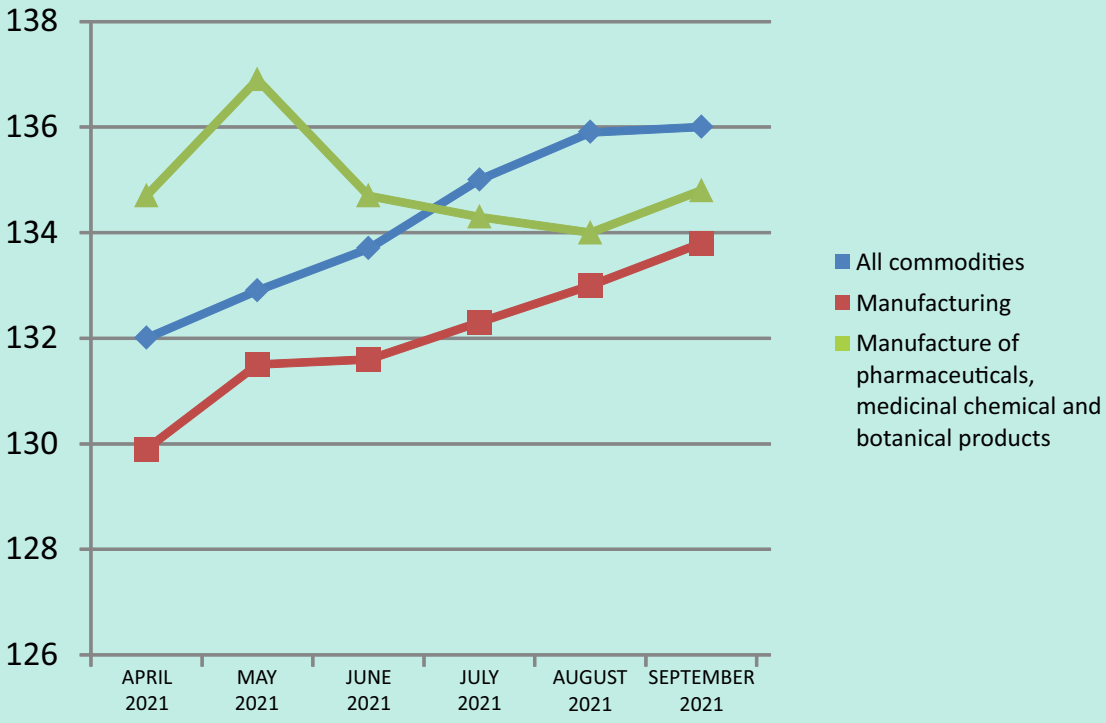
Investment Intentions in Terms of IEMs Filed

(Source: DPIIT)



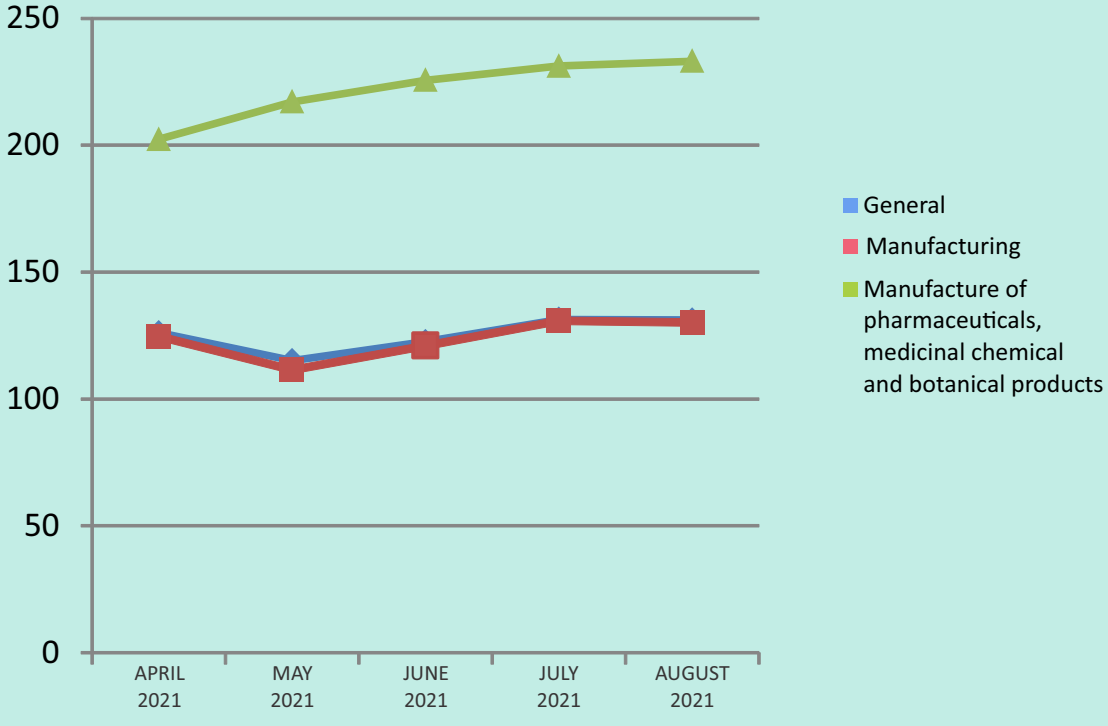
Wholesale Price Index (WPI)

(Base 2011-12) (Source: DPIIT)



Index of Industrial Production (IIP)

(Base 2011-12) (Source: MoSPI)



FAQs
(Frequently Asked Questions)

Question: What is the role of NPPA for price regulation of medicines?

Answer: NPPA provides ceiling price to all drugs notified under Schedule-I of the DPCO, 2013 and monitors price trends so that drugs remain affordable.

Question: What is "Ceiling Price"?

Answer: Ceiling price of Scheduled formulations covered under National List of Essential Medicines (NLEM) are fixed under Para 4 and revised under Para 16 of DPCO 2013. MRP in such cases is Ceiling Price plus applicable taxes.

Question: Whether NPPA has any role to regulate prices of non-scheduled drugs?

Answer: The Government monitors the Maximum Retail Price (MRP) of all drugs including non-scheduled formulations to ensure that no manufacturer increases the MRP of a drug more than ten percent of maximum retail price during the preceding twelve month and any manufacturer violating the provisions is liable to deposit the overcharged amount along with the interest. (Para 20 of DPCO 2013)

Question: Whether manufacturers have to take permission of the Government before discontinuing the manufacture of essential medicines?

Answer: As per Paragraph 21 of DPCO, 2013, manufacturers have to take permission of the Government before discontinuing the manufacture of essential medicines.

Question: What is the grievance redress mechanism related to pricing, shortage and non-availability of medicines?

Answer: The Pharma Jan Samadhan (PJS) provides the consumer with an effective and time bound grievance redress system to effectively deal with complaints related to pricing, shortage and non-availability of medicines. Apart from the internet- based online facility, there is a consumer Help Line also, which can be used to lodge complaints.

Question: Is there any tool to check the authenticated MRP of medicine?

Answer: Yes. 'Pharma Sahi Daam' is an online search tool through which prices of scheduled / Non-Scheduled medicines can be instantly checked.

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

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