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.

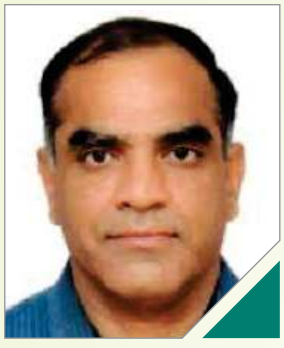
DISCLAIMER:

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.

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

From 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 seventh issue of the NPPA bi-monthly e-Newsletter.

As NPPA strives to strike a balance between the interests of the consumers and the Pharma Industry within the ambit of the DPCOs notified from time to time, NPPA team has included an article on **Drug Price Control Orders: Over the Years.** The said article traces the evolution of regulatory arch with regard to drugs pricing in the country keeping the twin objectives of affordability and availability as the core. In addition, there is a short article on experience sharing by SDC, Jammu & Kashmir.

Our inaugural issue in October 2021 had carried an article on **"National List of Essential Medicines (NLEM): Important tool for accessibility and affordability of quality medicine in India.** It is quite fortuitous that in this October issue we are covering the launch of National List of Essential Medicines (NLEM), 2022. NLEM, 2022 covering 384 drugs was launched by Dr Mansukh Mandaviya, Union Minister for Health and Family Welfare as he launched National Lists of Essential Medicines (NLEM) 2022 on 13th September 2022. The list has addition of 34 drugs, while 26 from the previous list have been dropped. The medicines have been categorized into 27 therapeutic categories.

As you are aware, NPPA celebrated twenty-five years of its existence on 29th August 2022 and on the occasion a panel discussion on the topic "Robust data collection for evidence-based policy making in Pharmaceutical and Medtech sector" was held. The panel discussion was chaired by Dr. V.K. Paul, Member Health, NITI Aayog and had expert panelists drawn from different areas. The panel discussion was moderated by Shri Satya S. Sundaram, E&Y. In this issue we present to you the highlights of the panel discussion.

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)

DRUG PRICE CONTROL ORDERS: OVER THE YEARS

(By: NPPA Team)

Introduction

A wide variety of products such as food grains, textiles, fertilizers etc., were regulated under the Essential Commodities (EC) Act, 1955 but not drugs. In the aftermath of World War-II there was shortage of essential medicines in the country and during the Indo-China war in 1962, the prices of medicines increased substantially. Therefore, the price control over drugs was first introduced in the country in 1962 under the Defence of India Act, 1915 with the promulgation of the Drugs (Display of Prices) Order, 1962 and the Drugs (Control of Prices) Order, 1963. These orders led to freezing of the prices of drugs with effect from 01.04.1963. Thereafter, a series of pricecontrol orders were notified through various orders in the country from time to time based on different principles.

The Price Control Order of 1963 was revisited in 1966 and subsequently, the Drugs (Prices Control) Order 1970 was promulgated. The Drugs (Prices Control) Order of 1966 and the Drugs (Prices Control) Order of 1970 were issued under the Essential Commodities Act, 1955 (EC Act,1955) by declaring drugs to be essential commodities and subsequent orders have also been issued under Section 3 of EC Act, 1955.
Cost based pricing came into effect with the notification of Drugs (Prices Control) Order of 1979. This was the underlying principle of the Drugs (Prices Control) Order, 1987 and the Drugs (Prices Control) Order, 1995 (DPCO, 1995). There was a shift towards market-based pricing in the National Pharmaceutical Pricing Policy, 2012 (NPPP, 2012) and accordingly, Drugs (Price Control) Order, 2013 was notified on 15th May 2013.

Drugs Prices Display and Control Order, 1966

According to the Drugs Prices Display and Control Order of 1966, it was obligatory for manufacturers of drugs to obtain prior approval of the Government if prices of such formulations as of 30th June 1966 were to be increased. However, based on the industry representations regarding increase in prices of raw materials and packing materials, which were not frozen, the Government amended the 1966 Order in August 1968. According to this amendment[1] :

- Formulations sold under pharmacopoeia names were exempted from price approval
- Prices of existing formulations were increased on a case-by case basis after studying the cost structure and appropriateness for the increases sought by manufacturers
- New drugs developed through original research and marketed for the first time were also exempted from price control.

Based on Tariff Commission recommendation, prices of 18 bulk drugs, 49 formulations were brought under price control based on "cost-plus" formula.

Drugs (Price Control) Order, 1970 (DPCO 1970)

Drugs (Price Control) Order, 1970 was promulgated on 16th May 1970 and it was issued under Section 3 of the EC Act, 1955 as was the Drugs Prices Display and Control Order, 1966. It was the first comprehensive price

1 Discussion paper#236: Government's Policies and Growth of Pharmaceutical Industry in India 1947-2018: A Review Prasanta Kumar Ghosh, RIS

control order and the formula fixed was as under:

$$RP = (MC + CC + PC) \times (1 + MU \div 100)$$

Where, RP=Retail Price, MC=Material Cost, CC=Conversion cost or cost of formulation, PC=Packing charges and includes cost of packing material and packaging expenses, MU=Mark-up meant to cover forwarding charges, promotion expenses, after sales service and trade commission up to the retail level

The mark-up fixed ranged from 75% in the case of formulations to 150% for new drugs i.e. those containing new entities. The mark-up could be increased to 100% in case of new combinations of existing drugs. Manufacturers thus had the option of fixing prices within the ceiling of 75% mark-up for 18 essential drugs, and 150 for others. This was, however, subject to the condition that gross profit before tax did not exceed 15% of sales[2]. Hence, the DPCO, 1970 involved direct control on the profits of the companies and indirect control on selected essential drugs while capping remaining medicines at their prevailing price[3].

Drugs Prices (Control) Order, 1979

Based on the recommendations of Hathi Committee[4], the government evolved the first Drug Policy of India which was promulgated in March 1978 (DP, 1978) and the Drugs Prices (Control) Order 1979 (DPCO, 1979). DPCO, 1979 was promulgated on 31st March 1979 and price control was imposed on 370 bulk drugs and formulations made there from. Based on Hathi Committee recommendations, the bulk drugs were classified into three categories based on their therapeutic efficacies. The three categories were authorized different levels of mark-ups as indicated below:

i. Category I of the third schedule of DPCO,1979 (Life-saving): 40% (23 No. of drugs)

ii. Category II of the third schedule of DPCO,1979 (Essential): 55% (20 No. of drugs)

iii. Category III of the third schedule of DPCO,1979 (Less essential): 100% (327 No. of drugs)

Formulations made from these 370 drugs constituted more than 80% of the market and the formulations considered most essential were given a lower mark-up so as to keep their prices low. The formula for working out the retail price was:

$$RP = (MC + CC + PM + PC) \times (MU + 100)/100 + \text{taxes}$$

Where RP: Retail Price, MC: Material Cost, CC: conversion cost, PM: Packing Material Cost, PC: packing cost, MU: Mark-Up.

Drugs Prices (Control) Order, 1987

The span of price control under DPCO, 1979 was large covering about 370 bulk drugs and over 4,000 formulations marketed in about 20,000 packs. It was proposed toreduce this to a considerable extent and make the price control system lesscumbersomebut more effective. With this backdrop and the recommendations of Kelkar Committee Report[5], the Government came out with the Drug Policy, 1986 (DP,1986) entitled 'Measures for Rationalization, Quality Control and Growth of Drugs and Pharmaceuticals Industry in India'. The Drug Policy 1986 was implemented through the Drugs Prices (Control) Order, 1987 (DPCO, 1987) and it also drew from the recommendations of the Kelkar Committee Report. In DPCO, 1987, the numbers of bulk drugs under price control were reduced from 370 to 142.

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2 Joseph, R.K. (2015). Pharmaceutical Industry and Public Policy in Post-reform India
3 Ajay Bhaskarabhatla, 2018. "Regulating Pharmaceutical Prices in India," India Studies in Business and Economics, Springer, number 978-3-319-93393-1, June.
4 https://pharmaceuticals.gov.in/sites/default/files/Hathi_Committee_report_1975_0.pdf
5 https://www.oecd.org/competition/sectors/46138891.pdf

As laid down in the DP, 1986; in the DPCO 1987, two categories of formulations and bulk drugs (required to make such formulations) were promulgated to be price controlled. The terminology of "mark-ups" was changed to MAPE.

Drugs Prices (Control) Order DPCO-1995

Based on the New Drug Policy, 1994, the new DPCO was announced in 1995. 74 bulk drugs were identified (listed in Schedule-I) for which the prices were to be controlled under DPCO, 1995. These represented 40% of the total market[6]. NPPA was also set-up in 1997 and it continued with the implementation of DPCO, 1995. The NPPA fixed/revised the prices on the basis of the DPCO formula giving MAPE of 100% on the ex-factory cost of the medicine. Under DPCO-1995, the prices of bulk drugs and formulations were fixed on the basis of actual costs plus a mark-up and the prices of formulations (final drugs) were fixed on a cost based formula, as follows :

Retail Price = (M.C + C.C. + P.M. + P.C.) X (1+MAPE/100) + E.D.

Where M.C denotes material cost including drug cost and other pharmaceutical aids; C.C. indicates conversion cost; P.M. means packing material cost of formulation; P.C. connotes packing of shipment; MAPE denotes Maximum Allowable Post-Manufacturing Expenses which includes trade margin as well as distribution and promotion costs and E.D. indicates excise duty.

Therefore, the Government enunciated the National Pharmaceuticals Pricing Policy, 2012 (NPPP-2012) which replaced the Drug Policy enunciated in September, 1994 as Modifications in Drug Policy, 1986 (Drug Policy 1994). The National Pharmaceuticals Pricing Policy 2012 presently seeks to limit itself to the central objective of promulgating the principles for pricing of Essential Drugs as laid down in the National list of Essential Medicines - 2011

National Pharmaceutical Pricing Policy, 2012 (NPPP, 2012)

NPPP, 2012 was notified on 07.12.2012. The key principles for regulating the prices of essential drugs are:

- **Essentiality of drugs** as specified under National List of Essential Medicines (NLEM): Price of medicines is fixed because they are considered essential.
- **Regulating the prices of formulations only** (i.e., medicines used by consumers and not applicable to any upstream products such as bulk drugs or intermediaries), as opposed to regulation of both bulk drugs and their formulations under DPCO-1995.
- **Fixing the ceiling price of formulations through Market Based Pricing (MBP)** as opposed to cost based pricing in DPCO-1995 as it is easy to obtain price data than cost data.

Drugs (Prices Control) Order, 2013 (DPCO-2013)

Based on the principles of NPPP, 2012, the DPCO-2013 was notified on 15th May, 2013 under section 3 of the EC Act, 1955. It marked the shift from Cost Based Pricing (CBP) to Market Based Pricing (MBP). Also, prices of formulations were to be fixed instead of bulk drugs. There were 348 medicines in the National List of Essential Medicines 2011 (NLEM) which were included in the First Schedule of the DPCO, 2013. Schedule I of the DPCO 2013 was revised on 10.3.2016 based on National List of Essential Medicines 2015, and it covers 30 therapeutic categories and includes the medicines for HIV, cancer, diabetes, Heart Diseases, ENT amongst others. There were 948 formulations covering 376 medicines. Coronary Stents were added later on

6 https://pharmaceuticals.gov.in/policy/pharmaceutical-policy-2002

22.12.2016 taking total medicines to 377 and number of therapeutic categories to 31. In March, 2022 two animal vaccines, Foot and Mouth Disease-FMD (Trivalent) Oil Adjuvant and Brucella abortus (S19 strains) freeze dried were also added to Schedule-I.

Ceiling Price Fixation

Under the market-based approach followed under DPCO, 2013, the ceiling price of a scheduled drug (NLEM as notified in Schedule-I of DPCO) is determined by first working out the simple average of PTR in respect of all brands of that particular drug formulation having a market share of 1 percent and above, and then adding a notional retailer margin of 16 percent to it. Ceiling price of a scheduled formulation in case of absence of competition or in case of cartelization by few players is fixed by making certain adjustments as suggested in the DPCO. The MRP for that particular drug formulation must not exceed the notified ceiling price plus applicable taxes.

Retail Price Fixation

NPPA also fixes retail price of a new drug (as defined in 2(u) under DPCO, 2013), which is also non-scheduled formulation under DPCO, 2013. New drug is a formulation launched by an existing manufacturer of a drug of specified dosages and strengths as listed in the NLEM by combining the drug with another drug either listed or not listed in the NLEM or a formulation launched by changing the strength or dosages or both of the same drug of specified dosages and strengths as listed in the NLEM. Retail price of a new drug is calculated by following the same steps as mentioned for calculation of ceiling price of Scheduled formulation.
In addition, as per Para 19 of the DPCO-2013 gives power to the NPPA to control the prices of drugs that are not under the NLEM under extraordinary circumstances in public interest.

Conclusion

The shifts in drug pricing regime over a period of time have been significant. However, the enabling provisions for drug price control are embedded in different statutes as indicated below:

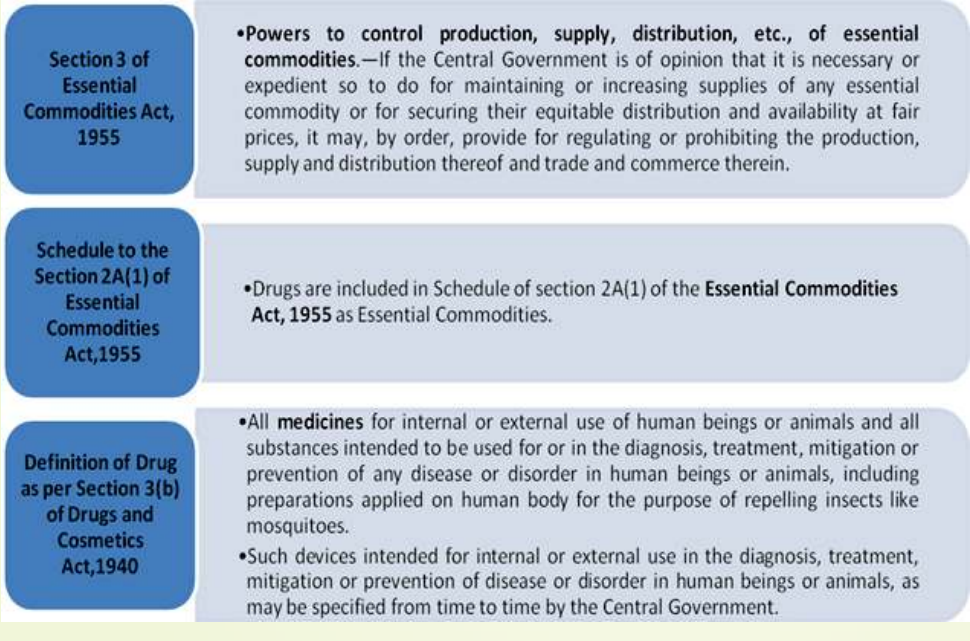

Figure: Enabling provisions for Drug Price Control

The World Health Organisation (WHO) guideline on country pharmaceutical pricing policies (2020) note that affordable access to safe and efficacious pharmaceutical products is at the core of global efforts towards achieving universal health coverage . Hence, keeping in pace with the evolving economic landscape in the country and working towards making drugs has affordable has been at the centre of government's efforts.

REGULATORY NEWS

News related to pricing of drugs

- Ceiling prices for 890 scheduled formulations (National List of Essential Medicines, 2015) and Retail prices for 2145 non-scheduled formulations have been fixed under DPCO, 2013 till 30th September, 2022.
- As on 30th September, 2022, 234 Authority meetings have been conducted of which 102 meetings are under DPCO 2013. The details of recent meetings are given as below:

Meeting No.	Held on	Retail Prices Approved & Notified
232nd (overall) & 100th Meeting under DPCO 2013	05.08.2022	45 Formulations & notified vide SO. 4002(E) dated 24.08.2022
233rd (overall) & 101st Meeting under DPCO 2013	07.09.2022	37 Formulations & notified vide SO. 4341(E) dated 15.09.2022
234th (overall) & 102nd Meeting under DPCO 2013	27.09.2022	40 Formulations & notified vide SO. 4588(E) dated 29.09.2022

- Details of retail prices notified for various formulations based on the decision taken in 100th, 101st & 102nd 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	62	Tablet	6.36 – 25.33
2	Antihypertensive	6	Tablet	7.22 – 13.40
3	Cardiac	7	Tablet	10.04 – 16.70
4	Hypertension	5	Tablet	5.21 – 17.82
5	Antibiotic	4	Suspension	1.77 – 168.43
6	Pain management	6	Tablet/ Infusion	3.02-122.19
7	Antineoplastic	1	Injection	15554.49
8	Haemophilia A	1	Injection	11606.67
9	Others	30	Tablet/ Capsule/ Drops/ Infusion / Injection/ Suspension	0.87 – 96.15

- During the 102nd meeting of the Authority under DPCO 2013, the prices of 'Liquid Medical Oxygen (LMO)' and 'Oxygen Inhalation (Medicinal gas) in cylinder' was extended upto 31.12.2022 or until further orders whichever is earlier.
- During the 102nd meeting of the Authority under DPCO 2013, the prices of Heparin Injection 1000IU/ ml and Heparin Injection 5000IU/ ml was extended upto 31.12.2022 or until further orders whichever is earlier.

News related to pricing of Medical devices

- NPPA, vide notification S.O. 4343(E) dated 15th Sept 2022 has fixed/revised the ceiling price of Orthopaedic Knee Implants for Knee Replacement System, the ceiling price will be monitored as per the provisions of DPCO, 2013. The ceiling price of orthopaedic knee implants will be reviewed after a period of one year.
- NPPA vide OM dated 4 Oct,2022 clarified in respect of trade margin for coronary stent that the notes mentioned in S.O. 1502(E) dated 30th Mar 2022 shall only be applicable; without any changes in the notified ceiling price, till further orders.

FDA Approves First Cell-Based Gene Therapy to Treat Adult and Pediatric Patients with Beta-Thalassemia who Require Regular Blood Transfusions (August 17, 2022)

The U.S. Food and Drug Administration approved Zynteglo (betibeglogeneautotemcel), the first cell-based gene therapy for the treatment of adult and paediatric patients with beta-thalassemia who require regular red blood cell transfusions.

Zynteglo is a one-time gene therapy product administered as a single dose. Each dose of Zynteglo is a customized treatment created using the patient's own cells (bone marrow stem cells) that are genetically modified to produce functional beta-globin (a haemoglobin component).

Transfusion-dependent beta-thalassemia, is the most severe form of the condition, generally requires life-long red blood cell transfusions as the standard course of treatment.

Read more

FDA Warns Manufacturer for Marketing Illegal Flavored Nicotine Gummies (August 18, 2022)

The U.S. Food and Drug Administration issued a warning letter for marketing illegal flavored nicotine gummies – the first warning letter for this type of product. These types of gummies are of particular public concern because of their resemblance to kid-friendly food or candy products and the potential to cause severe nicotine toxicity or even death among young children.

The manufacturer, VPR Brands LP (doing business as, "KraveNic"), markets gummies that have 1 milligram (mg) of nicotine each and are available in three flavors – Blueraz, Cherry Bomb and Pineapple. The packaging claims that the products contain tobacco-free nicotine. This firm has not submitted a premarket tobacco product application (PMTA) to the FDA, and does not have a marketing authorization order to manufacture, sell or distribute these products in the U.S.

Read more

FDA Approves First Treatment for Acid Sphingomyelinase Deficiency, a Rare Genetic Disease (August 31, 2022)

The U.S. Food and Drug Administration approved Xenpozyme (Olipudase alfa) for intravenous infusion in pediatric and adult patients with Acid Sphingomyelinase Deficiency (ASMD), a rare

genetic disease that causes premature death. ASMD is caused by the lack of an enzyme needed to break down a complex lipid, called sphingomyelin, that accumulates in the liver, spleen, lung, and brain. Patients with ASMD have enlarged abdomens that can cause pain, vomiting, feeding difficulties, and falls.

Xenpozyme is the first approved medication to treat symptoms that are not related to the central nervous system in patients with ASMD. Xenpozyme is an enzyme replacement therapy that helps reduce sphingomyelin accumulation in the liver, spleen, and lung.

Read more

INTERNATIONAL NEWS

FDA Approves New Treatment Option for Patients with ALS (September 29, 2022)

The U.S. Food and Drug Administration approved Relyvrio (sodium phenyl butyrate/taurursodiol) to treat patients with amyotrophic lateral sclerosis (ALS), commonly referred to as Lou Gehrig's disease.

Amyotrophic Lateral Sclerosis is a rare disease that attacks and kills the nerve cells that control voluntary muscles. It causes the nerves to lose the ability to activate specific muscles, which causes the muscles to become weak and leads to paralysis. ALS is a progressive disease that continues to get worse over time. Most cases will result in death from respiratory failure, usually within three to five years from when the symptoms first appear.

The FDA granted this application Priority Review designation. It also received orphan drug designation, which provides incentives to assist and encourage the development of drugs for rare diseases.

Read more

Coronavirus (COVID-19) Update: FDA Authorizes Moderna and Pfizer-BioNTech Bivalent COVID-19 Vaccines for Use as a Booster Dose in Younger Age Groups (October 12, 2022)

The U.S. Food and Drug Administration amended the emergency use authorizations (EUAs) of the Moderna COVID-19 Vaccine, Bivalent and the Pfizer-BioNTech COVID-19 Vaccine, Bivalent to authorize their use as a single booster dose in younger age groups. The Moderna COVID-19 Vaccine, Bivalent is authorized for administration at least two months following completion of primary or booster vaccination in children down to six years of age. The Pfizer-BioNTech COVID-19 Vaccine, Bivalent is authorized for administration at least two months following completion of primary or booster vaccination in children down to five years of age.

With authorization, the monovalent Pfizer-Bio NTech COVID-19 Vaccine is no longer authorized as a booster dose for individuals five through 11 years of age. Both the Moderna COVID-19 Vaccine and Pfizer-BioNTech COVID-19 Vaccine continue to be authorized for primary series administration in individuals six months of age and older.

Read more

First therapy to treat transplant patients with post-transplant lymphoproliferative disease (October 14, 2022).

The European Medicines Agency (EMA) has recommended a marketing authorization in the European Union (EU) for Ebvallo (tabelecleucel) for the treatment of adult and paediatric patients who experience a serious complication following solid organ transplantation (SOT) or bone marrow transplantation (hematopoietic cell transplant - HCT) called EBV+ PTLD.

This is one of the most important malignancies after transplantation. It is a result of the immunosuppression caused by the medication required to reduce the possibility of rejection of the transplanted organ or cells and the most common form of this condition is associated with the Epstein-Barr virus. Ebvallo is indicated in patients after a transplant and who have received at least one prior therapy when the symptoms of the disease come back after treatment (relapsed) or when the treatment does not work (refractory).

Read more

DR MANSUKH MANDAVIYA LAUNCHES NATIONAL LISTS OF ESSENTIAL MEDICINES (NLEM) 2022

"Union Health Ministry is taking various steps under vision of Hon. Prime Minister Shri Narendra Modi ji towards Sabko Dawai, Sasti Dawai. In this direction, National List of Essential Medicines (NLEM) plays an important role in ensuring accessibility of affordable quality medicines at all levels of healthcare. This will give boost to cost-effective, quality medicines and contribute towards reduction in Out of Pocket Expenditure on healthcare for the citizens." This was stated by Dr Mansukh Mandaviya, Union Minister for Health and Family Welfare as he launched National Lists of Essential Medicines (NLEM) 2022 on 13th September 2022.

384 drugs have been included in this list with addition of 34 drugs, while 26 from the previous list have been dropped. The medicines have been categorized into 27 therapeutic categories.

The primary purpose of NLEM is to promote rational use of medicines considering the three important aspects i.e., cost, safety and efficacy. It also helps in optimum utilization of healthcare resources and budget; drug procurement policies, health insurance; improving prescribing habits; medical education and training for UG/PG; and drafting pharmaceutical policies. In NLEM, the medicines are categorized based on level of healthcare system as-P- Primary; S- Secondary and T- Tertiary.

While congratulating the stakeholders for the revised NLEM which takes the country forward in the direction of provisioning of affordable healthcare to its citizens, Dr Bharati Pravin Pawar, Union Minister of State stressed on enhancing awareness regarding Antimicrobial Resistance (AMR) which "is emerging as a big challenge for our scientists and community and we need to create awareness in the society about AMR".

PIB Link : https://pib.gov.in/PressReleasePage.aspx?PRID=1858931

OTHER NEWS AND EVENTS

Activities conducted under Swachhata Campaign 2.0

National Pharmaceutical Pricing Authority conducted Swachhata Abhiyan during the period of September-October 2022. Under this Abhiyan following activities were carried out in compliance with Govt. instruction in this regard:

- Disposal of Bio- Medical waste: Bio-medical items available in the form of tablets, capsule, strips, injection etc. in NPPA were reviewed, examined, identified and disposed off with due procedure.

- Identification/Disposal of old unused material/ furniture: Old unused material/ furniture lying at different places within NPPA office premises were identified and disposed off during this period.

- Weeding out of files/records: Chairman, NPPA reviewed status of old physical files/old records/Reports in different divisions and directed that the files/records which are no longer necessary as per the record retention schedule should be weeded out during this implementation period of Swachhata Campaign 2.0. In compliance with these directions, 2244 old files were weeded out by different divisions of NPPA. Further action to preserve the files/records in compactor is also being taken.

- Identification of pending Parliamentary Assurances/ PG cases & MP/ VIP references: During Swachhata Abhiyan period, it was ensured not keep any no reference from MPs/ VIPs, Parliamentary Assurance and PG case pending.

- IPDMS: During this period, the progress of number of new companies registered in IPDMS and issues raised by the companies were reviewed and directed that the issues raised by the companies should regularly monitored for early resolution.

- PMRU participation: During this period all the PMRUs have also actively participated in the Swachhata Abhiyan and conducted cleanliness activities in their respective PMRU state Office.

- PMRU participation: During this period all the PMRUs have also actively participated in the Swachhata Abhiyan 2.0 and conducted cleanliness activities in their respective PMRU state Office

हिंदी पखवाड़ा का आयोजन

पिछले वर्षों के समान ही, वर्ष 2022 के सितंबर माह के दौरान राष्ट्रीय औषध मूल्य निर्धारण प्राधिकरण में हिंदी दिवस एवं हिंदी प्रोत्साहन पखवाड़ा का आयोजन कियागया। पखवाड़ा आयोजनकेदौरान विभिन्न प्रतियोगिताएं आयोजित की गईं, जिसमें कार्यालय के कार्मिकों ने बढ़-चढ़कर भाग लिया और पुरस्कार भी प्राप्त किए। इस वर्ष प्रयोग के तौर पर आशु-भाषण प्रतियोगिता को शामिल किया गया, जिसमें ज्वलंत एवं समसामयिक मुद्दों पर प्रतिभागियों को अपने विचार प्रकट करने का अवसर प्राप्त हुआ। इससे कार्यालय के सदस्यों कि प्रतिभाएं भी उजागर हुईं और उनकी सक्रिय भागीदारी भी रही जिससे कार्यालय में जीवंतता का अनुभव हुआ।

पुरस्कार विजेताओं को हिंदी प्रोत्साहन पखवाड़ा समापन समारोह के अवसर पर अध्यक्ष महोदय के द्वारा पुरस्कार राशि और प्रमाण-पत्र प्रदान किए गए। अध्यक्ष महोदय ने इस अवसर पर लोगों को अपने दैनिक कार्य में हिंदी का अधिकाधिक प्रयोग करने के लिए प्रोत्साहित किया और धन्यवाद ज्ञापन के साथ समारोह को समाप्त किया गया।

Training Programme for PMRUs on 29th and 30th August

So far, Price Monitoring and Resource Units (PMRU) have been established in 25 States/UTs under Consumer Awareness, Publicity and Price Monitoring (CAPPM) Scheme. A two (2) days training programme on 29th-30th August 2022 was organised by NPPA in Delhi for the officials of PMRUs. The PMRU training programme was inaugurated by Ms. S.Aparna, Secretary, DoP on 29th August 2022 in the presence of Shri Pant, Chairman, NPPA, Shri Tingal, Joint Secretary, DoP and Dr. Kotwal, Member Secretary, NPPA. A PMRU Training Manual was also launched at the inaugural session.

The training was conducted on various subjects related to pricing under DPCO, monitoring of prices of scheduled and non-scheduled formulation, documentation of sample purchase, IPDMS software, Conducting Surveys, activities of PMRUs, PFMS, etc. To make the training programme more attractive and to encourage the participants a quiz programme was also organised at the end of training programme where winners were awarded.

NPPA's interaction with PMRUs

National Pharmaceutical Pricing Authority (NPPA) organised an interaction meeting with PMRUs on 21th September 2022 through video conferencing under the Chairpersonship of Chairman NPPA Shri Kamlesh Kumar Pant, IAS, on matter **'Assessment of Manpower Status, Fund Utilization and other Parameters of PMRUs and Steps taken thereto'.** The representatives of PMRUs of Maharashtra, Karnataka, West Bengal, Madhya Pradesh, Rajasthan, Jharkhand, Chhattisgarh, Haryana, Puducherry, Ladakh, and Himachal Pradesh participated in the meeting. Necessary guidance on various points were provided in order to increase the performance of the PMRU states.

EXPERIENCE SHARING BY PMRU, JAMMU & KASHMIR

Ms. Lotika Khajuria
State Drugs Controller, Jammu & Kashmir

The Price Monitoring & Resource Unit (PMRU), Jammu & Kashmir (an initiative of National Pharmaceutical Pricing Authority, Department of Pharmaceuticals, Ministry of chemicals & Fertilizers, Government of India) started its function in April, 2022. The said body has a mandate to detect violation of the provisions of the Drug Prices Control Order, 2013 and also ensuring availability of medicines at the notified prices. Since its inception in the UT of Jammu & Kashmir, over 210 field inspections have been carried out and 31 violations are reported so far, which generally relate to lesser-known manufacturers. The size of pharma industry in the country and the product range is voluminous and therefore the regulatory surveillance on pricing remains a matter of challenge. The existing surveillance mechanism over the pricing of medical products also needs to be strengthened.

Union Territory of Jammu & Kashmir is a consuming state and the medical products which travel to this territory originate mainly from the manufacturing houses located outside the UT. During COVID-19 pandemic, the department of Drug & Food Control Organization, J&K played a pivotal role in maintaining unhindered supply of COVID management drugs and also kept a check on the allocated drugs viz., Remdesivir, Tocilizumab, Liposomal Amphotericin B, etc. It was ensured that their supply is restricted to public distribution system viz. Jammu & Kashmir Medical Supplies Corporation Ltd (JKMSCL) so that chances of unethical trade practices are checked.

The Government of Jammu & Kashmir has promoted establishment of Pradhan Mantri Bhartiya Jan Aushadhi Kendras & Amrit Pharmacies across the UT particularly in tertiary care & secondary care health institutions. As on date over 220 Jan Aushadhi Kendras and 19 AMRIT pharmacies exist / operate in Jammu & Kashmir. Hon'ble Prime Minister of India during his recent visit in Jammu had e-inaugurated 108 Jan Aushadhi Kendras. The volume of business in these establishments is seeing steady increase and the volume of business in Pradhan Mantri Bhartiya Jan Aushadhi Kendras was Rs. 17.98 Crore from April, 2022 to September, 2022. Similarly, AMRIT pharmacies have been instrumental in making Ayushman Bharat Scheme successful in the UT. As on 15th September, 2022, 8.45 Lakh patients have benefitted from AMRIT pharmacies. The value of drugs dispensed at MRP is nearly Rs. 2 Crores. These stores are offering uninterrupted services (24x7).

As a proactive approach, the PMRU, J&K is holding seminars / camps for generating mass awareness and sensitize the consumers about do's and don'ts. The seminars / workshops are attended by experts/eminent dignitaries from allied fields. In the ensuing months, the PMRU, J&K shall continue to hold such programmes in far flung areas for sensitization of rural population. All these efforts can help us to make the consumers aware who in turn can become our ambassadors for the larger cause.

The PMRU, J&K publishes all price ceiling related notifications issued by National Pharmaceutical Pricing Authority, Department of Pharmaceuticals, Government of India, from time to time, through print media for the information of consumers / stakeholders.

Coordinated effort by stakeholders can contribute to make available drugs at affordable prices to the consumers.

HIGHLIGHTS OF THE PANEL DISCUSSION HELD ON THE TOPIC "ROBUST DATA COLLECTION FOR EVIDENCE-BASED POLICY MAKING IN PHARMACEUTICAL AND MEDTECH SECTOR" ON 29TH AUGUST 2022

To commemorate the 25 years of existence of National Pharmaceutical Pricing Authority (NPPA), a programme was organised on 29thAugust, 2022. The inaugural session was followed by a panel discussion on the topic "Robust Data collection for policy making in Pharmaceutical and Medtech sector" chaired by Dr. V.K. Paul, Member Health, NITI Aayog. The panel discussion was moderated by Shri Satya S. Sundaram, E&Y. The expert panellists drawn from different areas having linkages with the topic under the discussion spoke. The expert panellists in the discussion were: Dr. Viranchi Shah, National President, IDMA; Shri Rajiv Mishra, Adviser, Department of Economic Affairs; Dr. V. G. Somani, Drug Controller General of India; Shri Ganesh P. Sabat, CEO, Sahajanand Medical Technologies Ltd; Shri Ashish Bhatnagar, Vice President, National Institute of Smart Government; Ms. Deepti Srivastav, Deputy Director General, Ministry of Statistics and Programme Implementation; and Shri Saurabh Thukral, Senior Specialist, NITI Aayog.

Dr. VK Paul, Member (Health), NITI Aayog in his opening remarks noted that policies and programme are driven by reliable data and evidences on ground. It is the need of the hour to look at new policies, new ideas and new thoughts to take India's development forward. In the contexts of health, pharmaceutical and medical devices, data is required on the following:

- Needs of the people regarding the medicines and medical devices
- On accessibility of medicines and medical devices
- On affordability of medicines and medical devices
- On innovation to come out with new technologies.
- Data to enhance existing quality of medicines and medical devices
- Data on "how to become self-sufficient" in

terms of developing new technologies

- On people perception & participation through which consumer's requirement, expectation, grievances can be known

Shri Rajiv Mishra, Adviser, DEA, MoF emphasized that since Independence, India has witnessed several successful major reforms and these reforms were successful because of availability of good data in different government departments. He highlighted the recent example of COVID pandemic during which government took various measures based on data. The available broad data was further validated and analysed to ensure the proper implementation of lockdown strategy. He however, noted that data from different government sources is crucial and fruitful once the data is analysed and compiled systematically. During the pandemic, government imposed localized lockdown in some parts of the country to ensure that economic activities would not be hindered. India also looked at other developed countries and their data to tackle down the pandemic more effectively.

Ms Deepti Srivastava, DDG, MoSPI mentioned that Indian Pharma is an important sector as it is contributing 20% of the global generic pharma industry and 62% of the global demand of vaccines. Good quality timely data is an important key for policy makers and private sector too. She informed about the two surveys through which pharma related data is also being collected:

- **Annual surveys of Industries** – Data is collected on annual basis by collecting important information from manufacturing factory which includes checking of Balance Sheet, total production cost and cost of salaries etc.
- **Price survey:** An exhaustive activity of data collection from micro level which includes visits to the markets in every district to collect data on prices of day-to-day products including the medicinal products. Currently, data of 9 drugs is being collected which would be increased in coming month.

Keeping in view the mandate of NPPA related to availability and affordability of medicines, she assured of full cooperation if NPPA requires any kind of data related information and guidance on pharmaceutical products to develop data collection system.

Shri Saurabh Thukral, Senior Specialist, NITI Aayog emphasised that data is an important tool and we need to think on "how we can use data responsibly". He further mentioned that in case of personal and private data, there has to be a process/ framework in place so that the data is not misused or used to track individual information. There has to responsible process of data sharing and data analytics for informed decision making. He cited examples of:

(i) Account aggregator Platform of RBI: A platform launched by RBI is a framework for "how the financial data should be shared"? This framework is based on the consent of an individual and helps in three ways:

- It facilitates data protection where user consent is mandatory to transfer data from one financial institution to another.
- It facilitates ease of sharing of data as it doesn't require authentication.
- Data validation process is also reduced.

(ii) Ayushman Bharat Digital Mission (ABDM): Electronic Health Records are stored in order to provide them healthcare to the patients and user consent framework is in place.

Dr. V.G. Somani, DCGI, CDSCO also noted that data is an important tool in formulating broad policies and decision-making strategy in the country. In terms of pharmaceutical products, data starting from R&D till the Pharmaco-vigilance level requires capturing as "ALCOA"-Accurate, Legible, Contemporaneous, Objective, and Attributable. These 5 principles need to be adhered to during the data collection at each point of time and will need to building integrity in itself.

Dr. Viranchi Shah, National President, IDMA congratulated NPPA for ensuing the affordability, accessibility, and availability of medicines in India and also congratulated on the wonderful transformation that has happened in the last 25

years from Cost Based Approach (CAB) to a Market Based Approach (MBA). He also highlighted the various e-initiatives of NPPA like IPDMS, Pharma Sahi Daam, in order to make sure that right data comes and objective data base are being framed and implemented. Initiatives taken by The consultative process followed by NPPA during the implementation of IPDMS 2.0 was appreciated and he opined that having a common platform to collaborate and bring all the data together for policy making would be useful.

Shri Ganesh P Sabat, CEO, Sahajanand Medical Technologies Ltd mentioned that NPPA is working as a regulator as well as a facilitator to ensure affordability of medicines and medical devices. He focused on affordability of medical devices to the consumers and suggested that can have an independent non-partisan research agency to look at what should be the therapy cost in India in order to create pricing guidelines. This would help in launch of new and innovative medical products. He was of the view that setting pricing guidelines on medical product will help in evolving medical device industry in a broad-based manner.

Shri Ashish Bhatnagar, VP, NISG highlighted two principles of data collection:

- Collected data should abide by the data privacy policy
- Collected data should be socially acceptable

It was highlighted that data collection should always be Object oriented. It was informed that in terms of data collection and analysis there are technologies available from infrastructure as well as application perspective where work can be initiated on multiple datasets of different Ministries available on their separate servers. Multiparty computing can help access data residing in various servers. He also focused on "Meta Data" that allows creation of structures and standards that will enable correlation and integration of data across various datasets.

Shri Kamlesh Kumar Pant, Chairman NPPA while summing up the panel discussion thanks all the panellists for a vibrant discussion. He further informed that data plays an important role in the decision-making process at NPPA. Collection, compilation, creation and analysis of market-based data is an integral part in the functioning of the NPPA. The market-based data is the most essential ingredient for NPPA to take various decisions under the DPCO, 2013. He assured that suggestions/ ideas coming out in this panel discussion will be examined carefully for further necessary action.

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.

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