NPPA
AFFORDABLE MEDICINES FOR ALL
राष्ट्रीय औषध मूल्य निर्धारण प्राधिकरण
(रा.औ.मू.नि.प्रा.)

सत्यमेव जयते

NATIONAL PHARMACEUTICAL PRICING AUTHORITY

Department of Pharmaceuticals
Ministry of Chemicals & Fertilizers
Government of India

AN OVERVIEW OF DRUG PRICING IN INDIA

सभी के लिए वहनीय दवाईयाँ

Committed Towards Accessibility, Availability & Affordability of Medicines for All

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GOVERNMENT OF INDIA

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INTRODUCTION

The Indian pharmaceutical industry is a significant player in the global pharmaceutical landscape and ranks 3rd globally in pharmaceutical production by volume. India accounts for 60 percent global vaccine production and thus has the world's largest vaccine production facility by volume. India is also the largest global supplier of generic medicines, having a 20-22 per cent share in the global supply of generic drugs in terms of volume. This has earned it the sobriquet the “pharmacy of the world”. It contributes a significant 1.72% to the India's GDP. In terms of its size, the Indian Pharmaceutical Industries is currently valued at $ 50 Billion and is expected to reach $ 130 billion by 2030. Indian medicines reach 200+ countries contributing to availability of affordable quality medicines, wellness products, bulk drugs, and intermediates. The Indian Pharmaceutical Industries played a very significant role in supply of drugs during COVID pandemic. India produces more than 500 APIs and 60,000 generic drugs across 60 therapeutic categories. The Indian pharmaceutical industry includes a network of 3,000 companies and 10,500 manufacturing units.

While the pharmaceutical sector was growing, the government was cognizant of its role in providing affordable healthcare to its people. The World Health Organisation (WHO) guideline on country pharmaceutical pricing policies (2020) also notes that affordable access to safe and efficacious pharmaceutical products is at the core of global efforts towards achieving universal health coverage. Keeping in view the socio-economic milieu, the government is aware about the importance of keeping drugs affordable and through various policy interventions since early 1960's has ensured the availability, affordability and accessibility of drugs .

Evolution of Policy and Regulatory Framework for Pricing of Drugs

A wide variety of products such as food grains, textiles, fertilizers etc., were regulated under the Essential Commodities Act, 1955 (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 price control orders were notified through various orders in the country from time to time based on different principles. The span of control of prices as well as the nature of control of prices under various orders has varied as per the underlying principles in the respective Drug Policies.

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 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:

- 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.

In the meantime, in 1966 itself the government also requested the Tariff Commission (TC) to examine the cost structure of 18 essential bulk drugs and their formulations. The TC submitted its **"Report on the Fair Selling Prices of Drugs and Pharmaceuticals"** to the Government in August 1968. Based on the Commission report, the government on 30th April 1970 undertook following steps:

Prices of 18 bulk drugs, 49 formulations studied by TC and other formulations too were brought under price control based on "cost-plus" formula. Detailed formula for calculating the retail price was given along with the percentage of markup.

It was also informed that a suitable order incorporating the formula would be promulgated soon.

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

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

RP= (MC+CC+PC) × (1+MU÷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. 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.

THE HATHI COMMITTEE REPORT

In 1974, the government appointed a committee under the chairmanship of Rajya Sabha MP Shri Jaisukhlal Hathi to enquire into the conditions prevailing in the sphere of pharmaceuticals in the country and find ways to make India self-sufficient in production of drugs. The Committee submitted its report in 1975 which is widely known as the **Hathi Committee report** and it had 224 wide-ranging recommendations. The report strongly emphasized a greater role for the public sector in the manufacturing of drugs, and amongst other points recommended the creation of a National Drug Authority, the introduction of a list of essential medicines, highlighted the role of R&D in the growth of the drugs and pharmaceutical sector, etc. The committee had identified 44 drugs derived from

synthetic sources as essential drugs.

Drug Policy-1978 and the Drugs Prices (Control) Order, 1979

Based on the recommendations of Hathi Committee, 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). The stated objectives of the DP, 1978 were:

1. Country should be self-reliant in technology;
2. There should be self-sufficiency in drugs; and
3. Quality drugs should be adequately available at reasonable prices.

Salient Features of Drug Policy, 1978

- To maximize production of bulk drugs locally: compulsory manufacturing of bulk drugs to qualify to sell formulations
- Provide leadership to the PSUs
- Reduction in imports of bulk drugs
- To provide encouragement for growth of local industry
- Division of drugs into three groups depending on who could produce them: Public Sector; Indian /domestic sector; open to all sectors including the foreign sector
- Reduction in selling prices of essential drugs and their formulations
- Production bulk drugs by high

DPCO, 1979 was promulgated on 31st March 1979 and price control was imposed on 370 bulk drugs and formulations made therefrom. 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) x (MU+100)/100+ taxes

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

In the case of the imported formulations, the prices were fixed differently. The landed cost was to form the basis for fixing its price along with such margin as the government may allow from time to time. Usually, a maximum margin of 50% on the landed costs was provided for fixing maximum retail prices (MRPs). Provisions in DPCO-1979 were made for encouraging R&D activity by way of exempting the prices of locally conducted research and R&D-developed new products from control.

The concepts of fixation of the retention price and pooled price and fixation of leader prices of formulations were introduced in DPCO, 1979. Leader prices of formulation specified in Categories I, II and III were fixed by the Government and the price so fixed would operate as ceiling sale price for the manufacturers. However, in cases where the selling price

was less than the leader price fixed under the DPCO, 1979, the manufacturer had to obtain prior approval of the Government for increasing the selling price of the formulation. In cases of prices being higher than the leader prices, the manufacturer had to reduce the sale price to the level of the leader price fixed by the Government. Such lowering of prices would remain frozen unless and until the Government permits an increase in the sale price.

A provision of Drug Prices Equalization Account (DPEA) for collecting excess amounts from companies was also introduced. If the companies had utilized bulk drugs produced at lower prices than the prices allowed/ considered for price fixation of their formulations, excess amount was to be deposited in DPEA. However, the implementation of DPEA created different kinds of administrative problems and led to litigation. Currently, Department of Pharmaceuticals (DoP), Government of India is the custodian of the DPEA.

THE KELKAR COMMITTEE REPORT

In 1984, the Government constituted another expert committee to look into the issue of drug pricing known as the Kelkar Committee. The Committee recommended the exclusion of a number of drugs from the purview of price control. Various suggestions were made for determining the criteria for inclusion and exclusion. It also recognized the need for liberalizing the profitability curbs.

Drug Policy, 1986 (Measures for Rationalization, Quality Control and Growth of Drugs and Pharmaceuticals Industry in India)

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 to reduce this to a considerable extent and make the price control system less cumbersome but more effective. With this backdrop and the recommendations of Kelkar Committee Report, 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'.

Objectives of Drug Policy, 1986

Ensuring abundant availability, at reasonable prices, of essential life saving and prophylactic medicines of good quality;

Strengthening the system of quality control over drug production and promoting the rational use of drugs in the country;

Creating an environment conducive to channelising new investment into the pharmaceutical industry, to encouraging cost-effective production with economic sizes; and

To introduce new technologies and new drugs and strengthening the indigenous capability for production of drugs.

DP, 1986 proposed to have two categories of formulations and bulk drugs required in place of three categories which existed as per DPCO, 1979. Category I would consist of drugs required for the National Health Programme and the MAPE (maximum allowable post manufacturing expense incurred from the stage of manufacturing to retailing and manufacturers' margin) allowed for drugs in this category would be 75%; category II would consist of drugs other than those in category I but which are also considered essential for the health needs and a MAPE of 100% for formulations would be allowed while fixing the prices for this category of drugs.

The Policy discontinued the *fixation of the retention price and pooled price and fixation of leader prices of formulations of* DPCO, 1979 and consequently the DPEA.

DRUGS PRICES (CONTROL) ORDER, 1987

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 significantly reduced from 370 to 142.

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.

NEW DRUG POLICY 1994 AND DRUGS PRICES (CONTROL) ORDER DPCO-1995

The Government of India appointed a Standing Committee in the Ministry of Chemicals and Fertilizers in February 1990 to review Drug Policy 1986 and DPCO-1987. Consequent on the study and recommendations of the Standing Committee, government came out with a new policy, which was New Drug Policy-1994 in September 1994.

The New Drug Policy liberalized the criteria for selecting bulk drugs, or formulations, for price control. In addition, industrial licensing was abolished for all bulk drugs. All hindrances to capacity expansions were removed, and it was expected that, as a result, supply would rise, resulting in higher competitive pressures. Foreign investment up to 51 per cent was also permitted in the case of all bulk drugs, their intermediates and formulations. FDI above 51 per cent could also be considered on a case-to-case basis. Nevertheless, five bulk drugs; Vitamin B1, Vitamin B2, Folic Acid, Tetracycline and Oxy-tetracycline were reserved for the public sector till 1998.

The drug price control system was revised and there would be a single list of scheduled bulk drugs and formulations based thereon, with uniform MAPE of 100%. The criteria of 'market competition' and 'annual turnover' were introduced in identifying drugs to be brought under price control.

The New Drug Policy, 1994 envisaged the setting up of National Pharmaceutical Pricing Authority (NPPA). It was set-up in 1997 as an independent body of experts in the Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals (DoP). NPPA was delegated the powers to implement and enforce the then extant Drugs (Prices Control) Order 1995. As per the Resolution and powers delegated to NPPA from time to time, it performs a wide variety of functions.

Functions of NPPA

a. To implement and enforce the provisions of the DPCO, 1979, 1987, 1995 and 2013 in accordance with powers delegated to it.

b. To monitor the availability of medicines & medical devices, identify shortages, if any, and to take remedial steps.

c. To undertake and/or sponsor relevant studies in respect of pricing of drugs/formulations.

d. To collect / maintain data on production, exports and imports, market share of individual companies, profitability of companies etc. for bulk drugs and formulations.

e. To deal with all legal matters arising out of the decisions of the Authority.

f. To render advice to the Central Government on changes/ revisions in pharmaceutical policy.

g. To render assistance to the Central Government in parliamentary matters relating to pharmaceutical pricing.

Composition of the Authority and Authority Meetings

NPPA is a five Member body comprising of:

- Chairman (in the rank of Secretary or Additional Secretary of Govt. of India).
- Member Secretary (in the rank of Joint Secretary to the Govt. of India)
- Three ex-officio Members, one each from:
  - I Adviser, Department of Economic Affairs
  - II Adviser, O/o Chief Adviser Cost, Department of Expenditure
  - III Drug Controller General of India, Ministry of Health and Family Welfare

Drugs Prices (Control) Order, 1995 (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. 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.

After the promulgation of the DPCO-1995 and assessment of the condition of the pharmaceutical industry, Government of India decided to strengthen R&D base of the pharmaceutical industry and reviewed the prevailing drug price control mechanism to assess if alternative models from the current procedures could be considered for price regulation of formulations. In this context, two separate committees were constituted in 1999.

PHARMACEUTICAL RESEARCH POLICY & PRICE CONTROL POLICY REVIEW COMMITTEES

Two committees-the Pharmaceutical Research and Development Committee (PRDC) and the Drug Price Control Review

Committee (DPCRC) were set up by the government in 1999.

PRDC Recommendations

PRDC was constituted to study and identify events and procedures which were required to strengthen R&D base of the pharmaceutical industry. PRDC submitted its Report to the Government in 1999. The findings and recommendations of PRDC are summarized below:

- The low level of profitability in the pharmaceutical industry combined with the comparatively small size was the reason for low investment in R&D.
- PRDC emphasized the need for upgrading the human resource in skill development and in acquisition of latest tools for R&D and suggested methods to generate funds for conducting R&D vigorously.
- It further cited opportunities for India for clinical trials because of population size and availability of more patients.
- It also emphasized the need for strengthening and modernizing Indian system of medicine.
- The PRDC also felt the need for maintaining higher levels of IPR management for strengthening IPR system with action points for the government, judiciary, industry, Science & Technology and educational system.
- The Committee also recommended creation of newer structures for the Central Drugs Standard Control Organization (CDSCO) to supplement its effort towards compliance with global regulatory requirement pertaining to quality, efficacy and safety of medicines.

PRDC did not, however, prepare any quantitative or semi-quantitative road map for the discovery of newer classes of APIs; starting from drug discovery to full drug development strategy to clinical research to introduction in the market. It is recognized globally that nearly 10-12 years are needed to come to the stage of marketing a new drug, starting from the stage of developing newer concepts.

DPCRC recommendations

DPCRC in its report made the following major recommendations:

- ★ The guiding factors to identify specific drugs were to be based on mass consumption, and even in the absence of adequate competition to include important drugs needed for national health programme.
- ★ Adequate health insurance cover should be instituted by both the public sector and the private sector so as to become less dependent on price control measures for obtaining medicines.
- ★ Public health-care system shall be expanded progressively by raising budgetary provisions and by improving supply of essential medicines to improve the public healthcare system of the country.
- ★ DPCRC method of determining prices of bulk drugs: The price could be ascertained by consulting the purchase documents/ information from the drug industry journals, purchase documents of the producers of formulations etc. This method would avoid having exposure to the confidential information of processes and operations data of the production of bulk drugs.
- ★ For the imported bulk drugs, the import data available from the

Directorate General of Health Services (DGHS), the Central Exercise authorities or the Annual Cost Audit Reports may be consulted.

- DPCRC method of selecting list of bulk drugs to be price controlled: The 'mass consumption' formulations could be identified from ORG MARG Report which contains approximately 180 groups/ categories of pharmaceutical formulations.
- Once the list of bulk drugs was made out, the low cost drugs could be eliminated from price control on the basis of "per day cost of a medicine" and the criterion should be that the 'per day cost' of the medicine should not exceed Rs 2.
- DPCRC suggestions of price control of pharmaceutical formulations: DPCRC suggested to take into consideration prevailing MRPs of those formulations prevalent in the market as the 'bench mark-prices', where the formulations had registered a MAT sale value of Rs 10 crore or above with a market share of 10% or above in the group/category of formulations to be price controlled because such formulations represented to mass consumption category.
- z could be allowed linking notified prices with such other Government notified factors to be used as measures for inflation such as the Consumer Price Index (CPI) of the industrial workers/ agricultural labors etc.
- If the MRPs of the formulations thus selected were declared by the government then all the other manufacturers would fall in line and would fix prices of their z the MRPs of the identified formulations.
- An additional 8% cost be allowed for formulations manufactured under WHO GMP certification, and further, another additional 2% be allowed for improved packaging material usage. In addition, a further 3% of the ex-factory cost should be allowed for enabling companies to upgrade their manufacturing premises to meet the US FDA/MCA standards, which was considered to be the highest standard of manufacturing and documentation for pharmaceutical formulations.
- The price control method then existing in the country should move away from the "controlled regime" to the "monitoring regime" over a period of time.
- Good Manufacturing Practices (GMPs) prescribed under the rules needed to be established rigorously in all the manufacturing units over a period of two years so as to minimize manufacturing sub-standard and spurious drugs.
- The DPCRC recommended that the WHO-GMP standards should be made a basic criterion for granting a drug license to manufacture a drug in the country. It further recommended that Government should develop a data bank on pharmaceutical sector and devise a simplified format in the DPCO to collect information.
- DPCRC also recommended that the availability and price situation of formulations in the market should be reviewed periodically with meetings with the consumers' interest group, industry and trade.

National Pharmaceutical Policy 2002 (not Implemented)

The next pharmaceutical policy was formulated by the Government in 2002, which drew heavily from the PRDC and DPCRC reports and recommendations. It was announced on 15th February 2002.

This policy, inter-alia, proposed a radical shift in the price control of pharmaceutical formulations from a price "controlled regime" to a price "monitoring regime". It also proposed to reduce the number of price-controlled drugs under DPCO,1995 from 74 to 38. A Public Interest Litigation (PIL) was filed in Hon'ble Karnataka High Court by Lt. Col. (Retired) K.S. Gopinath and B.V. Bhaskar against Union of India and Others praying under Article 225 of the Constitution of India to produce all records of the Pharmaceutical Policy 2002 and quash the same on the ground that the policy had been framed like a business policy and on enforcement it would take away life-saving and essential medicines out of the ambit of the Drugs Price Control Order, which would be highly detrimental to public interest.

Hon'ble Karnataka High Court, based on the PIL, issued a stay order directing Government not to implement the Pharmaceutical Policy 2002. The Central Government challenged the stay and appealed to the Supreme Court of India against the stay, ordered by the Karnataka High Court. The Supreme Court on 10.03.2003 had lifted the stay but directed the Indian Government to evolve criterion such that the essential life-saving drugs do not fall out of price control. While lifting the stay, the Hon'ble Supreme Court directed that Central Government may evolve such procedures and criteria that the essential life-saving drugs were not to fall outside the price control. Relevant portions of the Supreme Court order read as under: *"Meanwhile, we suspend 'the operation of the order to the extent it directs that the Policy dated: 15.2.2002 shall not be implemented. However, we' direct that the petitioner shall consider and formulate appropriate criteria for ensuring essential and lifesaving drugs not to fall out of price, control and further directed to review drugs which are essential and lifesaving in nature till 2nd May, 2003."*

Thus, the National Essential Drug List, 1996 was reviewed and a new list called the National List of Essential Medicines (NLEM), 2003 was brought out and it had 354 drugs. This was subsequently pruned down to 348 in NLEM, 2011. However, the National Pharmaceutical Policy 2002 was not implemented.

PRONAB SEN COMMITTEE REPORT

In November 2004, the Government also set up a Task Force under the Chairmanship of Principal Advisor, Planning Commission. Dr. Pronab Sen to look into the issue of price control options other than price control and other issues and to make recommendations for making available life saving drugs at reasonable prices. The basis of drugs to be considered was the NLEM 2003, being the latest list at that time. The Pronab Sen Committee submitted its recommendations in September, 2005. It recommended price ceiling for 314 medicines that fall under essential drugs and it should be worked out on the weighted average of top three brands of a drug by value of single ingredient formulations prevailing in the market as on April 1, 2005. In cases where there are less than three brands, the average of all existing brands would be taken. The price regulation should be on the basis of 'Essentiality' of the drug and it should be applied only to formulations and not to upstream products, such as bulk drugs. The ceiling price of essential drugs should normally not be based on cost of production but on readily monitorable market based benchmarks.

Draft National Pharmaceuticals Policy, 2006 and Draft National Pharmaceutical Pricing Policy, 2011

The Drug Policy, 1994 needed to be revised to meet the challenges brought about by the competitive international pharmaceutical industry in a globalised economic environment, as much as meeting the country's requirements for safe and quality medicines at reasonable prices. The government circulated the draft National Pharmaceuticals Policy 2006 on 28th December 2005 with objectives, inter-alia, to ensure availability at reasonable prices of good quality medicines within the country; to improve accessibility of essential medicines for common man particularly the poorer sections of the population; to promote greater research and development in the pharmaceuticals sector by providing suitable incentives in this regard. However, this policy was not notified.

Draft National Pharmaceutical Pricing Policy, 2011 was released by Department of Pharmaceuticals on 25th October 2011 for public comments. It was based on the National List of Essential Medicines (NLEM)-2011 and on the Report of Task Force headed by Dr. Pronab Sen which had submitted its report in September 2005. Task Force had recommended that price ceiling for 314 medicines that fall under essential drugs should be worked out on the weighted average of top three brands of a drug by value. This criterion was criticized and taking into account the comments as well as criticisms, government finalized the National Pharmaceuticals Pricing Policy, 2012.

Therefore, the Government enunciated the National Pharmaceuticals Pricing Policy, 2012 (NPPP-2012) which seeks to replace the Drug Policy enunciated in September, 1994 as Modifications in Drug Policy, 1986 (Drug Policy 1994). The NPPP-2012 is in continuation of the Policy announced earlier in 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 were identification of 'essentiality' of medicines/formulations; intent to control the prices of essential formulations only and not the bulk drugs used in the making of such formulations; and the prices of essential medicines to be determined based on 'market based' information.

The NPPP-2012 was essentially the 'modified' concept of Drug Policy-2002 where the intention announced was to control the price of 'essential medicines' based on the market capture of such formulations as determined and published by reputed private organizations like the ORG-MARG utilizing the MAT values of essential formulations in each therapeutic category. The NPPP, 2012 envisages regulation of the prices of formulations only, identified on the basis of essentiality of drugs. Further, the basis of fixing the ceiling price of formulations has been changed from cost based to Market Based Pricing (MBP) in NPPP-2012. Thus, as per NPPP-2012, the three aspects of the regulation of prices of drugs are as

follows:

- **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 15thMay, 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.

Enabling provisions for Drug Price Control

Section 3 of Essential Commodities Act, 1955

Powers to control production, supply, distribution, etc., of essential commodities-If the Central Government is of opinion that it is necessary or expedient so to do for maintaining or increasing supplies of any essential commodity or for securing their equitable distribution and

Schedule to the Section 2A(1) of Essential Commodities Act, 1955

Drugs are included in Schedule of section 2A(1) of the Essential Commodities Page 9 Act, 1955 as Essential

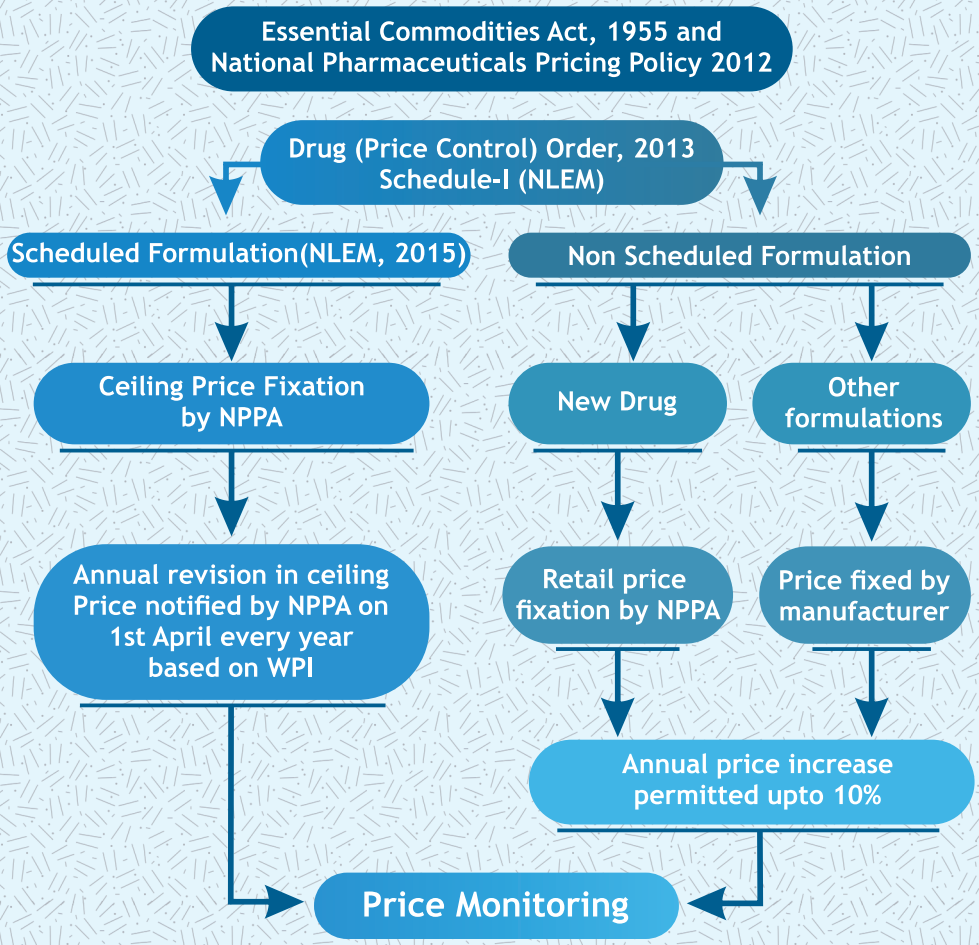
Commodities. Definition of Drug as per Section 3(b) of Drugs and Cosmetics Act, 1940

- All medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes.
- Such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government.

OVERVIEW OF DRUGS (PRICES CONTROL) ORDER, 2013 (DPCO-2013)

Essential Commodities Act, 1955 and
National Pharmaceuticals Pricing Policy 2012The DPCO-2013 was notified on 15thMay, 2013 by the Ministry of Chemicals & Fertilizers (MoC&F) and NPPA is mandated with the task of implementing the DPCO, 2013, which aims at making available essential and lifesaving medicines to all through the instrumentality of price control. The price control is applied to specific formulations with reference to the medicine (active pharmaceutical ingredient), route of administration/ dosage form and strength as contained in the First Schedule. The overview of the DPCO mechanism as it exists today is depicted below:

Overview of the DPCO,2013 mechanism



National List of Essential Medicines with specific reference to NLEM, 2022

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, 2015 and now in 2022.

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. In NLEM, 2022, a new section has been added in the list for the medicines which have been considered essential for supportive management of COVID-19.

As per Report of the Core-Committee for Revision of National List of Essential Medicines 2022, the criteria for inclusion of a medicine in NLEM are as follows:

- The medicine should be approved/ licensed in India.
- The efficacy and safety profile of the medicine should be based on robust scientific evidence. - The medicine should be useful in disease which is a public health problem in India.
- All medicines enlisted in National Health Programmes/ National Disease Control Programmes are as such essential and hence included in the NLEM 2022.
- The medicine should be affordable to the community in the Indian context. - The medicine should be readily accessible at P, S, T healthcare levels
- When more than one medicine are available from the same therapeutic class, preferably one prototype/ best suited medicine of that class to be included after due deliberation and careful evaluation of their relative safety, efficacy, availability and affordability.
- Overall cost of therapy was considered and not just the unit cost of the medicine.
- A Fixed Dose Combination was generally not included unless the combination had unequivocally proven advantage over individual ingredients administered separately, in terms of increasing efficacy, reducing adverse effects and/or improving compliance.

CEILING PRICE FIXATION OF A SCHEDULED FORMULATION UNDER DPCO, 2013

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 su
ggested in the DPCO. The MRP for that particular drug formulation must not exceed the notified ceiling price plus applicable taxes.

The ceiling price of a scheduled formulation of specified strengths and dosages as specified under the first schedule is calculated as under:

Step 1.
First the Average Price to Retailer of the scheduled formulation is calculated.
Average Price to Retailer, P(s) = (Sum of prices to retailer of all the brands and generic versions of the medicine having market share more than or equal to one percent of the total market turnover on the basis of moving annual turnover of that medicine) / (Total number of such brands and generic versions of the medicine having market share more than or equal to one percent of total market turnover on the basis of moving annual turnover for that medicine.)

Step 2.
Thereafter, the ceiling price of the scheduled formulation i.e. P(c) is calculated as below:
P(c) = P(s) x (1+M/100), where M = % Margin to retailer and its value =16
All the existing manufacturers (including importers and marketers) of a scheduled formulation, selling branded or generic or both versions of that formulation at a price higher than the ceiling price plus local applicable taxes are required to reduce it to at least that level. At the same time, all existing manufacturers (including importers and marketers) of that formulation who are selling it below that price are required to maintain their existing MRP. Implementation of the price notification is to be communicated, in Form-V of Schedule II to the DPCO 2013, to all dealers, State Drug Controllers and NPPA immediately. Also the current price list of scheduled drugs has to be displayed by every dealer and retailer.

The ceiling price fixed for each scheduled formulation becomes operative and legally enforceable from the date on which the price is notified in the Gazette of India Extraordinary. The provisions of Paragraph 24 of DPCO, 2013 cast an obligation on the manufacturers to ensure compliance with the prices fixed or revised by the NPPA, from the date of price notification by issuing a revised price list or supplementary price list, in required, in Form V to dealers, the retailers, State Drug Controllers and the Government.

The manufacturers and retailers are responsible for complying with the notified prices from the date of notification in sale of all available stock including pre-manufactured batches of concerned formulation for which ceiling price or retail price has been fixed or revised by the NPPA. As per para 26 of DPCO, no person shall sell any formulation to any consumer at a price exceeding the price specified in current price list or price indicated on label of the container or pack thereof, whichever is less.

The notified ceiling price with respect to each scheduled formulation is valid for a period of five years from the date of original price notification, subject to annual revision to be notified by NPPA which would be effective from the first day of April every year as per the annual WPI notified by the DPIIT with respect to the previous calendar year. The revision may mean increase or decrease in ceiling price depending upon whether the WPI is positive or negative. The manufacturers (including importers and marketers) are free to avail themselves of the annual revision in case of increase, without

obtaining prior approval of the Government, but they are required to exercise their decision in this regard within 15 days of such revision and report to the NPPA in Form-II of Schedule II to DPCO 2013, failing which it shall be construed that the company has opted for non-revision of MRP and the concerned manufacturer shall be liable to deposit the amount charged over and above the pre-revised MRP, along with interest from the date of overcharging.

Schedule I of the DPCO 2013 was revised on 11.11.2022 based on National List of Essential Medicines 2022, and it covers 29 therapeutic categories and includes the medicines for HIV, cancer, diabetes, Heart Diseases, ENT, coronary stents amongst others. Therapeutic category wise formulations/drugs under NLEM 22

Therapeutic category wise formulations/drugs under NLEM 22

THERAPEUTIC CATEGORY	NUMBER OF DRUGS
Medicines used in Anaesthesia	20
Analgesics, Antipyretics, Non-steroidal Anti-inflammatory; Drugs (NSAIDs), Medicines used to treat Gout and Disease; Modifying Agents used in Rheumatoid Disorders	14
Antiallergics and Medicines used in Anaphylaxis	6
Antidotes and Other Substances used in Management of Poisonings/Envenomation	13
Medicines used in Neurological Disorders	20
Anti-infective Medicines	108
Anti-cancer agents including Immunosuppressive and Medicines used in Palliative Care	63
Medicines affecting Blood	13
Blood products and Plasma substitutes	7
Cardiovascular Medicines	30
Dermatological Medicines (Topical)	12
Diagnostic Agents	7
Dialysis components (Haemodialysis and Peritoneal Dialysis)	2
Antiseptics and Disinfectants	7
Diuretics	4
Ear, Nose and Throat Medicines	4
Gastrointestinal Medicines	14
Hormones, other Endocrine Medicines and Contraceptives	25
Immunologicals	18
Medicines for Neonatal Care	3
Ophthalmological Medicines	16
Oxytocics and Abortifacient	7
Medicines used in treatment of Psychiatric Disorders	17
Medicines acting on the Respiratory tract	7
Solutions correcting Water, Electrolyte disturbances and Acid-base disturbances	8
Vitamins and Minerals	8
Medicines for COVID 19 management	5
Coronary Stents	2
Medicines for animal use	2
Total number of Drugs	388(462 with duplication)

FIXATION OF RETAIL PRICE OF A NEW DRUG UDNER DPCO 2013

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.

Price fixation in case of extra-ordinary circumstances under Para 19 of DPCO

In addition, as per Para 19 of the DPCO-2013, "Notwithstanding anything contained in this order, the Government may, in case of extra-ordinary circumstances, in it considers necessary so to do in public interest, fix the ceiling price or retail price of any drug for such period, as it may deem fit and where the ceiling price or retail price of the drug is already fixed and notified, the Government may allow an increase or decrease in the ceiling price or the retail price, as the case may be, irrespective of annual wholesale price index for that year."

The 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. NPPA has used Para 19 to cap the prices of drugs as under:

- In 2014, NPPA capped the MRP of 106 non-scheduled drug formulations which includes 22 diabetic and 84 cardiovascular drugs.
- NPPA has fixed ceiling price of Cardiac Stents being scheduled formulation under the DPCO, 2013, resulting in price reduction for Coronary Stents, which worked out to 85% for Bare Metal Stents and 74% for Drug Eluting Stents.
- Ceiling price of Orthopaedic Knee Implants was fixed in August 2017, resulting in price reduction for Orthopaedic Knee Implants which worked out up to 69%.
- rade Margin of non-scheduled formulations of 42 select Anti-cancer medicines capped under "Trade Margin Rationalization" approach as a pilot for proof of concept, wherein price of above 500 brands of medicines were reduced up to 90%.
- NPPA invoked Paragraph 19 of the DPCO, 2013 to regulate the price of Oxygen Concentrators, Pulse Oximeter, Blood Pressure Monitoring Machine, Nebulizer, Digital Thermometer and Glucometer under "Trade Margin Rationalisation" Approach in June/July 2021.

Trade Margin Rationalisation (TMR)

Trade margin is the difference between the price at which the manufacturers sell the drugs to stockist / distributors (price to stockist) and the final price to patients (maximum retail price excluding taxes).

Currently, the non-scheduled segment comprises around 80-82% of the total market share and it is noted that the current regulation is not able to limit the exorbitant retail margins. Thus, to address this issue the concept of TMR has been conceptualized. TMR is a less stringent mechanism to regulate prices as it allows market dynamics to operate as each manufacturer is free to fix its own MRP. This flexibility, while ensuring better prices for the consumer, also provides for flexibility with the manufacturers to ensure availability of the required resources for research and development.

Thus, this concept endures regulation for better and more affordable access while making available the necessary incentive to the industry to grow.

Exemptions Under Para 32 Of Dpco,2013

Para 32 of DPCO,2013 grants exemptions from provisions of DPCO,2013 under certain conditions. However, for availing these exemptions under Para 32, it is necessary that manufacturer/ marketer should apply to NPPA with necessary documents. The self-invocation of para 32 will amount to violation under DPCO-2013.

MAJOR MILESTONES OF NPPA IN IMPLEMENTATION OF DPCO, 2013

2013
Erstwhile, DPCO 1995 was replaced by DPCO 2013.
Drug pricing methodology shifted from cost based to market based methodology

2014
Capped the MRP of 106 cardiac and anti-diabetic non- scheduled drugs under Para 19 of DPCO 2013

2015
Integrated Pharmaceutical Dalatabase Management System (IPDMS) was launched

2016
Schedule-I of DPCO 2013 was amended by incorporating NLEM 2015.
Ceiling prices of scheduled formulations are fixed under NLEM 2015
NPPA started uploading draft working sheet prior to its approval to ensure transparency

2017
Fixed the ceiling prices of coronary stents
Fixed the price of Knee Implants

2018
The ceiling of coronary stents were re-fixed

2019
The price of non-scheduled formulations of 42 anti-cancer drugs were capped based on Trade Margin Rationalization Approach

2020
NPPA implement Ecosystem with a view ensure timely disposal of applications

2021
The price of six medical devices were rationalized based on Trade Margin Rationalization approach

2022
Authority under DPCO 2013 conducted its 100th meeting
NPPA completed 25 years

Monitoring Of Availability Of Scheduled Formulations Under Para 21 Of DPCO,2013

As per the provisions under Para 21 of DPCO 2013, NPPA monitors the availability of drugs, identifies shortages, if any, and takes remedial steps to ensure availability of drugs to the consumers. As and when the reports of shortages of particular drug(s) in any part of the country are received, the concerned companies are immediately asked to send stocks to the affected areas and to make the drugs available. In cases where shortages are apprehended, NPPA also directs the companies to continue or increase the production under Para 3 of DPCO, 2013.

During the COVID-19 pandemic in the country, NPPA played an active role in addressing the exigencies arising out of the pandemic and undertaking necessary measures to ensure continued availability of life saving essential medicines and medical devices throughout the country. NPPA had greater interaction with Industry, manufacturers; All India Organisation of Chemists and Druggists (AIOCD); SDCs; District Magistrates (DM) etc., to ensure that supply chains were not compromised.

Any individual or consumer organization or stockist / distributor / dealer / retailer or State Drug Controller can lodge complaints at PJS portal of NPPA, through the toll-free number 1800111255 & Email - monitoring-nppa@gov.in. PJS is an online complaint redress system for speedy and effective resolution of complaints with respect to availability of drugs, overpricing of drugs, sale of 'new drugs' without prior price approval (WPA) and refusal to supply or sell drugs.

PRICE MONITORING AND RESOURCE UNITS

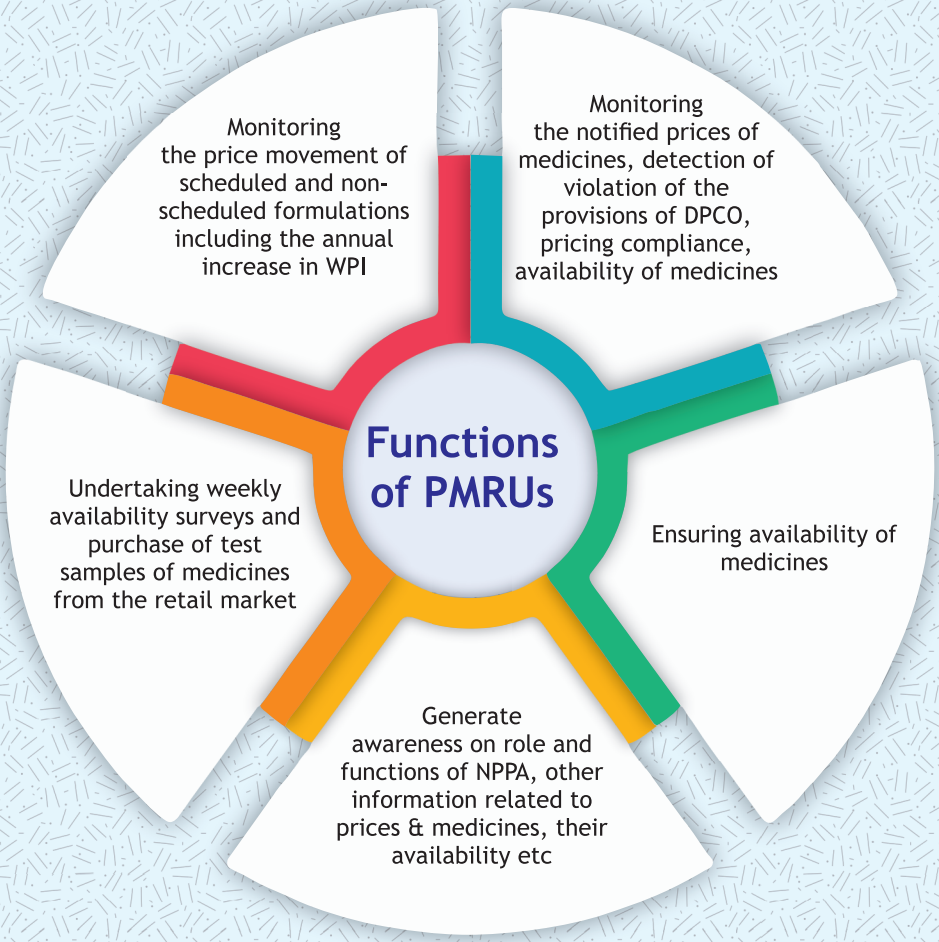
NPPA is implementing a Central Sector Scheme, the Consumer Awareness, Publicity and **Price Monitoring (CAPPM).** The Scheme has following two components:

A. Assistance for setting-up of PMRUs in State/UTs: Modalities of setting up of PMRUs at State/UT level and working under the direct supervision of respective SDCs. Under the component, assistance is extended to State/UTs to set-up PMRUs.

B. IEC activities under CAPPM: The Information, Education & Communication (IEC) activities aim to create general awareness and disseminate information regarding the functioning of NPPA, availability of medicines, prices of medicines, etc.

The scheme is implemented & monitored at the Central level by the NPPA and executed through PMRUs, registered as Society in the State/UT concerned.

Till end of September 2024, Thirty-one (31) Price Monitoring and Resource Unit (PMRU) have been set up in the States/ UTs till date, viz.: Kerala, Gujarat, Odisha, Rajasthan, Punjab, Haryana, Tripura, Nagaland, Uttar Pradesh, Andhra Pradesh, Mizoram, Jammu & Kashmir, Karnataka, Telangana, Maharashtra, Goa, Madhya Pradesh, Chhattisgarh, Jharkhand, Puducherry, West Bengal, Ladakh, Himachal Pradesh, Bihar, Uttarakhand, Meghalaya, Arunachal Pradesh, Chandigarh, Assam, Dadra & Nagar Haveli and Daman & Diu and Lakshadweep. Setting up of PMRUs in the other States/ UTs are in progress. The PMRUs perform different functions to assist NPPA as well as the SDCs in executing their duties as per their mandate

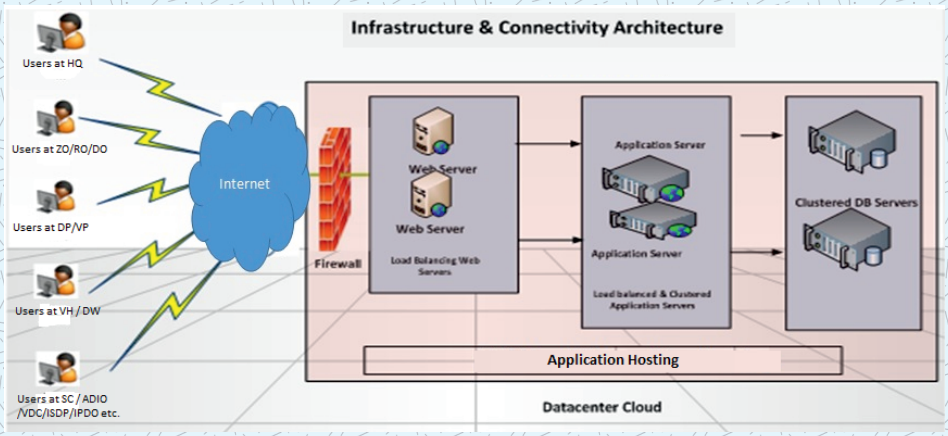


THE INTEGRATED PHARMACEUTICAL DATABASE MANAGEMENT SYSTEM (IPDMS) 2.0:

The Integrated Pharmaceutical Database Management System (IPDMS) 2.0 of NPPA is a comprehensive digital platform designed to manage, regulate, and monitor various aspects of pharmaceutical products related to their prices and availability. Key features include a centralized database, real-time data collection, automated reporting, compliance monitoring, advanced data analytics, and a stakeholder portal. The system is a significant step towards enhancing transparency, efficiency, and accountability in the pharmaceutical and medical devices sector.

IPDMS 2.0 allows the companies to submit all the statutory Forms under DPCO,2013 of pharma products and medical devices in an online mode with user friendly interface. Submission of these Forms is a major regulatory compliance requirement under the DPCO, 2013 and their submission on-line facilitates the pharma and medical device industry.

IPDMS 2.0 Deployment architecture



IPDMS 2.0

The Pharma Sahi Daam (PSD) mobile app, integrated with IPDMS 2.0 allows consumers to verify drug prices, compare brands, and access information in real-time, thus promoting transparency and informed decision-making.

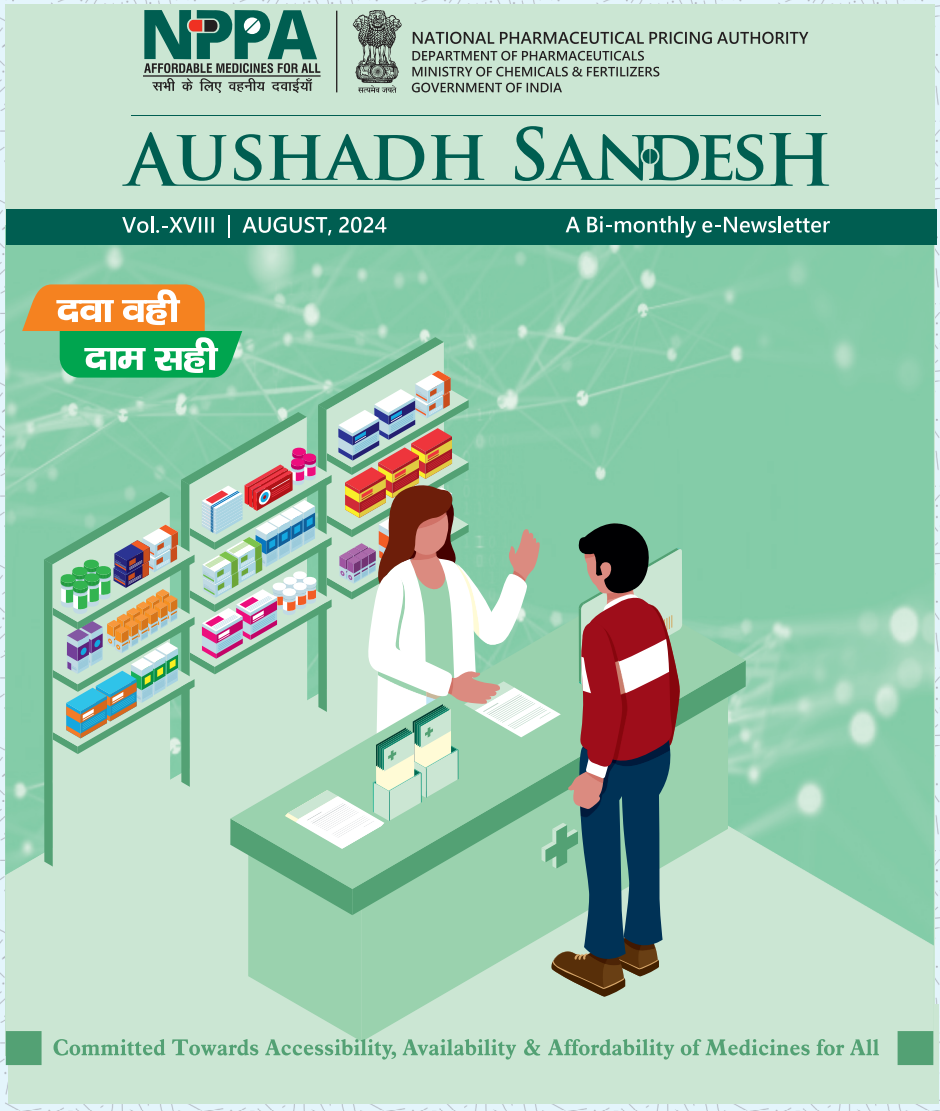
The uses and the salient features of PSD are:

- PSD facilitates consumer to verify the ceiling prices for a particular medicine
- Users can search for the prices of different brands by formulation name, and can also define the dosage form and strength of the formulation
- Users can search for medicines by their generic names or brand names and compare prices across different brands or generic versions
- Users can compare the prices of alternate brands for the same formulation
- User can also search a particular medicine by voice search (Speech recognition)

Search and Complaint registering feature of PSD

NPPA PUBLICATIONS

e-Newsletter of NPPA (Aushadh Sandesh): A bi-monthly e-Newsletter containing information on the latest development in the pharmaceutical sector in India as well as globally. Eighteen editions of the e-newsletter have been published till August, 24 and these can be accessed at: https://www.nppaindia.nic.in/newsletter



Other Publications available on https://www.nppaindia.nic.in/book

- A Coffee Table Book on Indian Pharmaceutical sector published in 2023
- Publication titled "An Overview of Drug Pricing@NPPA 25 Year Odyssey" (2022)

NPPA

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