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

An Overview of Drug Pricing

@NPPA 25 Year Odyssey

Committed Towards Accessibility, Availability & Affordability of Medicines for All

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डॉ. मनसुख मांडविया
DR. MANSUKH MANDAVIYA

स्वास्थ्य एवं परिवार कल्याण
व रसायन एवं उर्वरक मंत्री
भारत सरकार
Minister for Health & Family Welfare
and Chemicals & Fertilizers
Government of India

MESSAGE

I compliment the National Pharmaceutical Pricing Authority (NPPA) on completion of 25 years of its service to the nation. The setting-up of NPPA was an important milestone in the Pharmaceutical sector and as a regulator: Its role has been marked by high degree of professional competence and transparency. It has kept pace with the best practices in the drug price regulatory regime, when it transitioned from DPCO, 1995 to DPCO, 2013 in ensuring that essential medicines are available to the consumers at reasonable prices.

While establishing itself as the Pharmacy of the world at the global level, the Pharmaceutical sector has equally catered to the domestic demand. Keeping in view the needs of different stakeholders, both in Pharmaceutical as well as Medical Devices sector, NPPA has streamlined its processes facilitated by the use of digital technology.

Furthermore, during the COVID-19 pandemic in the country, NPPA played an active role in addressing the exigencies arising out of COVID-19 pandemic and undertook necessary measures to ensure continued availability of life saving essential medicines throughout the country. It has played an important role in ensuring fair play and I am sure that it would continue to play its role with the same passion and zeal in the coming years too.

This publication that traces 25 years of eventful journey of NPPA is an excellent attempt to document the past and also reflect on what needs to be done in future. Best wishes and congratulations to all the employees of NPPA on this important milestone.

(Dr. Mansukh Mandaviya)

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भगवंत खुबा
ಭಗವಂತ ಖೂಬಾ
BHAGWANTH KHUBA

रसायन एवं उर्वरक एवं
नवीन एवं नवीकरणीय ऊर्जा राज्य मंत्री
भारत सरकार
Minister of State for
Chemicals & Fertilizers and
New & Renewable Energy
Government of India

24.08.2022

MESSAGE

The National Pharmaceutical Pricing Authority (NPPA) came into existence 25 years ago and it was a significant milestone in the pharmaceutical sector. NPPA's role as a regulator is to work towards a Healthy Nation by making medicines accessible and affordable while creating an enabling environment for the sector as a whole.

Today, India has a strong pharmaceutical sector and this narrative of growth also mirrors the role played by NPPA in domestic market through its transparent functioning. As the pharmaceutical and medical devices sector surges ahead to adopt new technologies, it is important that the regulatory framework also evolve. It is expected that NPPA would be at the forefront addressing these challenges, taking all stakeholders along and at the same time enabling access to medicines at reasonable prices.

This publication traces not only the 25 years of journey of NPPA but also gives a bird's overview of the evolution of drug pricing regulatory regime in the country. I would like to congratulate NPPA on bringing this publication.
Best wishes and congratulations to employees of NPPA and hoping that NPPA will continue to work together with all the stakeholders for reaching greater heights.

(Bhagwanth Khuba)

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डॉ. विनोद कुमार पॉल
सदस्य
Dr. Vinod K. Paul
MEMBER

सत्यमेव जयते

भारत सरकार
नीति आयोग, संसद मार्ग
नई दिल्ली–110 001
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25th August, 2022

Message

India has made considerable strides towards affordable health care in the country. In this regard, National Pharmaceutical Pricing Authority (NPPA) that came into existence 25 years ago has also significantly contributed towards making medicines accessible and affordable while creating an enabling environment for the sector as a whole.

Though the Out of Pocket Expenditure (OOPE), which is expenditures directly made by households at the point of receiving health care, is on decline, it is still 48.8% of the Total Health Expenditure (THE). Also, 30% of the population still lacks any form of financial protection for health. In this background, the role played by NPPA is very important as it is ensuring affordability of essential drugs by fixing their prices and monitoring the prices of all drugs. However, there will be new and emerging challenges like the one we faced in COVID pandemic and the regulatory framework will have to keep pace with them.

This publication tracing the 25 years of eventful NPPA journey is an excellent attempt to chronicle the work done, pause, and reflect on what needs to be done moving forward. I would like to congratulate NPPA on bringing out this publication.

My congratulations and best wishes to the employees of NPPA on reaching this important milestone and hoping that NPPA will continue to work with same vigour and zeal in the years to come.

(Vinod Paul)

स्वच्छ भारत
एक कदम स्वच्छता की ओर

सुश्री एस. अपर्णा
सचिव
Ms. S. Aparna
Secretary

भारत सरकार
रसायन और उर्वरक मंत्रालय
औषध विभाग
Government of India
Ministry of Chemicals & Fertilizers
Department of Pharmaceuticals

Dated 25th August, 2022

MESSAGE

It is heartening to note that National Pharmaceutical Pricing Authority (NPPA) has successfully completed 25 years of its regulatory service to the nation. NPPA was set-up to implement the Drug Prices Control Order and also monitor the prices of drugs as its functions involved fixation of drug prices and their monitoring while ensuring availability too. During these 25 years, NPPA saw the smooth transition from DPCO, 1995 to DPCO,2013, which marked fundamental change in drug pricing regime in the country.

NPPA has not only performed exceedingly well on its core functions but it took a number of steps to ensure the availability of essential drugs during the COVID-19 pandemic in the country. Under the overall guidance of Department of Pharmaceuticals, NPPA had actively monitored the equitable distribution of COVID management drugs to address the supply gaps and stabilize the demand.

The principles on which NPPA was built are simple: transparency and objectivity and it has strived continuously to improve on both accounts. Through its active coordination with the stakeholders in the sector, it ensured smooth functioning of the pricing framework. By bringing out this publication, NPPA has undertaken an important activity i.e. documenting and chronicling its history. At this time, it also reflects on the future and way ahead. Affordability and availability of quality products should continue to be an area of importance as we move toward Universal Healthcare.

I extend my warm greetings and congratulations to NPPA and its employees on this occasion.

(S. Aparna)

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सत्यमेव जयते

आज़ादी का अमृत महोत्सव

NPPA
AFFORDABLE MEDICINES FOR ALL

भारत सरकार
रसायन एवं उर्वरक मंत्रालय
औषध विभाग
राष्ट्रीय औषध मूल्य निर्धारण प्राधिकरण
Government of India
Ministry of Chemicals & Fertilizers
Department of Pharmaceuticals
National Pharmaceutical Pricing Authority

Kamlesh Kumar Pant, IAS
Chairman

Dated: 24th August,2022

MESSAGE

This year marks the completion of 25 years of National Pharmaceutical Pricing Authority. The pharmaceutical sector has had a fascinating story since independence and today we have reached a stage of being called pharmacy of the world. The drug pricing regulatory regime has also evolved over the years. As the regulator, it is incumbent upon NPPA to play an active role and ensure that it fulfils its mandate of making drugs available at reasonable prices to all.

It is also an opportune time to reflect upon the evolution of the sector in the last two and a half decades and our journey as the regulator. NPPA's interventions have taken many forms within the larger mandate given. Throughout this process, we have endeavoured to maintain a strong focus on transparency while balancing the interests of various stakeholders within the prevailing regulatory system. As we celebrate 25 years and the spectacular growth of the Indian pharma sector, it is also important for us to reflect and plan for the future in line with the vision of the Government. The Out of Pocket expenditure on health is still amongst one of the highest in the world. Also, Indian pharma industry has to scale up in value terms, go up the value chain and focus on research and development. Therefore, it is important for us to prioritise and examine further regulatory interventions that can help in contributing to affordable and advanced healthcare.

This publication touches upon the journey of NPPA in a short and succinct manner. Let me extend special thanks to officers of NPPA who have put in lot of effort in chronicling the journey. We also look forward to continued support from all the stakeholders to achieve our future goals

(Kamlesh Kumar Pant)

CONTENTS

Executive Summary

This year the National Pharmaceutical Pricing Authority (NPPA) completes 25 years of its existence. Much has changed during this period since NPPA first came into being as the drug pricing regulatory authority. NPPA started its journey with the implementation of Drug Price (Control) Order, 1995 (DPCO, 1995). DPCO, 1995 was promulgated two years prior to setting up of NPPA. The premise of DPCO, 1995 was cost based pricing of drugs. Between DPCO, 1995 and DPCO, 2013, which is in vogue today, a lot has changed. NPPP, 2012 brought in a paradigm shift in the drug pricing regulatory regime which moved from cost based pricing to market based pricing. Also, the drug pricing method from bulk drug pricing to formulation based pricing. The universe of drug price regulation has also reduced over a period of time. However, the pillar of essentiality remains common in both the DPCOs. NPPA has performed the twin functions of ensuring availability of medicines at reasonable prices. Its mandate has also enhanced with all the medical devices coming within the category of drugs with effect from April, 2020.

The shift in drug pricing regime was significant. NPPA managed the transition with precision and objectivity. This publication is an attempt to record not only the growth of NPPA but also of the drug price regulatory policy in the country as a whole. Chapter-1 gives glimpse of the organisational structure of NPPA and its roles. It also documents the important activities which are carried out by NPPA including the implementation of Consumer Awareness Publicity, Promotion and Monitoring Scheme (CAPPM), a central sector scheme.

Chapter-2 presents an overall view of the pharmaceutical as well as medical devices sector in the country. There is wealth of data on this topic and hence the coverage in the chapter has been kept to provide an overview only and by no means it is exhaustive. Chapter-3 documents the evolution of drug price control, drug price policy and regime in the country from 1960s onwards. It brings to fore the fact that how Drug Price (Control) orders have evolved keeping pace with the industry demands and overall shift happening in the Indian economy. It provides a fascinating overview of the transition in the drug pricing that has happened in the country over decades.

Chapter-4 documents the important milestones achieved by NPPA through its various interventions. NPPA provided not only prices for drugs under DPCO, 1995, but also has given ceiling prices for 890 formulations under DPCO, 2013; 2023 retail prices for new drugs and a number of interventions under Para 19 covering drugs as well as medical devices. Para 19 was used by NPPA during unprecedented COVID pandemic to ensure that there is no shortage of essential drugs in the country.

Chapter-5 lays down the way-forward for NPPA. Technology is the harbinger of change and NPPA will be using it to its fullest by its new initiatives of implementing Integrated Pharmaceutical Database Management (IPDMS) ver. 2.0. At the same time, it endeavours to make information on prices of drugs as well as registering all complaints by consumers easy and accessible. To achieve these objectives, new version of Pharma Sahi Daam Mobile App is also launched which would improve the interface of NPPA with its important stakeholder i.e., the consumer.

This publication attempts to cover important milestones along with the 25 years journey of NPPA. However, as they say, there are still miles to go to ensure that medicines and medical devices are made more affordable to the consumers.

Chapter 1

An Introduction to NPPA

Background to NPPA

Pricing as an instrument has been used to ensure continued availability and affordability of essential life saving drugs with improved access to consumers. The drug price regulation in the country finds its genesis way back from Drugs (Display of Prices) Order, 1962 and the Drugs (Control of Prices) Order, 1963 issued under the Defense of India Act, 1915. 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.

Prior to setting-up of the National Pharmaceutical Pricing Authority (NPPA), an independent body of experts in the Ministry of Chemicals and Fertilizers (MoC&F), Department of Chemicals and Petrochemicals in 1997; the implementation of DPCOs was with the government itself. With the setting-up of Department of Pharmaceuticals (DoP) in 2008 under MoC&F, NPPA is now its attached office.

The Tariff Commission & its predecessor bodies, that is, Tariff Board, Interim Tariff Board, first Tariff Commission (TC) & the Bureau of Industrial Costs & Prices (BICP) were closely associated with the costing and pricing of drugs with the charter of advising the Government on industrial costs and prices, and on issues relevant to cost reduction, improvement in industrial efficiency and pricing of industrial products. The BICP was constituted in 1970 and among commodities under price control, a major concern of BICP was pricing of drugs and pharmaceuticals, coal and sugar[1]. A number of reports were submitted by the Tariff Commission/ BICP and a list is at **ANNEX-I.** With the formation of NPPA in 1997, the task of price fixation, revision and other related matters for Bulk Drugs and Formulations along with related manpower was transferred from BICP to NPPA. With the approval of the Union Cabinet, an independent Tariff Commission under Department of Industrial Policy and Promotion was created in 1997 and in 1999 BICP was merged with the Tariff Commission.

Functions of NPPA

The functions of NPPA, *inter-alia*, include fixation and revision of prices of scheduled formulations under the Drugs Prices Control Order (DPCO), as well as monitoring and enforcement of prices. The key principles for regulation of prices as per the extant National Pharmaceuticals Pricing Policy (NPPP), 2012 are *essentiality of drugs; control of formulations prices only; and Market Based Pricing*. The aim of the Drugs Prices Control Order (DPCO), 2013 is to

[1]https://tc.nic.in/site/writereaddata/siteContent/20201026142244747 9Document%20on%20the%20Tariff%20Commission%20Volume%201.pdf

make available essential medicines to all at reasonable prices through the instrumentality of price control. The National List of Essential Medicines (NLEM) of the Ministry of Health & Family Welfare is adopted as the primary basis for determining essentiality and is incorporated in the First Schedule of the DPCO, 2013, as scheduled medicines for the purpose of price control. NPPA also provides inputs to Government on pharmaceutical policy and issues related to affordability, availability and accessibility of medicines. As per the Resolution and powers delegated to NPPA from time to time, it performs a wide variety of functions **(Figure 1.1)**.

Figure 1.1: Functions of NPPA

सत्यमेव जयते

GAZETTE OF INDIA

EXTRAORDINARY
PART - I Section - I
Published by Authority

New Delhi, Friday. August 29, 1997 / Bhadrapad 7, 1919

MINISTRY OF CHEMICALS AND FERTILIZERS
(Department of Chemicals and Petrochemicals)

RESOLUTION

F.No. 33/7/97 Pl

1. Whereas the prices of bulk drugs and the formulations included in the Schedules categories are being fixed by the Government of India as per the Drugs (Prices Control) Order, issued from time to time under the provisions of section 3 of the Essential Commodities Act, 1955 (1 O of 1955} and the Government have been experiencing that the present mechanism for the fixation and revision of prices of bulk drugs and formulations is cumbersome, complicated and time consuming.

2. And whereas, after careful consideration, the Government is of the opinion that to streamline and simplify the procedure and to bring about a greater degree of transparency as well as objectivity, an expert body should be constituted with the powers, interalia, to fix prices and notify the changes therein, if any, of bulk drugs and formulations, from time to time, under the Drugs (Prices Control) Order.

3. Therefore, the Government have now decided to establish an independent body of experts to be called as the National Pharmaceutical Pricing Authority, consisting of a Chairperson in the status of the Secretary to the Government of India, Members having expertise in the field of pharmaceuticals, economics and cost accountancy and Member Secretary in the status of Joint Secretary/ Additional Secretary to the Government of India, and the same is entrusted with the task of price fixation revision and other related matters such as updating the list of drugs under price control by inclusion and exclusion on the basis of the established criteria/ guidelines. The National Pharmaceutical Pricing Authority shall be empowered to take final decisions, which shall be subject to review by the Central Government as and when considered necessary. The Authority shall also monitor the prices of decontrolled drugs and formulations and oversee the implementation of the provisions of the Drugs (Prices Control) Order. In addition to the

above mentioned functions, the Authority is entrusted with certain other functions as detailed in the Schedule annexed to the Resolution.

4. The Authority shall have power to regulate its own procedure for performing the functions entrusted to it. It shall be to call for notes, memorandum, results of studies, data and other material relevant to its work, from official and non-official bodies / organizations, and hold discussions with them. The Authority shall be empowered to maintain close touch with the Ministries of the Central Government, State Governments, Industry, consumers and other related organizations.

5. The expenditure of the Authority shall be borne by the Central Government.

6. The Head Quarters of the Authority will be at New Delhi.

7. The Authority shall be established and start functioning from the date of publication of this resolution in the Oficial Gazette.

SCHEDULE

Other functions of the National Pharmaceutical Pricing Authority

(1) To implement and enforce the provisions of the Drugs (Prices Control) Order in accordance with the powers delegated to it.

(2) To deal with all legal matters arising out of the decisions of the Authority.

(3) To monitor the availability of drugs, identify shortages, if any, and to take remedial steps;

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

(5) To undertake and/or sponsor relevant studies in respect of pricing of drugs/ pharmaceuticals;

(6) To recruit/appoint the officers and other staff members of the Authority, as per rules and procedures laid down by the Government;

(7) To render advice to the Central Government on changes/revisions in the drug policy;

(8) To render assistance to the Central Government in the parliamentary matters relating to the drug pricing.

ORDER

Ordered that a copy of this Resolution be communicated to all the State Governments, Union Territory Administration, Lok Sabha and Rajya Sabha Secretariats and the concerned Ministries and Departments of the Government of India.

Ordered also that the Resolution be published in the Gazette of India for general information.

N.R. BANERJI, Secretary

Office of NPPA

NPPA began its journey from a one room in Shastri Bhawan and then to 19th Floor, Jawahar Vyapar Bhawan, Janpath, Tolstoy Marg, New Delhi. In 2000, NPPA office was again shifted to Jhandewalan Extension, Link Road, New Delhi. However, since September 2003, NPPA has been housed in the 3rd and 5th Floor of the YMCA building, Jai Singh Marg, New Delhi.

Composition of the Authority and Authority Meetings

NPPA is a five Member body comprising of:

1. Chairman (in the rank of Secretary or Additional Secretary of Govt. of India).
2. Member Secretary (in the rank of Joint Secretary to the Govt. of India)
3. 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

NPPA recently held its 100thmeeting under the DPCO, 2013 and 232ndmeeting (overall) on 05th of August 2022. It was a milestone of 100 meetings under DPCO,2013 with around one meeting a month being convened.

Leadership and organizational structure

Over the years, the Authority has been chaired by an excellent set of dynamic leaders and all of them have contributed in diverse ways to the shaping of the pharmaceutical pricing landscape. Chronology of officers who have held the post of Chairman (Table 1.1) and Member Secretary (Table 1.2), NPPA are given below:

Table 1.1: List of Chairmen

S. No.	Name	From	To
1.	Shri Kamal Pande	27.09.1996	30.09.1997
2.	Shri K. Kosal Ram	16.10.1997	05.05.1999
3.	Shri Arun Kumar	05.05.1999	31.12.2000
4.	Shri R.Ramanathan	01.01.2001	31.01.2001
5.	Shri B.S.Baswan	09.04.2001	30.04.2002
6.	Shri P.K.Mishra	06.05.2002	22.09.2002
7.	Shri Arun Kshetrapal	23.09.2002	31.03.2004
8.	Shri Vinay Bansal	01.04.2004	31.01.2005
9.	Shri Satish Chandra	21.02.2005	31.10.2005

S. No.	Name	From	To
10.	Shri Ashok Kumar	05.12.2005	07.07.2008
11.	Shri A.K.Banerjee	05.09.2008	05.10.2009
12.	Shri S.M.Jharwal	05.10.2009	30.04.2011
13.	Shri G.Balachandhran	04.05.2011	14.12.2011
14.	Shri C.P.Singh	10.06.2012	10.06.2014
15.	Shri Injeti Srinivas	11.06.2014	28.12.2015
16.	Shri Bhupendra Singh	18.01.2016	01.03.2018
17.	Shri R.K.Vats	13.04.2018	26.11.2018
18.	Ms. Shubhra Singh	10.12.2018	13.08.2021
19.	Shri Kamlesh Kumar Pant	24.08.2021	Till date

Table 1.2: List of Member Secretaries

S. No.	Name	From	To
1.	Shri S. M. Jharwal	02.07.1997	16.04.1999
2.	Shri S. K. Sood	16.04.1999	14.08.2000
3.	Shri K. D. Tripathi	14.08.2000	30.06.2001
4.	Shri Pradip Mehra	18.07.2001	17.07.2006
5.	Shri Arun Jha	25.08.2006	06.03.2009
6.	Shri Om Prakash	18.05.2009	03.06.2012
7.	Shri Sanjay Kumar	20.12.2012	19.12.2013
8.	Shri Amit Khare	29.08.2014	07.04.2015
9.	Ms. Sharmila Joseph	15.04.2015	11.07.2017
10.	Shri Rakesh Ranjan	14.08.2017	30.04.2018
11.	Ms. Ritu Dhillon	11.05.2018	15.05.2020
12.	Dr. Vinod Kotwal	24.06.2020	Till date

Divisions in NPPA

The divisions in NPPA are broadly divided along the functional lines and the current organogram is as at **Figure 1.2.**

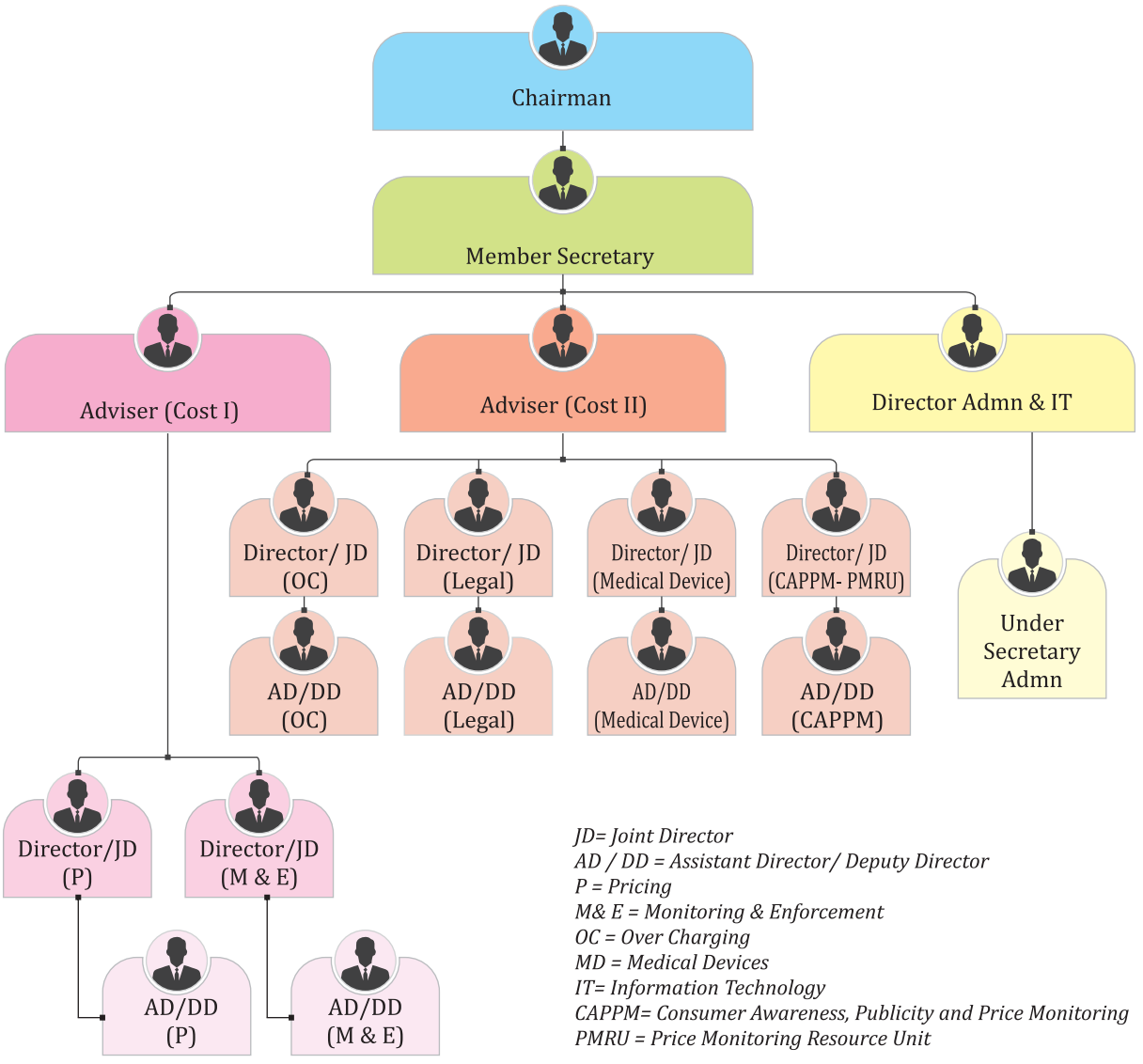


Figure 1.2: NPPA Organogram

Roles and responsibilities of various divisions of NPPA are as follows:

Pricing Division

Looks after the work related to fixation of ceiling prices of scheduled medicines and retail prices of new drugs as per the provisions of DPCO 2013. Para 4 of DPCO, 2013 provides the methodology for calculation of ceiling price of scheduled formulations; Para 5 of DPCO, 2013 is related to fixation of retail price of New drugs under DPCO, 2013 and Para 6 of DPCO, 2013 applies in case of no reduction in price due to absence of competition. The prices are fixed based on the market based data, inter-alia, by taking simple average prices of all those manufacturers who have market share more than or equal to 1% of total market turnover on the basis of Moving Annual Turnover (MAT) of a specified medicine. The ceiling/retail price is derived by adding 16% margin on the simple average price to the retailer (PTR) for the specified medicine. As provided for under the Order, the local taxes if actually paid, wherever applicable on actual basis are added to the ceiling price to arrive at the Maximum Retail Price (MRP) to the consumers.

NPPA has till date (31.07.2022) fixed Ceiling Price of 890 formulations under National List of Essential Medicines (NLEM, 2015) and Retail Price of 2023 new drugs under DPCO, 2013. In certain cases, prices are revised as well as fixed under para 19 of DPCO,2013 too.

Monitoring & Enforcement (M&E) Division

Monitoring of prices of drugs

Monitoring division monitors the prices of scheduled as well as non-scheduled drugs under DPCO, 2013. In cases where the prices of scheduled drugs are found to be more than the applicable ceiling price plus taxes, then action is initiated against the company for such violation. Increase in the price of drugs beyond the permissible limit is also monitored; Wholesale Price Index (WPI) increase in case of scheduled drugs and 10% annual increase in case of non-scheduled drugs is the maximum increase permissible, which may or may not be availed by the companies.

Monitoring activities are done based on the references received from the Price Monitoring Resource Units (PMRUs), State Drugs Controllers (SDCs), samples purchased from the open market, reports from market-based database and complaints reported through the grievance redressal portals i.e., Pharma Jan Samadhan (PJS) of NPPA, Centralized Public Grievance Redress and Monitoring System (CPGRAMS) or any other reliable source.

Ensuring availability of drugs

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.

Discontinuation of Scheduled drugs

The discontinuation requests filed by companies under Para 21 of DPCO, 2013 are processed and wherever considered necessary, directions are issued for continued production/ import of the drug for 12 months, for which discontinuation is proposed. In certain cases, Para 3 of DPCO, 2013 is also invoked for issuing directions for continued production/ import of drugs. NPPA also monitors that companies do not discontinue the manufacturing of scheduled drugs, without prior intimation to NPPA. Action is initiated under DPCO, 2013 and Essential Commodities Act, 1955 for such violations.

Complaints/ Grievance handling

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.

Other miscellaneous responsibilities

- Handling cases related to refusal to sell medicines
- Analysis of data for monitoring and enforcement purpose
- Maintenance of market-based data
- Monitoring of compliance with Uniform Code for Pharmaceutical Marketing Practices (UCPMP)
- Research and Studies work on the issue related with pricing of drugs
- Bringing out bi-monthly E-newsletter **"Aushadh Sandesh"**

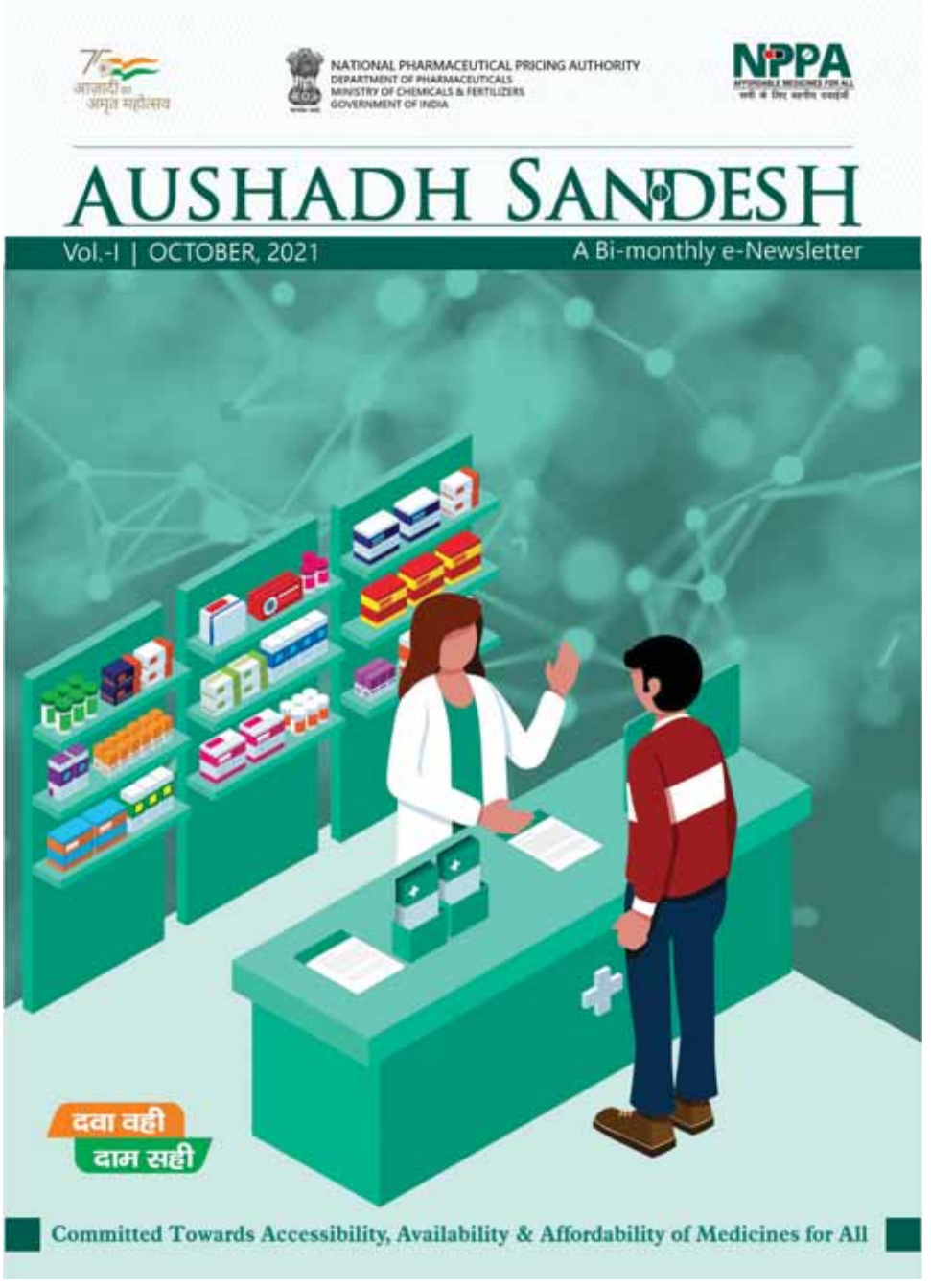


Figure 1.3: First issue of Aushadh Sandesh launched in October 2021

Overcharging (OC) Division

Responsible for examination and further processing the overcharging cases as per the reports received from Monitoring and Enforcement division. The replies submitted by the companies are examined and if the replies are not found satisfactory and prima facie overcharging case is established, Show Cause Notice (SCNs) is issued in following scenarios:

- Based on the quantitative data provided by the company
- Quantum of overcharging is determined on the basis of market database when the company has not provided the quantitative data
- In cases, where market database is not available, SCNs are issued without quantification.

The explanation of the defaulting pharmaceutical companies are sought through the SCNs along with CA/CMA certified quantitative data (in case not submitted after preliminary notice). Once an overcharging case has been established, Demand Notices (DNs) are issued based on data submitted by the companies or available market based database. If the company fails to deposit the overcharged amount within the time limit specified in the DN, the case is referred to the concerned District Collector for recovery of demanded amount from the defaulting companies as arrear of Land Revenue. NPPA strives to reduce the pendency of cases by regular follow up with the District Collector and support of PMRUs.

In overcharging cases, at any stage between SCN to DN, if the concerned company requests for a personal hearing, the same is granted at the level of Chairman or Member Secretary. After the personal hearing, speaking order is passed considering the submission made in the personal hearing and documents submitted by the company.

Medical Devices (MDs) Division

Division is responsible for work related to MDs including co-ordination for data collection of medical devices with government agencies/private sector etc. It also undertakes analysis of pricing of medical devices and monitoring to ensure that not more than 10% annual increase in MRP is availed. Further, action as undertaken by OC division is also undertaken for MDs.

Monitoring of Price Movement of Medical Devices

As per Ministry of Health & Family Welfare (MoH&FW) Notification dated 11th February, 2020; all Medical Devices have been notified as 'Drugs' w.e.f. 1st April 2020. Hence, all the medical Devices have come under regulation of Drugs & Cosmetics Act, 1940, Medical Devices Rules, 2020 and Drugs (prices Control) Order, 2013 under Essential Commodities Act, 1955. This enables the government to regulate the quality, efficacy and prices of Medical Devices in the country.

Para 20 of the DPCO, 2013 is also applicable on non-scheduled Medical Devices and their MRP monitored to ensure that no manufactures/importers can increase the MRP more than 10% in preceding twelve months. In cases where violation of above provision is found, NPPA issues overcharging notices to the defaulting companies.

Four (4) medical devices namely (i) Cardiac Stents (ii) Drug Eluting Stents (iii) Intra Uterine Devices (Cu-T) and (iv) Condoms are scheduled medical devices (included in the Schedule-I of the DPCO, 2013) and are under price control.

Legal Division

Legal Division is responsible for rendering legal advice to the Authority on all regulatory issues and the divisions of NPPA. Legal division handles all the litigation matters in various Hon'ble Courts/Tribunals across the country where NPPA/DoP is a party. Broadly, the issues involved in the court cases are related to price notifications issued by NPPA; challenge to OC demand raised and interest levied; without price approval cases; trade margin issue etc.

Administration & Establishment and IT

Important functions performed by the Administration & Establishment division are:

- Establishment/service matters relating to Group 'A' (Gazetted), 'B' (Gazetted & Non-gazetted) & 'C' posts belonging to various cadres. These posts belong to various cadres of Central Secretariat Service (CSS), Central Secretariat Stenographers Service (CSSS), Central Secretariat Clerical Service (CSCS), Indian Cost Accounts Service (ICoAS), Indian Economic Service (IES), Subordinate Statistical Services (SSS), Post under Central Staffing Scheme and Ex-cadre posts comprising of the Staff Car Driver, Multi-Tasking Staff (MTS)
- All administrative and matters relating to medical reimbursement & children education allowance, pension of the officers and employees of NPPA
- Service matters includes framing/review of Recruitment Rules, creation of posts, appointments, promotions, maintenance of Service Books, Annual Performance Appraisal Reports (APARs), posting/transfer, pay-fixation, increments, grant of leaves/LTC, grant of various advances, retirements benefits/processing of vigilance cases/clearances and disciplinary cases
- Engaging and payment of wages to contractual staff
- Formulation of Budget Estimates, Revised Estimates, Supplementary Demands for grants, surrender of savings and submission of reports on Budget matter
- Implementation of Official Language Policy of the Government in NPPA, functions of Hindi Salahakar Samiti/Official Language Implementation Committee, etc.
- Purchase/Maintenance/Repair of all office equipment as per Rules
- Nomination of officers for workshops, seminars, conferences, trainings arranged by various institutes/departments of government
- To coordinate & compile information for submission of Annual Report of NPPA, material for Monthly D.O. for the Cabinet and monthly D.O. from FA to Secretary Expenditure

Technology Deployment

NPPA website: Data Repository

NPPA website (www.nppaindia.nic.in) is rich repository of various orders/notifications/circulars etc. issued from time to time and arranged chronologically. The website is updated with the latest information relevant to various stakeholders. All the information regarding prices fixed of scheduled formulation, new drugs, under Para 19 and any other initiative of NPPA is available on the website. It provides information on various subjects including-

✓ National Pharmaceutical Pricing Policy and Drug Price Control Orders

- ✓ Authority Meeting minutes, Multi-Disciplinary Committee (MDC) minutes and information regarding other important decisions
- ✓ Information regarding prices of formulations including the draft calculation sheets of proposed drug prices are placed on the NPPA website
- ✓ Information related to CAPPM Scheme and PMRUs
- ✓ Bi-monthly newsletter of NPPA
- ✓ Link to PJS

Integrated Pharmaceutical Database Management System (IPDMS)

Over a period of time NPPA has implemented digital initiatives to perform its various functions. It had launched the Integrated Pharmaceutical Database Management System (IPDMS) in 2015. IPDMS is an online platform for filing statutory forms prescribed under DPCO, 2013 by the pharmaceutical manufacturer/ marketer/ importer/ distributor companies. As on 31.07.2022, 981 Pharma companies and 89,553 products are registered under IPDMS. Web-based IPDMS ver. 2 launched in August 2022 upgrades the current IPDMS with latest technological interface. Multi-instance architecture of IPDMS 2.0 has the capability to connect multiple users over a public network infrastructure.

Mobile Application 'Pharma Sahi Daam' and 'Search Medicine Price' Utility

Pharma Sahi Daam (PSD) is a mobile app for the benefit of the common people to search the brand name, composition, ceiling price and MRP of the drugs available in India. Ceiling Price of scheduled drugs can also be searched by using the tool 'Search Medicine Price' available on the website of NPPA (www.nppaindia.nic.in). The app or search medicine price tool facilitates consumers to verify whether drugs are being sold within the approved price range and also to detect any case of overpricing by pharmaceutical company/ chemist. If there is any ceiling price violation, the buyer can lodge a complaint against company/ chemist on PJS. An improved version of PSD with enhanced features is launched in August 2022.

Social Media presence

NPPA has social media platforms for dissemination of information viz. Twitter Account (NPPA~India (@nppa_india) and Face Book Account (@india.nppa).

Price Monitoring and Resource Units (PMRUs) Division

PMRU division of NPPA is implementing the Central Sector Scheme viz 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 aims 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.

NPPA is in the process of establishing PMRUs at State/UT level that are societies registered under the

Societies Registration Act having its own Memorandum of Association/Bye laws. So far, PMRUs have been set up in twenty five (25) States/UT viz. Kerala, Gujarat, Odisha, Rajasthan, Punjab, Nagaland, Tripura, Uttar Pradesh, Mizoram, Jammu & Kashmir, Andhra Pradesh, Haryana, Karnataka, Telangana, Maharashtra, Goa, Madhya Pradesh, Chhattisgarh, Jharkhand, West Bengal, Puducherry, Ladakh, Himachal Pradesh, Bihar and Uttarakhand. The PMRUs are to perform different functions to assist NPPA as well as the SDCs in executing their duties as per their mandate **(Figure1.4).**

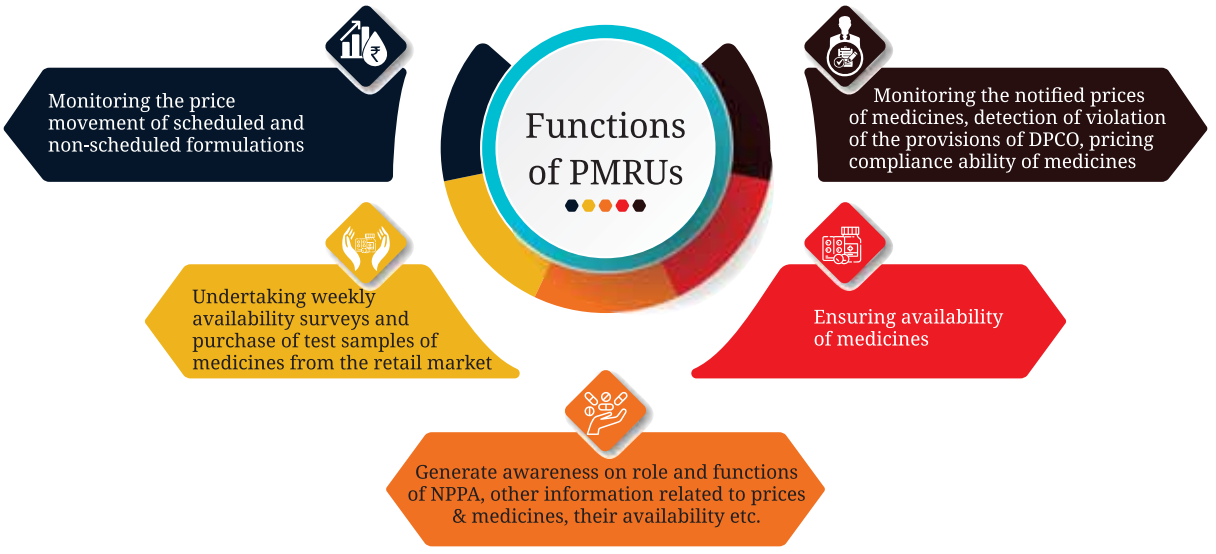


Figure 1.4: Functions of PMRUs

Major Decisions/ Steps taken by NPPA

NPPA has contributed to affordable medical care in India by virtue of pricing of drugs/ medical devices, especially essential drugs, at affordable prices. Some of the important decisions/steps taken by NPPA towards this end are:

- Notified norms for Conversion Cost, Packing Charges, and Process Loss under para 7 of Drugs Prices Control Order (DPCO), 1995 on 13th July, 1999.
- Notified norms for Conversion Cost, Packing Charges, Process Loss, Packaging Material norms for non-PVC bag on port bag 500 ml on 28.11.2011 and 27.12.2012.
- DPCO-2013 notified on 15.05.2013 in supersession of DPCO-1995 and NPPA fixed the ceiling prices of medicines under NLEM, 2011, which were subsequently revised when NLEM, 2015 was notified as Schedule-I of DPCO,2013.
- NPPA capped the MRP under Para 19 of DPCO, 2013 in respect of 106 Cardiac and Anti-diabetic non-scheduled formulations on 10.07.2014.
- Separate ceiling price for IV Fluid 100 ml/250ml/500ml and 1000ml having special features on 24.06.2016.
- Guidelines for identification and initiation of OC cases issued on 07.10.2016.
- Fixation of Ceiling Price of Coronary Stents on 13.02.2017.
- Fixation of Ceiling Price of Orthopaedic knee implants for knee replacement system on 16.08.2017.
- Revising in Ceiling Price of Cardiac Stents on 12.02.2018.

- Separate ceiling price for MDI and DPI containing Budesonide, Budesonide+ Formoterol and Tiotropium on 21.02.2019.
- Capping of Trade Margin @ 30% for non-scheduled 42 Anti-cancer drugs on 26.02.2019.
- Upward Price revision of 21 Scheduled formulation under Para 19 of DPCO, 2013 (One-time price increase of 50% from present ceiling price) on 09.12.2019.
- Incentivization for incremental innovation based on formula recommended by Multidisciplinary Committee of Experts on 09.12.2019.
- Methodology for Price Fixation of off-patented medicines approved by Authority in its meeting held on 20.01.2020.
- Fixation of ceiling price based on Institutional Data from time to time under DPCO, 2013.
- Separate ceiling price for ringer lactate injection 100 ml/250ml/500ml and 1000ml having special features on 03.03.2020.
- Monitoring of MRP of all Medical Devices notified as Drugs w.e.f. 01.04.2020 (Gazette Notification No. SO 1232(E) dated 31st March, 2020).
- Issue of O.M. dated 26.08.2020 on development and implementation of Eco-system for handling & disposing various applications received in NPPA.
- Revision in guidelines for discontinuation of scheduled formulations on 14.08.2020.
- Fixing of Maximum Price for Liquid Medical Oxygen (LMO) and Oxygen Inhalation (Medicinal gas) in cylinder on 25.09.2020
- Trade Margin Rationalization approach used for regulating prices of Oxygen Concentrators and five other medical devices used on COVID-19 treatment, viz. Blood Pressure monitor, Digital thermometer, Nebulizer, Pulse Oximeter and Glucometer in June/July 2021.

Price Fixation of Scheduled Medicines

National List of Essential Medicines (NLEM) 2015 contains 966 scheduled drug formulations (including formulations as per explanation 1 to Schedule – I of DPCO 2013) spread across 31 therapeutic groups. NPPA fixes the ceiling price of formulation listed in Schedule I of DPCO and also for formulations listed under Explanation-I to Schedule – I of DPCO 2013. As on 31.07.2022, NPPA has fixed the ceiling prices of 890 formulations under DPCO, 2013 as follows:

Table 1.3: Ceiling Prices of Medicines fixed under different categories

Category	Number of Medicines	Number of Formulations
Anti-Cancer	44	86
Anti-TB	14	35
Anti-HIV	11	39
Anti-Diabetics	5	12
Cardiovascular	30	74
Others	254	644
Total	**358**	**890**

The prices are notified through Gazette Notifications and also uploaded on NPPA website. The ceiling prices become operative and legally enforceable from the date on which the price is notified in the Gazette.

Retail Price fixation

NPPA fixes the retail price of medicine based on the Form-I application received from the manufacturing/ marketing companies. The notified retail prices are applicable only to the applicant manufacturing/ marketing companies. The retail prices of the medicine are fixed as per the methodology applicable for fixation of ceiling price as per DPCO, 2013. NPPA has notified retail prices of 2023 'new drugs' [those qualifying as 'new drugs' as per para 2(u) of DPCO, 2013] till 31.07.2022.

Review Order

Any company aggrieved by the orders of NPPA may file review application with DoP under para 31 of DPCO, 2013 and DoP after giving opportunity of personal hearing passes necessary review directions on merit. 188 number of review orders have been passed during last five years ie 1.4.2017 to 31.07.2022.

Exemptions granted under Para 32 of DPCO, 2013

To promote research & innovation, Para 32 of DPCO 2013 provides for exemption from provisions of DPCO 2013 to manufacturer(s) producing a new drug including Medical Devices, patented under the Indian Patent Act, 1970 for a period of five years from the date of commencement of its commercial marketing by the manufacturer in the country. The exemptions granted by NPPA till date is as given in **Table 1.4**.

Table 1.4: Exemptions granted under Para 32 of DPCO, 2013

S. No.	Company	Formulation	Para reference/ Date of Notification
1	Torrent Pharmaceuticals Limited	Prasugrel HCL 10mg (Film coated) + Aspirin 75mg (Entric coated)*	Para 32 (iii) 21st August, 2014
2	Torrent Pharmaceuticals Limited	Olanzapine Pamoate Prolong release power for Suspension#	Para 32 (iii) 25th March, 2015
3	Wockhardt Limited	Insulin Human Injection 200IU/ml, Isophane Insulin 200IU/ml, 70% Isophane Insulin + 30 Insulin Human injection 200IU/ml*	Para 32 (iii) 20th November, 2015
4	Sun Pharmaceutical Industries Ltd	Gemcitabine ready to use infusion bags 10mg/ml (Ready to use infusion bags 1200mg/120ml, 1400mg/140ml and 1600mg/160ml)	Para 32 (ii) 08th November, 2019
5	Meril Lifesciences Pvt. Limited	Sirolimus Eluting BioResorbable Vascular Scaffold System (MeRes100)"MeRes100 (Cardiac Stent)	Para 32 (ii) 28th February, 2020

S. No.	Company	Formulation	Para reference/ Date of Notification
6.	Sun Pharmaceutical Industries Ltd	'Fixed Dose Combination (FDC) of Silver Sulfadiazine IP (Nanonized) 0.5% w/w and Chlorhexidine Gluconate 0.2% w/w topical cream'	Para 32 (i) 31.12.2020
7.	Torrent Pharmaceuticals Limited	"Tapentadol Nasal Spray 225mg/ml" in which each spray (0.1ml) contains Tapentadol Hydrochloride 22.5mg + Benzalkonium Chloride (50%) 0.02%w/v (As preservative)	Para 32 (i) 01.07.2021

* On expiry of the exemption period, the retail price was fixed by Authority for the formulation(s) being a 'new drug' in its 84th meeting held under DPCO, 2013 on 10th March 2021

#Non-scheduled formulation and price is to be monitored only on expiry of exemption period

Price Revision of Anti-Cancer Drugs Based on Trade Margin Rationalization

NPPA capped the Trade Margin of selected 42 Anti-Cancer non-scheduled formulations, recommended by Expert Committee of Ministry of Health & Family Welfare, under the 'Trade margin Rationalization (TMR)" approach on 27th February 2019. The Pilot was taken up as Proof of Concept, invoking provision of paragraph 19 of DPCO, 2013, under extra-ordinary circumstances in public interest. As per data submitted by manufacturers, the MRP for 526 brands have been shown reduction up to 91%. This has resulted in notional annual savings of ₹ 984 crore per annum to cancer patients. Percentage wise reduction in prices of brands is as follows: -

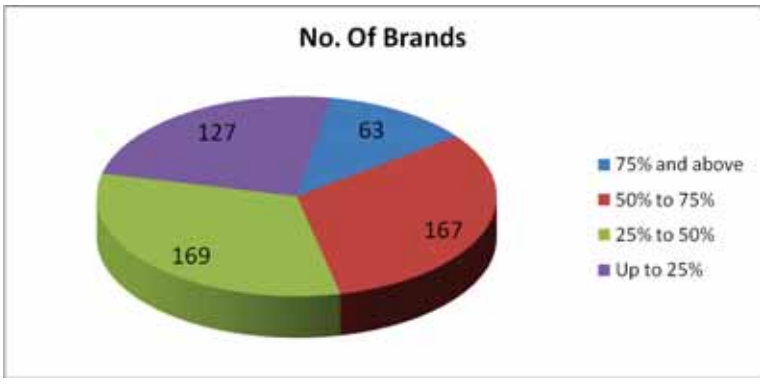


Figure 1.5: Number of brands impact by TMR on anti-cancer drugs

Savings to the Consumers

The fixation of ceiling prices of scheduled formulations listed in NLEM 2015 (revised Schedule-I) has enabled savings of ₹ 2643 crore to the consumers in addition to the saving of ₹ 4,547 crore to consumers on account of price fixation of coronary stents. Fixation of ceiling prices of scheduled formulations under Schedule-I of NLEM 2011 enabled savings of ₹ 2422.24 crore to the consumers. The para 19 price notifications of anti-diabetic and cardiovascular drugs resulted in savings of approximately ₹ 350 crore to the consumers. NPPA has also fixed the price of the Non Scheduled Orthopaedic Knee Implants that enabled savings of ₹ 1500 crore to the consumers. As mentioned

above, savings of ₹ 984 crore is estimated through the trade margin rationalization of anti-cancer drugs to the consumers. Thus, regulation of prices of medicines under DPCO 2013 by NPPA has resulted in net savings of approximately ₹ 12447 crore per annum to the consumers **(Figure 1.6).**

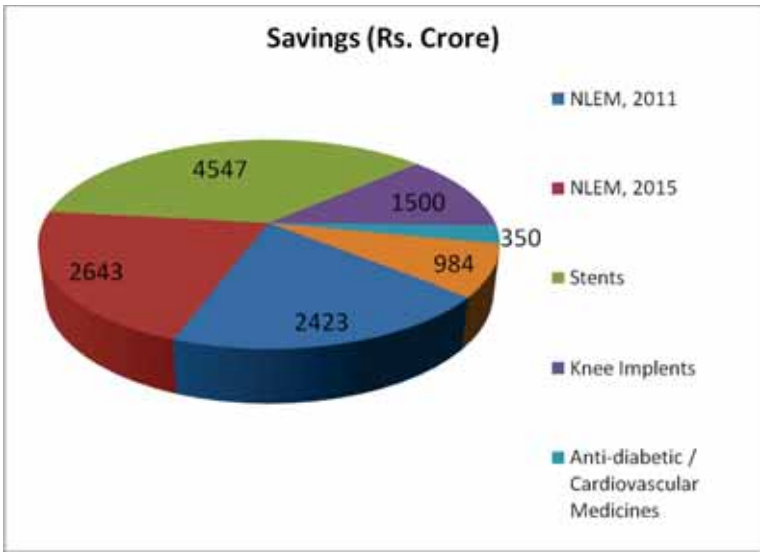


Figure 1.6: Savings to consumers

Recovery of Overcharged Amount

The overcharged amounts are recovered from the pharmaceutical company along with interest and penalty thereon from the date of overcharging. As on 31st March, 2022 NPPA has initiated about 2215 cases of overcharging. Amount of ₹ 1319.13 Crore under DPCO 1995 & 2013 has been recovered from pharmaceutical companies as on 31st March, 2022. Action for recovery of the overcharged amount along with interest thereon is a continuous process. NPPA takes action as per the provisions of DPCO, 1979, DPCO 1987, DPCO 1995, and DPCO 2013 read with Essential Commodities Act, 1955.

Standing Committee on Affordable Medicines and Health Products (SCAMHP)

Under the chairmanship of Member (Health), NITI Aayog, Government constituted the Standing Committee on Affordable Medicines and Health Products (SCAMHP) in January 2019 as a recommendatory body to NPPA regarding prices of drugs and health products. It has Chief Economic Adviser, Ministry of Finance; Secretary, Department of Health Research; Vice-Chairperson, NLEM; Director General of Health Services, MoH&FW; and Joint Secretary, Department for Promotion of Industry and Internal Trade (DPIIT) as its members. The committee can also invite subject experts from related fields.

Multidisciplinary Committee of Experts (MDC)

As per para 15(1) of DPCO, 2013, the government may constitute a Standing Committee of Experts with a view to recommend the retail prices of new drugs on the principles of "Pharmacoeconomics". DoP vide Order dated 30.11.2017 constituted the MDC, which was further amended by corrigendum dated 10.01.2018. MDC has members from CDSCO, ICMR and NIPER with Advisor (Cost) as the convener. The Committee has been empowered to invite or co-opt any other specialist as required.

Chapter 2

State of the Pharmaceutical and Medical Devices Sector

Introduction

Globally, Indian pharmaceutical industry is known for its generic medicines and low-cost vaccines and ranks third in pharmaceutical production by volume and fourteenth by value. During the past nine years, the sector has grown steadily at Compound Annual Growth Rate (CAGR) of 9.43%. India's domestic pharmaceutical market was at US$ 42 billion in 2021 and is likely to reach US$ 65 billion by 2024 and further expand to reach ~US$ 120-130 billion by 2030. India is home to more than 3,000 pharma companies with a strong network of over 10,500 manufacturing facilities as well as a highly skilled resource pool.

Trends in Indian Pharmaceutical Industry

Major segments of Indian Pharmaceutical Industry include generic drugs, Over the Counter (OTC) medicines, bulk drugs, vaccines, contract research & manufacturing, biosimilars and biologics. India is the largest supplier of generic medicines with 20% share in the global supply by manufacturing 60000 different generic brands across 60 therapeutic categories. Indian pharmaceutical sector supplies over 50% of global demand for various vaccines, 40% of generic demand in the USA and 25% of all medicine in the UK.

Presently, over 80% of the antiretroviral drugs used globally to combat AIDS (Acquired Immune Deficiency Syndrome) are supplied by Indian pharmaceutical firms. Access to affordable HIV treatment from India is one of the greatest success stories in medicine. There are 500 API manufacturers contributing about 8% in the global API Industry. Because of the low price and high quality, Indian medicines are preferred worldwide, thereby rightly making the country the “pharmacy of the world”.

The sector generates trade surplus and the quantity and the value of the drugs exported and imported during the last five years **(Table 2.1)** is as under: -

Table 2.1: Export and Import of Drugs and Pharmaceuticals

Year	Export		Import	
	Quantity (MT)	Value (₹ in Crore)	Quantity (MT)	Value (₹ in Crore)
2017-18	665934	1,06,038	319143	31,161
2018-19	674084	1,28,028	364975	38,976
2019-20	524757	1,40,537	386186	40,139
2020-21	642718	1,74,064	403878	46,808
2021-22	1075906	1,75,040	423966	60,060

Source: DGCIS, Ministry of Commerce and Industry.

Therapeutic segment Analysis

As per the analysis of Pharmatrac database, in the past five years, the highest growth has been seen in the Urology segment at 9.78% though the sales data in absolute terms was not very high. However, Cardiac and Respiratory therapeutic category of drugs have high sales and also had a CAGR between 8.29%- 8.50%. This was followed by CAGR between 7.44%-7.47% in the anti-diabetic, hormones and vitamins/minerals category. Vaccines are mostly supplied to institutions and hence vaccines showing negative CAGR of 3.70% may not reflect the true picture as Pharmatrac market

database does not capture institutional sales **(Table 2.2)**.

Table 2.2 Growth in different Therapeutic segments during past five years

Therapeutic segment	Sales 2017-18 (₹ in Crore)	Sales 2021- 22 (₹ in Crore)	CAGR (%)
Anti-Infectives	16,850	23,807	7.16%
Cardiac	14,591	21,915	8.47%
Gastro Intestinal	13,756	19,622	7.36%
Anti-Diabetic	11,075	15,879	7.47%
Vitamins / Minerals / Nutrients	10,437	14,945	7.44%
Respiratory	9,111	13,569	8.29%
Pain / Analgesics	8,303	11,740	7.17%
Derma	8,155	10,642	5.47%
Neuro / CNS	7,348	9,898	6.14%
Gynecological	6,200	8,015	5.27%
Anti-Neoplastics	2,546	3,063	3.77%
Ophthalmic / Otologicals	2,259	2,669	3.39%
Hormones	2,143	3,072	7.47%
Vaccines	2,133	1,767	-3.70%
Urology	1,510	2,408	9.78%
Blood Related	1,450	1,800	4.42%
Others	1,149	1,450	4.76%
Sex Stimulants / Rejuvenators	690	956	6.74%
Stomatologicals	584	1,015	11.69%
Anti-Malarial	524	559	1.29%
Grand Total	1,20,815	1,68,791	6.92%

Source: Pharmatrac Market Database

A further analysis of sales during FY 2021-22 and CAGR from 2017-18 of top three drug groups in a particular super group has been carried out and is shown in **Table 2.3.** The highlights are:

- Macrolides are a class of antibiotic that includes Erythromycin, Azithromycin, Clarithromycin, etc. In the anti-Infectives super group, 'Macrolides and similar other types' grew at a CAGR of 12% though Cephalosporin's had the highest sale in this super group.
- In cardiac super group, Platelet Aggregation Inhibitors grew at CAGR of 12%.
- Insulin Analogues Basal (for example Glargine) in the anti-diabetic super group grew at 12%. Benign Prostatic Hypertrophy (BPH) Products in Urology super group had a CAGR of 14%. Amongst the Pain/Analgesics super group, non-narcotics and anti-pyretic also had a CAGR of 16%.

- Under the Derma super group, Topical Antibiotics and/or Sulphonamides had CAGR of 13%. Stomatologicals deal with the oral health of the patients and this drug group showed a CAGR of 15%.
- Amongst the Anti-Neoplastics super group, sales of immunosuppressive agents grew by 14%.

Table 2.3: Drug Super group and top selling 3 Drug groups (Sales 2021-22 and CAGR from 2017-18 onwards)

Super Group	Top three Drug Groups	Sales (₹ in Crore)	CAGR
Anti- Infectives	Cephalosporin's	7,947	7%
	Broad Spectrum Penicillin	3,225	7%
	Macrolides And Similar Types	2,217	12%
Cardiac	Statins	2,178	8%
	Platelet Aggregation Inhibitors	1,691	12%
	Beta-Blocking Agents, plain	1,613	8%
Gastro Intestinal	Gastroprokinetics	4,289	9%
	Anti-ulcerants Acid Pump Inhibitors	2,382	9%
	Intestinal Anti-Infective Antidiarrheal	1,152	12%
Anti- Diabetic	Oral Anti-diabetics	12,409	10%
	Human Insulin Premix	1,022	2%
	Insulin Analogues Basal	900	12%
Respiratory	Other Cough & Cold Preparations	4,066	11%
	Bronchodilators	3,942	10%
	Systemic Antihistamines	2,723	9%
Vitamins / Minerals / Nutrients	Calcium Products	2,533	6%
	Traditional Antioxidants (Multivit. / Multimineral)	2,553	14%
	Other Vitamins	2,273	14%
	B Complex	1,469	7%
Pain / Analgesics	Anti-Rheumatics, Non-Steroidal - Systemic	4,607	7%
	Non-Narcotics and Anti-Pyretic	2,415	16%
	Muscle Relaxants, Centrally Acting	1,173	9%
	Topical Anti-Rheumatic, Non-Steroidal	824	8%

Super Group	Top three Drug Groups	Sales (₹ in Crore)	CAGR
Neuro / CNS	Anti-Epileptics	4,421	9%
	Anti-Depressants and Mood Stabilizers	1,764	8%
	Atypical Antipsychotics	648	6%
	Anti-vertigo Products	601	7%
Gynaecological	Haematinics, Iron and All Combinations	2,842	7%
	Hormonal Contraceptives	1,570	6%
	Gonadotrophins, Including Other Ovulation Stimulants	709	1%
Derma	Topical Corticosteroid Combinations	2,121	7%
	Topical Dermatological Antifungal	1,433	0%
	Topical Antibiotics And / Or Sulphonamides	730	13%
Hormones	Systemic Corticosteroids, plain	1,081	10%
	Thyroid Preparation	821	12%
	Anti-Rheumatics, Corticosteroid Combinations – Systemic	232	7%
Anti-Neoplastics	All Other Anti-Neoplastics	1,543	4%
	Immunosuppressive Agents	486	15%
	Antimetabolites	291	4%
Ophthalmic / Otologicals	Artificial Tears and Ocular Lubricants	720	5%
	Miotics And Antiglaucoma Preparations	620	7%
	Ophthalmological Anti-Infectives	290	3%
Urology	Benign Prostatic Hypertrophy (BPH) Products	1,264	14%
	All Other Urological Products	619	12%
	Urinary Incontinence Products	318	11%
Vaccines	Pure Vaccines	1,040	-8%
	Combination Of Vaccines	299	-6%
	All Other Vaccines	247	23%

Super Group	Top three Drug Groups	Sales (₹ in Crore)	CAGR
Blood Related	Erythropoietin Products	574	6%
	Antifibrinolytics	476	7%
	All other Therapeutic Products	135	22%
Others	All Other Therapeutic Products	226	2%
	Pregnancy And Ovulation Tests	195	22%
	Antidotes	145	22%
Stomatologicals	Stomatologicals	1,006	15%
	All Other Anti-ulcerants	5	12%
Sex- Stimulants / Rejuvenators	Erectile Dysfunction Products	818	9%
	All Other Therapeutic Products	139	4%
Anti- Malarial	Anti-Malarial	559	2%

Source: Pharmatrac Market Database

Based on the sales data for the FY 2021-22, it is observed that the market share of large, medium and small companies across all categories was 77%, 20% and 4% respectively **(Table 2.4)**. In Anti-Infectives, Cardiac, Respiratory & Neuro categories, large companies have a high share (more than 85%) whereas in pain/analgesics, Derma, Gynaecological & Anti-Neoplastics the share of large companies was around 65%.

Table 2.4: Group of drugs and company size wise market share during FY 2021-22

Group of Drugs	Sales (₹ in Crore)	Market Share in % of companies		
		Large	Medium	Small
Anti-Infectives	23,807	89%	9%	2%
Cardiac	21,915	85%	14%	1%
Gastro Intestinal	19,622	76%	20%	4%
Anti-Diabetic	15,879	79%	19%	2%
Vitamins / Minerals / Nutrients	14,945	59%	36%	6%
Respiratory	13,569	82%	15%	3%
Pain / Analgesics	11,740	68%	26%	6%
Derma	10,642	66%	29%	5%
Neuro / CNS	9,898	88%	7%	5%
Gynaecological	8,015	67%	29%	4%
Hormones	3,072	85%	13%	2%
Anti-Neoplastics	3,063	61%	36%	3%

Group of Drugs	Sales (₹ in Crore)	Market Share in % of companies		
		Large	Medium	Small
Ophthalmic / Otologicals	2,669	65%	24%	11%
Urology	2,408	81%	17%	2%
Blood Related	1,800	62%	31%	7%
Vaccines	1,767	63%	30%	7%
Others	1,450	52%	37%	12%
Stomatologicals	1,015	54%	34%	11%
Sex Stimulants / Rejuvenators	956	88%	10%	2%
Anti-Malarial	559	89%	5%	6%
Grand Total	**1,68,791**	**77%**	**20%**	**4%**

Source: Pharmatrac Market Database

Note: Companies have been classified as Large, Medium and small based on the domestic turnover of ₹ 1,000 crore and above, between ₹ 100 crore to ₹ 1,000 crore and up to ₹ 100 crore respectively.

Analysis based on sales range and number of brands across all drug categories **(Table 2.5)** reveals that out of 262 brands with an annual sale of ₹ 100 crore or more, only 15 brands have annual sales of ₹ 400 crore or more. Out of total 52,498 brands, 3,326 brands with an annual sale of ₹ 10 crore or more have captured 80% of the market share.

Table 2.5: Sales range and brand wise market share across all drugs

Sales Range (₹ in Crore)	Number of Brands	Sales (2021-22) (₹ in Crore)	Market Share
Less than 1	40,420	4,333	2.57%
1-10	8,752	30,819	18.26%
10-50	2,675	57,255	33.92%
50-100	389	26,775	15.86%
100-200	186	25,283	14.98%
200-300	43	10,260	6.08%
300-400	18	6,238	3.70%
More than 400	15	7,828	4.64%
Grand Total	**52,498**	**1,68,791**	**100.00%**

Source: Pharmatrac Market Database

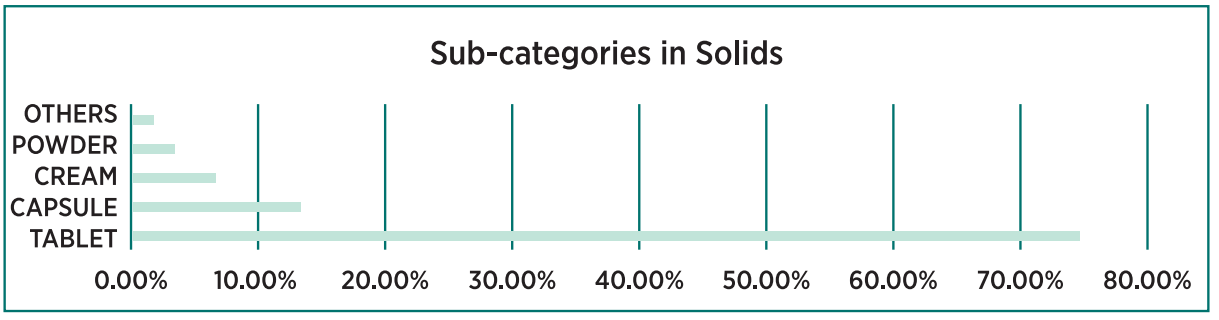
In the drug category-wise, the highest market share is held by solids (70%) followed by injectables and liquids **(Table 2.6).** Within the solids, tablets account for around 75% share, followed by capsules (around 12%) and then cream and powder **(Figure 2.1).**

Table 2.6: Drug Category-wise market share across all drugs

Drug Category	Sales in 2021- 22 (₹ in Crore)	Market Share	Top brands
Solids	1,18,117	69.98%	Fabiflu, Glycomet Gp, Augmentin
Injectables	24,098	14.28%	Mixtard, Monocef, Lantus
Liquids	22,030	13.05%	Betadine, Liv.52, Dexorange
Inhalants	3,487	2.07%	Foracort, Duolin, Budecort
Others	1,060	0.63%	Volini, Prega News, Ziverdo
Total	1,68,791	100.00%	

Source: Pharmatrac Market Database

Figure 2.1: Subcategories in Solids

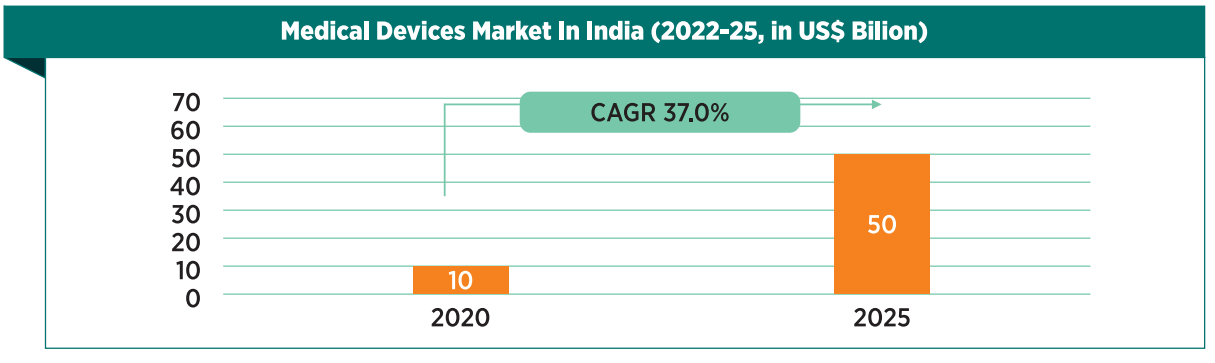


Source: Pharmatrac Market Database

Trends in Medical Devices Sector

India is one of the fastest growing markets in the global medical devices industry, expected to grow at a CAGR of 37 per cent and to reach US$ 50 billion in 2025[2] **(Figure 2.2)**. The factors influencing the growth of MD sector are depicted in Figure 2.3.

Figure 2.2: Growth trend of Indian Medical Devices Sector



[2]Adapted from https://www.ibef.org/industry/medical-devices

Figure 2.3: Factors affecting the Indian Medical Devices Industry[3]

India has an overall 75-80% import dependency on medical devices[4] (from countries such as US, China, and Germany). The details of the exports and imports in Medical Devices for FY 2020-21 and 2021-22 are shown in **Table 2.7**.

Table 2.7: Export and Import of Medical Devices

Financial Year	Export (US$ in Million)	Import (US$ in Million)
2020-21	2532.16	6240.55
2021-22	2923.16	8539.5

Source: Export Engineering Promotion Council (EEPC)

Segment / category wise import details of Medical Devices during FY 2020-21 and 2021-22 are given in Table 2.8 and the major export and import groups in Medical Devices are given in **Table 2.9.**

Table 2.8: Segment / category wise import details of Medical Devices

Category	FY 2020-21 (US$ in Million)	FY 2021-22 (US$ in Million)
Electronics Equipment (EL/EQ)	3568.64	5441.22
Consumables & Disposables (C/D)	1470.77	1623.55
IVD Reagent (IVD)	871.89	882.65
Implants (I)	225.63	423.06
Surgical Instruments (SI)	103.62	169.02

Source: EEPC

[3]Adapted from "Indian Medical Device Industry: Current State & Opportunities for growth" available at https://www.infosys.com/consulting/insights/documents/indian-medical-device-industry.pdf

[4]ibid

Table 2.9: Major Export & Import product groups in Medical Devices

S.No.	Top Export Product Groups	Top Import Product Groups
1.	Needles, catheters, cannulaes	Needles, catheters, cannulaes
2.	X-ray tubes	X-ray generators
3.	Electro-diagnostic apparatus	Chromatographs and electrophoresis instruments
4.	X-ray generators	Apparatus based on the use of X-rays
5.	Orthopaedic or fracture appliances	Ultrasonic scanning apparatus
6.	Artificial parts of the body	Ophthalmic instruments and appliances
7.	Electro-cardiographs	Artificial parts of the body
8.	Magnetic resonance imaging apparatus	Ozone therapy, oxygen therapy, aerosol therapy, artificial respiration or other therapeutic respiration apparatus
9.	Ultrasonic scanning apparatus	Magnetic resonance imaging apparatus
10.	Tubular metal needles and needles for sutures	Artificial joints for orthopaedic purposes

Source: EEPC

The Indian medical devices sector can be broadly categorized into the following four segments[5]:

Equipment & Instruments: Diagnosing imaging and IV diagnostic form a major part of equipment and instruments. Most of medical device imports are from the same category e.g.: MRI machines, CT scanners, ultrasound machines, dental drills, dental chairs, dental X-ray machines, etc.

Consumables and Disposables: Syringes, Needles, and Catheters form a major part of consumables and disposables. It is the only trade surplus segment of the medical device sector with domestic players having a larger market share, e.g., syringes, needles, catheters, bandages, and dressings. Most of the requirements are met through domestic manufacturing.

Implants: Implants segment is import-driven. However, few domestic companies in the implants segment are offering customized designs for the Indian population gaining a competitive advantage, e.g.; cardiac stents, knee & hip implants, artificial joints, dental fixtures.

Patient Aids: Hearing Aids, prosthetics and orthotics, pacemakers and others form the major part of the patient Aids segments and constitute 70% of the market collectively. Most of the import-driven segments are primarily sourced from Ireland, USA, Australia, Singapore, and China.

Indian Medical Device Market Size

Currently, India is counted among the top 20 global medical devices market and is the 4th largest medical devices market in Asia after Japan, China, and South Korea.

[5]https://www.nexdigm.com/data/resource/skp_the_medical_device_industry_in_india_.pdf

The Indian Medical Device Manufacturing industry is at the cusp of a great opportunity. Gujarat, Maharashtra, Karnataka, Haryana, Andhra Pradesh, and Tamil Nadu are the manufacturing hubs for medical devices in India. The Indian Government has identified medical devices as a priority sector for the flagship 'Make in India' program and is committed to strengthening the manufacturing ecosystem. The Production Linked Incentive Scheme (PLI) Promoting Domestic Manufacturing of Medical Devices and Production Linked Incentive Scheme for Pharmaceuticals (PLI 2.0) have been introduced to provide an impetus to India's vision of becoming a global manufacturing hub for medical devices.

As per the Medical Devices Rules, 2017, MoH&FW has divided medical devices into the following four categories:

- **Class A (Low Risk):** Medical devices such as surgical dressings, umbilical occlusion devices, bolster sutures, alcohol swabs, nasopharyngeal catheters, and Y-connectors, as an accessory to perfusion sets, etc. are included in this category
- **Class B (Low Moderate Risk):** Medical devices such as endoscopic forceps, vial adapters, suction cups, and catheters, feeding tubes, gastrointestinal tubes, etc. are included in this category.
- **Class C (Moderate-High Risk):** Medical devices such as anaesthesia conduction filter, introducer sheath, microcatheter, imaging catheter colonic stents, pancreatic instruments, etc. are included in this category.
- **Class D (High Risk):** Medical devices such as coronary stents, cardiac catheterization kits, cardiovascular, intravascular diagnostic catheters, occlusion catheters, etc. are included in this category.

Table 2.10 lists the key segments of MDs consumed in India and the % of import dependence for them. It also highlights the overall attractiveness for manufacturers to invest segment-wise.

Table 2.10: List of medical devices consumed most in India[6]

S. No	Key Segment	Sub-Segment	% of imports dependence	Share of the overall Medical Device Market	Overall attractiveness for Indian Manufacturers to Invest in this segment
1.	Consumables	Cardiac Catheter, Other needle, Syringe, Lab reagent, Suture, Strips & cartridge, Dialyzers and Filters, cannula	35%	16%	High
2.	Dental Products	Dental Implant, Artificial teeth, Dental instruments	60%	3%	Medium
3.	Diagnostics Imaging	X-Ray tubes, USG Probe, Radiation beam delivery system, Radiation generator unit, CT S can, MRI, PET Scan, ALPHA, BTA/GMA Radiation for other use in radiography equipment	52%	30%	Very High

[6]https://pharmaceuticals.gov.in/sites/default/files/medicaldevicemanufacturinginindia-asunrise-170221053503%20%281%29.pdf

S. No	Key Segment	Sub-Segment	% of imports dependence	Share of the overall Medical Device Market	Overall attractiveness for Indian Manufacturers to Invest in this segment
4.	IV Diagnostics	Lab reagent & accessories	67%	10%	High
5.	Orthopaedics & Prosthetics	Artificial joints & joint implants	62%	8%	High
6.	Others	Artificial dialysis apparatus & Haemo-dialyser, defibrillator, Lithotripsy equipment, ECHO, EEG, ECG, anesthesia equipments, Laparoscope, endoscope	83%	24%	Very High
7.	Patients Aids	Pacemaker, Hearing aid, Cochlear implant, Stents	50%	9%	Medium

Foreign Direct Investment in Pharmaceuticals

Pharmaceutical is one of the top ten attractive sectors for foreign investment in India. 100% foreign investment is allowed under automatic route in Medical Devices. Foreign investments in pharmaceuticals in Greenfield projects are allowed up to 100% under the automatic route and for Brownfield pharmaceutical projects, foreign investment beyond 74% to up to 100%, Government approval is required[7].

During FY 2021-22, the sector saw FDI equity inflow of USD Million 1,490 and the cumulative inflow from April 2000 to March 2022 was USD Million 19,452[8].

[7]https://pharmaceuticals.gov.in/sites/default/files/English%20Annual%20Report%202021-22%20%281%29.pdf

[8]https://dpiit.gov.in/sites/default/files/FDI_Factsheet_March_2022_23May2022.pdf

Chapter 3

Evolution of Policy and Regulatory Framework

Introduction

This chapter presents a historical overview of the evolution of drug price regulation in the country; and also the drug policies articulated by the government from time to time to provide overall policy direction for the sector. The government's efforts to regulate the prices of drugs have been to ensure their availability, affordability and accessibility. A wide variety of products such as food grains, textiles, fertilizers etc., were regulated under the 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 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[9]:

- 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[10]:

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.

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

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

Accordingly, 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 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[11]. 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[12].

The Hathi Committee Report [13]

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[14]:

a. Country should be self-reliant in technology;

b. There should be self-sufficiency in drugs; and

c. Quality drugs should be adequately available at reasonable prices.

[10]https://indianculture.gov.in/flipbook/1032

[11]Joseph, R.K. (2015). Pharmaceutical Industry and Public Policy in Post-reform India

[12]Ajay Bhaskarabhatla, 2018. "Regulating Pharmaceutical Prices in India," India Studies in Business and Economics, Springer, number 978-3-319-93393-1, June.

[13]https://pharmaceuticals.gov.in/sites/default/files/Hathi_Committee_report_1975_0.pdf

[14]https://www.epw.in/journal/1978/21/special-articles/new-drug-policy.html

Box 3.1: 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 technology

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[15], 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

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

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[16]. Currently, DoP is the custodian of the DPEA.

The Kelkar Committee Report [17]

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'*. The objectives[18] of the DP, 1986 are given in **Box 3.2.**

Box 3.2: 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.

[16]ibid

[17]https://www.oecd.org/competition/sectors/46138891.pdf

[18]https://www.nppaindia.nic.in/wp-content/uploads/2020/07/Drug-policy-1986.pdf

DP, 1986 proposed to have 2 categories of formulations and bulk drugs required in place of 3 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[19].

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[20].

It was under the New Drug Policy, National Pharmaceutical Pricing Authority (NPPA) was appointed to implement and enforce the provisions of the Drugs (Prices Control) Order 1995 in accordance with the powers delegated to it.

[19]https://www.oecd.org/competition/sectors/46138891.pdf

[20]Joseph, R.K. (2015). Pharmaceutical Industry and Public Policy in Post-reform India (1st ed.). Routledge India

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[21]. 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.

[21]https://pharmaceuticals.gov.in/policy/pharmaceutical-policy-2002

- 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 Excise 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 'benchmark 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.
- The revisions of MRPs where required 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 formulations taking into

consideration 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[22]. 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. However, it was perceived that it may result in drastic increase of prices of medicines required by the common man. 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 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:

[22]https://pharmaceuticals.gov.in/policy/pharmaceutical-policy-2002

"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[23].

Sandhu Committee Report

In August 2004, government also constituted a Committee under Shri G.S. Sandhu, Joint Secretary, Department of Chemicals & Fertilizers to examine the span of price control (including the trade margin) in the light of National Common Minimum Programme and the observations of Hon'ble Supreme Court in UOI vs. K.S. Gopinath & others (3668 of 2003). Shri Sandhu was also member of the Pronab Sen Committee. Committee in its interim report submitted in November, 2004 suggested the following trade margin:

Table 3.1 Recommendations of Sandhu Committee on Trade Margin

Category	Margin to Wholesaler	Margin to Retailer	Total Margin
Scheduled Drugs	8%	16%	24%
Non-Scheduled Drugs			
-branded category drug	10%	20%	30%
-generic category drug	15%	35%	50%

[23]https://pharmaceuticals.gov.in/sites/default/files/drpronabreport_0.pdf

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[24]. 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[25]. 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[26].

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 NPPP-2012 is in continuation of the Policy announced earlier in 1994.

The National Pharmaceuticals Pricing Policy 2012 limited 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:

[24]https://www.drugscontrol.org/pdf/draftNPP2006.pdf

[25]https://pharmaceuticals.gov.in/draft-national-pharmaceutical-pricing-policy-2011-comments-invited-30112011

[26]Joseph, R.K. (2015). Pharmaceutical Industry and Public Policy in Post-reform India

- **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.

To conclude, it can be opined that enabling provisions for drug price control are embedded in different statutes as indicated in **Figure 3.1.**

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 availability at fair prices, it may, by order, provide for regulating or prohibiting the production, supply and distribution thereof and trade and commerce therein.
Schedule to the Section 2A(1) of Essential Commodities Act, 1955	• Drugs are included in Schedule of section 2A(1) of the **Essential Commodities 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 disorder in human beings or animals, as, may be specified from time to time by the Central Government.

Figure 3.1: Enabling provisions for Drug Price Control

Chapter 4

Important Milestones in NPPA Journey

Introduction

As mentioned earlier, price control over drugs was first introduced with the promulgation of the Drugs (Display of Prices) Order, 1962 and the Drugs (Control of Prices) Order, 1963. Subsequently, the Drugs (Prices Control) Order 1970 was promulgated which had provision of mark-up applicable to essential and other formulations with overall profitability not exceeding 15 per cent on sales turnover. 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”] by declaring drugs to be essential commodities. 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].

The basic criteria adopted for inclusion of Drugs under Price Control, DPCO, 1995 is depicted below:

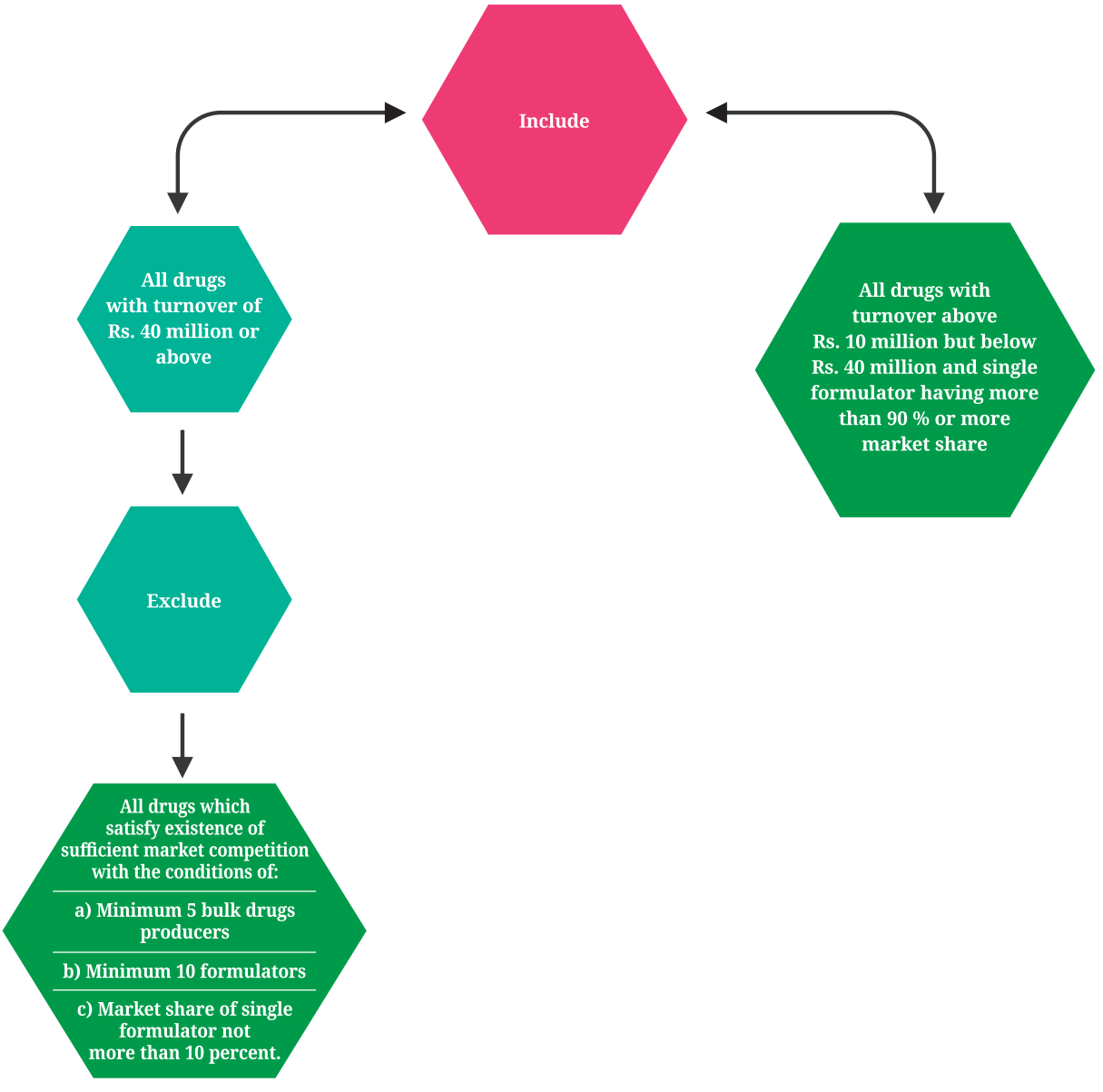


Figure 4.1: Criteria adopted for inclusion of Drugs under Price Control, DPCO, 1995

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

The DPCO-2013 was notified on 15th May, 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:

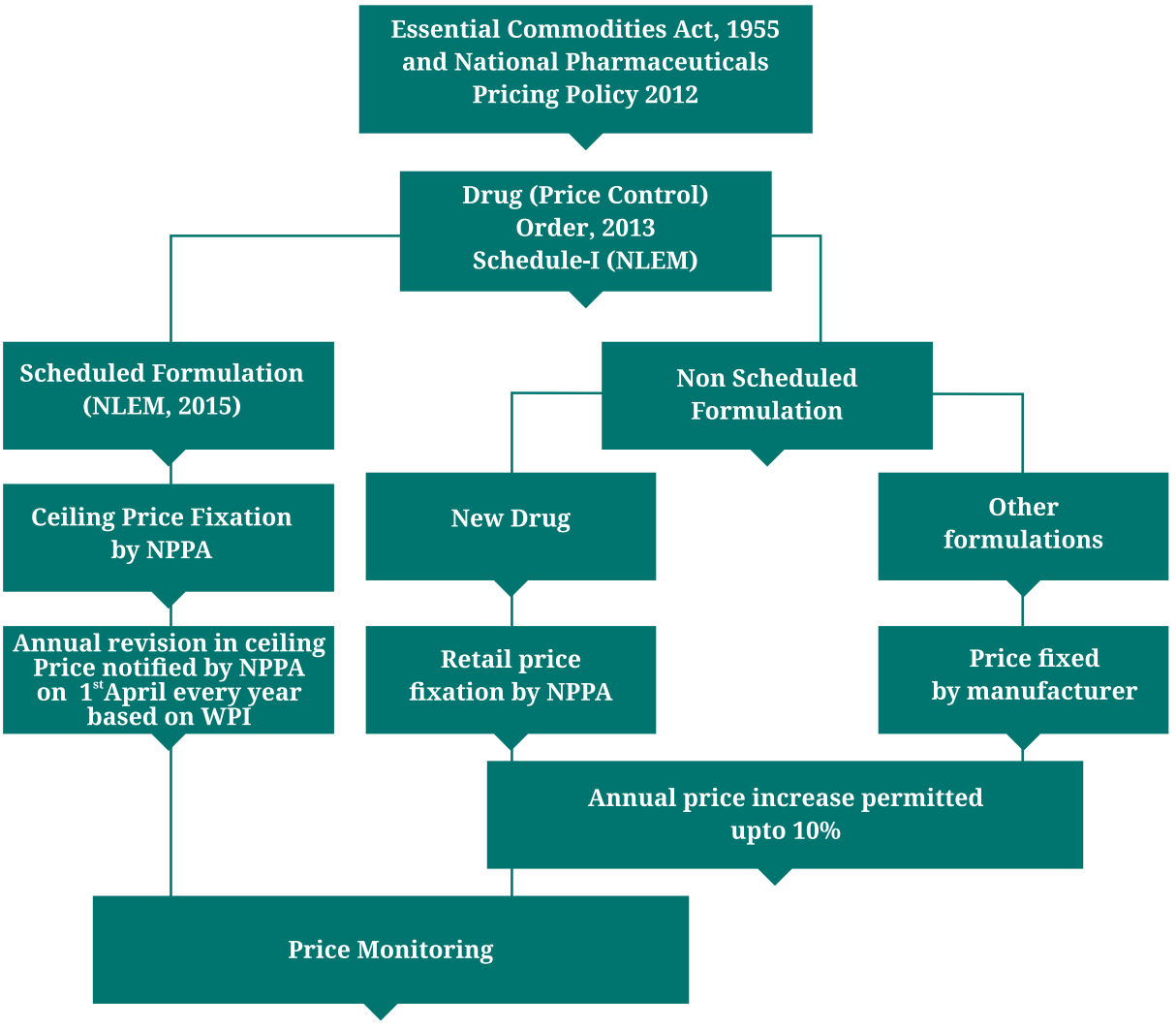


Figure 4.2: Overview of the DPCO mechanism

National List of Essential Medicines with specific reference to NLEM, 2015

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

medicines that are safe, efficacious, collectively address the majority of the public health concerns of India and are cost effective. NLEM is further intended to promote rational use of medicines. The NLEM was first published in India in the year 1996 and included 279 medicines. Later, it was revised in the year 2003, 2011, and 2015[27].

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[28].

As per Report of the Core-Committee for Revision of National List of Essential Medicines 2015, the criteria for inclusion of a medicine in NLEM are as follows:

- The medicine should be approved/licensed in India.
- The medicine should be useful in disease which is a public health problem in India.
- The medicine should have proven efficacy and safety profile based on valid scientific evidence.
- The medicine should be cost effective.
- The medicine should be aligned with the current treatment guidelines for the disease.
- The medicine should be stable under the storage conditions in India.
- When more than one medicine are available from the same therapeutic class, preferably one prototype/ medically best suited medicine of that class to be included after due deliberation and careful evaluation of their relative safety, efficacy, cost-effectiveness.
- Price of total treatment to be considered and not the unit price of a medicine.
- Fixed Dose Combinations (FDCs) are generally not included unless the combination has unequivocally proven advantage over individual ingredients administered separately, in terms of increasing efficacy, reducing adverse effects and/or improving compliance.
- The listing of medicine in NLEM is based according to the level of health care, i.e. Primary (P), Secondary (S) and Tertiary (T) because the treatment facilities, training, experience and availability of health care personnel differ at these levels.

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

[27]https://www.nppaindia.nic.in/wp-content/uploads/2021/10/NPPA-Newsletter-Oct-21.pdf
[28]ibid

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.

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 = 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, if 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.

In this context, the Hon'ble Supreme Court in *GlaxoSmithKline Pharmaceuticals Limited versus Union of India and Others, 2014 (SCC vol.II 753)* has held that the current price list is simply the price reflecting the currently operating notified price under DPCO and once price is notified for a formulation, it takes effect immediately and sale of the formulation to the consumer has only to be at the price specified in the current price list or price indicated on the label of the container or

pack thereof, whichever is less. An Office Memorandum has been issued in this regard by NPPA vide F.No. 25(5)/2014/Div-V/NPPA dated 13th April 2016.

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.

There were 348 medicines in the National List of Essential Medicines 2011 (NLEM) which were included in the First Schedule of the DPCO, 2013. The NPPA fixed the ceiling prices of 530 scheduled formulations of such medicines based on market-based pricing methodology. The details of reduction in prices of scheduled formulations effected under the DPCO, 2013 as compared to the highest price prevailed prior to the price fixation is as below:

Table 4.1: Reduction in prices of scheduled formulations (in NLEM, 2011) effected under DPCO, 2013

% reduction with respect to Maximum Price	Number of drugs
0<= 5%	80
5<=10%	50
10<=15%	57
15<=20%	43
20<=25%	65
25<=30%	49
30<=35%	26
35<=40%	34
Above 40%	126
Total	**530**

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 22.12.2016 taking total medicines to 377 and number of therapeutic categories to 31. In February, 2021 two animal vaccines, Foot and Mouth Disease-FMD (Trivalent) Oil Adjuvant and Brucella abortus (S19 strains) freeze dried were also added to Schedule-I.

The NPPA has fixed the ceiling prices of 890 scheduled formulations of medicines under the NLEM, 2015 till 31.7.2022. The detail of price fixed is available on the 'NPPA's' website www.nppaindia.nic.in. The details of reduction in prices of scheduled formulations effected under the DPCO, 2013 as compared to the highest price prevailed prior to the price fixation is as below:

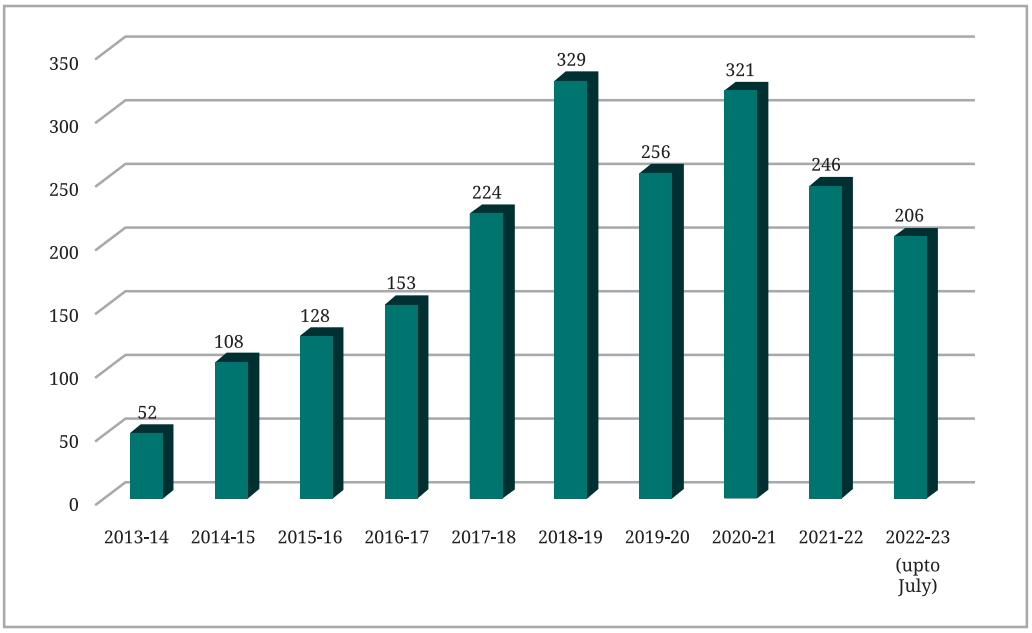
Table 4.2: Reduction in prices of scheduled formulations (in NLEM, 2015) effected under DPCO, 2013

% reduction with respect to Maximum Price	No. of formulations
0<= 5%	248
5<=10%	141
10<=15%	105
15<=20%	101
20<=25%	94
25<=30%	69
30<=35%	46
35<=40%	26
Above 40%	60
Total formulations in NLEM 2015	**890**

Retail price of a new drug

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. The year-wise bifurcation of number of drugs for which retail prices have been fixed under DPCO, 2013 till 31.07.2022 is given in **Figure 4.3.**

Figure 4.3: Number of Drugs for which Retail Prices fixed



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

As per Para 19 of the DPCO-2013, *"Notwithstanding anything contained in this order, the Government may, in case of extra-ordinary circumstances, if 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%.
- Trade 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.

NPPA also receives applications for upward price revision under para 19 of the DPCO, 2013 citing various reasons like increase in Active Pharmaceutical Ingredient (API) cost, increase in cost of production, exchange rate variation etc. resulting in unviability in sustainable production and marketing of the drugs. In the following cases, the requests for price increase have been considered:

- Based on the recommendation of Standing Committee on Affordable Medicines and Health Products (SCAMHP), ceiling price of shortlisted 21 scheduled formulations of 12 medicines were revised in December 2019 by allowing one time price increase of upto 50% on the then applicable ceiling price in public interest as an exceptional measure by invoking para 19 of the DPCO, 2013. The details of price revision as notified vide S.O. No. 4461 (E) dated 13.12.2019.
- In the wake of COVID pandemic to ensure continued availability, the ceiling price of Heparin Injection 5000 IU/ml and 1000IU/ml were also increased by allowing increase of 50% over the then applicable ceiling price vide notification dated 30th June, 2020. The revised ceiling prices are Rs. 24.39 per ml for Heparin 1000IU/ml and Rs. 60.54 per ml for Heparin 5000IU/ml. The revised ceiling prices have been extended up to 30.09.2022.
- NPPA, in exercise of extra ordinary powers, conferred by paragraph 19 of the Drug, (Prices Control) Order, 2013 and powers conferred under section 10(2)(l) of Disaster Management Act, 2005, in public interest, capped the price (ex-factory) of Liquid Medical Oxygen (LMO) to

₹ 15.22 per cubic meter (excluding GST) and the price (ex-factory) of Oxygen Inhalation (Medicinal gas) to ₹ 25.71 per cubic meter (excluding GST) vide notification dated 25th September 2020. The revised ceiling prices have been extended up to 30.09.2022.

- NPPA further invoked extra ordinary powers in public interest under para 19 of DPCO 2013 for upward revision of the ceiling prices of the 9 scheduled formulations of 3 drugs by giving one time increase of 50% from the present ceiling price. This was done to address the issue of repeated price control, importance of the drugs from the view of public health needs of the country, ensure availability of essential drugs to the general public, etc. The details of price revision as notified vide notified vide S.O. 2654(E) dated 01.07.2021.

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 of around 82% of the total market share and it is noted that the current regulation is not able to limit the exorbitant retail margin[29] . 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.

Committees on TMR constituted by Government

Sandhu Committee

On 19th August 2004, a Committee under the Chairmanship of the then Joint Secretary, Department of Chemicals & Petro-Chemicals, Shri G.S. Sandhu was constituted to examine the span of price control (including trade margin) in the light of observations of the Hon'ble Supreme court in case No. 3668/2003 and to suggest measures for fulfilling the objectives of National Common Minimum Programme (NCMP) to ensure the availability of life saving drugs at reasonable prices. The recommendations of the Committee are highlighted in chapter 3.

Sudhansh Pant Committee

In order to examine specific cases of high trade margins referred to the Ministry through various channels, a Committee on 'High Trade Margin in the sale of drugs' under the chairmanship of Shri Sudhansh Pant, Joint Secretary (Pharma), Department of Pharmaceuticals was constituted on 16th September 2015 to compare the prices of trade generics and regular channels of marketing and to give its recommendations. The Committee submitted a Report on 09.12.2015, after holding large scale consultation with various stakeholders. This report is in public domain since year 2015. The recommendations made by the Committee are as follows:

a. Trade margin on all drugs including stents and orthopeadic implants, whether scheduled or non-scheduled, ethical or non-ethical, generic or branded generics need to be capped.

[29]Ajay Bhaskarabhatla, 2018. "Regulating Pharmaceutical Prices in India," India Studies in Business and Economics, Springer, number 978-3-319-93393-1, June.

b. Margins are to be calculated backward by putting a cap on them. It is for the industry to decide the intra-trade margins at different levels. In order to monitor PTT, Form V of DPCO, 2013 may be suitable amended.

c. No cap on drugs, the retail price of which is upto Rs. 2 per unit, i.e., per tablet/ capsule/ vial/ tube/ bottle/ injection, etc. so that the apprehension of small value formulations going out of market may be ruled out.

d. There should be higher trade margin cap for lower value drugs and lower margins for higher value drugs. The graded trade margins as proposed by Sudhansh Committee are given in **Table 4.3** below :

Table 4.3: Proposed Trade Margin as per Sudhansh Pant Committee

S. No.	MRP in Rs.	Maximum TM as % of MRP	MAT value % (Pharmatrac October, 2015)
1.	Upto 2	No capping	5.19%
2.	More than 2 upto 20	50%	48.51%
3.	More than 20 upto 50	40%	13.28%
4.	Above 50	35%	33.03%

TMR intervention by NPPA: As already mentioned in chapter 1 NPPA has undertaken TMR on anti-cancer drugs in 2019 and six selected MDs in 2021.

Monitoring of Prices under DPCO, 2013

MPRs of all the Non-Scheduled Formulations are monitored by the Government under the provisions of Para 20(1) of the DPCO, 2013 to ensure that no manufacturer or importer tends to increase the MRP of a drug more than 10% during preceding twelve months and in all the areas where there is an increase beyond ten percent of maximum retail price, it shall reduce the same to the level of ten percent of maximum retail price for the next twelve months. As per Para 20(2) of the DPCO, 2013 read with the Essential Commodities Act, 1955, the manufacturer/importer shall also be liable to deposit the overcharged amount along with interest thereon from the date of increase in price in addition to the penalty.

Similarly, in case of scheduled formulations and new drugs, apart from price fixation, NPPA is also empowered to monitor the maximum retail prices .

Punishment for violating the DPCO, 2013

Non-compliance with the notified ceiling price or the MRP breaching the ceiling price plus applicable local taxes would be tantamount to overcharging the consumer, which is liable to be recovered along with interest thereon from the date of overcharging. The excess collection on account of overcharging along with interest is recoverable as arrears to land revenue under the Public Demand Recovery Act. Further, non-compliance of price notification issued by NPPA, depending upon the gravity of the offence, could also attract prosecution under the Essential Commodities Act (ECA), 1955.

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. List of cases where exemptions have been granted by NPPA have been listed in Chapter 1. The self-invocation of para 32 will amount to violation under DPCO-2013.

Ensuring availability of drugs during COVID

Monitoring supply of Remdesivir, Tocilizumab and Amphotericin and coordination with the manufacturers of Buffer drugs and Nodal Officers of States

In order to ensure equitable distribution of Remdesivir, Tocilizumab and Amphotericin across the country, DoP and MoH&FW made allocations during April-July 2021. Based on the allocation made by DoP, NPPA monitored equitable distribution to States/UTs to address the supply gaps and stabilize demand. Allocations made to seven Indian manufacturers of Remdesivir; one importer of Tocilizuamb; seventeen manufacturers of liposomal Amphotericin; and six manufacturers of conventional Amphotericin.

As a part of the measures being taken to strengthen the preparedness to meet any future surge, MoH&FW had issued guidelines to States/UTs for Buffer Stock Management of drugs used for COVID-19 wherein it was emphasized that the States must initiate procurement on priority for building up buffer stocks and that the buffer stocks should be in place by 31st July,2021. DoP assigned NPPA to actively coordinate with States/ UTs and the manufacturers, if any facilitation is required to monitor supplies once the purchase orders were placed by the States/UTs.

Regular meetings were held with the LOs of the manufacturer and Nodal Officers of States/UTs to ensure un-interrupted supply and also to resolve any issues/challenges faced by manufacturers/States/UTs. Apart from meetings and emails, regular monitoring was also done through; phone calls, messaging apps, etc.

Weekly Retail Availability Surveys and other measures

Weekly surveys to ascertain retail level availability of COVID management drugs and few selected medical devices by Price Monitoring Resource Units (PMRUs) were initiated from May and July 2021 onwards. This was supplemented with the availability surveys of Central Drugs Standard Control Organization (CDSCO). These surveys are still being conducted.

Also, Pharmatrac weekly data on sales, inventory days, etc. was being analysed as a proactive measure and in close coordination with CDSCO meetings were held with manufacturers as well as AIOCD. This two-pronged strategy involved monitoring the production level at the manufacturer(s) level and then the supply of the drugs in the trade channel.

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

COVID Drug Management Committee (CDMC) meetings were held on weekly basis under the chairmanship of Secretary (DoP) to review the activities undertaken for monitoring of production and supply of buffer drugs.

Meetings of Drug Coordination Committee (DCC), an inter-ministerial committee under the chairmanship of Secretary, DoP were held on regular intervals to review the activities undertaken for monitoring of production and supply of COVID drugs.

Shared Responsibility

Implementation of the DPCO 2013 is a shared responsibility of both NPPA and SDCs. Accordingly, most State Governments/ Union Territories have duly empowered the State Drug Controller and Drug Inspectors under paragraph 30 (1) of DPCO 2013, which allows any Gazetted Officer of the Central Government or of a State Government, as the case may be, to exercise the power of entry, search and seizure to ensure that the provisions of the DPCO have been complied with. Also, by setting-up PMRUs in States/UTs by NPPA that functionally work under SDCs will strengthen the monitoring infrastructure. It has been observed that cooperation from the state administrators in monitoring and enforcement activities can lead to more effective regulation[30].

Integrated Pharmaceutical Database Management System (IPDMS)

DPCO 2013 provides that initially the source of market based data shall be the data available with pharmaceuticals market data specializing company. The Government may in due course of time come out with other appropriate mechanisms of collecting/ obtaining the market based data relating to drugs and the decision of Government with respect to collection or obtaining of data shall be final.

The launch of IPDMS in 2015 by the Hon'ble Union Minister of Chemicals and Fertilizers, Shri Ananth Kumar was of significance because with the transition from DPCO 1995, which followed cost-based mechanism for price fixation, to the DPCO 2013, which follows market-based mechanism for price fixation, reference data and source of market-based data has assumed critical importance. Through this effort, the NPPA in due course wanted to establish an appropriate mechanism of obtaining market-based data related to drugs. A need for creation of database in NPPA was also felt to meet the need of having a database containing PTR and MAT value for each dose / strength of NLEM and 'new drug for their price fixation. Further, NPPA would be able to access price data with respect to each scheduled and non-scheduled formulation for monitoring of ceiling prices of scheduled formulation under Para 14 (2) and price movement of non-scheduled formulations medicines under Para 20 of DPCO, 2013.

IPDMS was developed in collaboration with National Informatics Centre (NIC) as a comprehensive online system with the objective of creating an appropriate mechanism of obtaining market-based data related to drugs as availability of reliable database is a necessary pre-requisite for carrying out various functions such as price fixation/revision, monitoring the production/availability of scheduled formulations and monitoring of prices of medicines. IPDMS was designed, developed and fine-tuned after detailed and extensive consultation with the industry.

As on 31.07.2022, 981 Pharma companies and 89,553 products are registered under IPDMS.

Web-based IPDMS ver. 2 launched in August 2022 upgrades the current IPDMS with latest technological interface. Multi-instance architecture of IPDMS 2.0 has the capability to connect multiple users over a public network infrastructure.

[30]ibid

➢ Though NPPA undertakes myriad activities in pursuit of its mandate; major milestones during the implementation of DPCO, 2013 have been shown in **Figure 4.4.**

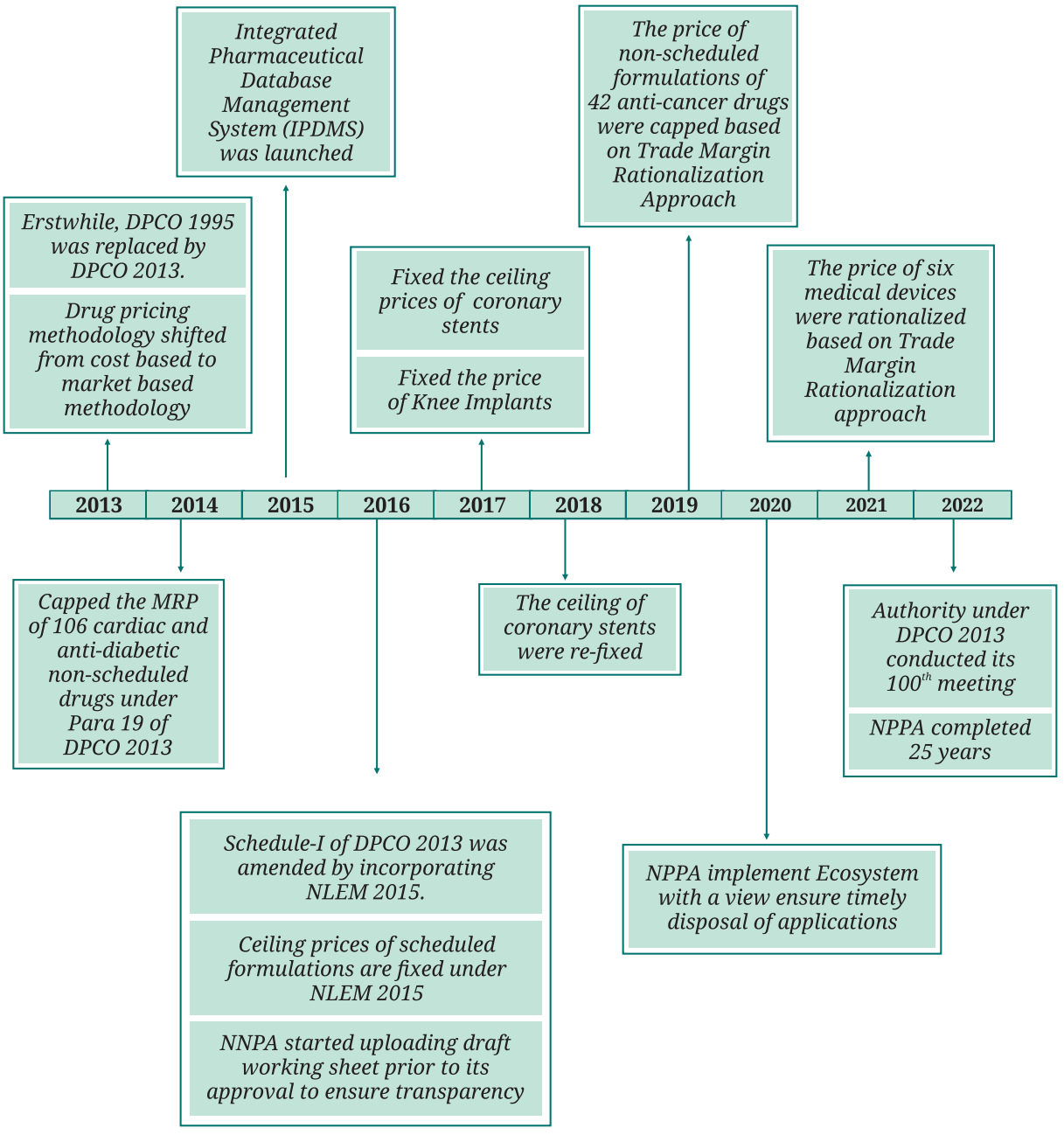


Figure 4.4: Major Milestones of NPPA in implementation of DPCO, 2013

Chapter 5

Current Challenges and Way Forward

Introduction

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[31]. To achieve the goal of ensuring equitable access to essential, high-quality and affordable medicines and other medical technologies countries follow a combination of strategies to (Figure 5.1).

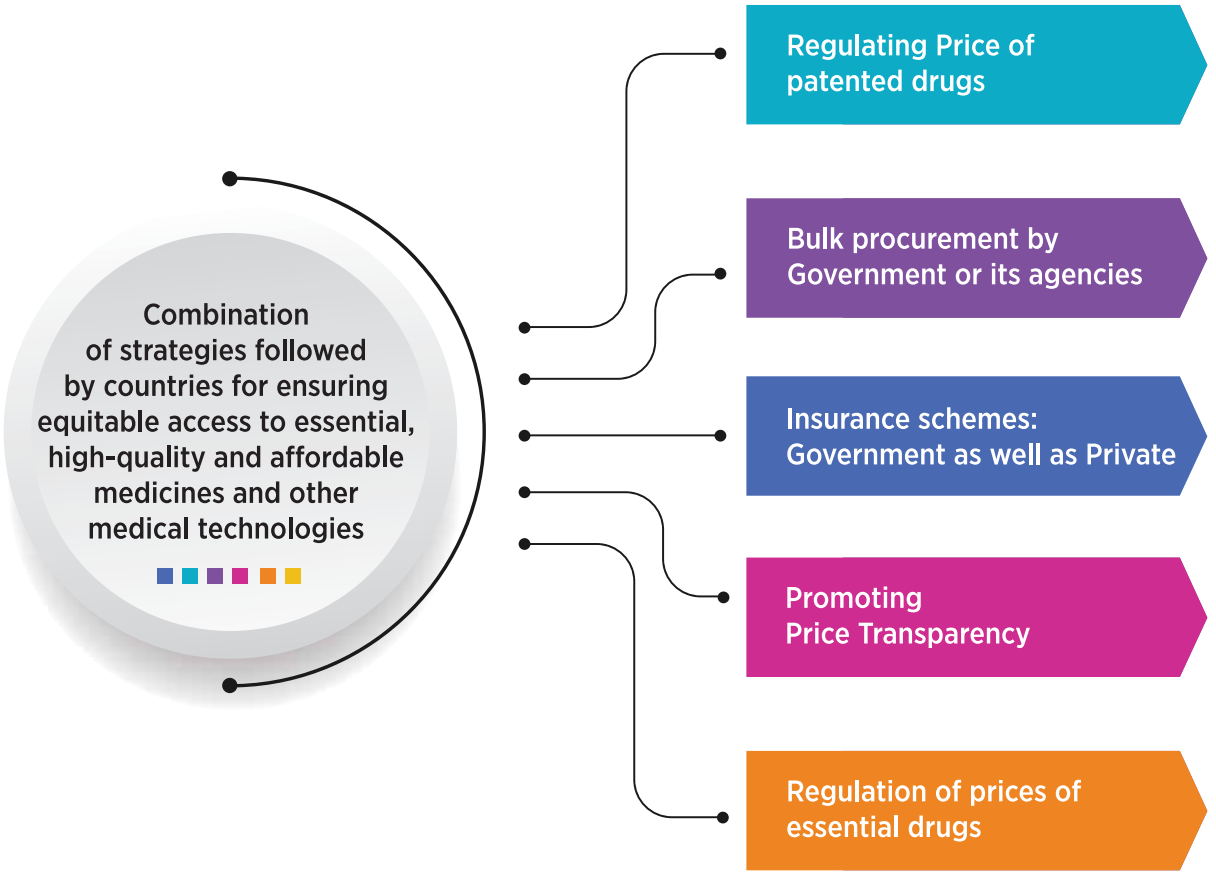


Figure 5.1: Strategies followed for ensuring access to essential drugs

These strategies include following different pricing policy approaches like value-based pricing; regulation of mark-ups across the pharmaceutical supply and distribution chain; external and internal reference pricing; tendering and negotiation; pooled procurement; cost-plus pricing; tax exemptions or tax reductions; promoting price transparency, etc.

The recent Inflation Reduction Act of 2022 of USA, under the Healthcare segment amongst other provisions requires the Centers for Medicare & Medicaid Services (CMS) to negotiate the prices of certain prescription drugs under Medicare beginning in 2026 (maximum prices for brand-name drugs that do not have other generic equivalents and that account for the greatest Medicare

[31]https://www.who.int/news/item/28-09-2020-who-publishes-pricing-policy-guideline-to-improve-affordable-access-to-medicines

spending) –starting with 10 drugs in 2026, increasing to 20 drugs by 2029. It also caps insulin out-of-pocket costs for Medicare beneficiaries at $35 per month and requires pharmaceutical companies to offer rebates to Medicare if they raise the price of drugs faster than the rate of inflation for beneficiaries[32]. Thus, drug prices are in one way or the other subject to controls and regulation in most of the countries.

India too follows a combination of approaches like pooled procurement by national programmes (e.g. for tuberculosis, vector-borne diseases and HIV/AIDS); tendering and negotiations by different government organizations; direct drug price control exercised through various DPCOs. Over a period of time, the healthcare is becoming affordable and the Out of Pocket Expenditure (OOPE), which is expenditures directly made by households at the point of receiving health care, is on decline (Figure 5.2). However, OOPE is still 48.8% of Total Health Expenditure (THE)[33]. THE constitutes current and capital expenditures incurred by Government and Private Sources including External funds. The per capita OOPE for NHA 2017-18 was Rs. 2097.

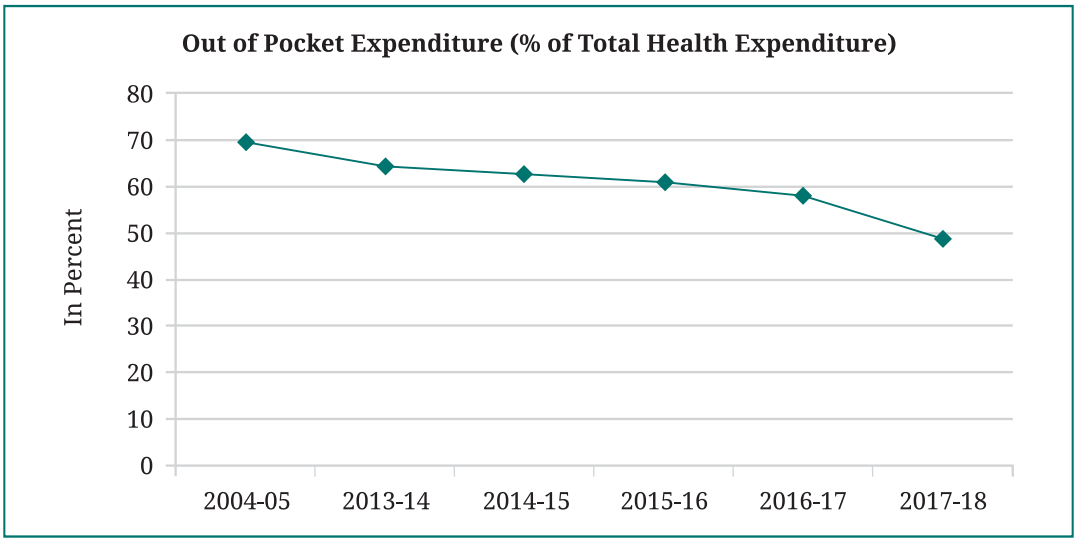


Figure 5.2: OOPE as % of THE

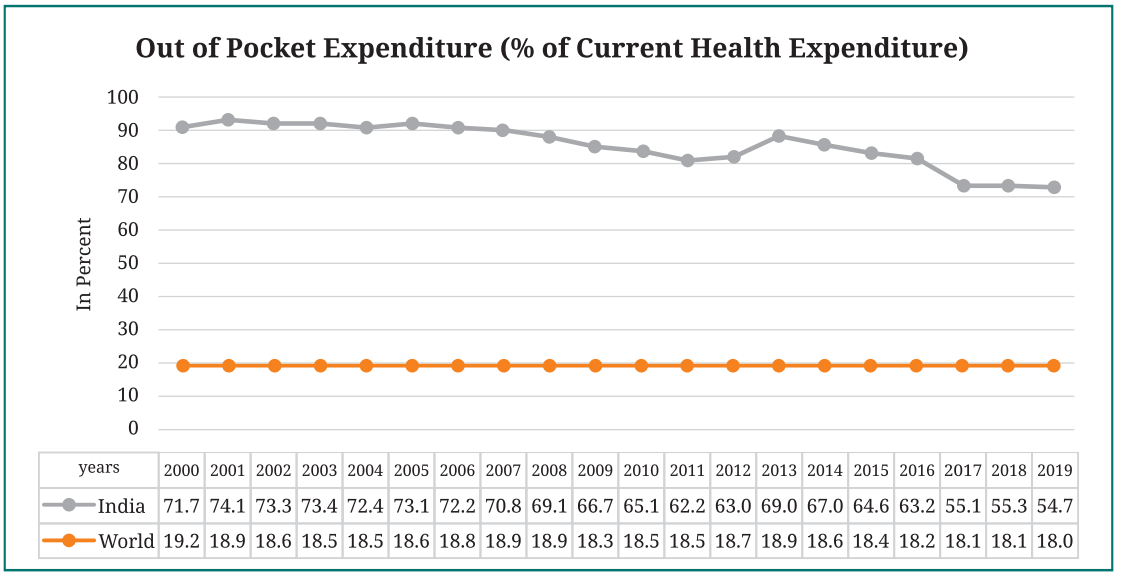
Source: National Health Accounts Data (2017-18)

Current Health Expenditures (CHE) constitutes only recurrent expenditures for healthcare purposes net all capital expenditures. OOPE as % CHE is also showing downward trend in the country, however, it is still higher when compared with global trends (Figure 5.3). Total Pharmaceutical Expenditure is 33.4 % of CHE (includes prescribed medicines, over-the-counter drugs, and those provided during an inpatient, outpatient, or any other event involving contact with health care providers)[34]. Hence, there is need to strike a balance between availability and affordability.

[32]https://www.mondaq.com/unitedstates/economic-analysis/1223352/the-inflation-reduction-act-of-2022

[33]https://nhsrcindia.org/sites/default/files/2021-11/National%20Health%20Accounts-%202017-18.pdf

[34]ibib



years	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
India	71.7	74.1	73.3	73.4	72.4	73.1	72.2	70.8	69.1	66.7	65.1	62.2	63.0	69.0	67.0	64.6	63.2	55.1	55.3	54.7
World	19.2	18.9	18.6	18.5	18.5	18.6	18.8	18.9	18.9	18.3	18.5	18.5	18.7	18.9	18.6	18.4	18.2	18.1	18.1	18.0

Figure 5.3: OOPE as % CHE for India as well as the World

Source: World bank data

Striking the balance between availability and affordability

The government through its various interventions is working on striking a balance between availability and affordability. Ayushman Bharat approved by the Indian government in March 2018, is an ambitious reform to the Indian health system to provide Comprehensive Primary Health Care (CPHC) and to achieve Universal Health Coverage[35].

Similarly, government is encouraging the use of quality assured generic medicines through its Pradhan *Mantri Bhartiya Janaushadhi Pariyojana* (PMBJP). PMBJP was launched by DoP in 2008 with an objective of making quality generic medicines available at affordable prices to all especially for the poor and the deprived ones. Under this scheme, dedicated outlets known as Pradhan Mantri Bhartiya Janaushadhi Kendras (PMBJK) are opened all over the country to provide generic medicines[36].Under the PMBJP, till 30.06.2022, 8742 PMBJKs have been opened across the country including Government Hospitals and Government premises and the Scheme has a product basket of 1,616 medicines and 250 surgical supplies. Prices of medicines sold through these outlets are 50-90% less than that of branded medicines prices in the open market. A target to open 9,300 PMBJKs by the end of financial year 2022-23 in the country has been kept.

NPPA has also contributed towards making medicines affordable through its various interventions like fixing of ceiling prices of 890 essential medicines; retail price fixation of 2023 new drugs; through control of anti-diabetic and cardio-vascular medicines. The price fixation of coronary stents and orthopaedic knee implants has also benefited the consumers.

Siddharth Mukherjee in his 2010 book, 'The Emperor of All Maladies: A Biography of Cancer' traces the history of cancer from its first identification 4,600 years ago by the Egyptian physician Imhotep. Today also cancer remains as one of the leading causes of adult illness and death due to chronic and non-communicable diseases (NCD) world-over including in India. Hence, to make

[35]https://medical.advancedresearchpublications.com/index.php/Preventive-Curative-CommunityMed/article/view/130

[36]https://pharmaceuticals.gov.in/sites/default/files/English%20Annual%20Report%202021-22%20%281%29.pdf

anti-cancer drugs affordable, apart from fixing ceiling prices of 86 formulations of scheduled cancer drugs, NPPA also brought 565 brands of 42 non-scheduled anti-cancer drugs under price control, through Trade Margin Rationalisation (TMR) in 2019. This has resulted in notional annual savings of Rs. 984 crore to cancer patients.

Incentivizing innovation

To promote research & innovation, Para 32 of DPCO 2013 provides for exemption from various provisions of DPCO 2013 and as indicated in chapter 1 exemption have been granted to various companies by NPPA.

NPPA also supports incremental innovations that could increase the therapeutic value and effectiveness of a drug and also provide incentives for the same. Incentivizing innovation would provide stimulus to the companies to innovate and up to 20% incremental price is given if the incremental innovation is supported by published journal, well designed study, adequate trial, and conclusive clinical data. In other cases of incremental innovation an incremental price increase up to 15% may be allowed.

Way Forward

- The drug price regulation in the country has evolved over a period of time keeping in view the principles that were embedded in the prevalent drug policies. For example, DPCO,2013 is governed by the principles of NPPP,2012. Hence, drug pricing regulations are adapting to the changing paradigms and will keep evolving keeping in view the overall objective of making available essential medicines at affordable prices.
- Globally as well as in India, the therapeutics and pharmaceutical landscape have changed rapidly with the advent of newer technologies and incremental innovations. Continuous and critical analysis of such technologies is warranted in the form of standardized and validated Health Technology Assessment (HTA) protocols.
- Technology deployment can help in multiple ways. It can lead to internal efficiencies within the organisation by encouraging transparency and accountability. At the same time, regulatory oversight can be strengthened by focusing on monitoring and enforcement activities facilitated through technology. Web-based IPDMS ver. 2 launched in August 2022 with multi-instance architecture will help in this endeavour.
- Close coordination with other agencies like CDSCO, ICMR, DGHS, Research Institutes etc. is already in place through various committees like MDC. This coordination can further be strengthened so that multi-stakeholder view is available.
- Growth of the pharmaceutical and medical devices sector in the country has facilitated in making healthcare affordable. The growth in the sector has been aided through government policy interventions/initiatives from time to time coupled with the entrepreneurial spirit of the industry. During the 2020-30 period, the Indian pharmaceutical industry is expected to grow at a CAGR of 12.3% to reach at USD 130 billion[37]. India is also one of the fastest growing markets in the global medical devices industry and is expected to grow at a CAGR of 15 per cent[38]. The growth in the sector is expected to benefit the consumers by bringing in affordable, innovative products/therapies in the market.

[37]https://home.kpmg/in/en/home/insights/2022/04/impact-pharma-industry-indian-economy-post-covid-era.html

[38]https://pharmaceuticals.gov.in/sites/default/files/English%20Annual%20Report%202021-22%20%281%29.pdf

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ii) Shri Sanjay Kumar, Adviser (Cost)

iii) Shri G. L. Gupta, Director (Admin, M&E)

iv) Ms. Rashmi Tahiliani, Joint Director

v) Shri R. Jegan., Joint Director

vi) Shri Saurabh Bansal, Deputy Director

vii) Shri Mahaveer Saini, Deputy Director

viii) Shri Prasenjit Das, Deputy Director

ix) Shri Rajesh Kumar T., Deputy Director

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Chronicling twenty-five year odyssey of an organisation in few pages is not an easy task and an effort has been made to provide a glimpse of the same. The team has worked diligently and with dedication to see this process from beginning to its completion and we hope readers would find this publication of interest and use to them.

(Dr. Vinod Kotwal)
Member Secretary
August 2022
New Delhi

ANNEX-I

LIST OF THE REPORTS SUBMITTED BY THE BUREAU OF INDUSTRIAL COSTS & PRICES/ TARIFF COMMISSION TO THE GOVERNMENT ON DRUGS

Year	Subject matter of the Report
1972-73	Report on fair selling prices of drugs and pharmaceuticals I) Part I covering 12 bulk drugs ii) Part II covering 8 bulk drugs iii) Part III covering 3 bulk drugs & Gelatine capsules iv) Part IV covering formulations iv) Part IV covering formulations
1974-75	Report on Bulk drug – Vitamin 'C'
1975-76	Separate Reports on Bulk drugs: Insulin, Vitamin B-12,Tolbutamide, Sulphadiazine, Streptomycin, Chloramphenicol, Amodiaquine, Vitamin A, Chloroquine Phosphate, Chlorpropamide, Penicillin, ICHQ, Tetracycline, Isonicotinic Acid Hydroxide, Sodium Salt of Para Amino Salicylic Acid & Para Amino Salicylic Acid, Prednisolone, ATS
1976-77	Report on Bulk Drug Vitamin C
1977-78	Separate Reports on Bulk Drugs: Dapsone, Pethidine Hydrochloride Procaine Hydrochloride
1978-79	Separate Reports on Bulk Drugs: Aspirin & Salicylic Acid, Betamethasone, Trimethoprim, Ampicillin Anhydrous, Sulphamethoxazole Separate Reports on Cat. III Bulk Drugs: Cyclizine Hydrochloride, Kanamycin A Acid Sulphate, Diloxanide Fureate, Vitamin B , Sulphaguanidine, Phenacetin, Xylocaine & Lignocaine, Analgin, Sulphadimidine, DEC Citrate, Phenobarbitone
1979-80	Separate Reports on Cat. III Bulk Drugs – Sulpha Cetamide, Dextrose Anhydrous,Ethyl Chloride, Indomethacin, Thiacetazone, Insulin, Dexamethasone, Halothane-ACCI, Tetrimisol-ACCI, Primidone-ACCI, Cetrimide-ACCI, Chlorhexidine Digluconate-ACC, Tolbutamide, Para-chloroMetaxylenol(PCMX), Boric Acid, Broxyquinoline, Brobenzoxaline, Cyproheptadine HCL Xanthinol Nicotinate, Glybedamide, – Cyclopenthiazide, Guanethidine Sulphate, etc. Report on Cat. I Bulk Drug – Hydrochlorothiazide
1980-81	Report on Cat. I Bulk Drug – Streptomycin Sulphate Report on Cat.II Bulk Drug – Chloroquine Phosphate Reports on Cat.III Bulk Drugs- Penicillin, – Calcium Lactgate, – Pheniramine Maleate, Bephnium Hydroxy Napthoate, Methdilazine Hydrochloride, Heparin sodium, Phenformin Hydrochloride, Diphenhydramine Hydrochloride, Dexazamethasone Trim ethyl Acetate, etc. Reports on Bulk Drugs: Metronidazole, Calcium Gluconate, Chlorpropamide, Diphtheria Antitoxin, Oxy-phenyl ,Butazone, etc.
1981-82	Reports on: Amoxicillin (Provisional), Riboflavin-5-Phosphate Sodium, Sulphamethizole, Trimethoprim Report on IDPL Drugs: Analgin, Phenacetin, Phenobarbitone, sodium Phenobarbitone, Sulphaguanidine and Sulphadimidine

Year	Subject matter of the Report
1982-83	Report on Cat.III Bulk Drugs: Sulphamethoxazole, Chloramphenicol Monostearyl Glycolate (Rich Starch (50:50) Reports on Bulk Drugs: Vitamin B – 1 Mononitrate, Caffeine Any hydrous, Dapsone, Vitamin D-3, Pethidine HCL, etc. Report on TAB/Cholera Vaccine
1983-84	Report on Bulk Drugs: Aspirin/Salicylic Acid IP, Buclosamide, Mebendazol, Tolbutamide, Dextrose Anhydrous, HCL Ephedrine, Benzocaine I.P, Procaine Hydrochloride, Silver Sulphadiazine, Anaesthetic Ether, Metronidazole
1984-85	Reports on Bulk Drugs: Ibuprofen , Vitamin A, Vitamin C, Betamethasone, Piperazine and its salts, Chloroquine Phosphate, L. Methyl Dopa, Insulin, Nitrofurazone, Prednisolone, Prednisolone Acetate, Hydrocortisone, Hydrocortisone Acetate, Prednisone, Nitrofurantoin,etc. Report on Conversion cost for soft Gelatine capsules Note on Pyrautal Pamate Category III Bulk Drug
1985-86	Reports on Bulk Drugs: Vitamin B 2, Furazolidone, Glybenclamide, Diphenoxylate Hydrochloride, Sulphaectamide and its derivatives, Vitamin B-12, PCMX, Streptomycin Sulphate, Carbamazepine
1986-87	Note on Bulk Drug Pseudo Ephedrine Hydrochloride/Sulphate Reports on : Penicillin and its salts, Tetracycline, Chlortetracycline HCl, Dimethyl Chlortetracycline, Clofazimine, Dexycline Para-Toluone Sulphate, Rifampicin, Xanthinol Micotinate
1987	Reports on: Riboflavin 51 Phosphate Sodium Vit. B2.Phosphate Sod., Sulphadiazine, Paracetamol, Sulphamosole, Cephalexin (LTLA), Rephalexin (Penisyth Chemicals), Levomisole (IEL Ltd.), Cephradine (M/s Synbictices Ltd.), Theophylline (P.D.), Oxy Tetracycline Hydrochloride, Rutin Vitamin Anti-Tetanus Serum (ATS), AntisnakeVenem Serum,etc.
1988	Reports on: Thiacetazone, Dexamethasone Trim ethyl Acetate, Erythromycin, Metronidazole (Escalation) M/s Unique Chemicals Ltd, Frusemide, Aspirin,etc.
1989	Aminophylline, Theophylline, Cephalexin, Parachloro Meta Xylenol (PCMX), Levamisone HCL Glybenclamide, Ibuprofen, Chloroquine Sulphate, Chloroquine Phosphate, Xylocaine Hydrochloride, Deamethasone, Furazolidone, Oxytocin, Clofazimine, Procaine Penicillin G IP, etc.
1990	Reports on: Insulin, Sulphadiazine Sulpha, Cetamide Sodium, Acetazolamide, Ephedrine Hydrochloride, Gentamycin Sulphate, Tetracycline Hydrochloride & Chlortetracycline HCL, Oxytetracycline and its Derivatives Ampicillin Sodium Sterile, Cloxacillin Sodium Sterile, Paracetamol, Salbutamol, Methyl dopa, Metronidazole, etc.
1991-92	Reports on Pilocarpine, Silver Sulphadiazine, Diclofenac Sodium, Rifampicin, etc.
1992-93	Reports on Bulk Drug: Vitamin 'C', Dexamethasone and its salt, Methyl Salicylate, Erythromycin, Aspirin

Year	Subject matter of the Report
1993-94	Report on the Committee to Review Drugs under Price Control Reports on: Paraxylene Dimethyl Terephthalate (DMT) and purified Terephthalic Acid (PTA), Furazolidone, Demethylchlor – Tetracycline HCL & Chlortetcycline, Ranitidine HCL, etc.
1994-95	Reports on Bulk Drugs: Tetracycline Hydrochloride, Oxytetracycline, Streptomycin Sulphate, Timolol Maleate, Chloramphenicol, Methyldopa, Clofazimine, Ephedrine Resinate, – Quinine Sulphate/HC, Prednisolone and Prednisolone Acetate & its derivatives, etc.
1995-96	Reports on Bulk Drugs: Chlorpropamide, Betamethasone & its derivatives, Crystalline insulin, Theophylline, Vitamin E, Caphazoline Sodium, Famotidine, Ciprofloxacin, Mefenamic Acid, etc.
1996-97	Reports on Bulk Drugs: Cefotaxime Sodium, Dextro propoxyphene HCL, Dexamethasone & its derivatives, Aspirin, Norfloxacin, Trimethoprim, Salbutamol Sulphate, – Chloroquine Phosphate, Aminophylline, Vitamin C, Erythromycin, etc.
1997-98	Reports on Bulk Drugs: Ranitidine, Rifampicin, Metronidazole, Vitamin B2-5 Phosphate, Mobhydroline, Pheniramine Maleate, PCMX, Vitamining Mononitrate

Source: Role and Structure of Tariff Commission Vol.II
(Accessible on:https://tc.nic.in/site/writereaddata/siteContent/
20201026142244886Tariff%20Commission%20Volume%202.pdf

ANNEX-II

Abbreviations

API	Active Pharmaceutical Ingredient
BICP	Bureau of Industrial Costs & Prices
CAGR	Compound Annual Growth Rate
CAPPM CDMC CDSCO CHE	Consumer Awareness, Publicity and Price Monitoring COVID Drug Management Committee Central Drugs Standard Control Organisation Current Health Expenditures
DCC CPGRAMS	Centralized Public Grievance Redress and Monitoring System Drug Coordination Committee
DoP	Department of Pharmaceuticals
DPCO	Drugs (Prices Control) Order
DNs	Demand Notices
DP	Drug Policy
EC, Act 1955 EEPC HTA	Essential Commodities Act, 1955 Export Engineering Promotion Council Health Technology Assessment
IPDMS	Integrated Pharmaceutical Database Management System
MAPE	Maximum Allowable Post Manufacturing Expense
MAT	Moving Annual Turnover
MDs	Medical Devices
MDC	Multi-Disciplinary Committee
MT	Metric Tons
MoC&F	Ministry of Chemicals and Fertilizers
MoH&FW	Ministry of Health & Family Welfare
MRP	Maximum Retail Price
NLEM	National List of Essential Medicines
NPPP,2012	National Pharmaceutical Pricing Policy, 2012

NPPA OC OOPE	National Pharmaceutical Pricing Authority Overcharging Out of Pocket Expenditure
OTC	Over The Counter
PJS PMBJP	Pharma Jan Samadhan Pradhan Mantri Bhartiya Janaushadhi Pariyojana
PMRUs	Price Monitoring and Resource Units
PSD	Pharma Sahi Daam
PTR	Price to the Retailer
SCNs	Show Cause Notices
SDCs	State Drugs Controllers
TC THE	Tariff Commission Total Health Expenditure
UCPMP	Uniform Code for Pharmaceutical Marketing Practices
USFDA WHO	United States Food and Drug Administration (USFDA) World Health Organisation
WPI	Wholesale Price Index

ANNEX-III

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ANNEX-IV

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ANNEX-V

List of Boxes

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- Website of NPPA (www.nppaindia.nic.in)
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