



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



# AUSHADH SANDESH

### Vol.-IV | APRIL, 2022

A Bi-monthly e-Newsletter



**Committed Towards Accessibility, Availability & Affordability of Medicines for All** 

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### About NPPA...

The National Pharmaceutical Pricing Authority (NPPA), an independent body of experts in the Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals was constituted by the Government of India vide resolution published in the Gazette of India No. 159 dated 29.08.97. The functions of NPPA, inter-alia, includes fixation and revision of prices of scheduled formulations under the Drugs Prices Control Order (DPCO), as well as monitoring and enforcement of prices. NPPA also provides inputs to Government on pharmaceutical policy and issues related to affordability, availability and accessibility of medicines.

The Authority is a multi-member body consisting of a Chairperson, a Member Secretary and three ex-officio members. Two of the three ex-officio members are from Department of Economic Affairs and Department of Expenditure respectively and third member is Drug Controller General of India.

The Drugs (Prices Control) Order, 2013(DPCO, 2013) was notified on 15.05.2013 under the Essential Commodities Act, 1955(EC Act, 1955) and is based on the broad guidelines of the National Pharmaceutical Pricing Policy (NPPP), 2012. The three key principles of the NPPP-2012 are as below:

- a. Essentiality of Drugs: The regulation of prices of drugs is on the basis of essentiality of drugs as per the medicines under NLEM-2011, NLEM-2015 as amended vide S.O. th 701(E) dated 10 March, 2016 has been incorporated as the First Schedule of DPCO 2013.
- b. Control of Formulations prices only: The prices of formulations only are to be regulated and not the prices of the Bulk Drugs and the resulting formulations as adopted in the Drug Policy 1994.
- c. Market Based Pricing: The ceiling prices of medicines are fixed on Market Based Pricing (MBP) methodology.

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Shri Kamlesh Kumar Pant, IAS Chairman National Pharmaceutical Pricing Authority Department of Pharmaceuticals Ministry of Chemicals & Fertilizers Government of India

## From CHAIRMAN'S DESK

I am happy to bring to you the fourth issue of the NPPA bi-monthly e-Newsletter.

Department of Pharmaceuticals organized the 7<sup>th</sup> edition of the International conference on Pharma and Medical Devices sector 2022 from 25<sup>th</sup> to 27<sup>th</sup> April. The theme for India Pharma was: 'India Pharma-Vision 2047: Transformative agenda for future' and for India Medical Device, it was 'Transforming Healthcare through Innovation & Integrated Services'. This issue highlights the brief summary of the conference.

This edition has an article written by Dr. Shafiqa Rasool and Dr. Mohammad Ishaq Geer of University of Kashmir on "**Coverage**, **utilization and impact of Ayushman Bharat Scheme on access to medicines in India**". The article explains how as a result of Ayushman Bharat scheme, the access including availability and affordability of medicines in India has improved.

I am also happy to share that NPPA has expanded its reach in one more State i.e. Himachal Pradesh in March 2022 by setting up Price Monitoring and Resource Units (PMRUs) there. Thus, the total tally of PMRUs in the country has reached 23.

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

With best wishes

ALA (Kamlesh Kumar Pant)

### COVERAGE, UTILIZATION AND IMPACT OF AYUSHMAN BHARAT SCHEME ON ACCESS TO MEDICINES IN INDIA

#### Shafiqa Rasool, Mohammad Ishaq Geer\*

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#### Abstract

A yushman Bharat (AB) is a government sponsored health insurance scheme that aims to cover about 100 million poor and vulnerable people in India. It provides benefit cover of Rs. 5 lakh per family per year with no cap on family size and the services are portable across the country. This scheme was launched by the Govt. of India in the year 2018 as a progressive step towards achieving Universal Health Coverage (UHC). It has two interlinked components, namely Health and Wellness Centres (HWCs) and the Pradhan Mantri Jan Arogya Yojana (PMJAY). The former aims to upgrade sub-centres and primary health centres to deliver comprehensive primary healthcare to the population whereas the latter is a national, publiclyfunded health insurance (PFHI) scheme covering secondary and tertiary care hospitalization for the most deprived 40 percent population of the country. Around 1350 medical and surgical packages are covered under this scheme, which include about all secondary and most of the tertiary care procedures. As a result of Ayushman Bharat scheme, access including availability and affordability of medicines in India has improved significantly.

### Introduction

Out-of-pocket expenditure (OOPE) on health in India is 62.6% of total health expenditure, which is one of the highest in the world and nearly thrice of global average of 20.5%. More than two-third of this OOPE is paid on consultation fees and medicines followed



by diagnostic tests. In India more than 300 million people face catastrophic expenditures and around 50 million people are pushed into poverty every year on account of OOPE on health. One of the main reasons for this is the limited access to healthcare services in public sector. The average cost per hospitalization is Rs. 20,000 which is more than annual consumer expenditure of nearly half of our population (1). OOP expenditure on medicines alone is high and accounts for 70% of total out-ofpocket expenditure which is more than twice that of consultation fees and diagnostic services (2).

Ayushman Bharat-PMJAY was launched with an aim to protect the population against these very financial hardships. As per WHO-World Medicines Situation Report of 2004, 65% of Indian population lacked access to medicines at that time (3) but as a result of AB-PMJAY scheme the access to medicines has considerably improved in India.

### Coverage and utilization of health services under AB-PMJAY

Ayushman Bharat Mission is playing an important role in working towards achieving Universal Health Coverage (UHC). Unlike previous schemes like Rashtriya Swasthya Bima Yojana (RSBY) and the Senior Citizen Health Insurance Scheme, the AB-PMJAY has no cap on family size and age (4). The identification of the beneficiaries under this scheme is being done on the basis of the Socioeconomic and caste census (SECC), 2011. The centre–state financing mode is same as in the National Health Mission. Indian states running similar schemes have been given an option to merge with PMJAY or run it in a parallel manner.

AB-PMJAY covers larger population, provides more comprehensive benefit package and incorporates a wider hospital network for healthcare delivery. The HWCs are committed to provide wider range of preventive, promotive, curative and rehabilitative healthcare services including treatment and services for non-communicable diseases and chronic communicable diseases like tuberculosis. These services were expanded keeping in view India's high OOP expenditure. Government of India has allocated Rs. 3,200 crore and also envisages contribution of private sector in the form of corporate social responsibility (5,6). As of 21 March 2022, a total of 74,947 AB-HWCs were operational which is set to reach the target of 1.5 lakh by December 2022.

The other component of Ayushman Bharat covers large section of the population. The number of people benefited are double the number benefited from previously launched health schemes. Once fully functional the benefits of HWCs are expected to be available to 100% of population in India. HWCs together with AB-NHPS will be synergistic in providing healthcare needs across all three levels of care and will also help in increasing accessibility, availability and affordability of healthcare and medicines (7).

#### Impact of AB PMJAY on access to health services

Various studies on AB-PMJAY have reported mixed responses on financial risk protection. High value of greater than Rs. 30,000 and very high value claim of greater than Rs. 1,00,000 make up 32% and 9% of PMJAY claim payouts respectively. This is indicative of the fact that this scheme has enabled access to services that would otherwise be OOP or catastrophic to the individual. However, PMJAY does not cover out-patient services that account for around 60% to 70% of the total OOPE in India (8).

In a retrospective study conducted among 160 patients registered at Ayushman Bharat cell of a Srinagar-based tertiary care hospital namely SKIMS between 26th December, 2020 and 20th February, 2021, every patient was found to have received the benefits of the scheme as a result which they had to pay nothing for their hospitalization and there was no need for them to sell their assets or borrow money for treatment thus bringing the prevalence of distress financing to zero level. This was found to be quite contrary to

### ARTICLE BY PHARMA EXPERTS

studies conducted by the same authors at the same centre before the launch of the scheme wherein prevalence of distress financing amongst cancer and chronic kidney disease patients was found to be more than 70% (9,10,11).

#### **Discussion and Conclusion**

India has made considerable progress in reducing maternal and child mortality under the national health mission. Ten to fifteen years ago communicable diseases along with maternal and nutritional disorders contributed to the major disease burden. Doubling the life expectancy from 31 years in 1947, when India got its independence to 68.3 years in 2017. However, in terms of healthcare access and quality India still stands at 145th position among 195 countries, lagging behind many countries (12). India, the sixth largest economy and largest democracy of the world has been improving its health-care facilities slowly since last few decades. As India moves towards the path of UHC, the focus should be on reduction of burden due to nonhospitalization care. High OOP spending on medicine needs to be addressed. Use of medicines should be rationalized and rational prescribing encouraged. To significantly reduce OOPE, the provision for free medicines should be increased (The Indian Express, 2021). The utilization of manpower under Ayushman Bharat has been proved to be successful by way of engagement and potential usage of nearly 1 million ASHA workers under the National Health Mission (NHM). The programme provides an innovative initiative of building a highly impactful health model with low cost along with the utilization of skilled workforce. All these facts prove that Ayushman Bharat has been beneficial for the country (13).

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### **REGULATORY NEWS**

#### News related to pricing of drugs

- As on 31.03.2022, over all 228 Authority meetings have been conducted and out of which 96 are under DPCO 2013. The 228<sup>th</sup> (Overall). The 96<sup>th</sup> meeting of the Authority under DPCO 2013 was held on 24.03.2022.
- Ceiling prices for 887 scheduled formulations (National List of Essential Medicines, 2015) and Retail prices for 1873 non-scheduled formulations have been

fixed under DPCO, 2013 till 31<sup>st</sup> March, 2022.

 Ceiling prices of 888 scheduled formulation (National List of Essential Medicines, 2015) revised based on WPI @ 10.76607% (to be applicable from 01.04.2022.

Details of Ceiling prices fixed for various formulations in 96<sup>th</sup> Authority Meetings are as follows:

SI. No.	Name of the Scheduled Formulation	Dosage form & Strength	Unit	Ceiling Price (Rs.)	Revised Ceiling Price (Rs. W.e.f. 01.04.2022)	Category
(1)	(2)	(3)	(4)	(5)	(6)	(7)
1	Framycetin	Cream 0.5%	1 GM	1.07	1.19	Antibiotic

- Retail prices of 56 new drugs for various pharmaceutical companies were fixed in the 96<sup>th</sup> meeting of the Authority under DPCO 2013 respectively.
- During the 96<sup>th</sup> meeting of the Authority under DPCO 2013, the prices of following items were also extended in public interest:

Details of Retail prices fixed for various formulations in 96<sup>th</sup> Authority Meetings are as follows:

S. No.	Therapeutic group	Total Number	Type of formulation	Retail Price Fixed Range (Rs.)
(1)	(2)	(3)	(4)	(5)
1	Anti-Diabetic	30	Tablet	5.63-20.025
2	Antihypertensive	4	Tablet	9.94-15.67
3	Cardio Vascular	1	Tablet	30.38
4	Hypertension	2	Tablet	4.465-6.697
5	Anti-bacterial	2	Infusion	1.32-7.42
6	Pain Analgesic	5	Tablet/Gel/ Spray/Patch	1.52-40.18
7	Others	12	Tablet/ Infusion/ Injection	3.27

Exemption granted to M/s Serum Institute of India Private Limited under Para 32 (ii) of DPCO, 2013 for their formulation "Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) IP (10-Valent) (PCV 10V)" in (i) single dose (0.5ml) vials, (ii) multi-dose (2.5ml) vial, and (iii) single dose (0.5ml) pre-filled syringes for a period of 5 years from the date of commencement of its commercial production in the country subject to it being co-terminus with the duration of Indian Patent.

SI. No.	Drug	Extended Till	Effective Order
1	Heparin Injection 5000IU/ml and 1000IU/ml	30.09.2022 or until further order whichever is earlier	S.O. 1507€ dated 30.03.2022
2	Liquid Medical Oxygen (LMO) and Oxygen Inhalation (Medicinal gas) in cylinder	30.06.2022 or until further order whichever is earlier	S.O. 1508€ dated 30.03.2022

#### News related to pricing of Medical devices

NPPA vide Gazette Notifications No. S.O. 1502(E), S. O. 1503(E), S. O. 1499(E) dated 30<sup>th</sup> March 2022 notified the revised ceiling price of medical devices as per the Annual Wholesale Price Index (WPI) @ 10.76607% as tabulated below:

SI. No.	Medical Device	Unit (in No.)	Ceiling price (in Rs.)*
1	Bare Metal Stents	1	9373.03
2	Drug Eluting Stents (DES) including metallic DES and Bioresorbable Vascular Scaffold (BVS)/ Biodegradable Stents	1	34128.13
3	Condoms	1	10.14
4	IUD containing Copper	1	319.22
5	Hormone releasing IUD	1	4295.01

### FDA Approves First Generic of Symbicort to Treat Asthma and COPD (March 15,2022)

The US, Food and Drug Administration approved the first generic of Symbicort (budesonide and formoterol fumarate dihydrate) Inhalation Aerosol for the treatment of two common pulmonary health conditions: asthma in patients six years of age and older; and the maintenance treatment of airflow obstruction and reducing exacerbations for patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema. This complex generic drugdevice combination product, which is a metereddose inhaler, should not be used to treat acute asthma attacks.

#### Read more

#### FDA Authorizes Second Booster Dose of Two COVID-19 Vaccines for Older and Immunocompromised Individuals (March 29, 2022)

The U.S. Food and Drug Administration authorized a second booster dose of either the Pfizer-BioNTech or the Moderna COVID-19 vaccines for older people and certain immunocompromised individuals. The FDA previously authorized a single booster dose for certain immunocompromised individuals following completion of a three-dose primary vaccination series. This action will now make a second booster dose of these vaccines available to other populations at higher risk for severe disease, hospitalization and death. Emerging evidence suggests that a second booster dose of an mRNA COVID-19 vaccine improves protection against severe COVID-19 and is not associated with new safety concerns.

#### Read more

### FDA Approves Treatment for Wider Range of Patients with Heart Failure (February 24, 2022)

The U.S. Food and Drug Administration approved Jardiance (empagliflozin) to reduce the risk of cardiovascular death and hospitalization for heart failure in adults. Jardiance was originally approved by the FDA in 2014 as a supplement to diet and exercise to improve glucose control in adults with type 2 diabetes. Jardiance is also approved to reduce the risk of cardiovascular death in adults with type 2 diabetes and established cardiovascular disease, and to reduce the risk of death and hospitalization in patients with heart failure and low ejection fraction.

#### Read more

## EMA establishes Cancer Medicines Forum with academia to optimise cancer treatments in clinical practice (March 31, 2022)

The EU, EMA, in collaboration with the European Organisation for Research and Treatment of Cancer (EORTC), has launched the Cancer Medicines Forum (CMF). Bringing together representatives from academic organisations and the European medicines regulatory network, the forum aims at advancing research into optimising cancer treatments and will contribute to foster high standards in cancer care in the European Union (EU)

Since its establishment in 1995, EMA has reviewed and recommended for approval over 170 cancer medicines that have gone on to play an important role in the treatment and management of various types of cancers. The field of oncology has seen the emergence of major innovations in recent years, including the arrival of personalised medicines, immunotherapies, and advanced therapy medicinal products. Such innovations have helped cancer patients across Europe by offering them new tools in their fight against the disease. However, at the time new medicines enter the market, there is an opportunity to improve many aspects with respect to their optimal use and integration into the existing array of treatments. Addressing these opportunities for treatment optimisation may require the conduct of studies to collect robust data to further guide clinical practice.

#### MHRA approves the Moderna COVID-19 vaccine 'Spikevax' for use in 6- to 11-year-olds (14 April 2022)

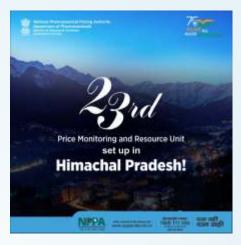
UK, MHRA (The Medicines and Healthcare products Regulatory Agency) has approved an update to the current UK approval of the Moderna COVID-19 Vaccine, or 'Spikevax', that allows its use in Great Britain (GB) in 6- to 11-year-olds. This approval takes into account the extension to use in children aged 6 to 11 years already approved by the European Medicines Agency on 2 March 2022, as the original GB licence for Spikevax in adults was approved by relying on the EU decision.

#### Read more

### **OTHER NEWS AND EVENTS**

### NPPA sets up 23<sup>rd</sup> PMRU in Union Territory of Himachal Pradesh in March, 2022

NPPA under Consumer Awareness, Publicity and Price Monitoring (CAPPM) Scheme has so far set-up Price Monitoring and Resource Units (PMRU) in 23 States/UTs. The 23<sup>rd</sup> PMRU was established in the State of Himachal Pradesh on 22.03.2022. Now, NPPA has its presence in following states/UTs 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 and Himachal Pradesh. This will help NPPA to trickle down the benefits of DPCO, 2013 at grass-root level with the help of PMRU to ensure that consumer at large is benefited.



#### Activities done by PMRU's

During the month of February and March 2022, NPPA has organized six (6) webinars with different PMRUs, details of which are as follows-

S.No.	Date	Subject of Webinar
1	24.02.2022	Webinar on "Guidance on Functioning of New PMRUs" with six PMRUs viz. Chhattisgarh, Jharkhand, Madhya Pradesh, Puducherry, West Bengal and Ladakh.
2	15.03.2022	Webinar on "Functioning and Review of New PMRUs" for 11 PMRUs viz. Odisha, Rajasthan, Andhra Pradesh, Karnataka, Telangana, Maharashtra, Goa, Chhattisgarh, Jharkhand, West Bengal and Puducherry
3	16.03.2022	Webinar on "Functioning and Review of New PMRUs" for 11 PMRUs viz. Kerala, Gujarat, Punjab, Haryana, Uttar Pradesh, Madhya Pradesh, Nagaland, Mizoram, Tripura, Ladakh and Jammu & Kashmir.
4	25.03.2022	Webinar with PMRU Ladakh to assist them to commence functioning.
5	30.03.2022	Webinar with PMRUs introducing them IPDMS 2.0
6	31.03.2022	Webinar with PMRU Himachal Pradesh on "Guidance on Functioning of New PMRUs"



### **OTHER NEWS AND EVENTS**

### 7<sup>th</sup> EDITION OF INTERNATIONAL CONFERENCE ON PHARMAAND MEDICAL DEVICES SECTOR 2022

The 7<sup>th</sup> edition of International conference on Pharma & Medical Device 2022 was organized by the Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, Govt of India with the Federation of Indian Chambers of Commerce and Industry (FICCI) during 25-27 April 2022.The annual flagship three-day conference was held at Dr Ambedkar International Centre, New Delhi.

Union Minister for Chemicals & Fertilizers and Health & Family Welfare, Dr. Mansukh Mandaviya inaugurated the International conference on Pharma and Medical Devices sector 2022 on 25<sup>th</sup> April 2022 in the presence of Shri Bhagwanth Khuba, Minister of State for Chemicals and Fertilisers. New and Renewable Energy, and other dignitaries. Dr. V.K. Paul, Member, NITI Aayog, Ms. S. Aparna, Secretary, Department of Pharmaceuticals, Dr. Balram Bhargava, Director General, ICMR, senior officials from government, FICCI and Invest India and CEOs of various Pharma and medical devices companies were also present at the conference.

Addressing the event, Dr. Mansukh Mandaviya, Union Minister of Health and Family Welfare and Chemicals and Fertilizers highlighted that the government has been working relentlessly to increase the number of doctors, medical institutions, health infrastructure including hospital, tertiary care centres, health and wellness centres in the country. "Conferences like India Pharma and India Medical Device 2022 provide a platform for industry, academia and policy makers to brainstorm and draft a plan for the next 25 years for the sector," he added.



Speaking on the occasion Shri Bhagwanth Khuba, Union Minister of State of Chemicals and Fertilisers noted that India is the pharma hub of the world with India's production being 5<sup>th</sup> in the world. He further noted that the Indian Medical sector currently standing at \$11 billion and is likely to reach \$50 billion by 2025.

Ms. S. Aparna, Secretary, Department of Pharmaceuticals while addressing the event emphasized the need to build an ecosystem for innovation in medical devices and drugs alongwith enhanced industry-academia linkages.

At the inaugural ceremony, three knowledge documents- 'Impact of the pharma industry on the Indian ecosystem in the post- COVID era', 'Enabling Growth and innovation in the Indian Medical Devices Sector' and a 'Compilation of important speeches by CEOs' were also released by the Union Minister. In addition to this, Dr. Mansukh Mandaviya also chaired two roundtable conferences with the Pharma and Medical Devices CEOs after the inaugural ceremony.

On day two of the conference, Shri Rajesh Bhushan, Secretary, Department of Health and Family Welfare Health Secretary and Ms. S. Aparna, Secretary, Department of Pharmaceuticals chaired a panel discussion with the pharmaceuticals industry CEOs in the presence of Shri Anurag Jain, Secretary, DPIIT on the theme 'Indian Pharma Vision 2047'. Shri Kamlesh Kumar Pant, Chairman, NPPA was also part of the panel discussion in the sessions on "Building Resilient Supply Chains" and "R&D and innovation in Medtech: Some Success Stores"



A Bi-monthly e-Newsletter : April, 2022

### KNOW YOUR REGULATOR/SECTOR

### UNDERSTANDING INDIAN DRUG MARKET

As per the provisions of DPCO 2013, Drugs are categorized as scheduled and non-scheduled formulation. Further, prices of certain Non-scheduled drugs are fixed under Para 19 of DPCO, 2013. During 2021-22, the market share of various categories of drugs is as follows:

ROW LABELS	SCHEDULED DRUGS	NON-SCHEDULED DRUGS	PRICE FIXED IN PARA-19	GRAND TOTAL
Market share in terms of Revenue	17.45%	80.49%	2.06%	100.00%
Market share in terms of Quantity sold	31.09%	67.65%	1.26%	100.00%

The share of above Drug categories for each Drug group is as follows:

ROW LABELS	SCHEDULED DRUGS	NON-SCHEDULED DRUGS	PRICE FIXED IN PARA-19	GRAND TOTAL
ANTI MALARIALS	58.02%	41.98%	-	100.00%
ANTI-NEOPLASTICS	51.21%	48.79%	-	100.00%
HORMONES	43.05%	56.95%	-	100.00%
CARDIAC	20.33%	67.14%	12.53%	100.00%
ANTI-INFECTIVES	32.44%	67.56%	-	100.00%
NEURO / CNS	24.44%	75.56%	-	100.00%
BLOOD RELATED	23.64%	76.36%	-	100.00%
OPHTHAL / OTOLOGICALS	19.37%	80.63%	-	100.00%
VACCINES	18.77%	81.23%	-	100.00%
PAIN / ANALGESICS	16.72%	83.28%	-	100.00%
GYNAECOLOGICAL	13.01%	86.99%	-	100.00%
GASTRO INTESTINAL	12.88%	87.12%	-	100.00%
ANTI DIABETIC	7.14%	89.37%	3.49%	100.00%
RESPIRATORY	10.58%	89.42%	-	100.00%
DERMA	5.39%	94.61%	-	100.00%
VITAMINS / MINERALS / NUTRIENTS	4.83%	95.17%	-	100.00%
OTHERS	3.29%	96.71%	-	100.00%
UROLOGY	1.67%	98.33%	-	100.00%
SEX STIMULANTS / REJUVENATORS	-	100.00%	-	100.00%
STOMATOLOGICALS	-	100.00%	-	100.00%
Grand Total	17.45%	80.49%	2.06%	100.00%

Source: Pharmatrac database, March 2022



### • Whether any approval is required from NPPA for launching a Drug?

No, approval of NPPA is not required for launching a Drug. However, where an existing manufacturer of a Scheduled drug launches a new drug, such existing manufacturer shall apply to NPPA for obtaining Retail Price, prior to the launch of such new drug.

### • Does New Drug mean all newly launched drugs?

No. Under DPCO, 2013, New Drug means a formulation launched by an existing manufacturer by combining a scheduled drug with another drug or by changing the strength or dosages or both of a scheduled drug.

### • Is Retail Price and Maximum Retail Price (MRP) one and the same thing?

No. Retail Price under DPCO, 2013 means the Price given by NPPA for a New Drug. The manufacturer of a New Drug can fix the MRP up to Retail Price plus local taxes and duties as applicable.

 Whether Retail Price is to be obtained by an existing manufacturer in case NPPA has already fixed the Retail Price of such formulation for some other manufacturer?

Yes, Retail Price needs to be obtained by all existing manufacturers in respect of all New Drugs separately.

### • What if a manufacturer launches a New Drug without obtaining Retail Price from NPPA?

Note: In such a case, the Retail Price shall be fixed by NPPA and the overcharged amount shall be recovered from the manufacturer along with interest and penalty. Further, action can also be taken under Section 7 of the Essential Commodities Act, 1955.

## Feedback and Complaint Redressal



### **Grievance Redressal**

Pharma Jan Samadhan: A web enabled system for grievance redressal – catering to consumers, distributors, dealers, retailers.

### **Information Dissemination**

**Pharma Sahi Daam:** One can easily search brand name, composition, ceiling price and MRP of the formulation – available to public.

Seminars and Workshops conducted by NPPA and by PMRUs

### Collaboration with State Governments

**PMRU:** To help NPPA to monitor notified prices and ensure availability of medicines. To spread awareness regarding the pricing of drugs, etc.

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### NATIONAL PHARMACEUTICAL PRICING AUTHORITY 3<sup>rd</sup> / 5<sup>th</sup> Floor, YMCA Cultural Center Building 1, Jai Singh Road, New Delhi, India

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