NPPA
AFFORDABLE MEDICINES FOR ALL
सभी के लिए वहनीय दवाईयाँ

सत्यमेव जयते

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

Azadi Ka Amrit Mahotsav

AUSHADH SANDESH

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A Bi-monthly e-Newsletter

दवा वही
दाम सही

Committed Towards Accessibility, Availability & Affordability of Medicines for All

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About NPPA...

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

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

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

a. **Essentiality of Drugs:** The regulation of prices of drugs is on the basis of essentiality of drugs as per the medicines under NLEM-2011, NLEM-2015 as amended vide S.O. th 701(E) dated 10 March, 2016 has been incorporated as the First Schedule of DPCO 2013.

b. **Control of Formulations prices only:** The prices of formulations only are to be regulated and not the prices of the Bulk Drugs and the resulting formulations as adopted in the Drug Policy 1994.

c. **Market Based Pricing:** The ceiling prices of medicines are fixed on Market Based Pricing (MBP) methodology.

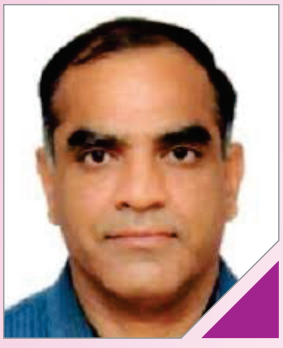
DISCLAIMER:

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

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

From CHAIRMAN'S DESK

सत्यमेव जयते



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

NPPA has the twin mandate of ensuring affordability and availability of medicines as per the various provisions of the DPCO. Thus, focusing on various aspects of availability, this edition of e-newsletter has an article written by Shri Subrato Dey, DGM, GS1 India on tracking and availability of Drugs. In the article, he explains the importance of supply chain visibility, the challenges faced by pharmaceutical supply chain and the need for a track-and-trace system. It is suggested that the industry needs to undertake supply chain digitalization combined with a standards-based data exchange between multiple stakeholders groups in the healthcare supply chain.

I also happy to inform that recently 26th Price Monitoring and Resource Units (PMRU) has been set-up in the State of Meghalaya in February 2023. This will further strengthen the NPPA activities at the State level with the help of PMRU and ensure that consumer at large are benefited.

A number of IEC activities were carried out by the PMRUs during the last two months. This issue highlights the IEC activities conducted by PMRUs of Karnataka and Goa.

As you all are aware that NLEM 2022 was released by MoH&FW in September 2022 and then notified as revised Schedule of DPCO, 2013 by DoP in November 2022. This issue contains some brief FAQs on NLEM 2022 and its linkages with drug pricing. NPPA has refixed the Ceiling prices for 400 scheduled formulations under DPCO, 2013 till 2nd February 2023.

I am very happy to bring to you the ninth issue of the NPPA bi-monthly e-Newsletter. NPPA wishes good health to all its readers; stay safe, stay healthy and follow all COVID appropriate behaviour.

(Kamlesh Kumar Pant)

TRACKING AND AVAILABILITY OF DRUGS

(By: Shri Subrato Dey DGM – Industry Engagement, GS1, India)

Today's supply chains are global networks comprised of manufacturers, suppliers, logistics companies, and chemists who collaborate to deliver drugs/medicines. As modern supply chains grow in size, they become more complex and diverse. Traditional supply chains rely on manual and disjointed data systems, which create information silos and make tracking products time-consuming.

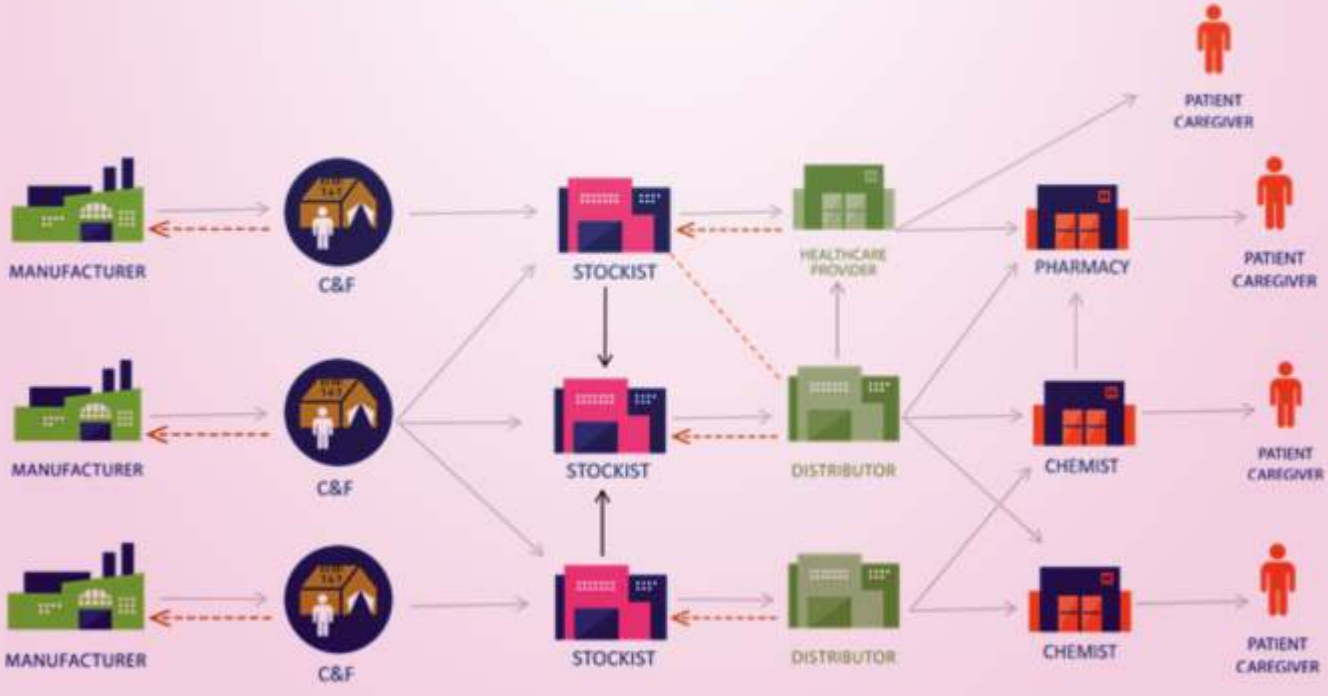
In the supply chain industry, track and trace refers to the ability to identify the past and present locations of all product inventory, as well as a history of product custody. There is growing interest in item tracking and tracing in supply chain and logistics networks for the benefit of end users.

Improved visibility into complex supply chains means fewer disruptions, higher customer satisfaction, and lower costs, leading to affordability. The ability to track movement from raw materials such as API to finished formulation drugs as they travel from supplier to manufacturer to consumer is referred to as "supply chain visibility".

The pharmaceutical supply chain faces challenges, including end-to-end supply chain visibility and the threat of falsified drugs or counterfeiting. Lack of visibility in the multi-tiered pharmaceutical supply chain has multiple repercussions. Drug shortages are one of them. It can have an adverse impact on patients, leading to increased costs and mortality.

The major reasons leading to drug shortages and the availability of drugs on pharmacy shelves can be classified as follows:

- Lack of visibility by manufacturers into product consumption and the potential supply chain may indicate drug shortages.



- Lack of getting the right information to the right people at the right time at multiple points across the supply chain to manage supply and demand imbalances.
- The reverse flow of information in the supply chain is missing, resulting in erroneous demand planning.

Medicine shortages have become a global issue in recent years. Drug shortages endanger health care quality and public health, with a wide range of consequences for various stakeholders, particularly patients. Patients face problems such as suboptimal treatment as a result of the use of alternative drugs, delayed care, extended hospitalisation, and readmission due to adverse events. One area for managing drug shortages is improving operations through the optimal use of a tracking system.

In today's volatile business environment, supply chain stakeholders must collaborate in real time to balance supply and demand and ensure on-time delivery. End-to-end visibility is required to effectively manage the extended supply network and make accurate forecasts. Real-time collaboration among stakeholders is essential for accomplishing the same. It also allows stakeholders in the supply chain to participate in demand and supply planning.

In order to achieve end-to-end visibility in the supply chain, a track-and-trace system needs to be setup. The other benefits of a track-and-trace system include reducing the risks posed by counterfeits and substandard drugs, as well as managing drug recalls and thus improving patient safety

Additional benefits of complete traceability in a digital supply network include:

- Improving efficiency and reducing waste.
- Improving supply chain collaboration to solve inter-enterprise problems more effectively and quickly.
- Improving resilience and agility to aid in the prediction of shortages and the security of supply during a crisis.

Globally, Turkey is one of the first countries to have successfully implemented end-to end pharmaceutical traceability throughout the entire regulated domestic supply chain. More than 2.5 billion drug units per year and more than 10 transactions for each drug are tracked and traced within the system. Similarly, the USA is implementing the Drug Supply Chain Security Act (DSCSA) to achieve interoperable tracing of prescription drugs sold and distributed in the country. Measures such as these are helping the pharmaceutical industry prevent falsified medicines from entering the drug supply chain and thereby ensuring the availability of genuine drugs.

Recent initiatives by the Ministry of Health and Family Welfare (MoHFW), Government of India, such as directing the top 300 pharmaceutical brands to apply barcoding and launching API traceability via QR codes, will help enhance the security of the pharmaceutical supply chain, thereby ensuring drug availability.

The industry needs to undertake supply chain digitalisation combined with a standards-based data exchange between multiple stakeholder groups in the healthcare supply chain. Technological solutions such as Blockchain, Artificial intelligence, Internet of Things and machine learning tools help provide insights that can be applied to supply decision-making, thereby minimising the impact of drug shortages. Initiatives by the government in the creation of a centralised drug registry and the sharing of data will also go a long way towards creating a resilient digital supply chain.

Note: GS1 India, a supply chain standards organisation setup under the Ministry of Commerce, Government of India, is working with industry, government, regulators, and other stakeholders in India to enable supply chain visibility and transparency, thereby enhancing patient safety, through the use of harmonised and interoperable standards.

REGULATORY NEWS

News related to pricing of drugs

- Ceiling prices for 400 scheduled formulations (National List of Essential Medicines, 2022) and Retail prices for 2262 non-scheduled formulations have been fixed under DPCO, 2013 till 2nd February 2023.
- As on 31st January, 2023, 240 Authority meetings have been conducted of which 108 are under DPCO 2013. The details of the recent meetings are given as below:

Meeting No.	Held on	Prices Approved & Notified
237(overall) & 105 Meeting under DPCO 2013	15.12.2022	(i) Retail prices for 10 formulations notified vide S.O. 5937(E) dated 19.12.2022. (ii) Ceiling prices for 119 formulations notified vide S.O. 5938(E) & 5939(E) dated 19.12.2022.
238(overall) & 106 Meeting under DPCO 2013	30.12.2022	(i) Retail prices for 36 formulations notified vide S.O. 86(E) dated 06.01.2023 (ii) Ceiling prices for 97 formulations notified vide S.O. 87(E) & 88(E) dated 06.01.2023 & Corrigendum S.O. 89(E) dated 06.01.2023 for 31 formulations
239(overall) & 107 Meeting under DPCO 2013	11.01.2023	(i) Retail prices for 12 formulations notified vide S.O. 193(E) dated 11.01.2023. (ii) Ceiling prices for 128 formulations notified vide S.O. 194(E) & 194(E) dated 11.01.2023
240(overall) & 108 Meeting under DPCO 2013	27.01.2023	(i) Retail prices for 18 formulations notified vide S.O. SO. 483(E) dated 02.02.2023 (ii) Ceiling prices for 54 formulations notified vide S.O. 484(E) and 485(E) dated 02.02.2023 (iii) Ceiling prices for 2 formulations having special features also notified vide S.O. 486(E) and 487(E) dated 02.02.2023

- Details of ceiling prices notified for various formulations based on the decision taken in 105th, 106th, 107th& 108thAuthority Meetings are as follows:

S.N.	Therapeutic Category	No. of formulations
1	Anti-malarial Medicines	15
2	Anti bacterials	72
3	Antiviral Medicines	6
4	Medicines used in the Management of HIV	24
5	Analgesics, Antipyretics, Non-steroidal Anti-inflammatory Drugs (NSAIDs), Medicines used to treat Gout and Disease Modifying Agents used in Rheumatoid Disorders	23
6	Anti-cancer agents including Immunosuppressives and Medicines used in PalliativeCare	63

S.N.	Therapeutic Category	No. of formulations
7	Cardiovascular Medicines	39
8	Gastrointestinal Medicines	6
9	Hormones, other Endocrine Medicines and Contraceptives	
	(a) Insulins and other Anti diabetic agents	5
	(b) Others	7
	(c) Thyroid and Antithyroid Medicines	10
10	Medicines used in Anaesthesia	10
11	Medicines acting on the Respiratory tract	8
12	Medicines used in Neurological Disorders	39
13	Medicines used in treatment of Psychiatric Disorders	25
14	Vitamins and Minerals	5
15	Others	43
	Grand Total	**400**

➲ Details of retail prices notified for various formulations based on the decision taken in 105th, 106th, 107th& 108thAuthority Meetings are as follows:

S. No.	Therapeutic group	Total Number	Type of formulation	Retail Price fixed Range(Rs.) (Excl. GST) per tablet/per ml
(1)	(2)	(3)	(4)	(5)
1	Anti-Diabetic	31	Tablet	11.60 – 30.11
2	Anti-Could	3	Tablet / Suspension	0.87 – 2.76
3	Analgesics	3	Tablet / Injection	5.39 – 31.08
4	Anti hypertensive	2	Tablet	6.10 – 8.34
5	Anti-fungal	3	Capsule	11.60 – 20.72
6	Anti-Infection	5	Suspension / Infusion/Tablet	24.00 – 2500.00
7	Cardiovascular	5	Tablet / Capsule	13.15 – 19.04
8	Antineoplastic	1	Injection	452.45
9	Vitamins	2	Suspension / Capsule	0.68 – 18.56
10	Others	21	Capsule/Tablet/Injection/Infusion/Patch	0.65 – 48.00

REGULATORY NEWS

- NPPA also issued the OM F. No. 19 (78) / 2014 / Div. II / NPPA dated 09.01.2018, about partially revised format of Form-I for applications of new drug under Para 2 (u) of DPCO 2013, which clearly contains the point 1 (j) as "The retail price for approval (with / without GST, if any).

- During the 105 meeting of the Authority under DPCO 2013 held on 15.12.2022, authority approved the "Framework for undertaking Suo Moto corrections in the notified prices by NPPA. The corrected working sheet shall be uploaded on NPPA's website for 10 working days for comments, if any. It was also noted that such rectifications may either lead to upward or downward revision of prices.

News related to Medical Device

- NPPA vide S.O. 2161(E) dated 3rd June 2021 issued notification under Para 19 of the DPCO, 2013 regarding capping the trade margin of Oxygen Concentrators at first point of sale (price to distributor) for fixation of Maximum Retail Price of the product up to 30th Nov 2021. This has been further extended up to 31th March 2023 vide S.O. 6177(E) dated 30th Dec 2022.

- NPPA vide S.O. 2808(E) dated 13th July 2021 issued notification under Para 19 of the DPCO, 2013 regarding capping the trade margin of five medical devices, namely, (i) Pulse Oximeter, (ii) Blood Pressure Monitoring Machine, (iii) Nebulizer, (iv) Digital Thermometer, and (v) Glucometer, at first point of sale (price to distributor) for fixation of Maximum Retail Price of the product upto 31st Jan 2022. This has been further extended upto 31th March 2023 vide S.O. 6176(E) dated 30th Dec 2022.

FDA Grants Accelerated Approval for Alzheimer's Disease Treatment (January 06, 2023)

The U.S. Food and Drug Administration approved Leqembi (lecanemab-irmb) via the Accelerated Approval pathway for the treatment of Alzheimer's disease. Leqembi is the second of a new category of medications approved for Alzheimer's disease that target the fundamental pathophysiology of the disease. These medications represent an important advancement in the ongoing fight to effectively treat Alzheimer's disease.

- Alzheimer's Disease is an irreversible, progressive brain disorder affecting more than 6.5 million Americans that slowly destroys memory and thinking skills and, eventually, the ability to carry out simple tasks. While the specific causes of Alzheimer's are not fully known, it is characterized by changes in the brain-including amyloid beta plaques and neuro fibrillary, or tau, tangles-that result in loss of neurons and their connections. These changes affect a person's ability to remember and think.
- Leqembi was approved using the Accelerated Approval pathway, under which the FDA may approve drugs for serious conditions where there is an unmet medical need and a drug is shown to have an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit to patients.
- Researchers evaluated Leqembi's efficacy in a double-blind, placebo-controlled, parallel-group, dose-finding study of 856 patients with Alzheimer's disease. Treatment was initiated in patients with mild cognitive impairment or mild dementia stage of disease and confirmed presence of amyloid beta pathology.
- Leqembi is indicated for the treatment of Alzheimer's disease. The labelling states that treatment with Leqembi should be initiated in patients with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was studied in clinical trials. The labeling also states that there are no safety or effectiveness data on initiating treatment at earlier or later stages of the disease than were studied.
- The FDA granted this application Fast Track, Priority Review and Breakthrough Therapy designations.
- The approval of Leqembi was granted to Eisai R&D Management Co., Ltd.

Read more

FDA Announces Action Levels for Lead in Categories of Processed Baby Foods (January 24, 2023)

The U.S. Food and Drug Administration is announcing draft guidance for industry on action levels for lead in processed foods that are intended for babies and children under two years of age, to help reduce potential health effects in this vulnerable population from dietary exposure to lead. The proposed action levels would result in significant reductions in exposures to lead from food while ensuring availability of nutritious foods. Today's action is part of Closer to Zero, which sets forth the FDA's science-based approach to continually reducing exposure to lead, arsenic, cadmium and mercury to the lowest levels possible in foods eaten by babies and young children.

- Foods covered by the draft guidance, Action Levels for Lead in Food Intended for Babies and Young Children, are those processed foods, such as food packaged in jars, pouches, tubs and boxes and intended for babies and young children less than two years old. The draft guidance contains the following action levels:

  - 10 parts per billion (ppb) for fruits, vegetables (excluding single-ingredient root vegetables), mixtures (including grain and meat-based mixtures), yogurts. custards/ puddings and single-ingredient meats.
  - 20 ppb for root vegetables (single ingredient).
  - 20 ppb for dry cereals.
- The FDA considers these action levels to be achievable when measures are taken to minimize the presence of lead and expects that industry will strive for continual reduction of this contaminant. The baby foods have differing action levels, to account for variances in consumption levels of different food products and due to some foods taking up higher amounts of lead from the environment. Action levels are one regulatory tool the FDA uses to help lower levels of chemical contaminants in foods when a certain level of a contaminant is unavoidable, for example due to environmental factors.

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FDA Denies Marketing of Two Vuse Menthol E-Cigarette Products Following Determination They Do Not Meet Public Health Standard (January 24, 2023)

The U.S. Food and Drug Administration issued marketing denial orders (MDOs) for two menthol e-cigarette products currently marketed by R.J. Reynolds Vapor Company. The currently marketed products include the Vuse Vibe Tank Menthol 3.0% and the Vuse Ciro Cartridge Menthol 1.5%. The company must not market or distribute these products in the U.S. or they risk FDA enforcement action. The company may resubmit applications or submit new applications to address the deficiencies for the products that are subject to these MDOs.

- The FDA determined that the applications lacked sufficient evidence to demonstrate that permitting the marketing of the products would be appropriate for the protection of the public health, which is the applicable standard legally required by the 2009 Family Smoking Prevention and Tobacco Control Act.
- Existing evidence demonstrates that non-tobacco-flavored e-cigarettes, including menthol flavored e-cigarettes, have a known and substantial risk with regard to youth appeal, uptake and use; in contrast, data indicate tobacco-flavored e-cigarettes do not have the same appeal to youth and therefore do not pose the same degree of risk.
- Today's issuance of these MDOs is just one of the many actions the FDA has taken to ensure any tobacco products that are marketed undergo science-based review and receive marketing authorizations by the FDA.
- To date, the FDA has authorized 23 tobacco-flavored e-cigarette products and devices. These are the only e-cigarette products that currently may be lawfully sold in the U.S.

Read more

FDA Approves First Oral Treatment for Anemia Caused by Chronic Kidney Disease for Adults on Dialysis (February 01, 2023)

The U.S. Food and Drug Administration approved Jesduvroq tablets (daprodustat) as the first oral treatment for anemia (decreased number of red blood cells) caused by chronic kidney disease for adults who have been receiving dialysis for at least four months. Jesduvroq is not approved for patients who are not on dialysis. Other FDA-approved treatments for this condition are injected into the blood or under the skin.

- Kidneys produce a hormone called erythropoietin, which signals the body to make red blood cells. In a person with chronic kidney disease on dialysis, the kidneys cannot produce enough erythropoietin, leading to reduced numbers of red blood cells.
- Jesduvroq increases erythropoietin levels. The effectiveness of Jesduvroq was established in a randomized study of 2,964 adults receiving dialysis. In this study, adults received either oral Jesduvroq or injected recombinant human erythropoietin (a standard of care treatment for patients with anemia due to

chronic kidney disease). Jesduvroq raised and maintained the hemoglobin (the protein in red blood cells that carries oxygen and is a common measure of anemia) within the target range of 10-11 grams/deciliter, similar to that of the recombinant human erythropoietin.

- The FDA granted the approval to GlaxoSmithKline LLC.

Read more

FDA approves first treatment for geographic atrophy (February 21, 2023)

SYFOVRE (pegcetacoplan injection) is the first and only treatment approved by the US Food and Drug Administration (FDA) for geographic atrophy (GA), a leading cause of blindness.

- GA is an advanced form of age-related macular degeneration (AMD). It is a progressive and irreversible disease caused by the growth of lesions, which destroy the retinal cells responsible for vision.
- The safety profile of SYFOVRE is well-demonstrated following~12,000 injections. The most common adverse reactions (≥ 5 percent) reported were ocular discomfort, neovascular AMD, vitreous floaters, and conjunctival haemorrhage.
- SYFOVRE is expected to be available by the beginning of March 2023. A marketing authorisation application (MAA) is under review by the European Medicines Agency (EMA) with a regulatory decision expected in early 2024.

Read more

EC approves first gene therapy for haemophilia B (February 21, 2023)

The first gene therapy for haemophilia B has been given conditional marketing authorisation in Europe by the European Commission. A conditional marketing authorisation (CMA) has been granted by the European Commission (EC) for HEMGENIX® (etranacogene dezaparvovec), the first and only one-time gene therapy for haemophilia B (congenital Factor IX deficiency).

- HEMGENIX is the first approved gene therapy for haemophilia B in the European Union (EU) and European Economic Area (EEA).
- This approval marks an important step forward in the treatment of haemophilia B, which could be transformative for people who are debilitated by bleeds into their muscles, joints and internal organs, alleviating the burden of lifelong intravenous infusions of Factor IX products," added Professor Miesbach.
- The US Food and Drug Administration (FDA) approved HEMGENIX in November 2022.

Read more

First-in-human gene therapy trial for major cardiac syndrome (February 08, 2023)

RMAT designation is designed to expedite the drug development and review processes for promising pipeline products, including gene therapies. A regenerative medicine therapy is eligible for RMAT designation if it is intended to treat, modify, reverse or cure a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug or therapy has the potential to address unmet medical needs for such disease or condition.

Danon disease is a rare and genetic cardiac disease. It is caused by mutations in the gene encoding lysosome-associated membrane protein 2 (LAMP-2), an important mediator of autophagy. Ultimately, this leads to heart failure and can be fatal for male patients.

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61ST ANNUAL CELEBRATIONS HELD ON 11TH FEBRUARY, 2023 OF INDIAN DRUG MANUFACTURERS' ASSOCIATION

Indian Drug Manufacturers' Association (IDMA), the largest associations of the drug manufacturers in the country with 1100 companies as its member had its the 61st annual celebrations on 11th February, 2023 at Mumbai. Dr. Vinod Kotwal, Member Secretary was invited as the Chief Guest. The stakeholders from the State as well Central government spoke on the occasion. Ms. Jyoti Sardesai, Director, FDA, Goa and Shri H. G. Koshia, Commissioner, FDA, Gujarat were felicitated on the occasion for their contribution in facilitating the growth of the pharma industry.

A publication titled – **India Pharma – Global Health Care** was also released on the occasion.

Shri Dilip Shanghvi, Managing Director, Sun Pharmaceuticals, who was the Guest of Honour at the occasion, in his address, inter-alia, covered following points:–

(i) the future potential of the Indian drug manufacturing;

(ii) the impact of increase in income, younger population and life expectancy going up and its relation to the requirement of drugs in the country;

(iii) need to keep abreast of the changing dynamics of the distribution channels globally and future proofing;

(iv) need to increase investment in research and development; and

(v) focus on quality.

Shri Rehan Khan, Managing Director, MSD India also spoke on the occasion and narrated the success of the Cambridge Square in Massachusetts, USA consisting of researchers, pharma companies, venture capitalists and IT companies which have nurtured an eco-system that is able to innovate and bring cutting edge research in pharma sector. This has resulted in launch of new drugs, vaccines and various other applications in the area of health care. He emphasised the need to nurture similar eco-system in India so that India could move-up the value chain of pharma industry.

Shri Parijat Ghosh, Partner, Bain & Co. made a presentation on recent trends in Mergers and Acquisitions (M&A). During his presentation, Shri Parijat Ghosh highlighted that Indian pharma sector was witnessing an increase in the M&As

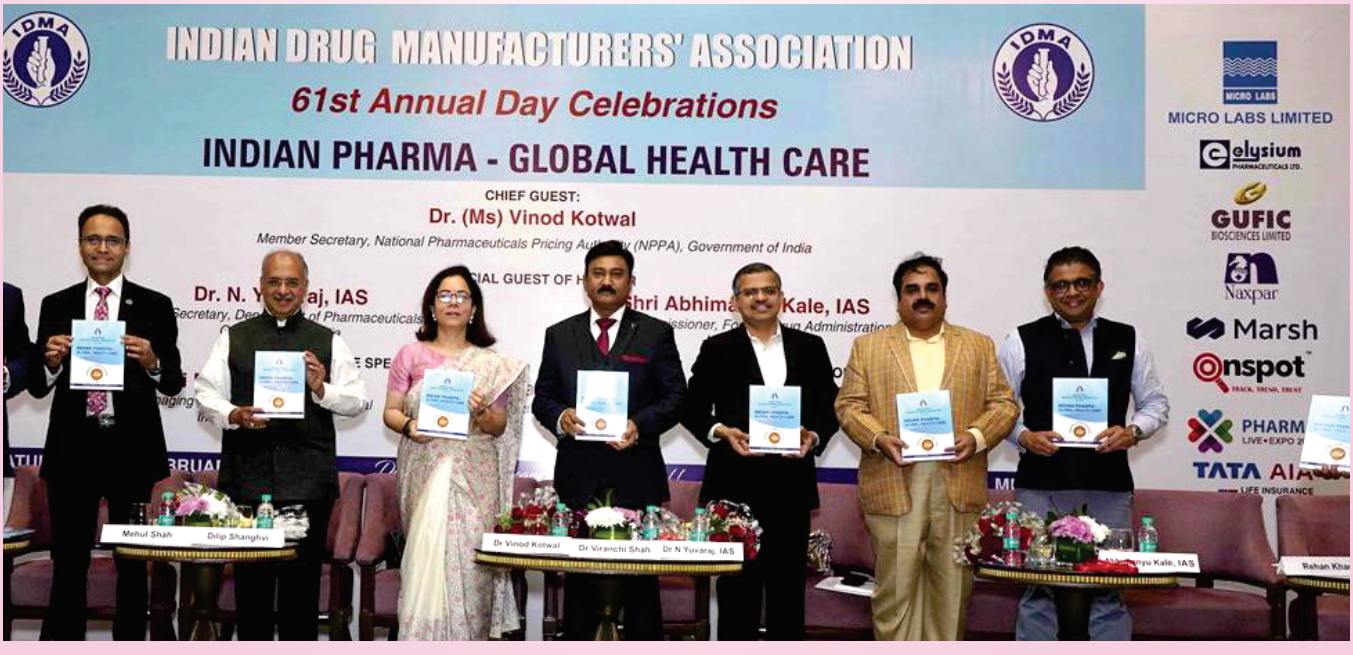
when compared to the global trends.

Dr. N. Yuvaraj, Joint Secretary, Department of Pharmaceuticals speaking on the occasion informed about the various schemes launched by the Department of Pharmaceuticals (DoP) to encourage manufacturing of drugs in the country. The DoP is committed to strengthening the pharma sector in the country. Focusing on the need for ensuring the quality of drugs produced in the country, he also highlighted the need for having good quality data which can help in better decision making.

Shri Abhimanyu Kale, Commissioner, Food and drug Administration, Maharashtra speaking on the occasion and informed that his office was ever-willing to facilitate industry in undertaking production and other activities. He, however, highlighted that it is important that Indian pharma sector continues to be known for its quality as well as cost advantage. Recent instances pertaining to the Indian pharma sector have cast a shadow on its reputation and all the companies need to assure that quality is not compromised in any way. He also informed that a number of consumer associations reported to him requesting to bring more drugs under the Schedule of DPCO 2013 so that they could become more affordable.

Dr. Vinod Kotwal, Member Secretary also spoke on the occasion and noted that Indian pharma industry has the triple advantage of cost, quality and scale. These qualities of Indian pharma sector have been leveraged not only to ensure supply of quality affordable drugs to the people in the country but also globally. NPPA played an important role in ensuring availability of essential drugs across the country in close coordination with the industry as well as State Drugs Authorities of various States and UTs. It was also informed that the IPDMS 2.0 launched by NPPA on 29th August, 2022 has been implemented and is being used by the industry for submission of various forms. However, it was emphasised that for any evidence-based policy making, it is important that good quality data is available. IPDMS will help in filling in that gap and she urged all the members to register in IPDMS, if not already done, and start filing the various forms through IPDMS. She also informed about the price fixation based on the revised Schedule I and it was informed that ceiling prices have been fixed in 400 formulations.

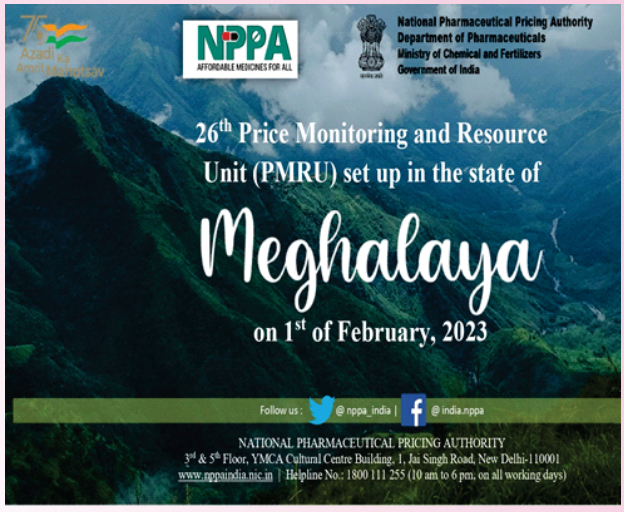
The vote of thanks was delivered by **Shri Mehul Shah, General Secretary, IDMA.**



OTHER NEWS AND EVENTS

NPPA SETS UP 26TH PRICE MONITORING AND RESOURCE UNIT (PMRU) IN THE STATE OF MEGHALAYA IN FEBRUARY, 2023

NPPA under Consumer Awareness, Publicity and Price Monitoring (CAPPM) Scheme has so far set-up Price Monitoring and Resource Units (PMRU) in 26 States/UTs. The 26th PMRU was established in the State of Meghalaya on 01.02.2023. Now, NPPA has its presence in the States/ UTs viz. Kerala, Gujarat, Odisha, Rajasthan, Punjab, Haryana, Tripura, Nagaland, Uttar Pradesh, Andhra Pradesh, Mizoram, Jammu & Kashmir, Karnataka, Telangana, Maharashtra, Goa, Madhya Pradesh, Chhattisgarh, Jharkhand, Puducherry, West Bengal, Ladakh, Himachal Pradesh, Bihar, Uttarakhand and Meghalaya. 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.



WEBINAR ON 'ACTIVITIES OF PMRUs'

An interactive online webinar was organised by NPPA on 27.02.2023 on 'Activities of PMRUs'. The main aim of the webinar was to provide guidance on functioning/ activities to be performed by PMRUs and submission of data and reports through IPDMS Software. The PMRUs in the State/ UTs have actively participated in the webinar.

CHAIRMAN, NPPA'S INTERACTION WITH PMRUs

National Pharmaceutical Pricing Authority (NPPA) organised an interaction meeting with PMRUs on 19th January, 2023 through video conferencing under the Chairpersonship of Chairman NPPA Shri Kamlesh Kumar Pant, IAS, to discuss and review of progress of PMRUs. The representatives of PMRUs of Andhra Pradesh, West Bengal, Bihar, Gujarat, Madhya Pradesh, Maharashtra, Odisha, Rajasthan, Uttar Pradesh, Chhattisgarh, Haryana, Jammu & Kashmir, Kerala, Punjab, Telangana, Puducherry, Goa, Himachal Pradesh, Ladakh, Mizoram, Uttarakhand, Tripura and Karnataka participated in the meeting. Necessary guidance on various points were provided in order to increase the performance of the PMRU states.

AWARENESS WORKSHOP ORGANIZED BY PMRU GOA

Goa State Price Monitoring and Resource Unit and Directorate of Food & Drugs Administration jointly organized a one-day State level Awareness Programme on 'Availability, Accessibility and Affordability of essential medicines at Panji on 24th November 2022. The program was inaugurated by secretary Health, Arun Kumar Mishra, IAS in the presence of Director, FDA, Ms. Jyoti Sardesai, Deputy Director NPPA, Saurabh Bansal and Dr. Preeti Tagde, Project Coordinator MPPMRU, Dr. Khullar President GPMA. The program was well attended by all stakeholders from Pharma industry, Pharma Trade, both the Pharmacy colleges and officials of FDA.

FDA holds programme on essential medicines

Secretary Health Arun Kumar Mishra, Director FDA Jyoti Sardesai among others at the programme.

AWARENESS PROGRAM ON IEC (INFORMATION EDUCATION AND COMMUNICATION) ACTIVITIES ORGANIZED BY PMRU KARNATAKA

Karnataka State Price Monitoring Resource Unit (KPMRU) and Drugs Control department have jointly organized an Awareness program under IEC activities on 25th January 2023 on affordability and availability of quality drugs and use of Pharma Sahi Dam APP at Dharamsthala Manjunatatheshwara Medical College, Dharwad Karnataka.

The concept of the Awareness program was to highlight the benefits given to Consumers by NPPA in providing (i) Pharma Sahi Dam App (ii) Search Medicine Price (iii) Pharma Jan Samadhan (iv) IPDMS. The participants were demonstrated use of 'Pharma Sahi Dam' for checking the right price of the medicine and they have downloaded the said App from the Google Pay.

The Programme was attended by more than 200 participants' viz. Officers of State Drug Control Department, KPMRU Staff, Doctors, Students of Pharmacy College, Dharwad Chemist & Druggist Association, Jan Seva Foundation and other Stake holders.

FREQUENTLY ASKED QUESTIONS

1. What is NLEM?

NLEM means National List of Essential Medicines, published by the Ministry of Health and Family Welfare as updated or revised from time to time. As per the World Health Organization (WHO), essential medicines are those that satisfy the priority health care needs of the population. 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 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 DPCO, 2013 through a notification in the Official Gazette. National Pharmaceutical Pricing Authority (NPPA) fixes/ revises the ceiling price of scheduled medicines specified in the first schedule of the DPCO, 2013 in accordance with the provisions of DPCO.

2. How has NLEM evolved and which NLEM is currently effective?

The first NLEM of India was prepared in 1996. Subsequently, the list has been revised in 2003, 2011 and 2015. In September, 2022, the NLEM 2015 was replaced with NLEM 2022 by the Ministry of Health & Family Welfare (MoHFW) and currently, NLEM 2022 is effective.

The details of addition, deletion and total number of medicines in successive NLEMs are as follows:

Year	2011	2015	2022
Number of medicines added	47	106	34
Number of medicines deleted	43	70	26
Total number of medicines	348	376	384

3. What is the impact of revision of NLEM on drug pricing?

The Department of Pharmaceuticals (DoP) has notified Revised Schedule I of DPCO 2013 on the basis of NLEM 2022 on 11.11.2022. The following will be the impact of such revision of Dirst Schedule-I:

a) The Ceiling Prices of the Scheduled Drugs, which were in the Schedule previously also, will be re-fixed on the basis of the methodology provided in the DPCO. Due to such price refixation, in most of the cases, the Ceiling Prices would reduce.

b) 34 medicines have newly become Scheduled medicines and NPPA will fix the Ceiling Prices of such drugs, for the first time, as per the methodology provided in the DPCO. This will reduce the average Selling Price of these drugs.

c) 26 medicines which have been deleted form the Schedule-I will now become Non-Scheduled drugs. Although no Ceiling Prices will be applicable on these medicines but the companies cannot increase the MRP by more than 10 % in a year from the existing MRP.

4. What is the methodology for the fixation of Ceiling Prices and MRP?

The Ceiling Prices is calculated for each scheduled formulation (medicine of specified strengths and dosages) separately.

The Maximum allowable MRP of a formulation is equal to Ceiling price + Local Taxes as applicable. Ceiling Price is calculated as Average PTR (Price to Retailer) plus 16% as Margin to retailers. The average PTR is calculated as simple average of PTR of all the brands/ generic versions having a market share of 1% or more.

The above calculations are done on the basis of the market-based data available with NPPA.

Feedback and Complaint Redressal

Grievance Redressal

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

Information Dissemination

- **Pharma Sahi Daam:** One can easily search brand name, composition, ceiling price and MRP of the formulation – available to public.
- **Seminars and Workshops** conducted by NPPA and by PMRUs

Collaboration with State Governments

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

NPPA
AFFORDABLE MEDICINES FOR ALL
सभी के लिए वहनीय दवाईयाँ

NATIONAL PHARMACEUTICAL PRICING AUTHORITY

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