

AUSHADH SANDESH

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A Bi-monthly e-Newsletter

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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.

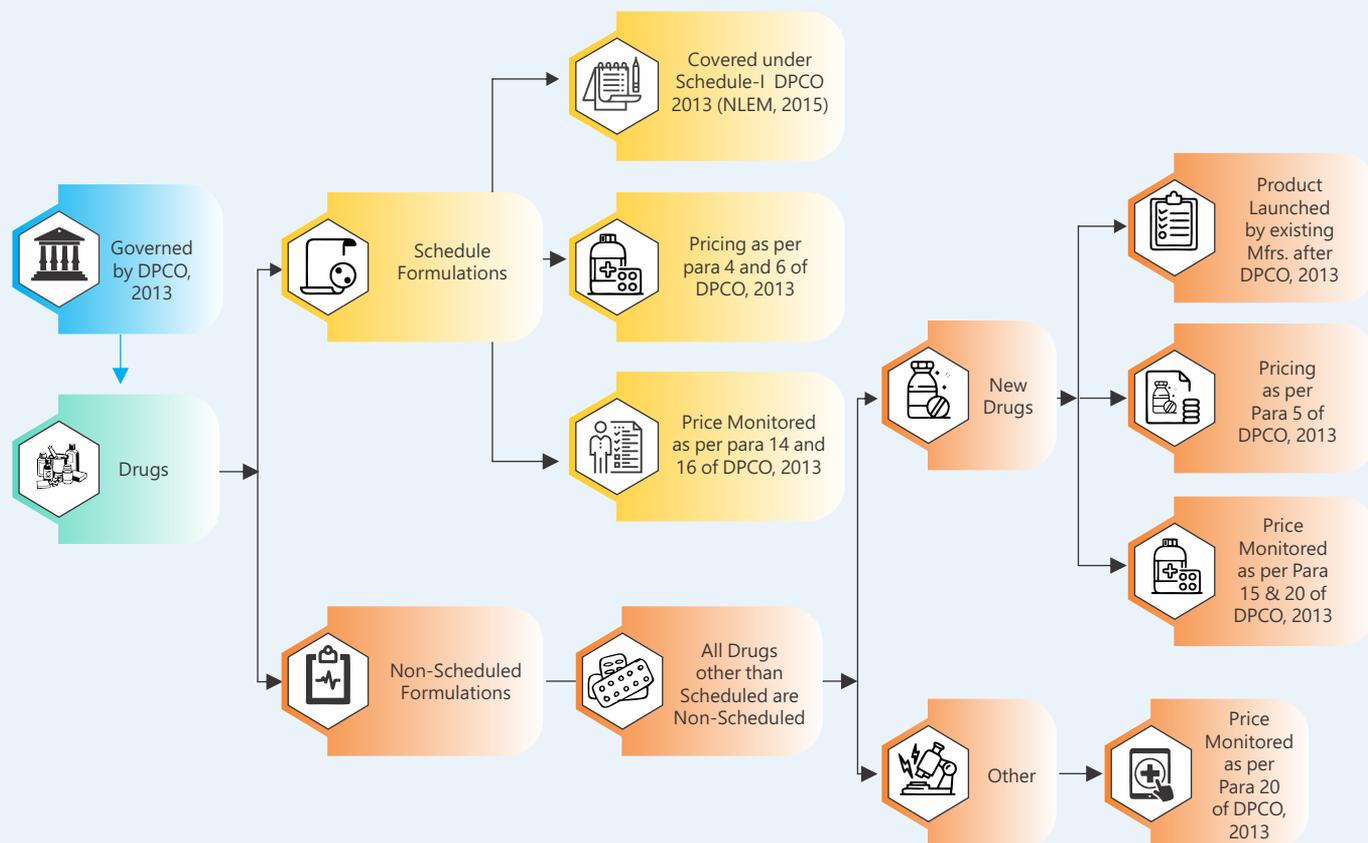
The Authority is a multi-member body consisting of a Chairperson, a Member Secretary and three ex-officio members. Two of the three ex-officio members are from Department of Economic Affairs and Department of Expenditure respectively and third member is Drug Controller General of India.

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:

- 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 and NLEM-2022 as amended vide S.O. 5249 dated 11.11.2022 has been incorporated as the First Schedule of DPCO 2013.
- 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.
- Market Based Pricing:** The ceiling prices of medicines are fixed on Market Based Pricing (MBP) methodology.

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P. Krishnamurthy, IAS
Chairman
National Pharmaceutical Pricing Authority
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Government of India

From CHAIRMAN'S DESK

It is with great pleasure that I present to you the twenty sixth issue of the NPPA bi-monthly e-newsletter, the AUSHADH SANDESH. The year continues to present opportunities and challenges, and the National Pharmaceutical Pricing Authority (NPPA) remains steadfast in its mandate to ensure the affordability and accessibility of essential medicines and medical devices for every citizen.

This edition highlights two important contributions that reflect both regulatory action and scientific advancement in the pharmaceutical and healthcare ecosystem.

The In-house Article on the Consumer Awareness, Publicity and Price Monitoring (CAPP) Scheme underscores NPPA's sustained efforts to strengthen consumer empowerment and grassroots-level price monitoring. Through the effective functioning of Price Monitoring Resource Units (PMRUs) across States and Union Territories, the CAPP Scheme has emerged as a vital mechanism for ensuring compliance with the provisions of the DPCO, 2013, improving availability of essential medicines, and enhancing public awareness about consumers' rights. The article captures how targeted IEC activities, market surveys, and digital platforms such as IPDMS 2.0 and Pharma Sahi Daam are contributing to a more transparent and accountable pharmaceutical market.

This issue also features an Expert Article on the discovery of the CRIB Blood Group, a landmark scientific achievement in Indian hematology research. The identification of a new blood group system after nearly four decades is a significant milestone with far-reaching implications for transfusion medicine, maternal-fetal health, and rare blood donor management. This contribution not only highlights India's growing research capabilities but also emphasizes the importance of preparedness within healthcare systems to address rare and complex clinical challenges.

NPPA remains committed to fostering a culture of knowledge-sharing and informed policy-making. We believe that by engaging with such comprehensive and evidence-based content, our readers from industry leaders to healthcare professionals and the public can better appreciate the complexities and advancements in the sector.

In continuation of our PMRU activities, thirty-six (36) State and District level Events/ Seminars have been organized by 13 (Thirteen) PMRUs in their respective States/ UTs. These events were aimed at raising awareness among people about Fixation of Ceiling Prices under NLEM 2022 and its significance in Healthcare, Drug Price Regulations under the provisions of DPCO, 2013, Role of NPPA in making the Drugs affordable and available for all, Functions of PMRUs, Pharma Sahi Daam Mobile App and IPDMS 2.0.

I extend my best wishes for an informative reading experience. Together, we will continue to work towards a healthier and more affordable India.

With best wishes

(Shri P .Krishnamurthy)

CAPPM SCHEME: STRENGTHENING CONSUMER AWARENESS AND PRICE MONITORING IN PHARMACEUTICALS - NPPA TEAM

The Consumer Awareness, Publicity and Price Monitoring (CAPPM) Scheme is a Central Government initiative implemented by the National Pharmaceuticals Pricing Authority (NPPA) since 2018. It is a central sector scheme that primarily benefits patients and consumers, while also supporting hospitals and other stakeholders by improving price transparency, educating consumers regarding NPPA's price control mandate, monitoring and enforcement activities, compliance, and availability of essential medicines. Aligned with Sustainable Development Goal 3 (Good Health and Well-Being), CAPPM complements initiatives such as the National Health Mission and Ayushman Bharat, and contributes to the Viksit Bharat 2047 vision by strengthening healthcare affordability and consumer empowerment.

The Scheme has two broad components

- i. Grant-in-Aid to PMRUs (State-level activities) for price monitoring and enforcement under DPCO, 2013; and
- ii. Advertisement and Publicity by NPPA (National-level activities), including print and electronic media campaigns, social media outreach, national workshops, and purchase of drug samples for compliance verification.

Price Monitoring and Resource Units (PMRUs)

Price Monitoring and Resource Units (PMRUs) act as an accessible support system for citizens to ensure the availability of medicines at notified prices and to address complaints related to overcharging of drugs. PMRUs are the extended arm of NPPA, which are registered as a Society in various States/Union Territories. They have their own Memorandum of Association/ Bye laws, and they function under the direct supervision of the concerned State Drug Controllers for increasing the outreach of NPPA. PMRUs have been established in 32 States/UTs, with the first being set up in Kerala on 03.01.2019 and the latest one in Delhi on 11.06.2025. The States/UTs have been categorized based on population, and the budget allocation, staff and infrastructure deployment have been laid down accordingly under the CAPPM Scheme guidelines.

Their functions broadly include the following:

Ensuring Availability and Price compliance: Under the DPCO, 2013, NPPA fixes ceiling prices for scheduled formulations. The non-scheduled formulations are monitored to ensure annual price increases do not exceed 10%. To ensure compliance, PMRU field staff regularly visit chemist shops, hospitals, and distributors to verify MRPs, price lists, bills, photographs, and test samples, identify violations such as overcharging, excess price increases, non-display of price lists, or non-availability of essential medicines. Suspected Over Changing cases are collected and reported to NPPA through Integrated Pharmaceuticals Database Management System (IPDMS) and the State Drug Controller.

Since 2022, PMRU Field Investigators also conduct weekly Market Surveys (M-Surveys) to monitor the availability of COVID-19 management drugs and devices. A tertiary care hospital serves as the reference point, with medical shops within and beyond 1 km forming two survey zones. Investigators select 20 shops per survey, plan and conduct visits, physically, verify stock, record item-wise availability, and enter data into IPDMS for real-time reporting. Submitted data is reviewed for accuracy, and weekly records are maintained for audits and follow-up, ensuring effective monitoring, regulatory oversight, and uninterrupted access to essential medicines and devices.



Functions of PMRU

IEC Activities: Apart from conducting market surveys and monitoring price movements of scheduled and non-scheduled drugs, PMRUs play a major role in generating awareness among the common public regarding the role of NPPA, DPCO, 2013 and other information related to medicine and their availability. While some IEC activities are undertaken regularly, such as periodic district-level and state-level awareness campaigns, seminars, and workshops. PMRUs also interact directly with general consumers, including students and patients, to promote consumer awareness. In addition, some PMRUs have adopted innovative methods to enhance outreach, such as organizing painting competitions, reel-making competitions, nukkad-nataks, hospital and block-level campaigns, gram panchayat meetings, consumer camps, seminars, workshops, and training programmes, to promote NPPA initiatives like Pharma Sahi Daam, Pharma Jan Samadhan, and price-regulation provisions.

Major IEC Activities: Consumer Awareness Topics



Role of NPPA

- Regulates medicine prices
- Ensures drug availability
- Monitors compliance & prevents overcharging
- Raises awareness on affordable medicine prices



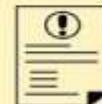
Price Regulation Under DPCO, 2013

- Issued under Essential Commodities Act.
- Covers all drugs in NLEM (Scheduled & Non-Scheduled).
- Empowers NPPA to monitor, penalize overcharging & revise prices.
- Drugs must be sold at/below NPPA-set ceiling price.



Pharma Sahi Daam App

- Enables consumers to check and compare medicine prices, avoid overcharging and report violations directly to NPPA.
- Ensures that vendors remain compliant with latest regulations and helps build customer trust through transparent pricing.



Pharma Jan Samadhan

- Grievance redressal platform - consumers can lodge complaints about overcharging, shortages, or non-availability.
- Ensures affordable medicines by enforcing price regulations.

Major IEC Activities and Consumer Awareness topics



IEC activities during the calendar year 2025



1500

District-Level Awareness Campaigns, Seminars & Workshops



1000

State-Level Awareness Campaigns, Seminars & Workshops



700

School-Level Programs



800

Interactions with Patients

Summary of IEC Activities conducted by PMRUs in 2025

Concluding Remarks

Ensuring that medicines are available at affordable prices is meaningful only when citizens are aware of their rights and know where to seek help. Under the CAPPAM Scheme, NPPA and PMRUs play a vital role in spreading awareness among consumers and enabling them to act against drug price violations.

By creating awareness, simplifying grievance redressal, and acting as a local point of contact, PMRUs empower citizens to participate actively in price monitoring. This consumer-centric approach strengthens transparency in the pharmaceutical market and ensures that the benefits of drug price regulation truly reach patients across the country.

Unveiling the CRIB Blood Group: A Landmark Discovery in Indian Hematology Research

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ABSTRACT

The identification of a new blood group system, Chromosomal Rare Indian Blood, CRIB, represents a significant advancement in the field of hematology. The official naming of CRIB (Cromer India Bengaluru) and its confirmation by the International Blood Group Reference Laboratory (IBGRL) in the UK. This paper details the discovery of the CRIB blood group in a 38-year-old woman Karnataka India, marking the first new blood group system identified in over 38 years. The identification of CRIB adds to the growing complexity of the human blood group systems and provides insight into genetic variations and their implications for transfusion medicine and maternal-fetal compatibility. This communication outlines the clinical significance, the methods employed for detection, and the potential challenges that come with this discovery.

Keywords: CRIB, Blood group, Hematology, Transfusion medicine.

1. Introduction

The concept of blood groups has been well-established since the early 20th century with the discovery of the ABO and Rh blood group systems. These systems, along with others like the MNS, Kell, Duffy, and others, have been essential in blood transfusion, organ transplantations, and understanding human genetics[1]. However, the identification of novel blood group systems remains rare, with the last significant discovery occurring in 1982 (the discovery of the RhAG blood group).

1. In this short communication, we describe the discovery of a novel blood group system termed "CRIB," identified in a 38-year-old woman in India, which adds a new dimension to blood typing and immunohematology[4,5]. The discovery was officially announced at the 35th Regional Congress of the International Society of Blood Transfusion (ISBT) in Milan, Italy[2].
2. **Case Report** The CRIB blood group was discovered in a 38-year-old South Indian woman in Karnataka, India during a cardiac operation, when her blood was found to be incompatible with all known donor samples [1]. During her blood typing, the standard tests for ABO and Rh groups did not match any known combinations. Upon initial observation, the woman was found to be negative for all common blood group antigens. Further tests, including agglutination and enzyme assays, suggested the presence of an unknown antigen. The woman's blood was sent to a specialized immunohematology laboratory for further investigation [1]
3. **Laboratory Methods** The discovery of the CRIB blood group was made using a combination of molecular genetics and serological techniques[2-6]. Initial blood typing was conducted using standard gel centrifugation methods, which failed to show the typical reactions seen with common blood groups [7-11]. The woman's blood was subjected to extended antigenic testing with a panel of anti-sera, including antibodies against all major blood group systems[12-16]. DNA

sequencing was then performed to identify genetic variations in the glycoproteins expressed on the surface of the red blood cells. Whole-genome sequencing identified a novel mutation in the CRIB1 gene, which encodes a glycoprotein believed to play a role in erythrocyte membrane stability[17-19]. The presence of the CRIB antigen was confirmed in the subject and further cross-checked against a large blood bank sample set, which revealed that this antigen had never been encountered before[20-22].

4. **Results** The patient, who was the first identified carrier of the CRIB antigen, was found to have no history of adverse transfusion reactions. Subsequent screening of family members revealed that the woman inherited this antigen from both parents, confirming that it followed a recessive inheritance pattern. Blood transfusion compatibility testing showed that the CRIB antigen could pose a risk in transfusion reactions if matched with individuals without the antigen, as the development of anti-CRIB antibodies could cause hemolytic transfusion reactions. Further population screening studies are being planned to assess the prevalence of the CRIB blood group in different ethnic populations, particularly in India, where the discovery was made.

Preliminary data suggest that the CRIB antigen is rare, with only a few other cases currently reported in India.

5. **Discussion** The discovery of the CRIB blood group is an important contribution to the understanding of human red blood cell antigen systems[23]. This new blood group may have significant implications for blood transfusion medicine, particularly for patients requiring multiple transfusions or those with rare blood types[24]. As with other blood group systems, it is essential to understand the potential for alloimmunization (development of antibodies against foreign blood group antigens), which can complicate future transfusions and lead to hemolytic reactions[25]. One of the most critical aspects of this discovery is its potential impact on maternal-fetal medicine. Women who are CRIB negative may develop anti-CRIB antibodies if they carry a fetus that expresses the CRIB antigen, leading to hemolytic disease of the newborn (HDN)[26-27]. Further research is needed to evaluate the risk of such a condition and to develop effective management strategies for pregnant women with anti-CRIB antibodies[26].

6. **Implications for Future Healthcare** The discovery of CRIB emphasizes the need for further investment in genetic blood typing and molecular diagnostics. Enhanced recognition of rare or atypical blood types by healthcare professionals is necessary to improve transfusion safety. Establishing global rare

DISCOVERY OF A NEW BLOOD GROUP SYSTEM CRIB

INTRODUCTION
Blood group systems and serological tests have been developed over the past 38 years to identify various antigens present on red blood cells.

CASE REPORT
A 38-year-old woman from India presented at a local hospital for routine blood typing prior to undergoing elective surgery. During her blood typing, the standard tests for ABO and Rh groups did not match expected patterns.

METHODS
Blood sample analysis and antigenic testing were performed using antisera. DNA sequencing was conducted to identify genetic variations in glycoproteins.

RESULTS
The patient was identified as the first carrier of the CRIB antigen. She had no history of adverse transfusion reactions.

CRIB antigen **CRIB negative**

blood donor registries could significantly reduce the time needed to find compatible blood during emergencies. Furthermore, CRIB's identification highlights the importance of considering rare blood types in the context of pregnancy and fetal health, especially with regard to hemolytic disease. This discovery also underscores the potential for more rare blood types to be uncovered, especially in populations with diverse genetic backgrounds. The identification of CRIB has already led to calls for the creation of CRIB-specific antibody screening kits, international rare blood registries, and increased training for transfusion specialists to better handle atypical cases.

7. **How Does the CRIB Blood Type Affect Pregnancy and Fetal Health?** The CRIB antigen is part of the Cromer blood group system, located on DAF proteins that protect red blood cells from immune destruction. The patient's unique blood profile, characterized by the absence of common antigens, could make her body react to transfused blood, even from O-positive donors. This highlights the challenge of finding compatible blood, as the patient would require CRIB-negative blood for safe transfusion. In pregnancy, if a woman carrying a CRIB-positive fetus becomes sensitized to the antigen, it could lead to maternal-fetal incompatibility and potentially cause HDN.
8. **Conclusion** The discovery of the CRIB blood group is a groundbreaking addition to the field of hematology, as it is the first new blood group system identified in over 38 years. This discovery opens the door to a better understanding of the genetic diversity of human blood groups and the potential risks and challenges in transfusion medicine. As more cases are identified and studied, the full clinical significance of the CRIB blood group will become clearer, potentially leading to new guidelines in blood typing, transfusions, and maternal-fetal medicine. It is imperative to continue research into rare blood types to ensure the safety and efficacy of transfusion therapies and improve clinical outcomes for patients worldwide.

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Declaration of competing interest: The authors do not declare any conflict of interest.

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1. Ceiling prices of 935 formulations are effective as on 31.12.2025. There has been average reduction of 16.82% on account of refixation under NLEM, 2022 leading to annual savings of Rs. 3802.11 Crores to the patients. The details of ceiling prices fixed under NLEM, 2022 and savings thereon are as follows

Therapeutic Category	No. of Medicines	No. of formulations	Annual Savings (Rs. In Crores)
Anti-infective Medicines	62	174	1248.92
Anticancer Medicines	59	120	294.34
Neurological Disorder Medicines	18	60	154.43
Psychiatric Disorder Medicines	14	41	42.6
Cardiovascular Medicines	26	61	474.26
HIV Management Medicines	20	24	21.93
Analgesics, Antipyretics, Non-steroidal Anti-inflammatory Drugs (NSAIDs)	11	24	112.8
Anti-Diabetic drugs	8	11	249.73
Hormones, other Endocrine Medicines and Contraceptives	16	33	256.41
Others	117	228	946.69
Unique Drugs / Formulations	332*	776	3802.11

*Some medicines are listed in various sections. The medicines are counted in both sections, but the formulation is counted only once in one of the sections.

2. Till 31.12.2025, 273th Authority meetings have been conducted of which 141th have been conducted under DPCO 2013. The details of the recent meetings are given as below:

Meeting No	Held on	Prices Approved & Notified
Meeting No. 273th (overall) & 141th meeting under DPCO 2013	23.12.2025	i. Retail prices for 37 formulations notified vide S.O 5975(E) Dated 24.12.2025.
Meeting No. 272th (overall) & 140th meeting under DPCO 2013	27.11.2025	i. Retail prices for 11 formulations notified vide S.O 5476(E) Dated 28.11.2025.

3. Retail prices for 3646 new drugs have been fixed under DPCO, 2013 till 31.12.2025. Details of 48 retail prices notified for various formulations based on the decision taken in 140th and 141th meetings are as follow:

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	5	Tablet	12.00 - 23.59
2.	Pain / Analgesics	9	Tablet/ Suspension	0.77 - 5.46

REGULATORY NEWS

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)
3.	Cardiovascular	5	Tablet	7.52 - 36.12
4.	Anti-Infective	8	Tablet/Suspension Ointment/Injection	1.74-1500
5.	Respiratory	7	Tablet/Syrup/ Suspension	0.95 - 49.00
6.	Vitamins/Minerals	4	Tablet/Syrup	15.6 - 19.24
7.	Others	10	Tablet/solution/capsule Suspension/Injection	1.39 - 133.97

IPDMS 2.0.



Chart1: Total number of registered companies at the end of December 2025

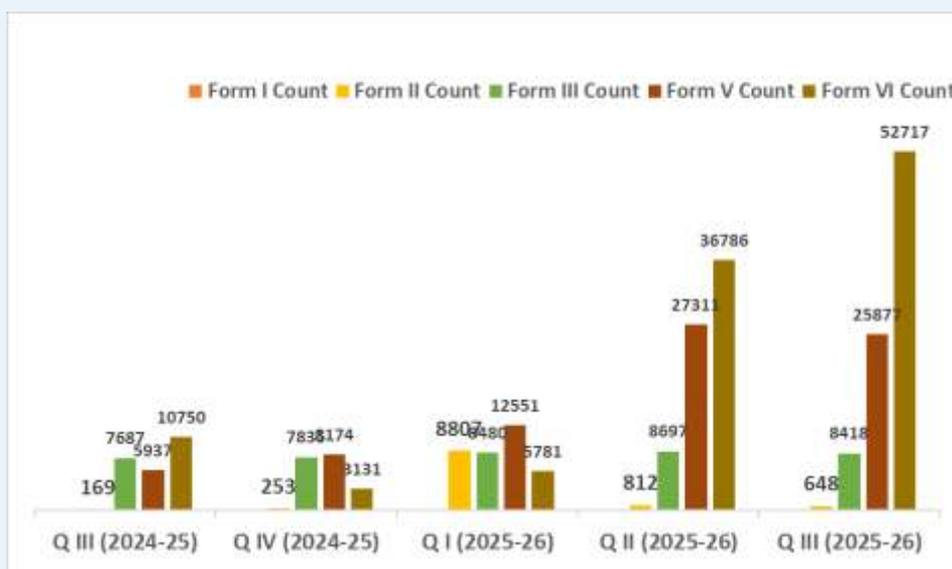


Chart 2: Forms (specified under Schedule II of DPCO, 2013) filed on IPDMS

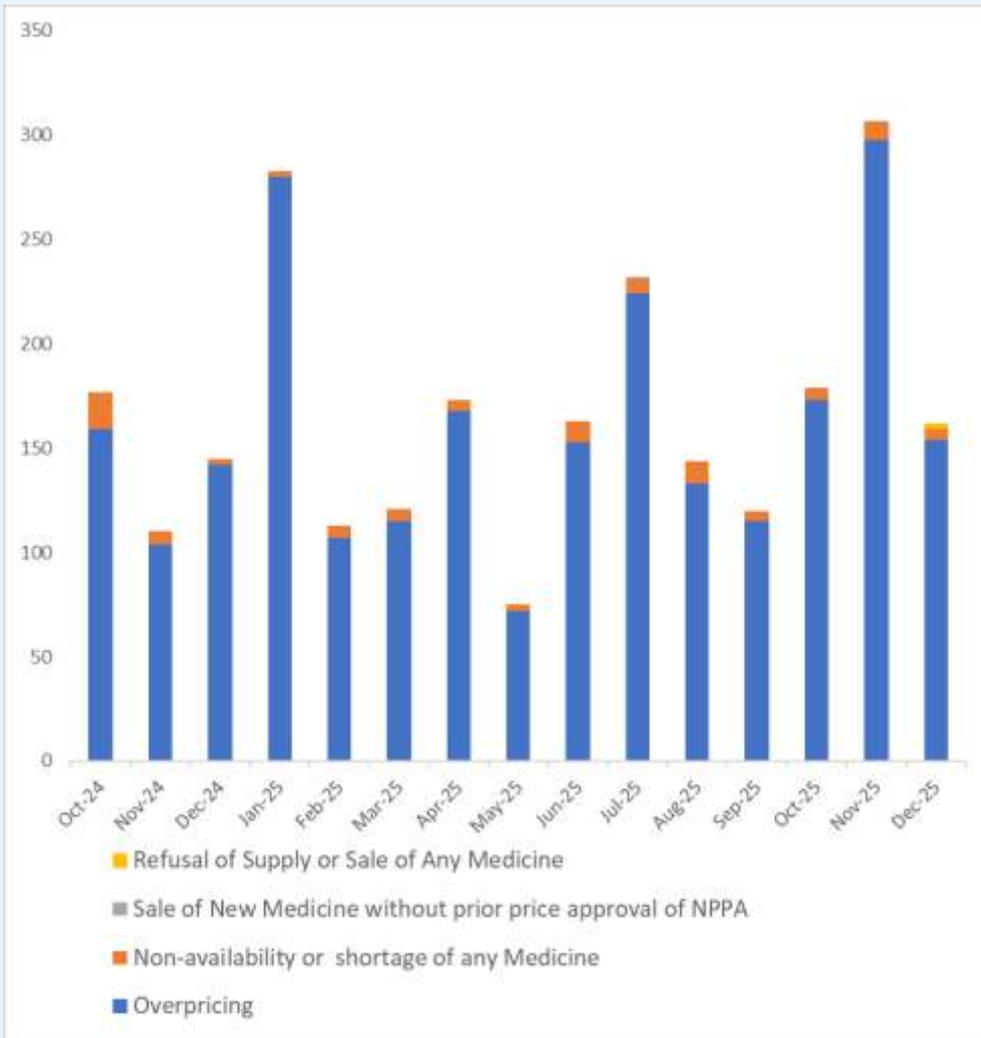


Chart 3: Number of complaints received on IPDMS / Pharma Jan Samadhan / Emails / CPGRAMS

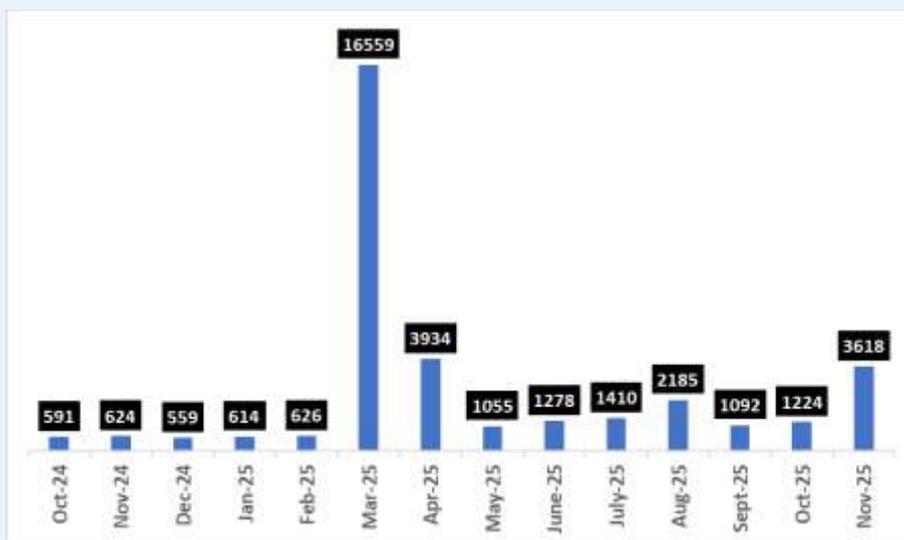


Chart 4: Number of Pharma Sahi Daam Mobile app downloads

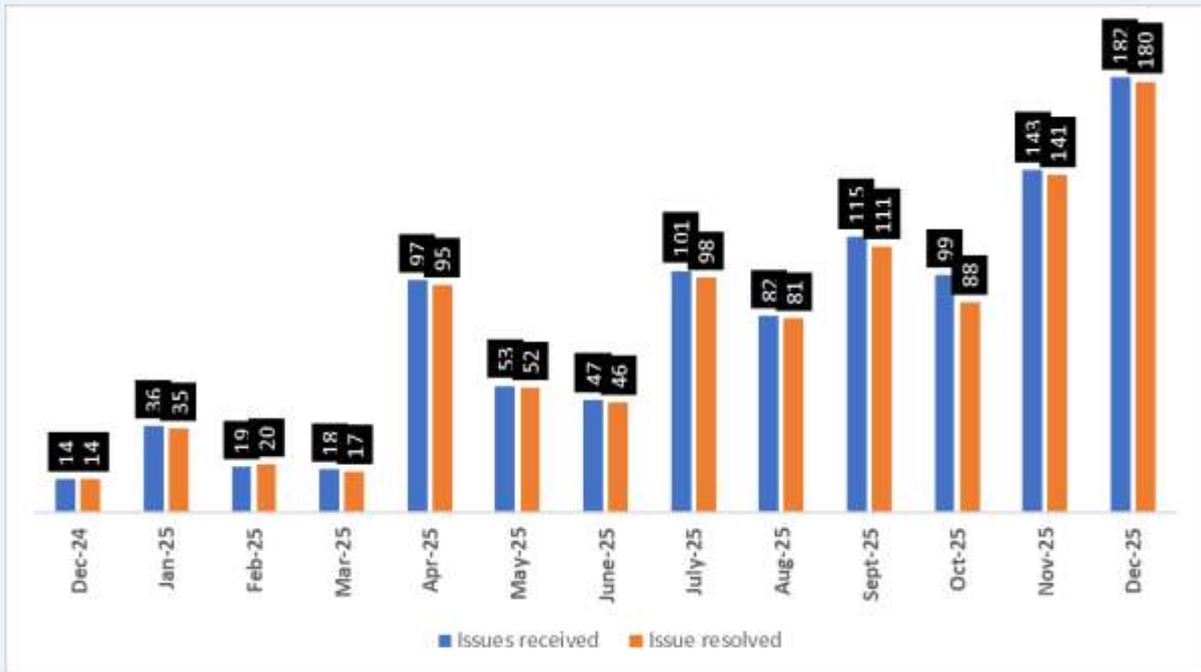
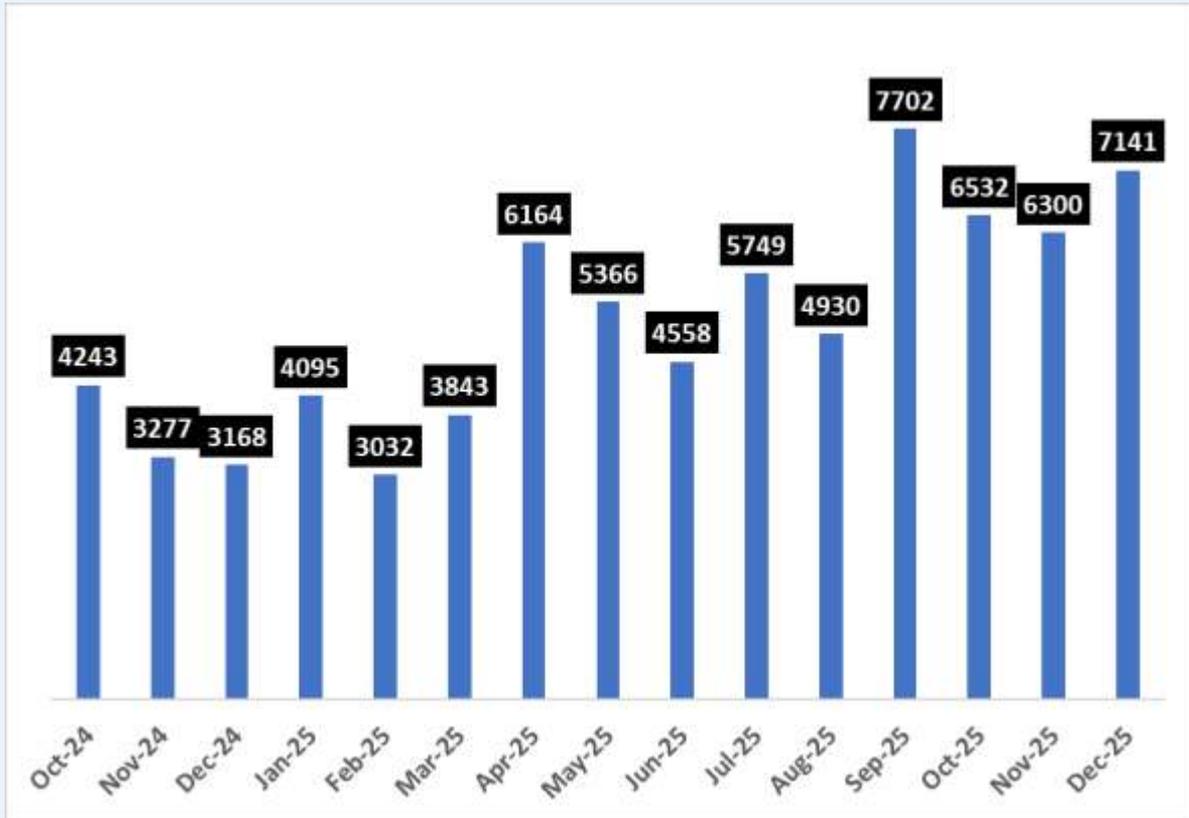


Chart 6: Issues received /resolved

FDA Approves Gene Therapy for Treatment of Spinal Muscular Atrophy (November 24, 2025)

The U.S. Food and Drug Administration approved Itivisma (onasemnogene abeparvovec-brve) for the treatment of spinal muscular atrophy (SMA) in adult and pediatric patients 2 years of age and older with confirmed mutation in the survival motor neuron 1 (SMN1) gene. Itivisma is an adeno-associated virus (AAV) vector-based gene therapy. SMA is an autosomal-recessive neurodegenerative disorder caused by mutations in the SMN1 gene, characterized by irreversible and progressive motor neuron loss, leading to progressive muscle atrophy and weakness, and subsequent paralysis and death in the most severe cases. SMA has an incidence of approximately 4-10 per 10,000 live births. Prior to the availability of effective treatment, SMA was considered one of the leading causes of infant mortality due to genetic disease in the U.S. ([Read more](#))



FDA Releases Draft Guidance on Reducing Testing on Non-Human Primates for Monoclonal Antibodies (December 02, 2025)



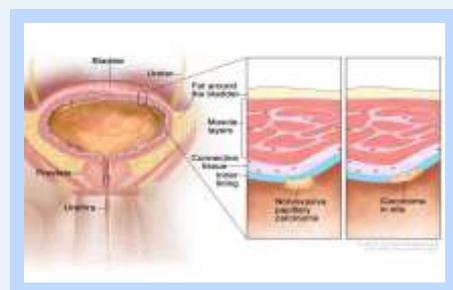
The U.S. Food and Drug Administration (FDA) issued draft guidance outlining specific product types for which the FDA believes six-month non-human primate toxicity testing can be eliminated or reduced. The guidance reflects the FDA's continued progress in modernizing nonclinical drug evaluation to make it more efficient and to reduce animal testing. In lieu of animal testing, the FDA is incorporating risk assessments that integrate human-relevant models — including computational toxicology, organoid systems, and real-world human safety data — into regulatory decision-making. ([Read more](#))

FDA Approves Nerve Scaffold for the Treatment of Sensory Nerve Discontinuity (December 03, 2025)

The U.S. Food and Drug Administration today granted approval for Avance (acellular nerve allograft-arwx) in surgical implantation. Avance is a peripheral nerve scaffold approved for sensory nerve discontinuities (< 25mm) (breaks in the pathway of sensory nerves) in adults and pediatric patients aged one month and older. Under the Accelerated Approval pathway, Avance is also approved for larger sensory nerve discontinuities (>25mm), motor and mixed nerve discontinuities. ([Read more](#))



New medicine to treat non-muscle invasive bladder cancer (12 December 2025)



EMA has recommended granting a conditional marketing authorisation in the European Union (EU) for Anktiva (nogapendekin alfa inbakicept) to treat adults with a type of bladder cancer that affects the lining of the bladder (non-muscle invasive bladder cancer, NMIBC) and that is at high risk of growing and spreading (carcinoma in situ, with or without papillary tumours). Anktiva is used when the cancer does not respond to treatment with Bacillus Calmette-Guérin (BCG), a therapy that stimulates the immune system to help treat bladder cancer. ([Read more](#))

First-in-class treatment to delay onset of type 1 diabetes (14 November 2025)

EMA has recommended granting a marketing authorisation in the European Union (EU) for Teizeild (teplizumab) to delay the onset of stage 3 type 1 diabetes in adults and in children from 8 years of age with stage 2 type 1 diabetes. Type 1 diabetes is a chronic autoimmune disease where the body's immune system destroys beta cells in the pancreas that produce insulin, a hormone that regulates blood glucose (sugar) by allowing it to move into cells to produce energy. As a result, glucose builds up in the blood and causes multiple symptoms, like thirst, hunger, frequent urination, weight loss and tiredness. Over time, it can affect major organs in the body, including the heart, blood vessels, nerves, eyes and kidneys. Patients need daily insulin injections to control their glucose levels. ([Read more](#))



Price Monitoring Resource Unit (PMRU), NPPA PMRU in Action: Highlights & Field Activities



The Price Monitoring Resource Unit (PMRU) is an extended arm of NPPA and is registered as a society. While PMRUs have already been established in 32 States/UTs to strengthen grassroots-level pharmaceutical price monitoring and to create awareness about the initiatives of NPPA for ensuring affordability and availability, the setup of PMRU in the remaining 04 States/UTs is underway. The PMRUs function under the direct supervision of the concerned state drug controllers. During the month of December 2025, several PMRUs conducted State level IEC activities.

State Level Events/Seminars by PMRUs: -

Twenty-Three (23) State and District level Events/ Seminars have been organized by 11 (Eleven) PMRUs in their respective States/ UTs, viz. Puducherry, Ladakh, Jammu & Kashmir, Goa, Chhattisgarh, Jharkhand, Uttar Pradesh, Lakshadweep, Kerala, Punjab and Tripura PMRU. These events were aimed at raising awareness among people about Fixation of Ceiling Prices under NLEM 2022 and its significance in Healthcare, Drug Price Regulations under the provisions of DPCO, 2013, Role of NPPA in making the Drugs affordable and available for all, Functions of PMRUs, Pharma Sahi Daam Mobile App and IPDMS 2.0. Major glimpses of the activities are as follows:

Glimpse of programs: -

1. Image: GOA PMRU



2. Jharkhand PMRU

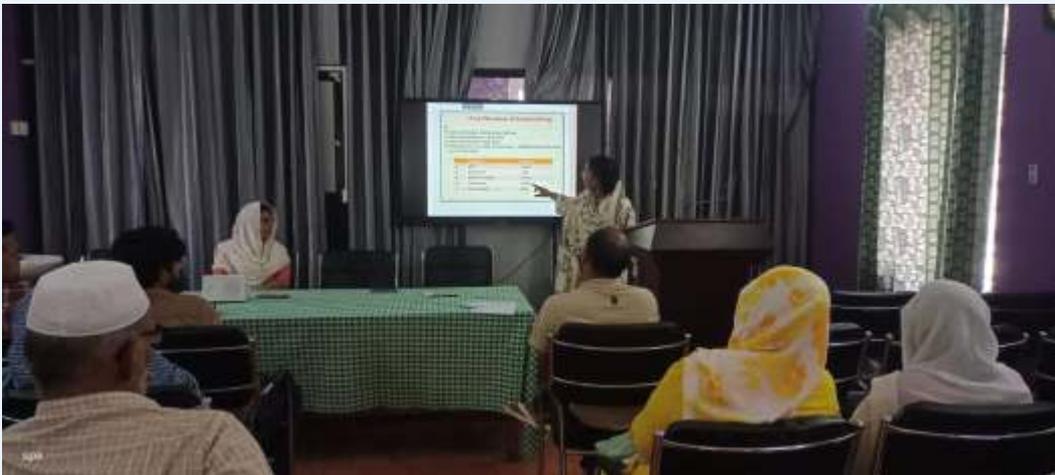


OTHER NEWS AND EVENTS

3. Ladakh PMRU



4. Lakshadweep PMRU



5. Puducherry PMRU



OTHER NEWS AND EVENTS

6. Chhattisgarh PMRU



7.J&K PMRU



OTHER NEWS AND EVENTS

8. Kerala PMRU



10. Tripura PMRU



OTHER NEWS AND EVENTS

11. Uttar Pradesh



Following is a brief on the activities carried out by PMRU Ladakh and PMRU, Puducherry

1. Ladakh PMRU: - Ladakh PMRU, established on 02 February 2022 and categorised under Category-III, operates with three staff (1 Project Coordinator, 1 Field Investigator, and 1 Data Entry Operator). The unit has been consistently engaged in Information, Education and Communication (IEC) activities and price monitoring activities. Till date, the Ladakh PMRU has conducted a total of 42 IEC activities and has reported 354 violation cases on the IPDMS portal.

In continuation of its outreach efforts, Ladakh PMRU conducted an IEC activity in collaboration with the Drug Regulatory Department, Union Territory of Ladakh, and organised a District Level Awareness Program at Government Higher Secondary School, Kargil, to disseminate general awareness regarding the Monitoring Prices of Medicines. Additionally, the team promoted initiatives such as Pharma Sahi Daam and Pharma Jan Samadhan.





2. Puducherry PMRU: - The Puducherry PMRU, registered on 29 October 2021 and placed under Category-III, functions with a two-staff (1 Project Coordinator, 1 Field Investigator). The unit continues to play a crucial role in pharmaceutical price monitoring, consumer awareness, and facilitating compliance with the NPPA's regulatory framework across the Union Territory. The Puducherry PMRU has undertaken a total of 88 IEC activities and has reported 535 violation cases on the IPDMS portal till date.

In its recent IEC initiatives, Puducherry PMRU conducted a District Level Awareness Program at Dr Sarvapalli Radhakrishnan Govt Arts College, Yanam, Puducherry. The program aimed to create awareness on ensuring the affordability and availability of essential medicines.





FAQ on Biosimilars

1. What are biologics and biosimilars ?

Answer :A biologic drug (biologics) is a product that is produced from living organisms or contains components of living organisms. Biologic drugs include a wide variety of products derived from human, animal or microorganisms using biotechnology.

Biosimilars are biological medicines that are highly similar to an already approved biological (reference) product in terms of quality, safety and efficacy. Biosimilars are not exact copies (unlike generics of small-molecule drugs) due to the inherent complexity of biologics as they have derived from living systems (<https://www.birac.nic.in/nbm/cms/page/biosimilar-products>)

2. Why are biosimilars a key focus area for India?

Answer: India has undergone a rapid epidemiological transition from infectious diseases to chronic non-communicable diseases (NCDs), many of which require biologic therapies for optimal management. Most advanced treatments for these conditions rely on biologics, which are expensive and often required long-term. Biosimilars are cost effective with improved affordability and treatment continuity once patents on originator biologics expire. India focuses on biosimilars as a cost-effective solution for delivering biologic therapies to its large population, addressing widespread chronic diseases, limited health-insurance coverage, and leveraging the country's strong biotech capabilities.

<https://gco.iarc.who.int/media/globocan/factsheets/populations/356-india-fact-sheet.pdf>

3. Which Indian authorities regulate biosimilars?

Answer: i.The Central Drugs Standard Control Organisation (CDSCO) under the Ministry of Health & Family Welfare is the national regulator responsible for approval of clinical trials, marketing authorisation and regulatory oversight of biosimilars.

ii.The Department of Biotechnology (DBT) under the Ministry of Science & Technology collaborates in setting the scientific framework for biological products.

4.Which guideline governs approval of biosimilars in India?

Answer: Approval of biosimilars in India is governed by the 'Guidelines on Similar Biologics', notified by CDSCO and DBT. These guidelines define requirements for quality, safety, efficacy, comparability studies, clinical trials, and post-marketing surveillance.

5.What is the government's vision for India's bio-manufacturing sector?

Answer : The Government aims to make India a leading global player in bio-manufacturing and the broader bioeconomy, driving innovation, sustainability, and economic growth. India's bioeconomy has already expanded rapidly and is targeted to grow from about \$165.7 billion in 2024 to \$300 billion by 2030, contributing significantly to GDP and employment

6. What is the BioE3 Policy?

Answer :BioE3 — Biotechnology for Economy, Environment and Employment is a national policy framework approved by the Union Cabinet to propel India's bio-manufacturing ecosystem and accelerate innovation-driven biotechnology development. It has been formulated under the Department of Biotechnology (DBT), Ministry of Science & Technology, with the goal of making biotechnology a key driver of economic growth, sustainability, and job creation in India. It promotes regenerative biomanufacturing and supports a circular bioeconomy aligned with India's net-zero goals.

7. What is the National Biopharma Mission (NBM)?

Answer : The National Biopharma Mission (NBM) is a Cabinet-approved, industry–academia collaborative mission launched by the Department of Biotechnology (DBT), Ministry of Science & Technology, Government of India, with support from the World Bank (\$250 million). It is formally titled “Innovate in India (i3): Empowering biotech entrepreneurs & accelerating inclusive innovation”. The mission is implemented through the Biotechnology Industry Research Assistance Council (BIRAC)

8. How do government initiatives strengthen India's biosimilar ecosystem?

Answer: Several government missions and schemes support the biosimilar ecosystem by funding research, infrastructure, and manufacturing capabilities:

- i. National Biopharma Mission (NBM) — supports development of biosimilars and biopharmaceutical products.
- ii. Promotion of Research & Innovation in Pharma MedTech (PRIP) — provides financial assistance for complex generics and biosimilars.
- iii. PLI Scheme for Pharmaceuticals — incentivises domestic biopharmaceutical manufacturing (including biosimilars).

9. What are some of the Biosimilars developed under NBM

Answer: Some of the NBM-Supported Biosimilars are as under: Insulin Glargine, Liraglutide, Insulin Lispro, Trastuzumab, Aflibercept, Ranibizumab, Ustekinumab, Human Serum Albumin; plus ongoing clone development for Ramucirumab, Golimumab and Factor VIII.

10. What is the current global environment for biosimilars?

Answer: Globally, biosimilars are increasingly being adopted as safe, effective, and affordable alternatives to originator biologics. Over the past decade, many countries have established regulatory pathways for biosimilar approval, and biosimilars are now widely used in therapeutic areas such as oncology, diabetes, autoimmune diseases, and growth disorders. The global biosimilar market is growing rapidly due to patent expiries of originator biologics, increasing healthcare costs, and rising demand for accessible biologic therapies. Regulatory bodies such as the WHO, US FDA, and EMA provide harmonized, science-based guidance on biosimilar development, comparability, and pharmacovigilance, fostering global regulatory convergence, reducing development uncertainty, and enabling broader adoption of biosimilars. These frameworks support market entry across regions and expand patient access to affordable biologic therapies worldwide.



REFLECTIONS AND CONTRIBUTIONS

Staff Spotlight" is a dedicated corner of this newsletter that highlights the thoughts, experiences, and efforts of the staff of NPPA. This section brings attention to the diverse voices and talents across our organization.

This Month's Feature-

हिंदी पखवाड़ा में द्वितीय पुरुस्कार विजेता के द्वारा स्वरचित कविता पाठ



चंचल कटारिया
(वाई.पी.) द्वारा

"अधूरी रह गई गोद " (एक माँ की चुप्पी में छुपा संसार)

जब पहली बार तु किलकारी लाई,
माँ की सूनी आँखों में चमक सी छाई ।
पर सबको बस वारिस की आस थी,
माँ ही थी जो तुझमें सारा जहाँ देख पाई ।
लोगों की बातें चुभती रही,
बेटी हुई है कहकर मुस्काने छिनली ।
पर माँ ने ओढ़ ली चुप्पी की चादर,
तेरे लिए हर ताना सह लिया बे असर ।

तेरे पहले स्पर्श में जीवन था,
माँ के सूबे आंचल में सावन था।
तेरे रोने की आवाज में संगीत था,
पर तेरे मुस्काने में माँ की प्रीत था
रातों को जब तू बुखार में तपती,
माँ आँखों में नीद की जगह दुआ भरती ।
तेरी हर आहट पर भाग के आती,
खुद भूखी रहकर तुझको खिलाती ।

तेरी स्कूल की पहली सुबह ,
तेरी तेरी आँखों में डर, माँ की पलकों में बाड़
तेरा हाथ पकड़ मुस्कुरा दी थी
पर लौट के रोई यते अकले - बिना आवाज
तेरे किशोर मन के उलझे सवाल,
माँ समझती रही, पर रह गई बेहाल।
तेरी उलझनों में खुद को छुपाया,
हर उत्तर बन, तुझे राह दिखाया।

जब तू बड़ी हुई, सपने संजोने लगी,
माँ की ममता अब छोड़ा पीछे रही।
तेरे हट निर्णय में वो मौन थी ,
उस दिल में तू ही उसकी कौन थी।
फिर आया वो दिन- चुभन से भरा ,
तेरी शादी का मंडप, माँ का तन्हा सवेरा ।
भीड़ थी, बाजे थे मुस्काने थी,
पर काँ की आँखों में ठहरी बरसातें थी ।

तेरी विदाई के घड़ी, वो रोई नहीं,
पर हर आशीर्वाद में टूटी कहीं ।
तेरे पायल की रुनझुन जब दूर हुई,
माँ की दुनिया भी उसी पल अधूरी हुई ।
तू चली गई, वो थम गई,
तेरी खिलखिलाहट के बिना, हर चीज गुम गई।
तू ससुराल में खुश है, वो जानती है
पर हर रात तेरे बिना चुपचाप से साती है
माँ का प्रेम बोलता नहीं - बस बहता है, उसकी पीड़ा
आँखों में नहीं , आत्मा से झलकती है
वो कुछ नहीं कहती वही जबसे अधिक सहती है।





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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