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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दवा वही
दाम सही

Committed Towards Accessibility, Availability & Affordability of Medicines for All

## 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 and NLEM-2022 as amended vide S.O. 5249 dated 11.11.2022 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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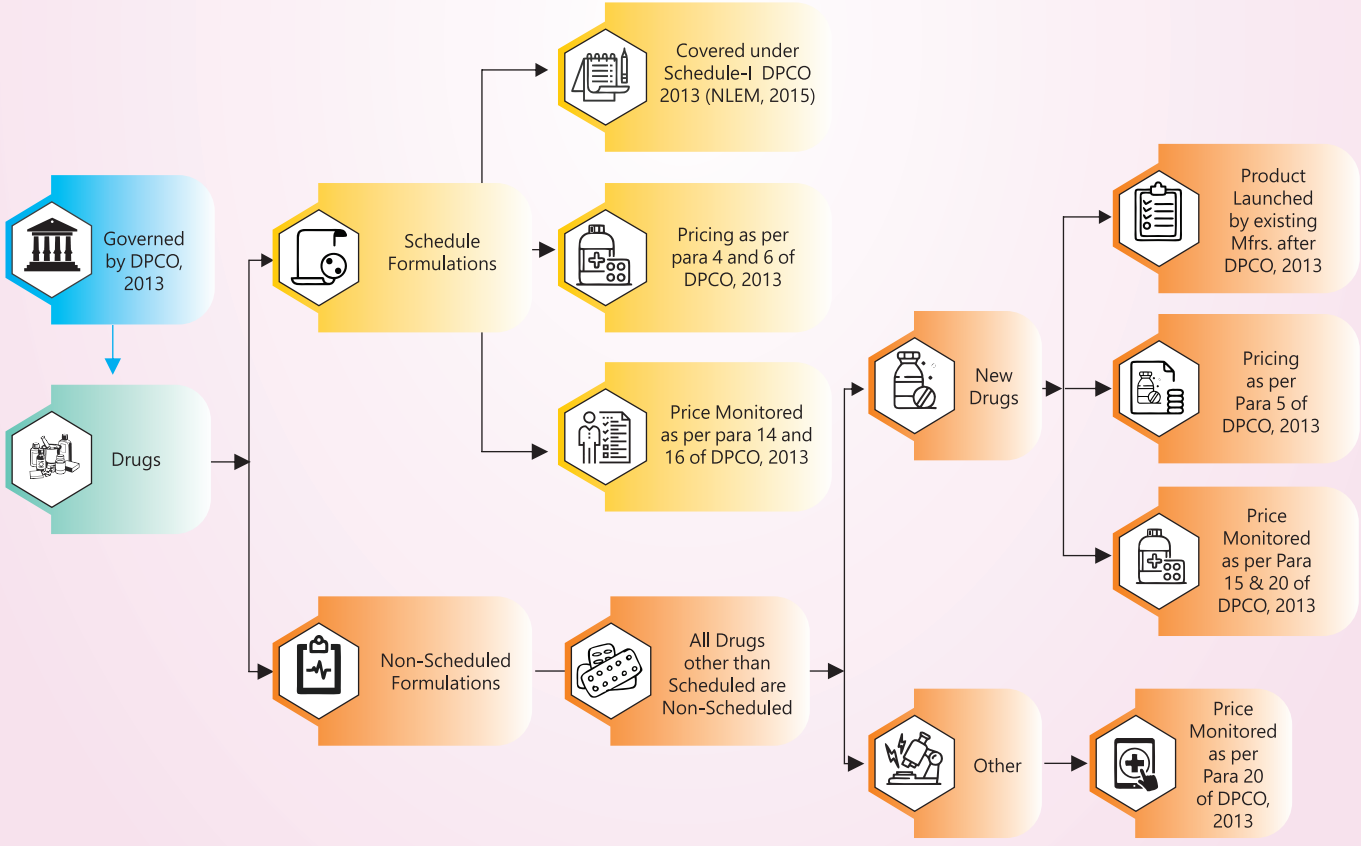




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# From CHAIRMAN'S DESK

सत्यमेव जयते

**P. Krishnamurthy,** IAS
Chairman
National Pharmaceutical Pricing Authority
Department of Pharmaceutical
Ministry of Chemical and Fertilizers
Government of India

It is my pleasure to present the XXVII edition of Aushadh Sandesh, which brings together insightful perspectives on emerging themes at the intersection of health, science, and public policy.

In this issue, an expert article - Neuroeconomics and the Science of Happiness: Rewiring the Neural Substrate for Optimal Well-Being', explores the evolving field of neuroeconomics and its relevance to human well-being, highlighting how insights from neuroscience and behavioral economics can help individuals make better decisions that promote long-term happiness and resilience.

The issue also features an in-house article-'Biopharmaceuticals: India's Path to Equitable Healthcare', which highlights the growing importance of biopharmaceuticals and biosimilars in strengthening healthcare access. With the announcement in the Union Budget 2026–27 of the 'Biopharma SHAKTI (Strategy for Healthcare Advancement through Knowledge, Technology, and Innovation) mission', supported by a ₹10,000 crore outlay to position India as a global biopharma manufacturing hub, the article examines how policy support, regulatory oversight, and price regulation are collectively shaping India's transition from generics to complex biologics while ensuring affordability for patients.

In addition, the issue includes another important article- 'Alzheimer's Disease Control and Affordable Care in India: Current Status and Policy Perspectives', which is a comprehensive analysis of Alzheimer's disease in India, and discusses the rising disease burden associated with demographic ageing, the challenges of diagnosis and long-term care, and the policy and fiscal measures being undertaken to improve accessibility and affordability of treatment.

Together, these contributions underscore the importance of integrating scientific innovation, behavioral understanding, and sound public policy to advance equitable and affordable healthcare for all.

In continuation of our PMRU activities, Twenty-Nine (29) State and District level Events/Seminars have been organized by 12 (Twelve) 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 gratitude to the authors for their interesting articles and my best wishes to the readers for an informative experience.

NPPA wishes good health to all its readers - सर्वे सन्तु निरामयाः ।

With best wishes

**(Shri P .Krishnamurthy)**

# Neuroeconomics and the Science of Happiness: Rewiring the Neural Substrate for Optimal Well-Being

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**ABSTRACT :** This research integrates neuroeconomics and positive psychology to optimize well-being by "rewiring" the brain's valuation circuits. Failures in flourishing often stem from temporal discounting, where the dorsolateral prefrontal cortex (dlPFC) fails to regulate the ventromedial prefrontal cortex (vmPFC) during decision-making. To counter this, "Internal Rewiring" leverages neuroplasticity via mindfulness and Episodic Future Thinking to strengthen self-regulation and future-value encoding. Simultaneously, "External Rewiring" utilizes behavioral "nudges" and commitment devices to engineer environments that bypass impulsive choices. By synthesizing these cognitive and architectural strategies, individuals can systematically correct valuation errors, fostering consistent decisions that prioritize eudaimonic meaning and long-term flourishing.

**Keywords:** Neuroeconomics, Temporal Discounting, Delayed Gratification, Eudaimonia, Prefrontal Cortex.

## I. Introduction

### A. The Paradox of Modern Happiness

Contemporary society faces a central paradox: despite unprecedented material wealth, global happiness levels such as those in Japan and India remain strikingly low. This suggests that well-being is not governed by wealth, but by neural principles that often clash with modern lifestyles.

### B. Neuroeconomics as a Solution

Neuroeconomics combines economics, psychology, and neuroscience to provide a mechanistic understanding of how we value choices. It identifies two critical constructs:

1) **Decision Utility:** The value we infer from making a choice (what we **think** we want).
2) **Experienced Utility:** The actual hedonic or affective value we feel from an outcome (what actually makes us happy).

A primary cause of unhappiness is the divergence between these two; individuals often choose options that do not maximize their actual well-being.

### C. The Neural Substrate of Well-Being

a) **Core Brain Regions -** Happiness is not a single "spot" in the brain but an integration of reward, control, and social systems. Key regions include:

1) **Ventromedial Prefrontal Cortex (vmPFC):** Computes the "subjective value" of different options, acting as a "common currency" for rewards like food, money, or social status.
2) **Dorsolateral Prefrontal Cortex (dlPFC):** The center for self-control and long-term planning. It modulates value signals in the vmPFC to help us choose long-term "flourishing" over immediate "pleasure".
3) **Ventral Striatum:** Involved in anticipatory reward and motivation.

### D. The Failure of Temporal Discounting

Failures in well-being are often linked to temporal discounting the tendency to devalue future rewards in favor of immediate ones. Neurally, this occurs when the dlPFC fails to exert enough functional control over the vmPFC, leading to impulsive choices that undermine long-term stability.

## II. The Internal Rewiring Protocol

"Rewiring" involves leveraging neuroplasticity to strengthen the pathways that prioritize long-term well-being.

### A. Cognitive Strategies (Internal Rewiring)

1) **Episodic Future Thinking (EFT):** By vividly imagining positive future outcomes, individuals can boost the vmPFC's encoding of future rewards, making them more "real" and competitive against immediate temptations.
2) **Mindfulness Training:** These practices strengthen the dlPFC, allowing for better self-regulation and a reduced emotional reaction to impulsive cues.
3) **Positive Psychology:** Activities like gratitude and savoring alter functional connectivity in the brain's reward circuits to increase the subjective value of prosocial and future-oriented options.

### B. Neuromodulation

1) **Neurofeedback (NF):** This non-invasive technique provides real-time data on brain activity, allowing individuals to volitionally "train" regions like the amygdala or prefrontal cortex to improve emotional regulation.

**Table-1: Internal vs. External Rewiring Strategies**

| Feature | Internal Rewiring (Cognitive) | External Rewiring (Architectural) |
|---|---|---|
| Primary Mechanism | Leverages **neuroplasticity** to change how the brain processes value. | Modifies the **choice environment** to simplify decision-making. |
| Neural Focus | Strengthens the **dlPFC-vmPFC** pathway and future-reward encoding. | Reduces the cognitive load and "willpower" required from the **dlPFC.** |
| Key Techniques | Mindfulness, Episodic Future Thinking (EFT), and cognitive reappraisal. | Nudges, default options, and pre -commitment devices. |
| User Effort | High initial effort; requires consistent practice to build mental "muscle." | Low effort; relies on setting up a system once to guide future behavior. |
| Outcome | Improved **internal regulation** and resilience against impulsive cues. | Mitigation of **hyperbolic discounting** through environmental design. |

## III. The Neurochemistry of Happiness (Dopamine vs. Serotonin)

True well-being requires understanding the difference between "wanting" and "liking".

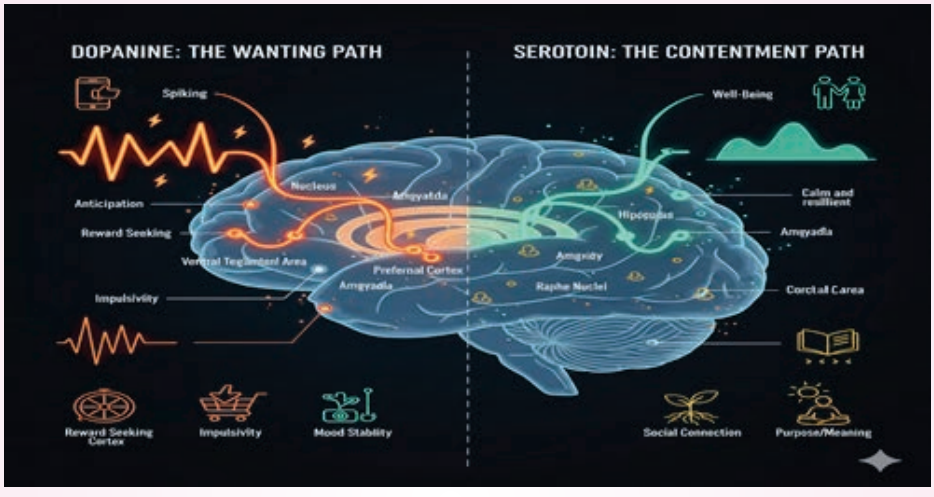
### A. The Dopamine Trap

1) **Function:** Dopamine is the chemical of anticipation and pursuit (wanting), not pleasure itself.
2) **The Trap:** Modern stimuli like social media "likes" and online shopping hijack this system. Constant chasing leads to the Hedonic Treadmill, where the "wanting" system is overactive but the actual "liking" system becomes numb, resulting in chronic stress and dissatisfaction.

### B. The Serotonin Path (Eudaimonia)

1) **Function:** Serotonin is the chemical of contentment and stability (Eudaimonia).
2) **Social and Purposeful:** It rewards social connection and meaningful contribution to a "tribe". High serotonin levels create a calm, resilient state that is less susceptible to the "ups and downs" of immediate rewards.

**Figure-1: Image comparing dopamine and serotonin pathways in the brain**




## IV. Implementation

### A. External Rewiring: Choice Architecture

Rather than relying solely on high-effort self-control, "External Rewiring" uses behavioral economics to optimize the environment.

1) **Nudges and Defaults:** Designing choices so the "well-being" option is the easiest or automatic choice.
2) **Commitment Devices:** Using tools to "lock in" future-oriented behaviors, bypassing the need for constant willpower.

### B. The Biological Levers for Serotonin

Individuals can actively boost their serotonin baseline through three primary physical interventions:

1) **Movement:** Moderate cardio exercise signals "productive survival behavior" to the brain.
2) **Sunlight:** Morning light exposure activates the brain's serotonin production centers (Raphe Nuclei).
3) **Gut Health:** Over 90 percent of the body's serotonin is produced in the gut; a diet rich in fiber and fermented foods supports this production.

## V. Conclusion

Rewiring the brain for happiness is a "plausible and empirically tractable goal". By treating well-being as a computational outcome and using both internal cognitive shifts and external environmental changes, individuals can move from the "frantic buzz" of dopamine to the "warm glow" of sustained eudaimonic flourishing.

# Biopharmaceuticals: India's Path to Equitable Healthcare

(By NPPA Team)

## Introduction:


The Union Budget 2026–27 announced the Biopharma SHAKTI (Strategy for Healthcare Advancement through Knowledge, Technology, and Innovation) mission to develop India as a global biopharma manufacturing hub and capture 5% of the global biopharmaceutical market share. With a □10,000 crore allocation over five years, the government aims to build the ecosystem for domestic production of biologics & biosimilars with special emphasis on non-communicable diseases (cancer, diabetes, autoimmune disorders). The priority areas include: establishing a nationwide network of accredited clinical trial sites for faster, more reliable drug testing; and strengthening human resource capacity through the creation of 3 new National Institutes of Pharmaceutical Education and Research (NIPERs) along with the upgradation of 7 existing NIPERs to address the growing requirement for specialised expertise in the biopharma sector.

## Understanding Biopharmaceuticals:

Biological therapeutics, commonly known as Biologicals or Biologics, are derived from natural and living sources, such as human, animal and plant cells, and microorganisms such as bacteria or yeast. Biologics can be composed of sugars, proteins, nucleic acids, or complex combinations of these substances and in some cases, may be living entities themselves, such as cells and tissues. Biological products include vaccines, blood and blood components, allergenics, somatic cells, gene therapies, tissues, and recombinant therapeutic proteins. [1,2]

Biological products are intended to treat, prevent or diagnose a wide range of medical conditions including chronic skin diseases, inflammatory bowel diseases, arthritis, kidney conditions, diabetes and cancer. They have revolutionized the treatment of many diseases, particularly chronic conditions linked to an overactive immune system or impaired immune surveillance.

Compared with conventional drugs, biologics often deliver superior clinical outcomes. However, challenges such as the expiry of patents and marketing exclusivities of innovator biologics, along with high cost, have driven the development of biosimilars.

Biosimilars are the biological products which is similar in terms of quality, safety and efficacy to the Reference Biological Product (RBP) licensed or approved in India, or any innovator product approved in International Council of Harmonisation (ICH) member countries.[3] Biosimilars are produced from the same types of sources (e.g., living organisms) and are given through the same dose & route of administration as the reference product. Biosimilars offer the same potential treatment benefits & similar potential side effects.[4]

## Beyond Generics: The Complexity of Biosimilars:

Generic drugs and biosimilars differ fundamentally in their nature and development. Generic drugs are

low–molecular weight compounds with simple, well-defined chemical structures that can be fully characterized and reproduced through chemical synthesis. Because their molecular structures are precisely known, they can be reproduced exactly through chemical synthesis, allowing manufacturers to create identical copies of the original drug once the patent expires. For instance, Paracetamol (also known as Acetaminophen) is a small-molecule drug that can be produced through chemical synthesis based on its known chemical formula $C_8H_9NO_2$. As a result, generic versions of such drugs are chemically identical to the reference product and are expected to have the same quality, safety, strength, dosage form, and therapeutic effect.

In contrast, biosimilars are high–molecular weight molecules with complex structures and potential for structural variation, making them more difficult to characterize. Their development and manufacturing are far more intricate than those of conventional drugs because biologics are produced using specialized biological processes rather than chemical synthesis. As a result, they are more difficult to purify and control, are sensitive to storage and handling conditions, and may carry a higher potential for immunogenicity compared to generic drugs.

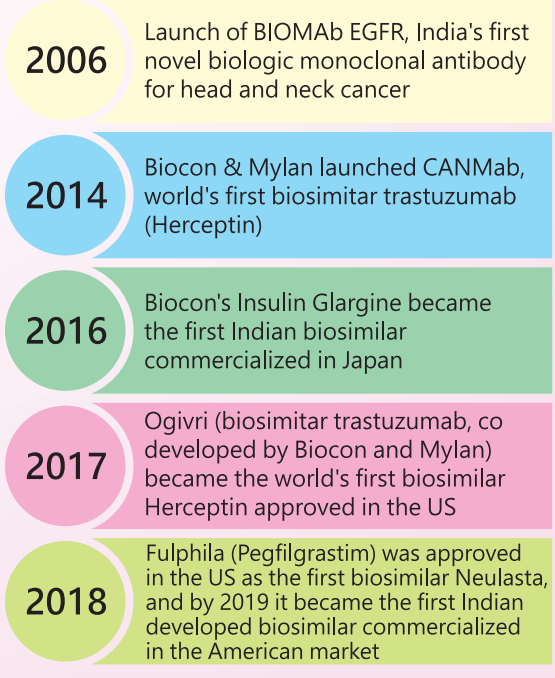
This difference stems from the nature of biologics themselves. Biologic medicines are produced using living organisms, which introduces inherent natural variability and results in slight batch-to-batch differences, even in the original reference product.[2] Manufacturing complexity also varies across biologics; for example, producing large molecules such as monoclonal antibodies (approximately 145,000–160,000 Daltons) is considerably more complex than manufacturing smaller biologics like insulin or certain hormones (around 6,000 Daltons). Because of this complexity, biosimilars are highly similar, but not identical products, to their reference biologic product & cannot be considered as simple "generic" versions of biologics.[5]

To safeguard patient safety and ensure therapeutic equivalence, biosimilars undergo a rigorous regulatory evaluation based on the "totality of evidence" approach. This stepwise process integrates extensive analytical characterization, functional studies, nonclinical data, pharmacokinetic and pharmacodynamic assessments, immunogenicity testing, and, where necessary, clinical studies. A product can only be considered a biosimilar if sufficient structural, functional, nonclinical, and clinical evidence collectively demonstrates that there are no clinically meaningful differences between the similar biological product and its reference biologic in terms of safety, purity, and potency.[4]

**India's Journey in Biosimilars- Milestones:**

India, being a global leader in manufacturing affordable, safe, and efficacious generic medicines, has steadily transitioned into biopharmaceuticals. The advent of humanized insulin in the 1980s marked the dawn of a new era in the pharmaceutical industry, paving the way for biologic therapies. Building on this foundation, India achieved several milestones.[6]

By January 2025, India had emerged as one of the largest biosimilar markets among developing nations, with over 135 approvals granted.[7] The country's biosimilar portfolio has grown from foundational biologics such as erythropoietin and filgrastim to advanced therapies including monoclonal antibodies. Indian companies not only dominate the domestic market but also play a significant role internationally, exporting biosimilars to many countries. Through strategic partnerships and co



development agreements, they have successfully entered highly regulated markets, reinforcing India's position as a global hub for affordable biopharmaceuticals.

**Regulatory Framework for Biosimilars in India**

Central Drugs Standard Control Organization (CDSCO) serves as India's national regulatory authority, responsible for evaluating the safety, efficacy, and quality of drugs across the country. CDSCO, in collaboration with the Department of Biotechnology (DBT), published the first set of guidelines in 2012 titled "Guidelines on Similar Biologic – Regulatory Requirements for Marketing Authorization in India." These guidelines laid out the regulatory pathway for manufacturing processes and quality standards. They were subsequently revised in 2016 to reflect evolving scientific and regulatory practices.

Most recently, in 2025, CDSCO released a draft of revised guidelines to further strengthen India's biosimilar framework, ensuring alignment with global standards while addressing new challenges in biopharmaceutical innovation. Further, Pharmacovigilance systems such as PvPI ensure long term safety monitoring. [4]

**Price Regulation of Biopharmaceuticals under DPCO, 2013**

National Pharmaceutical Pricing Authority (NPPA) under Department of Pharmaceuticals (DoP), Ministry of Chemicals and Fertilizers fixes the ceiling price of the scheduled medicines specified in the first schedule of the Drugs (Price Control) Order, 2013. The drugs listed in the National List of Essential Medicines (NLEM) by the Ministry of Health & Family Welfare are notified as Schedule-I of DPCO by DoP and are considered as scheduled drugs. The prices of scheduled drugs are regulated by fixing their ceiling prices and all the manufacturers of scheduled medicines (branded or generic) have to sell their products within the ceiling price (plus applicable Goods and Services Tax). This ensures availability of essential drugs at affordable prices.


Although drugs in the NLEM are not specifically categorized based on biologics or biosimilars, many biopharmaceutical drugs that are essential for public health are included in the NLEM and NPPA has fixed the ceiling prices of such drugs.

Currently, Schedule I of the DPCO, 2013 includes traditional biologics, specifically immunologicals such as sera, vaccines, and immunoglobulins, which are central to preventive and therapeutic interventions in human health. NLEM 2022 also includes vaccines for veterinary use. Further, the list also includes Tuberculin purified protein derivative (PPD) as a diagnostic agent for tuberculosis, marking an important addition in the diagnostic landscape.

Beyond traditional biologics, NLEM expands into advanced therapies by incorporating monoclonal antibodies such as Rituximab and Trastuzumab, along with other anticancer agents. This addition reflects the evolving landscape of cancer treatment and aligns with efforts to enhance access to innovative oncology therapies.

In the area of endocrinal and hormonal agents, the NLEM includes multiple forms of insulin such as soluble

insulin, intermediate acting insulin (NPH), insulin glargine, and premix insulin 30:70 (Regular + NPH), as well as human chorionic gonadotropin (hCG) injection, ensuring comprehensive coverage for diabetes and reproductive health.

Additionally, NLEM 2022 includes a broad spectrum of blood products and medicines affecting blood, including erythropoietin injection, fresh frozen plasma, platelet rich plasma or platelet concentrates, packed red blood cells, whole blood, coagulation factors and cryoprecipitate.

Together, these inclusions highlight the comprehensive nature of NLEM 2022, ensuring that essential biologics across diverse therapeutic areas, from infectious diseases and diagnostics to oncology, diabetes, reproductive health, haematology and transfusion medicine are available at affordable prices, thereby strengthening public health outcomes and accessibility for patients.

NPPA has also fixed the retail prices for various biologic & biosimilar 'new drugs', as defined under Section 2(1)(u) of DPCO, 2013, including recombinant human Erythropoietin Injection, Docaravimab + Miromavimab Injection & Recombinant Rabies G Protein Vaccine. The retail prices, so fixed by NPPA are applicable only to the applicant manufacturing/ marketing companies.

Furthermore, all price notifications for the formulations whose prices have been fixed by NPPA are available on the NPPA website, **www.nppa.gov.in.** Any person can also search the price of the scheduled formulations using the tool 'Search Medicine Price' available on the website of NPPA or through the Mobile App 'Pharma Sahi Daam'.

## Conclusion

To sum up, India's biopharmaceutical sector is steadily advancing with the launch of the Biopharma SHAKTI mission, expanded clinical trial infrastructure, and strengthened academic capacity. These initiatives build on the country's established role as a major global supplier of vaccines to UNICEF and WHO, while supporting the transition from generics to complex biologics and biosimilars. By combining affordability through price regulation, innovation in biologics, and growing expertise in biosimilars, India is enhancing healthcare access domestically and contributing meaningfully to global public health.

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# Alzheimer's Disease Control and Affordable Care in India: Current Status and Policy Perspectives

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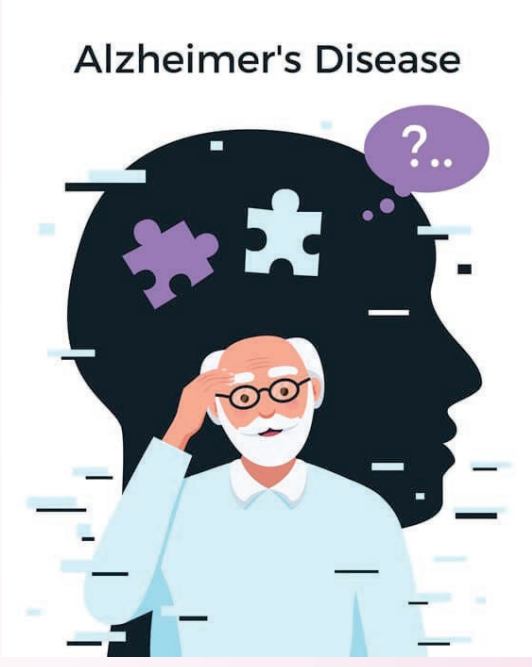
**Abstract**

Alzheimer's disease (AD) is a chronic, progressive neurodegenerative disorder and the leading cause of dementia globally, accounting for a substantial proportion of cognitive impairment in the elderly population. With increasing life expectancy and rapid demographic ageing, particularly in low- and middle-income countries such as India, the prevalence of Alzheimer's disease is rising steadily, posing significant public health, economic, and social challenges. The disease is associated with long-term healthcare needs, escalating treatment costs, and considerable caregiver burden, often extending beyond the capacity of existing health systems.




In addition to clinical management, critical issues related to affordability, accessibility, regional disparities, and health system preparedness strongly influence disease outcomes. In India, limitations in epidemiological data, uneven diagnostic infrastructure, and inadequate access to specialized care, especially in rural and underserved regions, further exacerbate the burden of Alzheimer's disease. High out-of-pocket expenditure on long-term therapy and supportive care remains a major barrier to equitable treatment.

This article examines the evolving burden of Alzheimer's disease in India, highlights gaps in data collection and service delivery, and discusses the emerging rural care crisis and affordability challenges. It also analyses key government initiatives, regulatory measures, and fiscal interventions, including price regulation, tax relief, and public health programs, aimed at improving access to affordable and quality care for Alzheimer's disease. Strengthening policy frameworks, enhancing early diagnosis, and ensuring affordable access to essential therapies are crucial to mitigating the growing impact of Alzheimer's disease in India.

## 1. Burden of Alzheimer's Disease and Rising Alzheimer's Disease Cases

Alzheimer's disease (AD) accounts for approximately 60–70% of all dementia cases worldwide, making it the most common cause of cognitive decline among older adults. The rapid rise in Alzheimer's disease prevalence is closely associated with increased life expectancy, demographic transition, and population ageing, particularly in low- and middle-income countries. According to global estimates, the number of people living with dementia is expected to more than triple by 2050, with a substantial proportion of this increase occurring in Asia, including India.

In the Indian context, Alzheimer's disease is emerging as a major public health challenge. Current estimates suggest that several million Indians are already affected by dementia, and this number is projected to increase sharply in the coming decades due to improved survival rates and a growing elderly population. Unlike many communicable diseases, Alzheimer's disease requires long-term, continuous care, often extending over several years, which significantly strains both household resources and the healthcare system. The burden of Alzheimer's disease extends far beyond direct medical costs. Families frequently bear the responsibility of caregiving, leading to loss of productivity, emotional stress, and financial hardship. Informal caregivers, often women, may be forced to reduce or abandon employment, resulting in indirect economic losses. In addition, the progressive nature of the disease leads to increasing dependency, necessitating assistance with daily activities, supervision, and eventually full-time care.

From a societal perspective, the rising burden of Alzheimer's disease has serious economic and social implications, including increased healthcare expenditure, demand for long-term care facilities, and pressure on social welfare systems. In the absence of timely diagnosis, affordable treatment options, and supportive public health interventions, Alzheimer's disease risks becoming a silent epidemic, disproportionately affecting vulnerable populations and widening existing healthcare inequities. Addressing this growing burden requires a coordinated strategy encompassing early detection, affordable pharmacological interventions, caregiver support, and robust regulatory and policy frameworks.

### 2. Disparities in Alzheimer's Disease Data Collection

Reliable epidemiological data are fundamental for evidence-based policymaking and effective health system planning; however, Alzheimer's disease remains substantially underdiagnosed and underreported, particularly in low-resource settings. In India, limited population-level screening, a shortage of trained neurologists and mental health professionals, and inadequate diagnostic infrastructure contribute to significant gaps in disease detection and reporting. Sociocultural factors, including stigma surrounding cognitive decline and the normalization of memory loss as a part of ageing, further delay clinical consultation and diagnosis.

Data disparities are especially pronounced in rural and underserved regions, where access to specialized care and standardized diagnostic tools is limited. Moreover, the absence of a unified national dementia registry and variations in surveillance practices across states result in inconsistent and fragmented reporting, undermining the accuracy of prevalence estimates. These limitations impede informed decision-making, constrain efficient resource allocation, and weaken the formulation of targeted public health interventions. Strengthening standardized data collection mechanisms, integrating dementia screening into primary healthcare, and improving reporting systems are essential to support effective Alzheimer's disease control strategies.

### 3. The Rural Alzheimer's Disease Care Crisis

Rural India faces disproportionately severe challenges in the prevention, diagnosis, and management of Alzheimer's disease, primarily due to structural limitations within the healthcare system. The availability of neurologists, psychiatrists, and geriatric care specialists remains extremely limited in rural and remote regions, while diagnostic facilities such as neuroimaging, cognitive assessment tools, and memory clinics are largely concentrated in urban centers. As a result, early detection of Alzheimer's disease in rural populations is rare, with most cases being identified only at advanced stages of the disease.

Low levels of awareness regarding dementia among both the general population and frontline healthcare providers further exacerbate the problem. Cognitive decline is frequently misattributed to normal ageing, leading to delayed healthcare-seeking behavior. In the absence of institutional care and structured support

services, Alzheimer's disease management in rural areas is overwhelmingly family-centered, with caregiving responsibilities falling on untrained family members. This informal caregiving model places significant emotional, physical, and financial strain on households, often without access to counseling, respite care, or social security support.

Geographical barriers, long travel distances to tertiary healthcare facilities, and high out-of-pocket expenditure create additional obstacles to timely diagnosis and continuity of care. These constraints contribute to poor treatment adherence and limited follow-up, ultimately worsening disease outcomes. Addressing the rural Alzheimer's disease care crisis requires a shift toward community-based, primary-care-led models of dementia care, integration of cognitive screening into primary health services, capacity building of community health workers, and improved referral linkages to specialist care through telemedicine and digital health platforms.

### 4. Affordability: The Other Alzheimer's Disease Crisis

Affordability represents one of the most critical yet under-recognized challenges in the management of Alzheimer's disease. Although currently available pharmacological therapies primarily offer symptomatic relief rather than disease modification, they require long-term and often lifelong administration. In addition to medication costs, patients incur substantial expenditure on diagnostic evaluations, periodic clinical consultations, supportive therapies, and management of disease-related complications. As the disease progresses, the need for continuous supervision, assistive devices, and institutional or home-based nursing care further escalates the financial burden.

In India, where healthcare financing is predominantly out-of-pocket, the economic impact of Alzheimer's disease is particularly severe. Comprehensive insurance coverage for chronic dementia care, long-term caregiving, and non-medical support services remains limited or absent in most public and private insurance schemes. Consequently, households often face catastrophic health expenditure, forcing difficult choices between continued treatment and basic living expenses. Financial constraints frequently lead to delayed diagnosis, irregular follow-up, poor treatment adherence, or premature discontinuation of therapy.

The affordability crisis is compounded by indirect costs, including loss of income of caregivers, reduced workforce participation, and long-term dependency. For economically vulnerable families, these cumulative costs can push households into poverty. Addressing affordability in Alzheimer's disease care requires policy-driven interventions, including price regulation of essential medicines, expansion of insurance coverage for long-term neurological care, integration of dementia services into publicly funded health programs, and targeted financial protection mechanisms to ensure equitable and sustained access to care.

### 5. Measures Taken by the Government to Make Alzheimer's Disease Treatment Affordable and Accessible

The Government of India has initiated multiple policy measures to address Alzheimer's disease and related dementias within broader public health and social welfare frameworks, recognizing the growing burden of neurodegenerative disorders in an ageing population. Alzheimer's disease is primarily addressed under national programs such as the National Programme for Health Care of the Elderly (NPHCE) and the National Mental Health Programme (NMHP), which aim to strengthen geriatric care services, improve access to mental healthcare, and promote early identification and management of age-related disorders at various levels of the healthcare system.

Under the Ayushman Bharat - Pradhan Mantri Jan Arogya Yojana (PM-JAY), eligible beneficiaries receive financial protection for secondary and tertiary care hospitalization, including selected neurological and mental health conditions. Although outpatient services and long-term dementia care are not

comprehensively covered, PM-JAY reduces the financial burden associated with acute hospital-based interventions and complications related to Alzheimer's disease. In parallel, the establishment of Health and Wellness Centres (HWCs) under Ayushman Bharat aims to strengthen primary healthcare delivery by integrating screening, referral, and follow-up services for elderly and chronic conditions, including cognitive disorders.

Additional government efforts focus on capacity building, awareness generation, and service integration. These include training healthcare professionals in geriatric and mental health care, promoting community-based interventions, and leveraging digital health platforms and telemedicine services to improve access in remote and underserved areas. Initiatives such as Tele-Mental Health services and district-level geriatric clinics contribute to early detection and continuity of care. Collectively, these measures reflect a gradual shift toward improving affordability, accessibility, and equity in Alzheimer's disease care, although further policy refinement and targeted financing mechanisms are required to address long-term care needs comprehensively.

### 6. GST and Customs Relief on Life-Saving Therapies

Fiscal policy interventions play an important role in improving the affordability and accessibility of healthcare interventions, particularly for chronic and long-term conditions such as Alzheimer's disease. In India, measures such as Goods and Services Tax (GST) rationalisation and customs duty exemptions on select life-saving medicines, medical devices, and diagnostic equipment are intended to reduce overall treatment costs and enhance patient access. By lowering indirect taxation, these policies help moderate price escalation across the pharmaceutical and healthcare value chain.

Although currently available Alzheimer's disease therapies are primarily symptomatic in nature, patients require sustained access to medicines, diagnostic services, and supportive care over extended periods. Reduced GST rates on essential drugs, diagnostic reagents, and medical devices such as neuroimaging equipment, cognitive assessment tools, and assistive technologies, can significantly lower out-of-pocket expenditure for patients and caregivers. Customs duty exemptions on imported active pharmaceutical ingredients (APIs), finished formulations, and specialized diagnostic equipment further support cost containment and supply chain stability.

In addition to pharmaceuticals, tax relief on supportive and assistive devices, including mobility aids and home-care equipment, contributes to improved quality of life and functional independence for patients with advanced disease. These fiscal measures complement regulatory and pricing interventions by addressing cost barriers at multiple levels of care. However, continued evaluation of tax structures, periodic review of eligible items, and alignment with evolving therapeutic and diagnostic needs are essential to ensure that fiscal policies effectively support affordable and equitable Alzheimer's disease care.

### 7. Conclusion

Alzheimer's disease is emerging as a major public health and socio-economic challenge in India, driven by rising prevalence associated with demographic ageing, increasing life expectancy, and epidemiological transition. The growing burden of the disease is compounded by significant gaps in epidemiological data, delayed diagnosis, and limited awareness, which collectively hinder evidence-based planning and effective resource allocation. Disparities in healthcare infrastructure and specialist availability have resulted in pronounced rural–urban inequities, leaving large segments of the population without timely access to diagnosis, treatment, and long-term care.

Affordability remains a central concern in Alzheimer's disease management. The long-term nature of

treatment, coupled with limited insurance coverage for chronic dementia care and high out-of-pocket expenditure, places a substantial financial burden on patients and caregivers. Indirect costs, including loss of productivity and caregiver income, further intensify the economic impact at the household and societal levels. While existing therapies provide symptomatic relief, sustained access to medicines, diagnostics, and supportive services is essential to maintain quality of life and delay functional decline.

Government initiatives under broader frameworks such as the National Programme for Health Care of the Elderly (NPHCE), the National Mental Health Programme (NMHP), and Ayushman Bharat represent important steps toward improving accessibility and financial protection. Complementary fiscal measures, including GST rationalisation and customs duty relief on essential medicines, diagnostics, and assistive devices, contribute to reducing treatment-related costs. However, these efforts require further strengthening and integration to address the full continuum of Alzheimer's disease care.

A comprehensive national dementia strategy is urgently needed, with a focus on early diagnosis, standardized data collection, community- and primary-care-led service delivery, caregiver support mechanisms, and sustained affordability of essential therapies. Strengthening regulatory oversight, expanding insurance coverage for long-term care, and aligning fiscal and public health policies will be critical to ensuring equitable, accessible, and affordable Alzheimer's disease care in India. Such a coordinated approach is essential to mitigate the growing impact of Alzheimer's disease on individuals, families, and the healthcare system.

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# REGULATORY NEWS

## News related to pricing of drugs

### Effective Ceiling Prices

Ceiling prices of 935 formulations are effective as on 28.02.2026, of which Ceiling prices for 776 scheduled formulations have been fixed / refixed under National List of Essential Medicines, 2022. 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.

### 1. Details regarding Authority meeting held

During the month of January and February 2026, two authority meetings i.e. 142nd and 143rd under DPCO, 2013 were held on 30.01.2026 and 27.02.2026 respectively wherein 36 retail prices were notified vide S.O. 449(E) dated 30.01.2026 and 20 retail prices were notified vide S.O. 1085(E) dated 27.02.2026.

### 2. Fixation of Retail Price

Retail prices for 3702 (approx.) new drugs have been fixed under DPCO, 2013 till 28.02.2026. Details of 56 retail prices notified for various formulations based on the decision taken in 142nd and 143rd meetings are as follow:

| S. No. | Therapeutic group | Total Number | Type of formulation | Retail Price fixed Range (Rs.) (Excl. GST) per tablet/per ml/ per capsule/per vial/per gm |
|---|---|---|---|---|
| (1) | (2) | (3) | (4) | (5) |
| 1. | Anti Diabetic | 9 | Tablet | 7.92 – 21.43 |
| 2. | Antineoplastics and Immunomodulating agents | 4 | Ointment / infusion | 33.33-8079.63 |
| 3. | Pain / Analgesics | 3 | Tablet/ Injection | 3.05-32.99 |
| 4. | Cardiovascular | 15 | Tablet/Capsule | 6.19 – 31.9 |
| 5. | Anti-Infective | 6 | Tablet/Drops /Injection | 8.00 -1835.79 |
| 6. | Respiratory | 3 | Tablet/Syrup | 0.98 – 4.64 |
| 7 | Vitamins/Minerals | 2 | Tablet | 14.37-16.62 |
| 8. | Gynaecological | 4 | Tablet/Capsule | 12.42-23.59 |
| 9. | Others | 8 | Oral Suspension/ Solution/ Capsules/ Tablet/ Get/ Kit | 1.75-167.21 |

### 3. Custom Duty Reduction on Lifesaving drugs

Government has recently exempted custom duty on 17 lifesaving drugs vide notification No. 02/2026-Customs dated 01.02.2026. Accordingly, NPPA issued OM dated 10.02.2026 directing manufacturer of these drugs to revise the MRP of said drugs/formulation in order to pass on the benefit of reduced custom duty to consumers. The revised prices are required to be reported in Form V and price list indicating changes to be issued to dealers, State Drug Controllers and the Government.

### 4. Exemption under para 32(ii) of DPCO, 2013 provided to M/s. Sun Pharmaceutical Industries Ltd. for Gemcitabine Infusion bags in three packs Viz. 1200 mg/120 ml, 1400 mg/140 ml, 1600 mg/160 ml expired

i. Gemcitabine is a widely used **chemotherapy medication** indicated for the treatment of several cancers, including pancreatic, lung, breast, and ovarian cancers.

ii. M/s. Sun Pharmaceutical Industries Ltd was granted exemption under para 32(ii) of DPCO, 2013 from the applicability of provisions of DPCO 2013, for ready-to-use infusion bag formulation of Gemcitabine in three packs Viz. 1200 mg/120 ml, 1400 mg/140 ml, and 1600 mg/160 ml for a period of five years from the date of the commencement of its commercial production in the country. The exemption was notified through S.O. 4064(E) dated November 8, 2019.

iii. The exemption period expired on Dec, 2025. Accordingly, NPPA has notified the retail prices for Ready to use Infusion Bags Gemcitabine Hydrochloride Injection 10 mg/ml for three pack sizes viz 1200 mg/120 ml, 1400 mg/140 ml, and 1600 mg/160 ml as under-

- 1200 mg/120 ml – ₹ 5,977.68
- 1400 mg/140 ml – ₹ 7,183.04
- 1600 mg/160 ml – ₹ 8,079.63

## IPDMS 2.0:

The Integrated Pharmaceutical Database Management System (IPDMS) is an integrated responsive cloud-based application. It is a system for online information collection, processing and communication portal to monitor and regulate the prices of medicines and medical devices, to ensure availability and affordability of drugs and medical devices in the country. The upgraded IPDMS 2.0 was launched on 29th August, 2022 and the charts given below capture the statistics from April 2024 to February 2026:


Chart1: Total number of registered companies at the end of February 2026

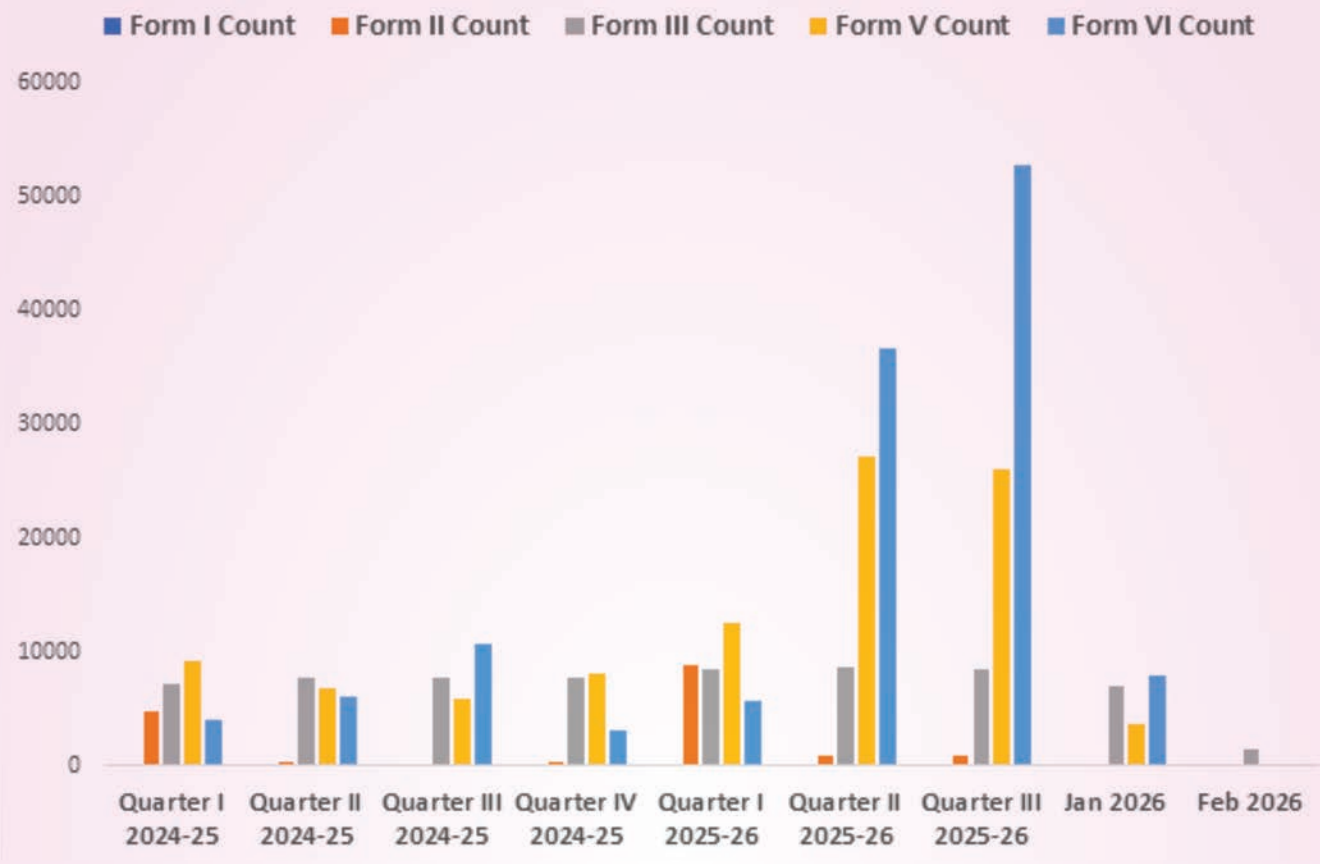



Chart 2: Forms (specified under Schedule II of DPCO, 2013) filed on IPDMS

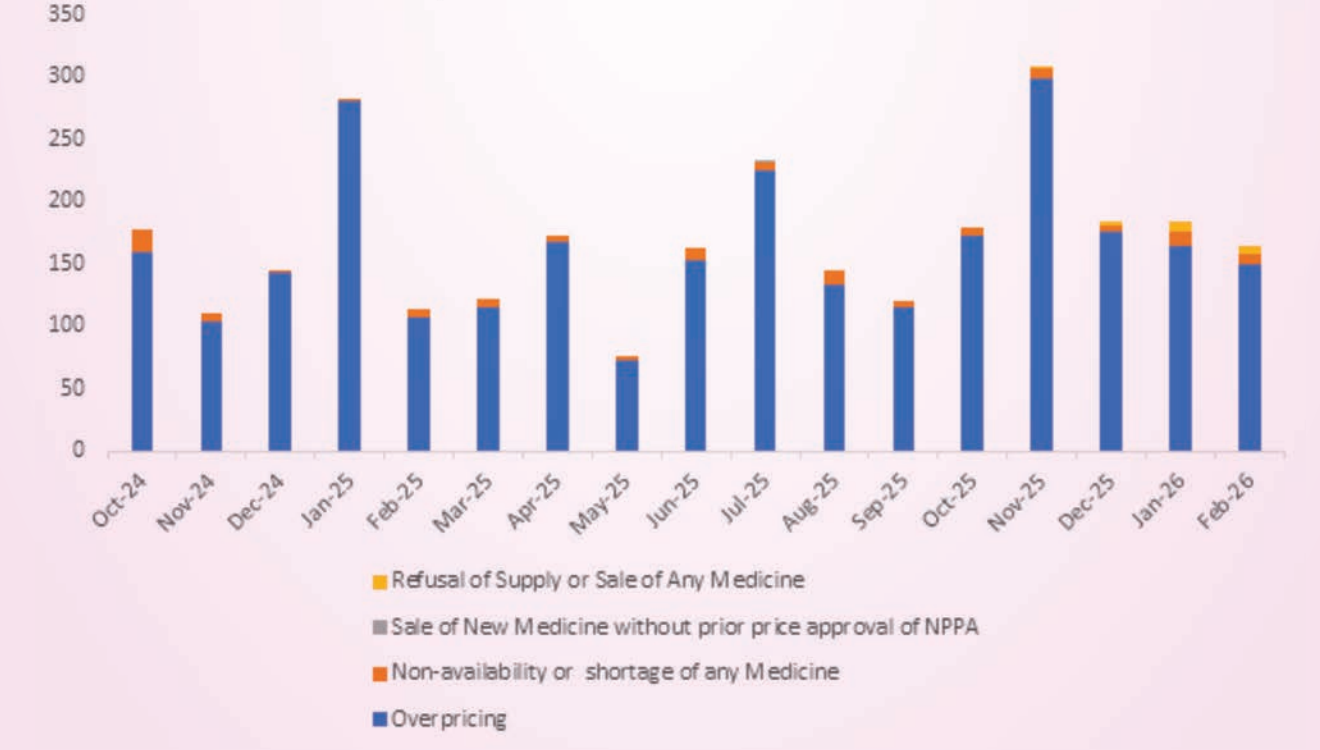



Chart 3: Number of complaints received on IPDMS / Pharma Jan Samadhan / Emails / CPGRAMS

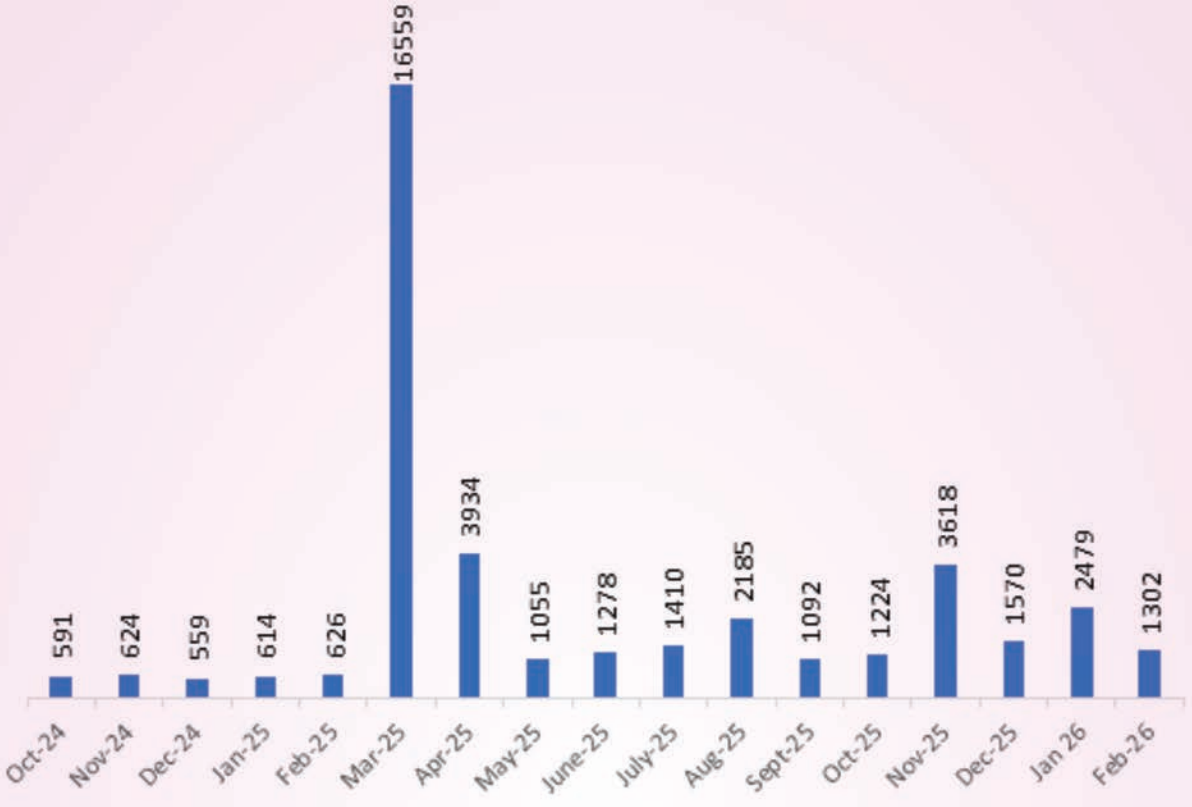



Chart 4: Number of Pharma Sahi Daam Mobile app downloads


Chart 5: Number of User logins in IPDMS 2.0

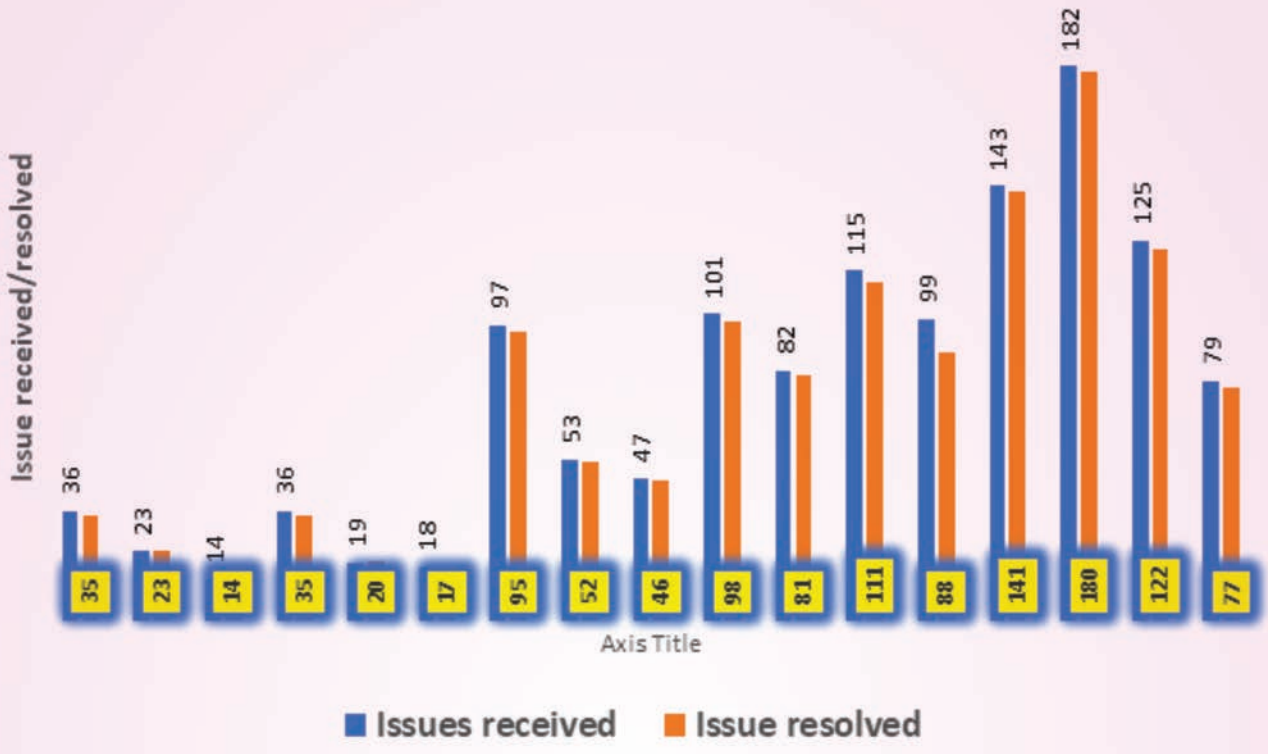



Chart 6: Issues received /resolved

**FDA Increases Flexibility on Requirements for Cell and Gene Therapies to Advance Innovation (January 11, 2026)**


The U.S. Food and Drug Administration today announced it is sharing information about the agency's flexible approach to overseeing chemistry, manufacturing and control (CMC) requirements for cell and gene therapies (CGT). The agency's more flexible approach has been, and is expected to continue to be, helpful in expediting product development and will help guide the FDA's evaluation of development strategies in preparation for a Biologics License Application (BLA) submission. Over the last decade, the FDA's Center for Biologics Evaluation and Research (CBER) has approved close to 50 CGTs. The transformative potential of these therapies has captured the imagination of the patient community and ignited product development.

**(Read more)**

**FDA Approves First Treatment for Children With Menkes Disease (January 12, 2026 )**

The U.S. Food and Drug Administration today approved the Zycubo (copper histidinate) injection as the first treatment for Menkes disease in pediatric patients. "With today's action, children with this devastating, degenerative disease will have an FDA-approved treatment option and the potential to live longer," said Christine Nguyen, M.D., Deputy Director of the Office of Rare Diseases, Pediatrics, Urologic and Reproductive Medicine in the FDA's Center for Drug Evaluation


and Research. "The FDA will continue to work with the rare disease community to advance drug development for patients with Menkes disease and other rare conditions."Menkes disease is a neurodegenerative disorder caused by a genetic defect that impairs a child's ability to absorb copper.

**(Read more)**

**FDA Intends to Take Action Against Non-FDA-Approved GLP-1 Drugs (February 06, 2026 )**

The U.S. Food and Drug Administration is announcing its intent to take decisive steps to restrict GLP-1 active pharmaceutical ingredients (APIs) intended for use in non-FDA-approved ompounded drugs that are being mass-marketed by companies — including Hims & Hers and other compounding pharmacies — as similar alternatives to FDA-approved drugs. These actions are aimed to safeguard consumers from drugs for which the FDA cannot verify quality, safety, or efficacy. We take seriously any potential

violations of the Federal Food, Drug, and Cosmetic Act.The FDA is also taking steps to combat misleading direct-to-consumer advertising and marketing following warning letters that were sent in the fall of 2025. In promotional materials, companies cannot claim that non-FDA-approved compounded products are generic versions or the same as drugs approved by FDA. They also cannot state compounded drugs use the same active ingredient as the FDA-approved drugs or that compounded drugs are clinically proven to produce results for the patient.

**(Read more)**

**FDA Approves First-of-Its-Kind Device to Treat Pancreatic Cancer Device Delivers Non-invasive Therapy and Supports Care at Home (February 12, 2026)**


The U.S. Food and Drug Administration has approved a first-of-its-kind device for the treatment of adult patients with locally advanced pancreatic cancer. Optune Pax, developed by Novocure, is a portable, non-invasive device that delivers alternating electrical fields, known as tumor treating fields (TTFields), to the abdomen. TTFields work by physically disrupting the rapid cell division that is characteristic of cancer cells, while minimizing damage to healthy tissue. "Having treated many patients with pancreatic cancer, I know how difficult the diagnosis can be. The pancreatic cancer community deserves better therapeutic options," said FDA Commissioner Marty Makary, M.D., M.P.H. "The FDA is working tirelessly to bring potentially promising therapies to people who need them."

**(Read More)**

**New single-dose oral treatment for human African trypanosomiasis (sleeping sickness) (27 February 2026)**

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)**

## 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 33 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 October 2025, several PMRUs conducted State level IEC activities.

## State Level Events/Seminars by PMRUs

Twenty-Nine (29) State and District level Events/ Seminars have been organized by 12 (Twelve) PMRUs in their respective States/UTs, viz. Puducherry, Jammu & Kashmir, Goa, Chhattisgarh, Jharkhand, Haryana, Lakshadweep, Meghalaya, Punjab, Rajasthan, Assam, 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 for PMRU, PUNJAB

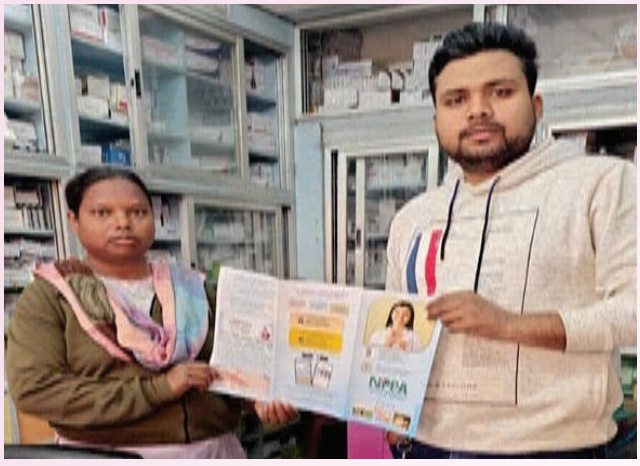
# PMRUs IN ACTION


Public Awareness Program on NPPA's Initiatives for Affordable Medicines at Government Senior Secondary School, Zirakpur


Punjab PMRU conducted an IEC Awareness Program at Wellcare Path Lab, Zirakpur, Punjab

Glimpse of programs for PMRU JHARKHAND

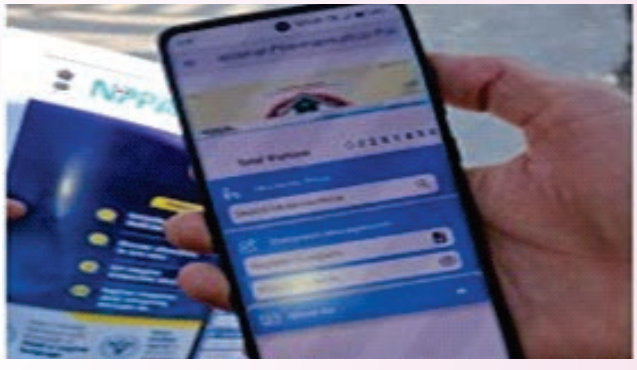
# PMRUs IN ACTION




Glimpse of programs for PMRU TRIPURA



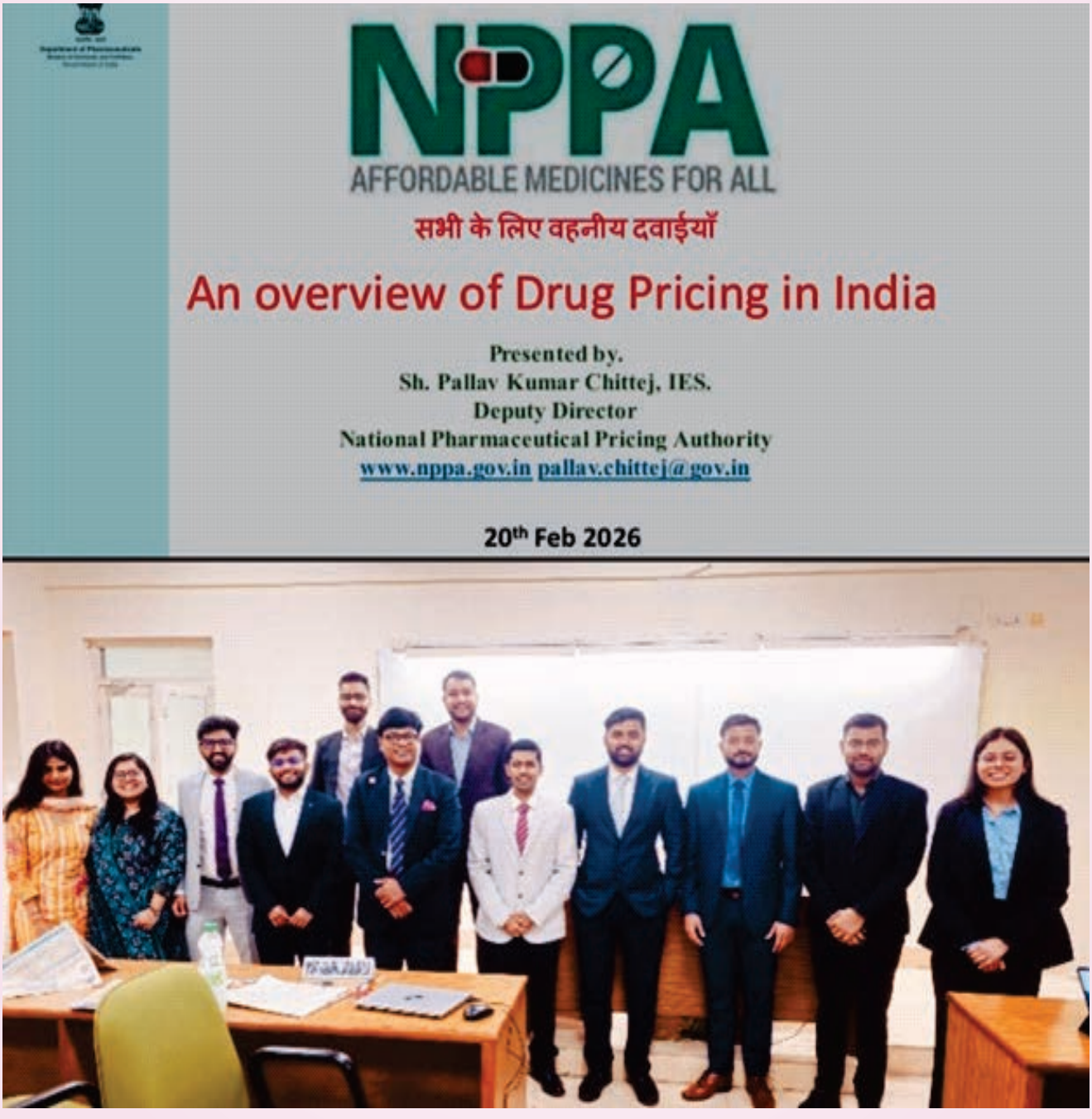
## Glimpse of programs for PMRU JAMMU & KASHMIR



# OTHER NEWS AND EVENTS

For the second consecutive year, Sh.Pallav Kr Chittej, Deputy Director, National Pharmaceutical Pricing Authority (NPPA), was invited by the Indian Economic Service (IES) cadre to lead an intensive interactive session at the Institute of Economic Growth (IEG). This engagement, held for the IES 2026 Batch of Training Officers, underscores the growing synergy between economic theory and regulatory practice in India's healthcare landscape. The session, titled "An Overview of Drug Pricing in India," focused on the delicate economic balancing act managed by the NPPA. As an attached office of the Department of Pharmaceuticals, the NPPA is tasked with a dual mandate: ensuring the affordability of essential medicines for over 1.4 billion citizens while maintaining the viability of the pharmaceutical industry, often hailed as the Pharmacy of the World."




# FREQUENTLY ASKED QUESTIONS

**1. What is mental health?**

Mental health refers to a person's emotional, psychological, and social well-being. It affects how individuals think, feel, and act, as well as how they handle stress, relate to others, and make choices.

(Source: Ministry of Health & Family Welfare)

**2. How common are mental health issues in India?**

According to the National Mental Health Survey (2015–16) conducted by the National Institute of Mental Health and Neurosciences (NIMHANS), approximately 10.6% of the adult population in India suffers from some form of mental illness, with nearly 150 million people requiring active mental health interventions.

**3. What are common types of mental health disorders?**

Common mental health disorders include:

I. Depression
ii. Anxiety disorders
iii. Bipolar disorder
iv. Schizophrenia
v. Substance use disorders

(Source: MoHFW, National Mental Health Survey)

**4. What are the symptoms of depression?**

Common symptoms of depression include:

i. Persistent sadness or low mood
ii. Loss of interest in previously enjoyable activities
iii. Fatigue or lack of energy
iv. Changes in sleep or appetite
v. Feelings of hopelessness or worthlessness

(Source: WHO India, MoHFW)

**5. Is mental illness treatable?**

Yes. Mental illnesses are treatable through a combination of approaches such as:

I. Medication
ii. Psychological counseling or psychotherapy
iii. Psychosocial support and rehabilitation Early diagnosis and continuous care significantly improve treatment outcomes.

(Source: National Mental Health Programme, MoHFW)

**6. What government support is available for mental health?**

The National Mental Health Programme (NMHP) provides support through:

i. District Mental Health Programme (DMHP) services in districts
ii. Mental health services in government hospitals
iii. Awareness and community outreach programmes
iv. Counseling and treatment services
v. NPPA contributes to mental healthcare by ensuring that essential psychiatric medicines remain affordable, price-regulated, and continuously available in the market, thereby supporting public health programmes and reducing the financial burden on patients.

(Source: MoHFW, NPPA)

**7. What is Tele-MANAS?**

Tele Mental Health Assistance and Networking Across States (Tele-MANAS) is a 24×7 tele-mental health service launched by the Ministry of Health & Family Welfare. The service provides:

i. Toll-free access to mental health professionals
ii. Multilingual support across states
iii. Free and confidential counseling services
Helpline Numbers:14416 or 1-800-891-4416

(Source: MoHFW)

**8. How can citizens access affordable medicines for mental health conditions?**

Affordable generic medicines for mental health conditions are available under the Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) through Janaushadhi Kendras. Benefits include:

i. Quality generic medicines at affordable prices
ii. Availability across thousands of Janaushadhi stores across India
iii. Reduced out-of-pocket expenditure for patients

(Source: Department of Pharmaceuticals)

**9. Are mental illnesses covered under health insurance in India?****

Yes. Under the Mental Healthcare Act, 2017, insurers are required to provide coverage for mental illness on par with physical illnesses. Health insurance schemes such as **Ayushman Bharat – Pradhan Mantri Jan Arogya Yojana (PMJAY) also include mental health services.

(Source: MoHFW, IRDAI)

**10. What rights do persons with mental illness have in India?**

The Mental Healthcare Act, 2017 guarantees several rights, including:

i. Right to access mental healthcare and treatment
ii. Protection from inhuman or degrading treatment
iii. Right to confidentiality and informed consent
iv. Right to community living and rehabilitation

(Source: Mental Healthcare Act, 2017)

**11. What support is available for students experiencing mental stress?**

The *Manodarpan initiative* of the Ministry of Education provides support for students through:

i. A national toll-free helpline for counseling (8448440632)
ii. Online mental health resources and guidance
iii. Counseling support for students, parents, and teachers

(Source: Ministry of Education)

**12. What steps can individuals take to maintain good mental health?**

Individuals can promote mental well-being by adopting healthy habits such as:

i. Getting adequate sleep and regular physical activity
ii. Maintaining supportive social connections
iii. Seeking help when experiencing prolonged stress or anxiety
iv. Avoiding excessive alcohol or substance use

(Source: MoHFW, WHO India)

# 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
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