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

Vol.-XXVIII | APRIL, 2026

A Bi-monthly e-Newsletter

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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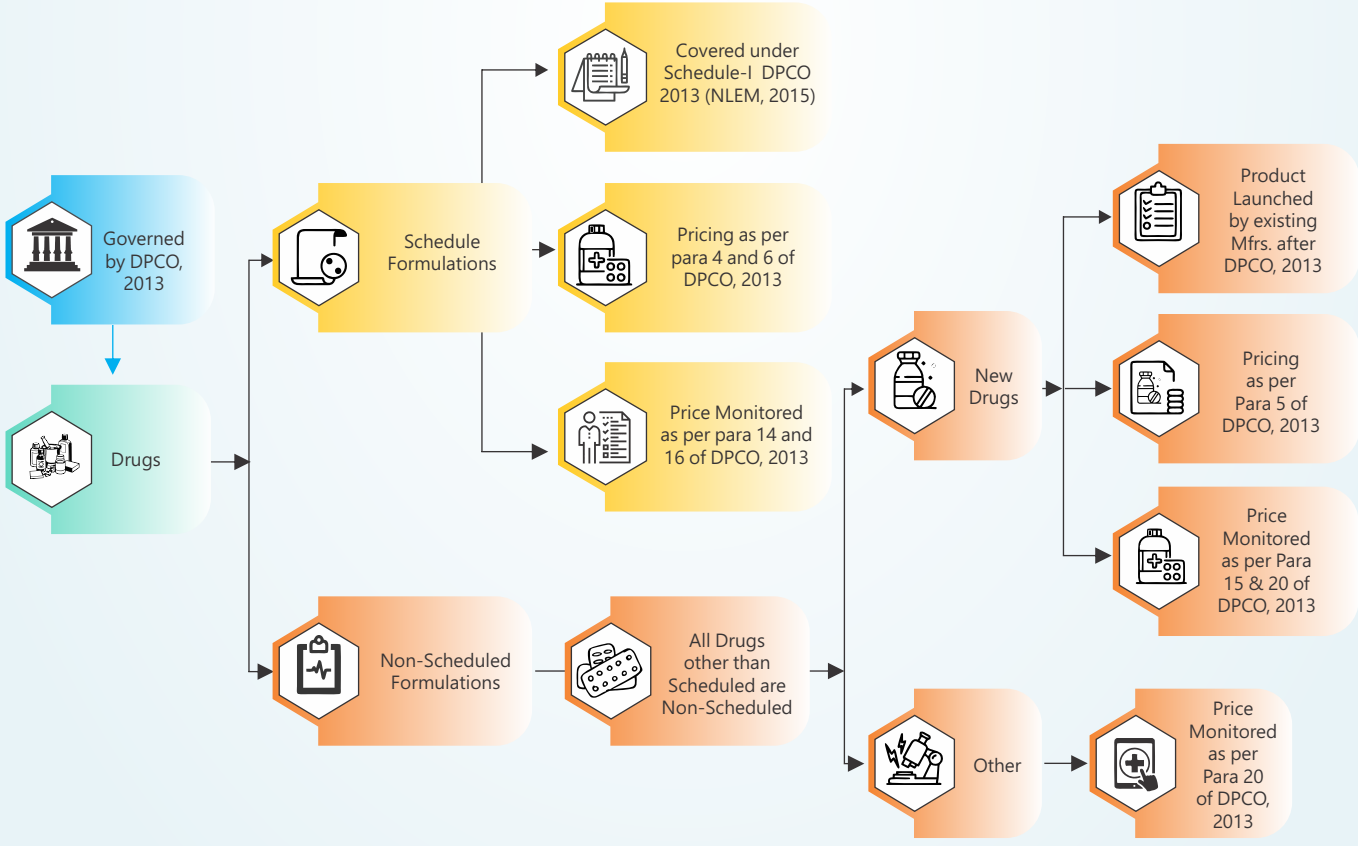

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From CHAIRMAN'S DESK

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 XXVIII edition of Aushadh Sandesh, which brings together insightful perspectives on emerging themes at the intersection of health, science, and public policy.

The present edition of the NPPA e-magazine highlights one of the most important pillars of public health policy—ensuring equitable and sustainable access to essential medicines and medical devices. The featured article by Prof. Rakesh Kumar Tekade and Prof. Shailendra Saraf offers valuable insights into the global and national challenges associated with affordability, accessibility, regulatory harmonization, and healthcare equity. Their discussion on essential medicines, coupled with the role of innovation, digital health, local manufacturing, and collaborative governance, strongly resonates with India's commitment towards Universal Health Coverage and patient-centric healthcare systems.

This issue also presents an informative in-house article on India's evolving regulatory framework for medical devices, showcasing the Government's strengthened approach towards affordability, safety, quality assurance, and industrial growth. The coordinated efforts of CDSCO, NPPA, and the Department of Pharmaceuticals continue to promote affordable healthcare while encouraging innovation and self-reliance in the sector. Pricing regulation, PMRU activities, IPDMS 2.0, and recent regulatory developments further reflect NPPA's sustained commitment towards transparency, consumer awareness, and public welfare.

In continuation of our PMRU activities, Twenty-Nine (29) 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 mMobile App and IPDMS 2.0.

This edition also includes an informative FAQ section on Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP), aimed at enhancing public awareness regarding affordable generic medicines through Jan Aushadhi Kendras, and the Government's efforts towards accessible healthcare for all.

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)

ARTICLE BY EXPERT

ENSURING EQUITABLE AND SUSTAINABLE ACCESS TO ESSENTIAL MEDICINES

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Abstract

Essential medicines are the medicines required to meet priority health needs. However, significant disparities in affordability, availability, and distribution exist, especially in low- and middle-income countries. Equal access to essential medicines is a primary requirement for addressing emerging global health threats and for complying with social justice norms. This article aims to offer a balanced discussion of essential medicines, taking into account the barriers (viz., medicine prices, regulatory hurdles, supply chain issues, and intellectual property problems). The ethical dimensions of essential medicines are also examined, with particular attention to the human rights of vulnerable groups. The article also presents case studies of emerging technologies (such as AI and digital health), sustainable manufacturing, and global collaboration as a way forward to achieve universal health coverage.

1. Introduction

Essential medicines are the list of medicines required to meet the vital health needs of individuals. They must be accessible to all in adequate quantities, proper dosage forms, and at a reasonable cost (WHO, 2026). It may be noted that the World Health Organization (WHO) has issued a model list of essential medicines to assist countries in creating their own list. About 8% maintain lists—97% in low and middle income nations versus 54% in high income countries. Its adoption differs from country to country, but its implementation greatly advances universal healthcare access worldwide (Wirtz et al., 2022).

Furthermore, the equity in healthcare ensures equal access to preventive, promotive, and curative services, regardless of identity or location (Banerjee, 2020). Equitable access to essential medicines helps in safeguarding health rights and reduces costs through generics and bulk purchasing. Notably, without it, the deprived populations face severe scarcity and cannot access healthcare. Barriers include patents, high pricing, and weak supply chains. Addressing the challenges of equitable and sustainable access to essential medicines requires collaboration among governments, the private sector, and communities, which is often supported by WHO strategies for universal access (Figure 1) (Perehudoff, 2020).

Figure 1: Diagrammatic illustration of increasing access to essential medicines through encouraging promotive actions.

For readers' information, the WHO's Essential Medicines List was first issued in 1977, which is now updated biennially, and includes 520 drugs, guiding over 150 countries in prioritizing safe, effective, affordable medicines **(Table 1)** (WHO, 2025a). The WHO Essential Medicines List includes anesthetics, pain relief, antidotes, anti-infectives, cardiovascular, gastrointestinal, hormonal, neurological, immunological, diagnostic agents, vitamins, minerals, and more, covering diverse therapeutic areas to meet global healthcare needs. Some common medicines from EML published by WHO are shown in **Table-1**

Table 1: Some common medicines from EML published by WHO

Category	Intended Purpose	Medicines	Remarks
Anaesthesia and Medical Gases	General and Local Anaesthetics and Sedation	Isoflurane, Propofol, Bupivacaine, Lidocaine, Atropine, Midazolam, Nitrous Oxide, Oxygen	• Inhalations and Injectables • Oxygen is essential for hypoxemia
Pain and Palliative Cures	Opioids,	Codeine, Fentanyl, Morphine	• Mild to severe pain, Supportive care • Transdermal patches, Oral solid/ liquid dosage forms
	Non-opioids and NSAIDS	Acetyl salicylic acid, Ibuprofen, Acetaminophen	
Anti-allergic and Medicines for Anaphylaxis	Medicines for common symptoms	Amitriptyline, Cyclizine, Diazepam, Fluoxetine, Haloperidol, Metoclopramide, Midazolam, Ondansetron	
Antidotes and Substances Used in Poisoning	Specific and Non-specific Antidotes	Activated Charcoal, Acetylcysteine, atropine, Naloxone, sodium Nitrite	• Oral Granules/ Powders • Injections
Neurological disorders	Central and Peripheral Nervous System	Carbamazepine, Diazepam, Levodopa + Carbidopa	Doasge Forms Suitability
Anti-Infective Medicines	Anti-bacterial, Anti-fungal, Anti-viral, Antibiotics	Amikacin, Ceftriaxone, Amoxicillin, Ampicillin, Gentamycin, Ritonavir, Zidovudine	Various generations of antibiotics according to the suitability of diseases

3. Barriers to Equitable Access

Medicine availability depends on health system capacity, and social factors such as gender, socioeconomic status, education, and geography. Billions of people lack easy access to essential medicines; high prices, weak supply chains, and poor governance worsen global healthcare inequities. Low income families struggle with high drug costs, leading to treatment avoidance. Women in low- and Middle-Income Countries (LMICs) face cultural and financial barriers, delaying care. Furthermore, budget shortages, limited insurance coverage, and direct medical costs force LMICs to deem essential medicines unaffordable despite their availability (Ahmadiani and Nikfar, 2016). Furthermore, the lack of affordable essential medicines restricts equitable health benefits (Ozawa et al., 2019). Pharmaceutical access faces barriers, primarily regulatory, supply chain, and patent-related restrictions, which aggravate the limited availability of affordable medicines globally. **Figure 2** outlines the impact of these barriers on health. Price regulation systems often fail, allowing generics above production costs. For the case in hand, the Sofosbuvir's hepatitis C treatment in the U.S. illustrates how healthcare pricing creates barriers to equitable treatment access (Iyengar et al., 2016).

Distinct regulatory, pricing, and reimbursement systems delay access to LMIC medicines, favoring the launches of new medicines in high income markets (Khadem Broojerdi et al., 2020). Innovator oncology drugs launch first in the U.S. and Europe, thereby reaching LMICs years later due to pricing negotiations (IQVIA, 2021). Weak regulatory systems and a lack of safety standards enable poor quality drug production, causing health crises. Biosimilars, despite lowering costs, face delays in developing nations due to complex approval processes and the absence of operating standards (Khadem Broojerdi et al., 2020).

Although low cost medicines exist, weak supply chains hinder distribution, especially in LMICs. Shortages of medicines at primary health centers stem from poor infrastructure, cold chain gaps, and inventory mismanagement (Årdal et al., 2021). It may be noted that the rural population, who usually do not take the health coverage, suffer the most. It is thus advisable that local manufacturing of affordable medicines be backed by robust distribution networks to ensure affordable access (Foundation, 2024).

IP protection of key technologies greatly restricts access to essential medicines by preventing generics from entering the market and supporting the deprived population (Ahmadiani and Nikfar, 2016). A notable study by Oke and his team demonstrates the conflicts between patent protection and public health requirements (Oke, 2022). On one hand, IP rights encourage innovation, but on the other hand, they hinder the affordability of medicine. Woods (2025) supports equity based pricing, while Iyer (2024) advocates integrating access mechanisms directly into pharmaceutical product development strategies. Furthermore, Agreements such as Trade-Related Aspects of Intellectual Property Rights (TRIPS) and TRIPS plus further add to these barriers by limiting the provision for compulsory licensing, parallel imports, and local generic production (Ahmadiani and Nikfar, 2016).

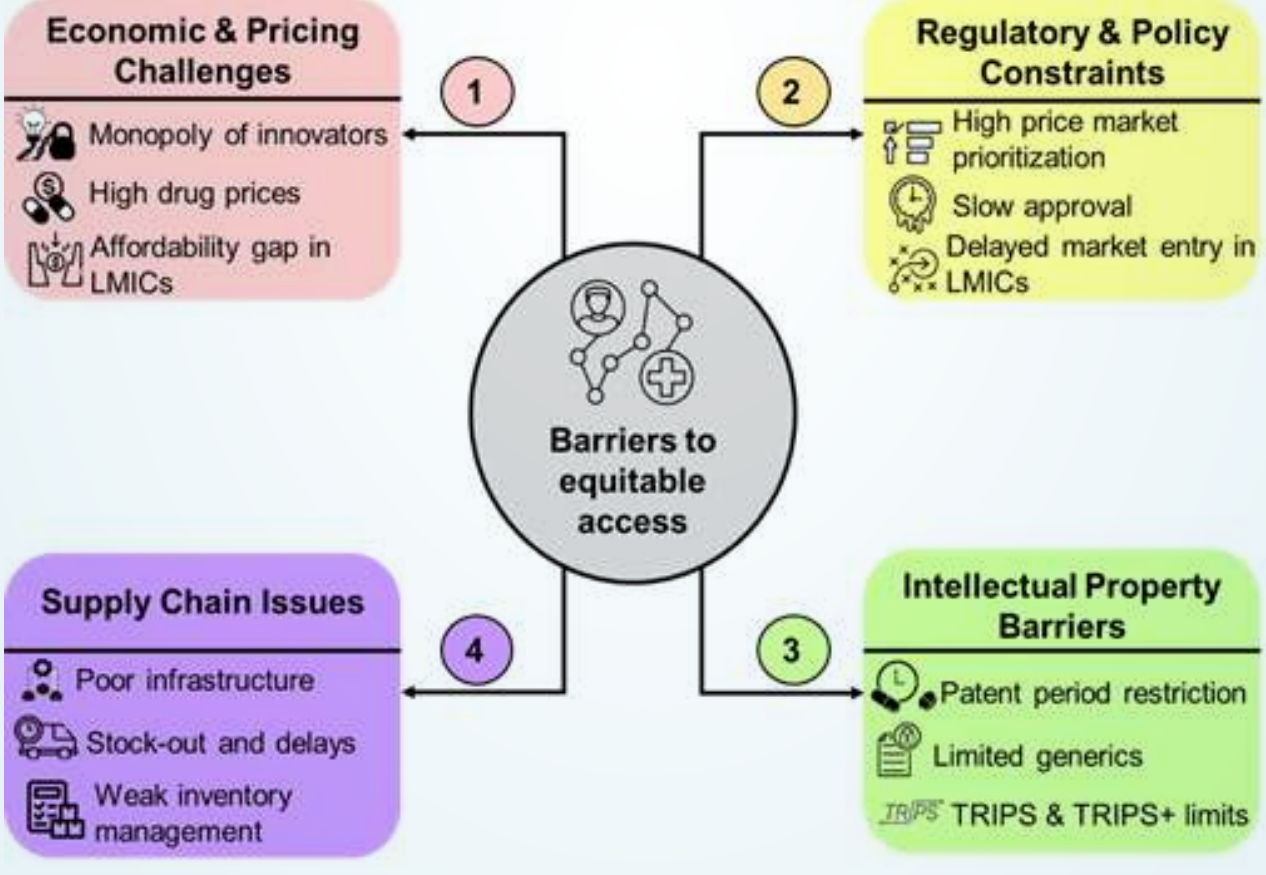


Figure 2: Schematic illustration of different barriers to equitable access to medicine

4. Ethical and Social Dimensions

International bodies also recognize access to essential medicines as part of the right to health. Researchers across the globe also advocate for offering fair opportunities to attain equitable access to essential medicines as a justice issue beyond economics (Perehudoff et al., 2019).

However, despite the existence of frameworks such as the International Covenant on Economic, Social, and Cultural Rights (ICESCR), notable barriers persist. Frequent stockouts of essential medicines weaken the primary health care. In such situations, patients have to rely on their own funds, which, in many cases, deepens inequalities. It may be noted that such financial burdens lead to dissatisfaction as well as mounting healthcare costs and, in many cases, reduced treatment adherence. In many cases, it has been observed that the global pharmaceutical market is primarily profit driven, and research funding targets only the profit-making segments. Such scenarios leave the orphan drug segments unattended. Such a situation needs urgent attention on ethical and human rights grounds. Alongside robust generic drug policies, the Governments of each country need to come up with a stronger procurement policy, drug distribution regulation, and supply chains monitoring to improve access to essential medicines (WHO, 2025b).

Niens and coworkers highlight that healthcare access depends on the ability of the patients to pay for their healthcare needs. This leaves underprivileged communities in a vulnerable situation to face the inequalities in access to essential medicines (Niëns et al., 2012). An inclusive policymaking approach with enhanced participation from all stakeholders may greatly help in deeply understanding the problem and in offering sustainable solutions (Herrera-Ramirez et al., 2026). Figure 3 illustrates the frameworks to ensure access to essential medicines in developing nations.

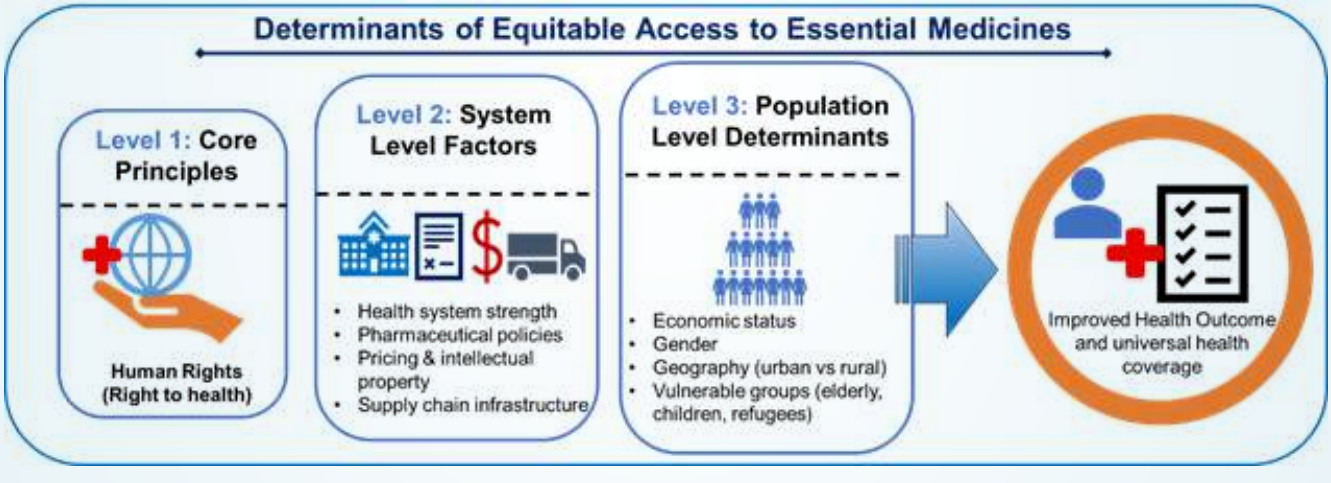


Figure 3. A Framework for Understanding Factors and Interventions Impacting Equitable Access to Essential Medicines in Developing Countries

5. Strategies for Improving Equitable Access to Essential Medicines

The above discussion clearly emphasizes that fair access to medicines requires strong governance not only at the national but also at the international level. Reforms to expand essential medicine lists, offer universal healthcare coverage, implement strict price controls, and implement pooled procurement of medicines may offer practical solutions to this problem.

Once drug patents expire, generic medicines enter the market at affordable prices. These generic medicines significantly improve affordability and access, boost competition, and ease healthcare budgets. Voluntary licensing to support the production of generics, especially in low- and middle-income countries, is also advocated to ease the situation. The governance must emphasize transparency in IP protection, drug pricing

of patented medicines, and boosting local production of medicines to ensure access to essential medicines (Ewen et al., 2017). The local manufacturing helps in strengthening supply chains and reducing import dependence (World Health, 2024). It may be noted that the treatment costs for HIV, cancer, diabetes, and cardiovascular diseases have dropped significantly due to the availability of cheaper generic medicines (Wanging et al., 2010).

Public firms alone often fail to ensure equitable access to medicine in low- and middle-income countries with constrained budgets and heavy disease burdens. Out-of-the-box financing approaches may help mobilize resources, reduce failure risk, and strengthen sustainability. This hybrid finance model, which combines public and private firms, is often backed by donors to foster drug development and expand production in intended areas. Public-private partnerships may also play a vital role in bridging the gaps that hinder access to medicine. It has been largely noted across the globe that governments often lack resources, while private firms usually hesitate to invest in non-profit-making segments. In this line, effective Public-private partnerships can support funding research and development, boost local manufacturing, academia-industry technology transfer, as well as strengthen supply chains for neglected diseases (The Global, 2024).

Although there are WHO guidelines that emphasize key domains, including cost reduction, supply availability, accountability, quality, and efficiency, to ensure improved access to essential medicines through digital platforms (Shaw et al., 2024, Konduri et al., 2018). Global organizations like the United Nations must also intensify their efforts to revise global regulatory frameworks and challenge strategies to expand the availability of essential medicines. Universal Health Coverage also needs to simplify the framework towards ensuring equitable and affordable access to essential medicines without additional financial hardship (Chattu et al., 2023). Table 2 presents key strategies for improving equitable access to essential medicines.

Table 2. Strategies for Improving Equitable Access to Essential Medicines Through Policy, Generics, Partnerships, and Financing

Strategy Area	Key Actions	Expected Impact	Key References
Policy reforms and governance	Strengthen national essential medicines lists, harmonize regulatory pathways, pooled procurement, price controls, and intellectual property flexibilities	Lower prices, faster approval, wider availability	(Ewen et al., 2017, World Health, 2025)
Generic medicines	Promote generic substitution, biosimilars, local manufacturing, voluntary licensing, and quality assurance	Reduced treatment costs and expanded access	(Waning et al., 2010, World Health, 2024)
Public–private partnerships	Collaborations among governments, industry, NGOs, and academia for manufacturing, supply chains, and innovation	Improved affordability, distribution, and sustainability	(Frost and Reich, 2010)
Innovative financing	Health bonds, blended finance, advance market commitments, pooled donor funds, and insurance expansion	Greater financial protection and long-term funding	(The Global, 2024, Wirtz et al., 2017, World, 2023)

6. Case Studies on Equitable Access to Essential Medicines

Several initiatives have been taken to enhance equitable access to medicines in low and middle-income countries. The introduction of "Dolutegravir" medicine marked a milestone in HIV treatment and became a preferred first-line therapy due to its therapeutic superiority. Notably, within three years, an affordable

generic version of Dolutegravir reached the market (Dorward et al., 2018). This represents a successful case study backed by the shared commitment of innovators and Governmental efforts.

In 2021, Pfizer and the Access to Medicine Foundation identified significant coverage gaps in access to essential medicines. Responding to this, in 2022, Pfizer launched An Accord for a Healthier World, with a pledge and commitment to provide all patented medicines and vaccines available in the US or EU on a not-for-profit basis to billions of people across 45 lower-income countries. Notably, vide agreements with 10 nations, including Ghana and Uganda, this program enabled access to 23 essential treatments for infectious diseases, cancers, rare, and inflammatory conditions (Inc., 2023).

Sanofi's Global Health Unit launched a non-profit initiative to improve access to 30 products across 40 countries, with a focus on non-communicable diseases. More than 1 million patients benefited from this program, including those using insulin glargine. Integrating the Sanofi Impact Fund with local healthcare and digital ecosystems, this holistic model also worked efficiently to make sure affordability and therapeutic availability of essential medicines (Sanofi, 2026).

The National Health Mission, through its rural and urban sub-missions, strengthens healthcare systems to ensure universal, affordable, and equitable services. In India, ASHA workers, mobile medical units, and public health centers are working efficiently in generating awareness, offering diagnosis and treatment on wheels, especially in underserved rural and urban communities (NHM, 2026).

7. Conclusion and Future Directions

Despite being a fundamental human right, ensuring equitable access to essential medicines remains a key challenge in healthcare. Persistent barriers such as economic constraints, regulatory fragmentation, and fragile supply chains continue to limit access, particularly in low- and middle-income countries. Overcoming these challenges demands society-driven innovation, healthcare policy reforms, and strong collaborative partnerships between governments, industry, and civil bodies. Ethical considerations must remain central, with vulnerable populations prioritized to ensure inclusivity. Sustainable practices such as local production of essential medicines and regulatory harmonization may help in reducing costs and import dependence.

Digital innovations, including real-time monitoring and integration of health metrics, must be engaged to strengthen transparency, efficiency, and proactive decision-making. These transformations are expected availability of essential medicines more effectively. Organizations like the UN and WHO may need to work in tandem and with commitment to harmonize regulatory frameworks and devise strategies to expand availability. Universal Health Coverage also needs to amend its framework to ensure equitable, affordable access to quality-assured essential medicines without financial hardship. Ultimately, equitable access is both a moral and a practical necessity for building robust healthcare systems. By fostering sustainability, cooperative collaboration, and joint innovation into global health strategies, the international community can move closer to ensuring essential medicines reach all who need them.

8. Acknowledgment

The authors would like to acknowledge the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, India, for supporting research on cancer, Parkinson's disease, and diabetes at NIPER-Ahmedabad. R.K.T. would also like to acknowledge the Gujarat State Biotechnology Mission (GSBTM) for supporting the work aimed at identifying novel and innovative solutions to tackle antimicrobial resistance (AMR; Project ID: 202425_40). R.K.T. would also like to acknowledge the Indian Council of Medical Research (ICMR), New Delhi, for grant file ID: 2021-14161 and grant File ID: IIRP-2023-4849/F1 for supporting research in the RKT lab.

9. References

AHMADIANI, S. & NIKFAR, S. 2016. Challenges of access to medicine and the responsibility of pharmaceutical companies: a legal perspective. DARU Journal of Pharmaceutical Sciences, 24, 13.

ÅRDAL, C., BARALDI, E., BEYER, P., LACOTTE, Y., LARSSON, D. J., PLOY, M.-C., RØTTINGEN, J.-A. & SMITH, I. 2021. Supply chain transparency and the availability of essential medicines. Bulletin of the World Health Organization, 99, 319.

BANERJEE, A. 2020. Equity and Quality of Health-care Access: Where Do We Stand and the Way Forward? Indian J Community Med, 45, 4-7.

CHATTU, V. K., SINGH, B., PATTANSHETTY, S. & REDDY, S. 2023. Access to medicines through global health diplomacy. Health Promot Perspect, 13, 40-46.

DORWARD, J., LESSELLS, R., DRAIN, P. K., NAIDOO, K., DE OLIVEIRA, T., PILLAY, Y., ABDOOL KARIM, S. S. & GARRETT, N. 2018. Dolutegravir for first-line antiretroviral therapy in low-income and middle-income countries: uncertainties and opportunities for implementation and research. Lancet HIV, 5, e400-e404.

EWEN, M., ZWEEKHORST, M., REGEER, B. & LAING, R. 2017. Baseline assessment of WHO's target for both availability and affordability of essential medicines to treat non-communicable diseases. PLOS ONE, 12, e0171284.

FOUNDATION, A. T. M. 2024. Access to Medicine Index 2024. Netherlands: Access to Medicine Foundation.

FROST, L. J. & REICH, M. R. 2010. Creating access to health technologies in poor countries. Health Affairs, 28, 962-973.

HERRERA-RAMIREZ, I., OROZCO-NUÑEZ, E., GUERRA, G., DRESER-MANSILLA, A. & MOLINA-SALAZAR, R. E. 2026. Access to Essential Medicines in Low- and Middle-Income Countries: A Systematic Review of Barriers and Facilitators. Int J Public Health, 71, 1608754.

INC., P. 2023. Pfizer Expands 'An Accord for a Healthier World' Product Offering to Include Full Portfolio for Greater Benefit to 1.2 Billion People in 45 Lower-Income Countries.

IQVIA. 2021. Global Oncology Trends 2021 [Online]. IQVIA Institute. Available: https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/global-oncology-trends-2021 [Accessed 16 April 2026].

IYENGAR, S., TAY-TEO, K., VOGLER, S., BEYER, P., WIKTOR, S., DE JONCHEERE, K. & HILL, S. 2016. Prices, costs, and affordability of new medicines for hepatitis C in 30 countries: an economic analysis. PLoS medicine, 13, e1002032.

KHADEM BROOJERDI, A., BARAN SILLO, H., OSTAD ALI DEHAGHI, R., WARD, M., REFAAT, M. & PARRY, J. 2020. The World Health Organization global benchmarking tool an instrument to strengthen medical products regulation and promote universal health coverage. Frontiers in medicine, 7, 553484.

KONDURI, N., ABOAGYE-NYAME, F., MABIRIZI, D., HOPPENWORTH, K., KIBRIA, M. G., DOUMBIA, S., WILLIAMS, L. & MAZIBUKO, G. 2018. Digital health technologies to support access to medicines and pharmaceutical services in the achievement of sustainable development goals. Digit Health, 4, 2055207618771407.

NHM. 2026. The National Health Mission [Online]. Available: https://nhm.gov.in/index4.php?lang=1&level=0&linkid=445&lid=38 [Accessed 16/04/2026 2026].

NIËNS, L. M., VAN DE POEL, E., CAMERON, A., EWEN, M., LAING, R. & BROUWER, W. B. 2012. Practical measurement of affordability: an application to medicines. Bull World Health Organ, 90, 219-27.

OKE, E. K. 2022. Patents, Human Rights, and Access to Medicine, Cambridge University Press.

OZAWA, S., SHANKAR, R., LEOPOLD, C. & ORUBU, S. 2019. Access to medicines through health systems in low- and middle-income countries. Health Policy Plan, 34, iii1-iii3.

PEREHUDOFF, K. 2020. Universal access to essential medicines as part of the right to health: a cross-national comparison of national laws, medicines policies, and health system indicators. Glob Health Action, 13, 1699342.

PEREHUDOFF, S. K., ALEXANDROV, N. V. & HOGERZEIL, H. V. 2019. Access to essential medicines in 195 countries: A human rights approach to sustainable development. Glob Public Health, 14, 431-444.

SANOFI 2026. Sanofi-GHU-Report-2025.

SHAW, J., ABEJIRINDE, I. O., AGARWAL, P., SHAHID, S. & MARTIN, D. 2024. Digital health and equitable access to care. PLOS Digit Health, 3, e0000573.

THE GLOBAL, F. 2024. Financing and funding.

WANING, B., DIEDRICHSEN, E. & MOON, S. 2010. A lifeline to treatment: the role of Indian generic manufacturers in supplying antiretroviral medicines to developing countries. Journal of the International AIDS Society, 13, 35.

WHO 2025a. The selection and use of essential medicines, 2025: WHO Model List of Essential Medicines, 24th list.

WHO 2025b. WHO guideline on balanced national controlled

medicines policies to ensure medical access and safety

Rapid communication.

WHO. 2026. Essential medicines [Online]. WHO. Available: https://www.who.int/news-room/fact-sheets/detail/essential-medicines#:~:text=Essential%20medicines%20are%20those%20that%20effectively%20and,of%20costs%2C%20affordability%20and%20other%20relevant%20factors. [Accessed January 2026].

WIRTZ, V. J., HOGERZEIL, H. V., GRAY, A. L., BIGDELI, M., DE JONCHEERE, C. P., EWEN, M. A., GYANSA-LUTTERODT, M., JING, S., LUIZA, V. L., MBINDYO, R. M. & MÖLLER, H. 2017. Essential medicines for universal health coverage. The Lancet, 389, 403-476.

WIRTZ, V. J., RAVINETTO, R. J. M. H. S. W. I. L. & PRACTITIONERS, M. I. C. T. F. P. H. 2022. Enhancing equitable access to essential medicines and health technologies. 320.

WORLD, B. 2023. Innovative financing for health.

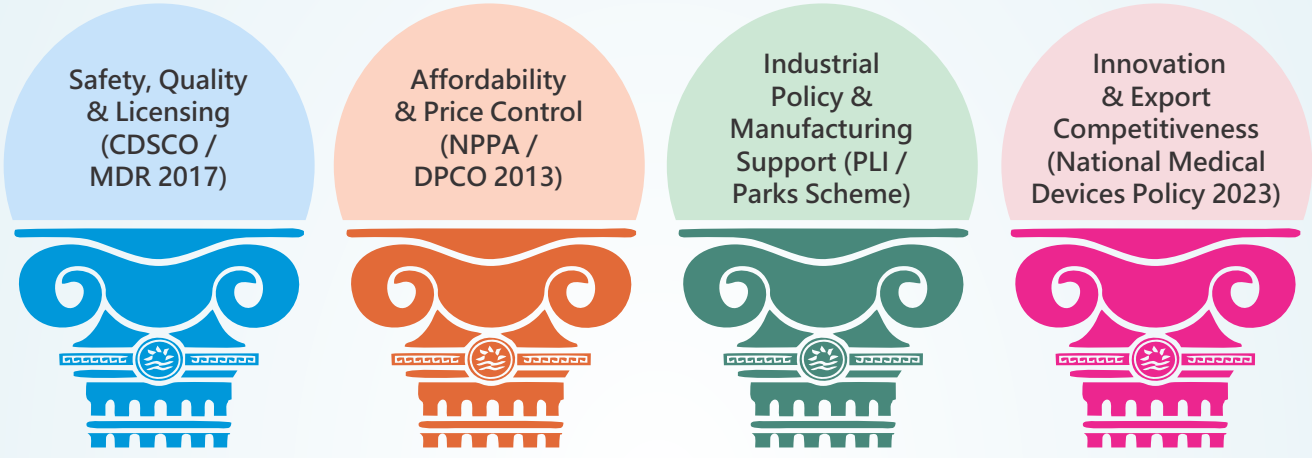
WORLD HEALTH, O. 2024. Essential medicines.

WORLD HEALTH, O. 2025. Ensuring equitable access to essential medicines and health technologies for noncommunicable diseases.

REGULATORY FRAMEWORK FOR MEDICAL DEVICE PRICING AND SAFETY IN INDIA

A strengthened approach towards affordability, safety, quality, and innovation

Four Pillars of India's Medical Device Regulatory Framework



1. Introduction

India's medical devices sector has emerged as one of the fastest-growing segments of the healthcare industry, driven by rising healthcare demand, technological advancements, and policy reforms. The sector plays a critical role in diagnosis, treatment, rehabilitation, and life support, ranging from simple consumables to high-end diagnostic and implantable devices. Medical devices are wide ranging from common medical procedures - like a bandage for a sprained ankle or syringe, to implanting an artificial hip or stent or any surgical intervention. As per WHO guidelines, today there are an estimated 2 million different kinds of medical devices on the world market, categorized into more than 22,000 generic devices groups.

Medical devices constitute a multi-disciplinary sector includes electro-medical equipment, implants, consumables and disposables, surgical instruments, and in-vitro diagnostic reagents, and is highly technology-driven and capital-intensive. With a growing emphasis on universal healthcare access, India has progressively strengthened its regulatory ecosystem to ensure that medical devices remain affordable, safe, effective, and accessible to patients.

2. Definition and Scope of Medical Devices

Medical device has been defined under the Drugs and Cosmetics Act, 1940 and Medical Devices Rules, 2017 and includes instruments, apparatus, implants, software, materials, or appliances intended for diagnosis, prevention, monitoring, treatment, or alleviation of disease and disability. The term "Medical Device" has been defined under sub-clause (iv) of clause (b) of Section 3 of the Drugs and Cosmetics (D&C) Act, 1940, and has further been notified by the Ministry of Health and Family Welfare vide notification dated 11.02.2020, as under:

Statutory Definition - D&C Act, 1940 (Notification dated 11.02.2020)

Medical Devices means - All devices including an instrument, apparatus, appliance, implant, material or other article, whether used alone or in combination, including a software or an accessory, intended by its manufacturer to be used specially for human beings or animals which does not achieve the primary intended action in or on human body or animals by any pharmacological or immunological or metabolic means, but which may assist in its intended function by such means for one or more of the specific purposes of:

(i) diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder;
(ii) diagnosis, monitoring, treatment, alleviation or assistance for, any injury or disability;
(iii) investigation, replacement or modification or support of the anatomy or of a physiological process;
(iv) supporting or sustaining life;
(v) disinfection of medical devices; and
(vi) control of conception.

A medical device is an in vitro diagnostic medical device (IVD) if it is a reagent, calibrator, control material, kit, specimen receptacle, software, instrument, apparatus, equipment or system, whether used alone or in combination with other diagnostic goods for in vitro use. An IVD device is used for in-vitro examination of specimens derived from the human body, including blood and tissue donations, solely or principally to provide information about a physiological or pathological state, a congenital abnormality or to determine safety and compatibility with a potential recipient, or to monitor therapeutic measures.

3. Institutional Regulatory Architecture

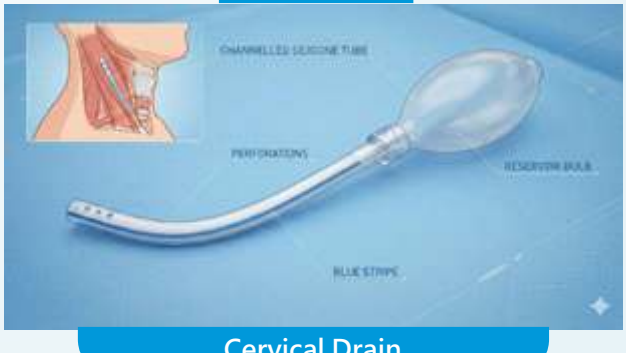
In India, the Central Drugs Standard Control Organization (CDSCO) under the Ministry of Health & Family Welfare, regulates medical devices under the Medical Devices Rules, 2017, and oversees licensing, import, manufacture, clinical investigation, and post-market surveillance to ensure compliance with prescribed safety and quality standards. The Central Drugs Standard Control Organization (CDSCO), functioning under the Ministry of Health and Family Welfare, is the primary regulatory authority responsible for overseeing the import, manufacture, sale, and distribution of medical devices in India.

CDSCO grants licenses, approvals, and registrations for medical devices to ensure their safety, quality, and efficacy in accordance with the prescribed regulatory standards. It also conducts inspections, enforces compliance with regulatory requirements, and manages the registration process, including review of technical documentation and post-market surveillance for monitoring safety and quality standards. Further, CDSCO classifies medical devices based on risk categories under the Medical Devices Rules, 2017, categorizing medical devices into Class A, B, C, and D, ranging from low-risk to high-risk devices.

CLASS A

Nasopharyngeal Catheters

CLASS B

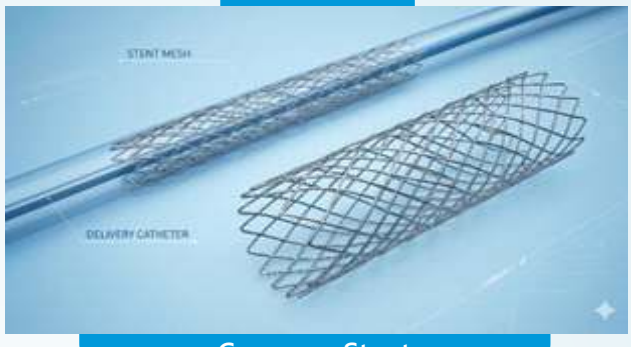


Cervical Drain

CLASS C

Knee Implant

CLASS D



Coronary Stent

National Pharmaceutical Pricing Authority (NPPA), under the provisions of the DPCO, 2013, regulates and monitors the prices of medical devices to ensure affordability and accessibility for the public.

Table 1: CDSCO Risk-Based Classification of Medical Devices under Medical Devices Rules, 2017

Class	Risk Level	Examples	Regulatory Pathway
Class A	Low Risk	Nasopharyngeal catheters, Surgical dressings, Alcohol swabs	Exempt / Self-declare
Class B	Low-Moderate Risk	IV cannula, Gastrostomy tube, Bone wires, Cervical drain	State Licensing
Class C	Moderate-High Risk	Orthopaedic implants, Brast implants, A-V shunt cannula, Bone cement	CDSCO Registration
Class D	High Risk	Heart valves, Pacemakers, Drug eluting stents, implantable defibrillators	CDSCO Approval

4. Pricing Regulation and Affordability

National Pharmaceutical Pricing Authority (NPPA), under the Department of Pharmaceuticals plays a vital role in protecting patients from excessive pricing of essential medical devices. NPPA fixes ceiling prices of medicines/medical devices included in the National List of Essential Medicines (NLEM) issued by the Ministry of Health and Family Welfare and incorporated in Schedule-I to the Drugs (Prices Control) Order, 2013 (DPCO, 2013). Ceiling prices have been notified for devices such as coronary stents, condoms, intrauterine devices (IUDs). All manufacturers, marketers and importers of scheduled medicines/medical devices are required to sell their products within such ceiling price (plus applicable Goods and Service Tax). In addition to these four (04) scheduled medical devices, NPPA also fixes and notifies the ceiling prices for Orthopaedic Knee Implants for knee replacement systems. Prices of medical devices which are not included in Schedule I of the DPCO are also monitored under the DPCO, 2013. NPPA monitors the Maximum Retail Prices of all non-scheduled medical devices and ensure that no manufacturer increases the maximum retail price of any medical device more than ten percent of maximum retail prices during preceding twelve months. Details of the medical devices for which prices are fixed are as follows:

Figure 4: NPPA Price Regulation Pathway under DPCO, 2013

Medical Device	Category	Initial Notification	Latest Status
Coronary Stents	Scheduled (DPCO)	S.O. 412(E), 13.02.2017	Revised per WPI; latest S.O. 1587(E) dt. 25.03.2026

Medical Device	Category	Initial Notification	Latest Status
Condoms	Scheduled (NLEM)	Notification 1791(E), 10.07.2014	Current ceiling: S.O. 1582(E) dt. 27.03.2026
Intra Uterine Devices (IUD)	Scheduled (NLEM)	1334(E) dt. 27.04.2017 & 1668(E) dt. 24.05.2017	Current ceiling: S.O. 1575(E) dt. 27.03.2026
Orthopaedic Knee Implants	Non-Scheduled (Para 19)	S.O. 2668(E), 16.08.2017	Extended to 15.11.2026 vide S.O. 5190(E) dt. 14.11.2025

Device-wise Pricing Details

- **Coronary Stents:** Coronary Stents were included in Schedule-I of DPCO, 2013 in December 2016. NPPA notified the ceiling prices for Coronary Stents under Para 19 of the DPCO, 2013 vide notification S.O. 412(E) dated 13.2.2017. The ceiling prices were subsequently revised from time to time considering annual Wholesale Price Index (WPI). NPPA vide notification S. O. 1587(E) dt. 25.03.2026 has revised the ceiling prices considering WPI @ 0.64956% during the calendar year 2025 over the corresponding period in 2024.
- **Condoms:** The Government has fixed ceiling prices for Condoms vide Gazette Notification No. 1791 (E) dated 10.07.2014 under NLEM, 2011. The current ceiling prices of the Condoms were notified vide Notification No. S. O. 1582(E) dt. 27.03.2026 under NLEM, 2022.
- **Intra Uterine Devices (IUD):** Ceiling prices for various categories of IUDs have been fixed vide Gazette Notifications No.1334 (E) dated 27.4.2017 and 1668(E) dated 24.5.2017. The current ceiling prices of the IUDs were notified vide Notification No. S. O. 1575(E) dt. 27.03.2026 under NLEM, 2022.
- **Orthopaedic Knee Implants for Knee Replacement System:** NPPA fixed the ceiling price of the orthopaedic knee implants, a non-scheduled medical device, for the first time on 16.8.2017 under para 19 of the DPCO, 2013 vide notification S.O. 2668(E). Subsequently, the validity of the ceiling prices was extended from time to time. Recently, NPPA extended the existing ceiling prices vide S. O. 5190(E) dt. 14.11.2025 extended the existing ceiling prices for further one (01) year i.e. up to 15.11.2026.

Further, during the COVID pandemic, NPPA capped the trade margin for five devices viz., oxygen concentrators, pulse oximeter, glucometer, blood pressure monitor, nebulizer and digital thermometer with an aim to regulate prices.

Registration of manufacturers/importers on NPPA portal, IPDMS 2.0:

The DPCO 2013 mandates registration and submission of forms by manufacturers/ importers of medical devices. For ease of doing business and improving compliance, NPPA has developed the Integrated Pharmaceutical Database Management System IPDMS 2.0. portal for online information collection, processing and communication to monitor and regulate the prices of medicines and medical devices. These measures contribute to price transparency and affordability for consumers. Manufacturers/importers are required to register on the portal and submit the required forms periodically to NPPA.

5. Policy Support and Industrial Development

Presence of high-quality infrastructure is vital for the growth of the medical devices sector in the country. The Department of Pharmaceuticals has framed the National Medical Devices Policy, 2023 which aims to position India as a global leader in medical device manufacturing and innovation. The policy focuses on six strategic pillars as shown:

Figure 3: Six Strategic Pillars of India's National Medical Devices Policy, 2023

The Government has made wide-ranging efforts to promote the medical device industry in the country, including through provision of financial assistance for the setting up of medical device industry. These include the following:

A. Production Linked Incentive (PLI) Scheme

Production Linked Incentive (PLI) scheme for promoting domestic manufacturing of Medical Devices: With a budgetary outlay of ₹3,420 crore and a five-year performance-linked incentive period from FY2022-23 to FY2026-27, the scheme provides financial incentive to manufacturers for incremental sales of domestically manufactured medical devices in the radiotherapy, imaging device, anaesthesia, cardio-respiratory and critical care and implant device segments. As of September 2025, 22 greenfield projects have been commissioned and production has started for 55 products, which include high-end medical devices on which the country has been highly import-dependent, such as linear accelerators, machines for MRI and CT scans and mammograms, C-arm X-ray machines, MRI coils and ultrasound machines. Till September 2025, cumulative eligible sales of ₹12,344.37 crore have been made under the scheme, including export sales worth ₹5,869.36 crore.

Parameter	Value (As of September 2025)
Budgetary Outlay	₹3,420 crore
Incentive Period	FY 2022-23 to FY 2026-27
Greenfield Projects Commissioned	22 (as of September 2025)
Products in Production	55
Cumulative Eligible Sales	₹12,344.37 crore
Export Sales	₹5,869.36 crore

B. Scheme for Promotion of Medical Devices Parks

The scheme aims to provide easy access to world-class, common infrastructure facilities to medical device units set up in medical device parks. The parks will provide common testing and laboratory facilities centre at one place reducing the manufacturing cost significantly and create a robust ecosystem for medical device manufacturing in the country. Three parks have been approved and are at an advanced stage of development in Greater Noida (Uttar Pradesh), Ujjain (Madhya Pradesh) and Kanchipuram (Tamil Nadu) districts. The total project cost of these is ₹871.11 crore, with Central assistance to the tune of ₹100 crore each for creation of common infrastructure facilities. It is expected to enhance industry's competitiveness and reduce production costs through optimization of resources and economies of scale.

C. Scheme for Strengthening Medical Device Industry

Launched on 8.11.2024 with a financial outlay of ₹500 crore, the scheme aims to strengthen the medical device industry by providing support in critical areas, including manufacturing of key components and accessories, skill development, support for clinical studies, development of common infrastructure, and industry promotion and consists of the following sub-schemes:

- Common Facilities for Medical Devices Clusters
- Marginal Investment Scheme for Reducing Import Dependence
- Capacity Building and Skill Development for Medical Devices
- Medical Device Clinical Studies Support Scheme
- Medical Device Promotion Scheme

6. Conclusion

India's regulatory framework for medical devices has evolved into a comprehensive and strengthened system, integrating pricing control, quality assurance, and policy support. Going forward, continued regulatory strengthening, technological innovation, and domestic manufacturing expansion will play a critical role in improving healthcare accessibility and reducing dependence on imports. The coordinated efforts of Government, supported by national initiatives and global standards, ensure that medical devices remain affordable, safe, and effective, contributing to improved healthcare outcomes.

References

- Medical devices contribute to the attainment of the highest standards of health for individuals: https://www.who.int/publications/i/item/9789241512350
- Definition terms of Medical device & Vitro Diagnostic (IVD) Medical Device: https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/acts_rules/2016DrugsandCosmeticsAct1940Rules1945.pdf, https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2022/m_device/Medical%20Devices%20Rules,%202017.pdf
- Regulatory Framework of Medical Devices: https://nppa.gov.in/aboutnppa, https://www.cdsco.gov.in/opencms/opencms/en/Medical-Device-Diagnostics/Medical-Device-Diagnostics/
- Regulation of Pricing: https://nppa.gov.in/aboutnppa, https://www.pib.gov.in/PressReleasePage.aspx?PRID=2222523&reg=3&lang=2
- Policy support and industrial development: https://pharma-dept.gov.in/policy

News related to pricing of drugs

1. Ceiling prices of 935 formulations are effective as on 30.04.2026, 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. 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. As on 30.04.2026, 277 Authority meetings have been conducted of which 145 have been conducted under DPCO 2013. The details of the recent meetings are given as below:

276th (overall) & 144th meeting under DPCO 2013, held on dated 25.03.2025

1. Retail prices for 31 formulations notified vide S.O 1590(E) Dated 24.03.2026.
2. Ceiling price of the formulations were revised based on Wholesale Price Index (WPI) @0.64956% for the year 2025 over 2024 with effect from 1.4.2026. Accordingly, NPPA issued following notifications

i. Revised Ceiling Price (WPI adjusted) of 767 scheduled formulations under Schedule-I (NLEM 2022) of Drugs (Price Control) Order, 2013 notified vide S.O. 1575(E) dated 25.03.2026.

ii. Revised Ceiling Price (WPI adjusted) of 138 scheduled formulations under Schedule-I (NLEM 2015) of Drugs (Price Control) Order, 2013 notified vide S.O. 1581(E) dated 25.03.2026.

iii. Revised Ceiling Price (WPI adjusted) of 6 scheduled formulations under Schedule-I (NLEM 2011) of Drugs (Price Control) Order, 2013 notified vide S.O. 1582(E) dated 25.03.2026.

iv. Revised Ceiling Price (WPI adjusted) of 8 IV Fluids with packages having special features under Schedule-I (NLEM 2022) of Drugs (Price Control) Order, 2013 notified vide S.O. 1583(E) dated 25.03.2026.

v. Revised Ceiling Price (WPI adjusted) of 4 pack size of Ringer Lactate injection with packages having special features under schedule-I (NLEM 2022) under Drugs (Price Control) Order, 2013 notified vide S.O. 1584(E) dated 25.03.2026.

vi. Revised Ceiling Price (WPI adjusted) of 6 other IV Fluids with packages having special features under Schedule-I (NLEM 2022) of Drugs (Price Control) Order, 2013 notified vide S.O. 1586(E) dated 25.03.2026.

vii. Revised Ceiling Price (WPI adjusted) of 2 Coronary stent S.O. 1587(E) dated 25.03.2026 notified vide S.O. 1587(E) dated 25.03.2026.

viii. Revised Ceiling Price (WPI adjusted) of 2 (i) Piperacillin 2gm+ Tazobactum 250mg and (ii) Piperacillin 4gm+ Tazobactum 500mg under Schedule-I (NLEM 2022) of Drugs (Price Control) Order, 2013 notified vide S.O. 1588(E) dated 25.03.2026.

ix. Revised Ceiling Price (WPI adjusted) of 2 (i) Meropenem powder for Injection 500gm Dual chamber bag and (ii) Meropenem powder for Injection 1000gm Dual chamber bag under Schedule-I (NLEM 2022) of Drugs (Price Control) Order, 2013. notified vide S.O. 1589(E) dated 25.03.2026.

3. NPPA has granted exemption under Para 32 of the DPCO, 2013 to two companies. The details are as under-

I. M/s Wockhardt Limited was granted exemption under Para 32(i) in respect of the patented formulation "Nafithromycin 400 mg Tablets" vide notification S.O. 1593(E) dated 25.03.2026, and

ii. M/s Intas Pharmaceuticals Limited was granted exemption under Para 32(ii) for the formulation "Clozapine Extended Release 12.5 mg/25 mg/50 mg/100 mg/200 mg Capsule" vide notification S.O. 1585(E) dated 25.03.2026.

Meeting No. 277(overall) & 145th meeting under DPCO 2013, held on dated 30.04.2026

Retail prices for 42 formulations notified vide S.O 2167(E) Dated 30.04.2026.

3. O.M dated 25.03.2026 was issued regarding annual revision of ceiling price under Para 16 based on change in Wholesale Price Index (WPI) @0.64956% for the preceding calendar year 2025 over 2024.

4. Retail prices for 3775 (approx.) new drugs have been fixed under DPCO, 2013 till 30.04.2026. Details of 73 retail prices notified for various formulations based on the decision taken in 144th and 145th 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	8	Tablet	10.34 -22.77
2.	Pain / Analgesics	5	Tablet/ Suspension	0.79 – 10.58
3.	Cardiovascular	18	Tablet/Capsule	6.19 - 32.46
4.	Anti-Hypertensive	3	Tablet	11.99-23.17
5.	Anti-Infective	6	Tablet	25.00 – 63.94
6.	Respiratory	3	Tablet/Respiratory Solution	6.00– 7.5
7.	Vitamins/Minerals	8	Tablet/Drops/Syrups	0.88 -21.66
8.	Gynaecological, Hormones	13	Tablet	107.22-120.62
9.	Others	9	Tablet /Injection/Ointment	10.18-14,666.35

News related to pricing of Medical devices

NPPA, vide S.O 1587(E) dt.25.03.2026, S.O.1582(E) &S.O.1575(E) dt.27.03.2026 issued notifications regarding the fixation and revision of the ceiling prices of Medical Devices i.e Coronary stents Condoms and IUDs, respectively, based on the Wholesale Price Index (WPI) increase of 0.64956% for the year 2025 over 2024, in accordance with Paragraph 16(2) of the DPCO, 2013, read with Paragraph 13(2) of DPCO, 2013.

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 2025 to April 2026:

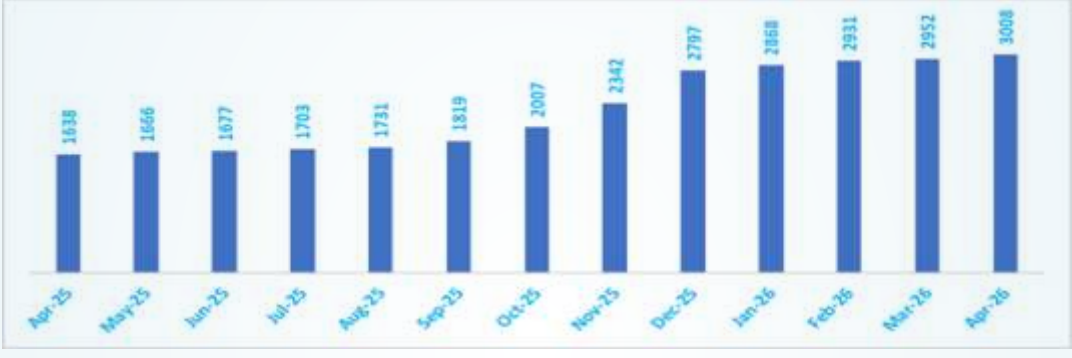


Chart1: Total number of registered companies at the end of April 2026

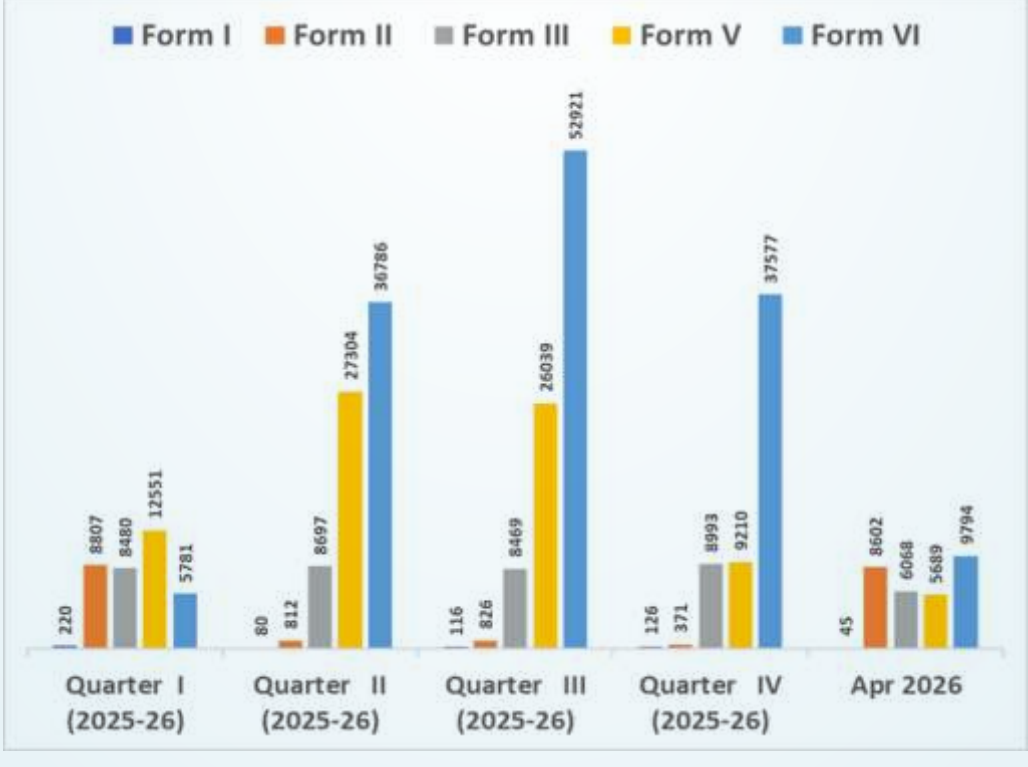


Chart 2: Forms (specified under Schedule II of DPCO, 2013) filed on IPDMS

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

Chart 4: Number of User logins in IPDMS 2.0

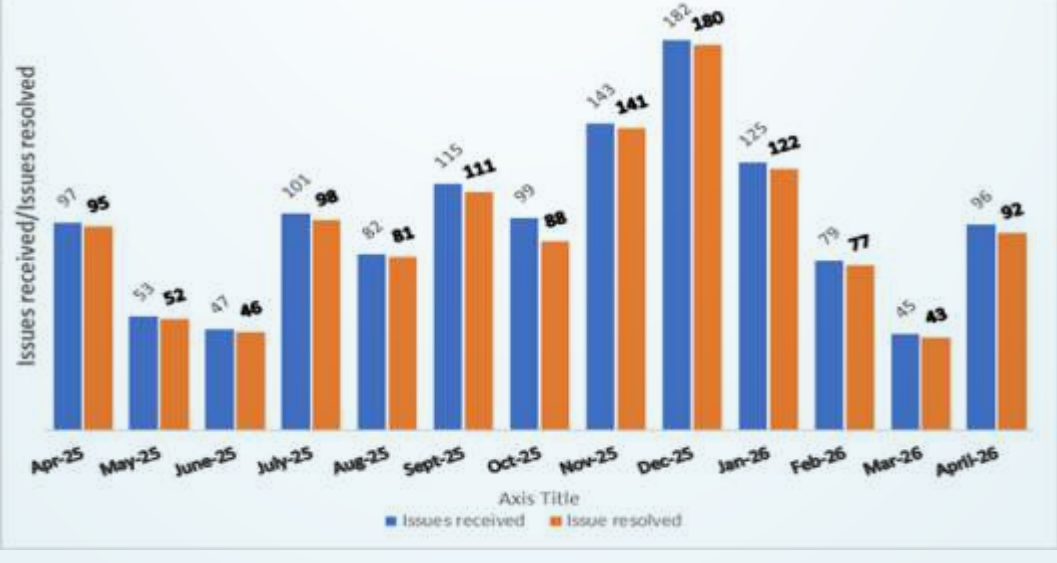


Chart 5: Issues received /resolved

FDA Takes Further Steps to Streamline Biosimilar Development and Make Medicines More Affordable (March 09, 2026)

The U.S. Food and Drug Administration announced its initiative to streamline the development of biosimilar medicines, which are like "generic" versions of biologic drugs. In new draft guidance issued today, the agency recommended streamlining unnecessary clinical pharmacokinetic (PK) testing when scientifically justified. This change could save biosimilar developers up to 50% of their PK study costs, or approximately $20 million, and help lower drug costs. Biologic medicines can be powerful treatments for many diseases, including autoimmune diseases and cancer, but are often expensive. Despite accounting for just 5% of prescriptions, biologics account for 51% of drug spending, and commonly cost hundreds of thousands of dollars per year. Biosimilars, like generic drugs, can give patients more affordable treatment options and increase access to medications that are otherwise unaffordable.

(Read more)

FDA Approves Drug to Treat Neurologic Manifestations of Hunter Syndrome (March 25, 2026)

The U.S. Food and Drug Administration approved Avlayah (tividenofusp alfa-eknm) to treat certain individuals with Hunter syndrome (Mucopolysaccharidosis type II or MPS II day for children and their families battling Hunter syndrome Hunter syndrome is a rare inherited lysosomal disorder in which sugar molecules called glycosaminoglycans build up within the cells' lysosomes. This substrate accumulation

affects physical and mental development by causing abnormalities in the skeleton, heart, respiratory system, brain, and other organs.

(Read more)

FDA Proposes to Exclude Semaglutide, Tirzepatide, and Liraglutide on 503B Bulks List (April 30, 2026)

The U.S. Food and Drug Administration is proposing to exclude semaglutide, tirzepatide, and liraglutide on the 503B bulks list, finding no clinical need for outsourcing facilities to compound these drugs from bulk substances. The 503B bulks list identifies bulk drug substances that outsourcing facilities may use in compounding under the conditions of section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act). In most cases, outsourcing facilities cannot compound drugs using bulk drug substances unless the substance appears on the 503B bulks list, or the compounded drug is on the FDA's drug shortage list at the time of compounding, distribution, and dispensing.

(Read more)

INTERNATIONAL NEWS

New medicine to reduce triglycerides in adults with familial chylomicronaemia syndrome (24 April 2026)

EMA has recommended granting a marketing authorisation in the European Union (EU) for Redemplo (plozasiran) to treat adults with familial chylomicronaemia syndrome (FCS). FCS is a rare inherited disease that prevents the body from breaking down lipids (fats). People with this condition have extremely high levels of triglycerides in their blood. This causes a range of symptoms, including severe abdominal pain, potentially fatal attacks of acute pancreatitis, hepatosplenomegaly (enlargement of liver and spleen), diabetes, lack of concentration, memory loss and fat-filled spots on the skin (called xanthomas). People with FCS must strictly limit their fat intake through diet. However, this is not always feasible nor sufficiently effective to reduce the level of triglycerides and prevent pancreatitis. Traditional lipid-lowering medications have minimal impact when it comes to reducing triglyceride levels in patients with FCS.

(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 29 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:

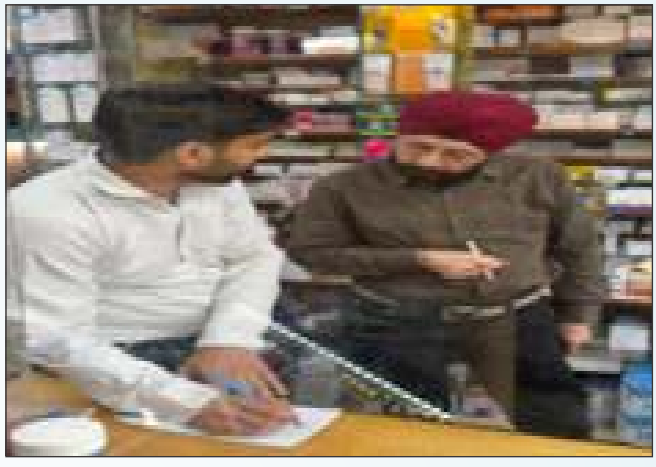
Twenty-Nine (29) State and District level Events/Seminars have been organized by 13 (Thirteen) PMRUs in their respective States/UTs, viz. Puducherry, Jammu & Kashmir, Goa, Chhattisgarh, Jharkhand, Haryana, Lakshadweep, Punjab, Rajasthan, Odisha, Kerala, Ladakh and Tripura PMRU. These events were aimed 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: -

JAMMU & KASHMIR PMRU

PMRUs IN ACTIONS

PUNJAB PMRU



GOA PMRU

RAJASTHAN PMRU

PUDUCHERRY PMRU

LAKSHADWEEP PMRU

LADAKH PMRU

PMRUs IN ACTIONS

ODISHA PMRU

JHARKHAND PMRU

HARYANA PMRU

Following is a brief on the activities carried out by Tripura & Kerala PMRU.

1. Tripura PMRU: Tripura PMRU, established on 25th June 2019, has conducted a total of 75 IEC activities and has reported 431 violation cases on the IPDMS portal. As part of its Information, Education and Communication (IEC) activities, TPMRU organized a seminar to create awareness on medicine price regulation, consumer rights, rational use of medicines, and digital empowerment through the "Pharma Sahi Daam" mobile application. The programme included awareness sessions on the role and functions of the National Pharmaceutical Pricing Authority (NPPA), provisions of the Drugs (Prices Control) Order (DPCO), responsibilities of TPMRU, and the growing concern of antimicrobial resistance. TPMRU also conducted a demonstration session on the "Pharma Sahi Daam" mobile application, educating participants on how consumers can verify the ceiling prices of scheduled medicines to ensure transparency and affordability.

PMRUs IN ACTIONS

2. Kerala PMRU: The Kerala PMRU, registered on 03rd January 2019, has undertaken a total of 80 IEC activities and has reported 176 violation cases on the IPDMS portal to date. In its recent IEC initiatives, the PMRU conducted an awareness talk on the "Role of National Pharmaceutical Pricing Authority in Affordability of Essential Drugs" as part of the nationwide campaign organized by the National Pharmaceutical Pricing Authority (NPPA) in the run-up to India@75 – Azadi Ka Amrit Mahotsav. Under the guidance of the Drugs Controller, Kerala State PMRU organized a radio talk show and awareness jingles in Malayalam, which were broadcast through All India Radio, Thiruvananthapuram, on October 25, 2021, at 11:00 AM. The programme highlighted the functions of NPPA, provisions under the Drug Price Control Order (DPCO), measures undertaken for price fixation of medicines, major interventions during the COVID-19 pandemic, and awareness initiatives such as the Pharma Sahi Daam mobile application and Pharma Jan Samadhan portal. It also emphasized the role of Price Monitoring and Resource Units (PMRUs), the State Drugs Control Department, and Kerala State PMRU Society in ensuring the affordability of essential medicines, while informing the public about grievance redressal and complaint registration mechanisms. The radio talk provided listeners with valuable insight into the structure and functioning of NPPA and strengthened public awareness regarding drug price control mechanisms and government-fixed ceiling prices for essential medicines.






NPPA Participation in State-Level Awareness Programme Organised by Jharkhand PMRU:

Shri Kumar Aman Bharti, Director (PMRU), participated in the State-Level Awareness Programme as a representative of the National Pharmaceutical Pricing Authority (NPPA) on 09th March, 2026, at the IPH Auditorium Hall, RCH Campus, Namkum, Ranchi.The Jharkhand Pharmaceutical Price Monitoring & Resource Unit (PMRU) has undertaken extensive awareness and outreach initiatives across the State. To date, the PMRU has conducted more than 47 IEC (Information, Education and Communication) activities, including district-level awareness camps, seminars, workshops, and community interaction programmes.

These initiatives have played a vital role in educating consumers, sensitising retailers and healthcare professionals, and enhancing awareness regarding the provisions of the Drugs (Prices Control) Order (DPCO), 2013, as well as the Pharma Sahi Daam App.

FAQs on Pradhan Mantri Bhartiya Janaushadhi Kendras (PMBJKs)

1. **What is Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP)?**

   Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) is a Government of India initiative aimed at providing quality generic medicines at affordable prices through dedicated outlets called Jan Aushadhi Kendras (JAKs/PMBJKs). The scheme is implemented by PMBI (Pharmaceuticals & Medical Devices Bureau of India) under the Department of Pharmaceuticals. (Department of Pharmaceuticals)

2. **What are Jan Aushadhi Kendras?**

   Jan Aushadhi Kendras are special medicine outlets that sell generic medicines, surgical items, and healthcare products at prices significantly lower than branded medicines. (Press Information Bureau)

3. **Are medicines sold at Jan Aushadhi Kendras safe and effective?**

   Yes. Medicines supplied under PMBJP are procured only from manufacturers compliant with WHO-GMP standards. Each batch is tested at NABL-accredited laboratories. (Press Information Bureau)

4. **How much can consumers save by purchasing medicines from Jan Aushadhi Kendras?**

   Medicines sold under PMBJP are generally priced 50% to 80% lower than branded medicines available in the market. (Press Information Bureau)

5. **How many Jan Aushadhi Kendras are operational in India?**

   Over 19,000 Jan Aushadhi Kendras are operational across the country at present. (Press Information Bureau)

6. **What types of medicines and products are available at Jan Aushadhi Kendras?**

   PMBJP offers medicines across 29 therapeutic categories, including anti-diabetic, cardiac, anti-cancer, antibiotics, gastrointestinal, and nutritional products. Surgical and medical consumables are also available. (Press Information Bureau)

6. **What types of medicines and products are available at Jan Aushadhi Kendras?**

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FREQUENTLY ASKED QUESTIONS

7. Is there any financial assistance provided for opening a Jan Aushadhi Kendra?

Yes. PMBI provides incentives and financial support to eligible applicants. Special incentives are also available for women entrepreneurs, SC/ST candidates, Divyangjan, and ex-servicemen. (Press Information Bureau)

8. What is the target for expansion of Jan Aushadhi Kendras?

The Government of India has set a target of opening 25,000 Jan Aushadhi Kendras by March 2027. (Press Information Bureau)

9. How can consumers locate nearby Jan Aushadhi Kendras?

Consumers can locate nearby Kendras through the Jan Aushadhi Sugam mobile application or the official PMBI website. (Press Information Bureau)

10. What is Jan Aushadhi Suvidha?

Jan Aushadhi Suvidha is an affordable oxo-biodegradable sanitary pad initiative under PMBJP aimed at improving menstrual hygiene among women. These sanitary pads are available at Re. 1/- at Jan Aushadhi Kendras. (Press Information Bureau)

11. What is the role of PMBI in PMBJP?

PMBI (Pharmaceuticals & Medical Devices Bureau of India) is the implementing agency responsible for procurement, supply, quality assurance, and expansion of Jan Aushadhi Kendras across India. (PMDB India)

12. How can complaints or queries related to Jan Aushadhi Kendras be addressed?

Consumers may contact PMBI through its toll-free helpline 1800-180-8080 or via the official website. (PMDB India)

STAFF SPOTLIGHT...

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-
स्वरचित कविता पाठ

By Ms. Priyanka Sharma
(YP Pharma)

"मायका"

मायका है वो जहाँ मेरी दुनिया खिली,
आँगन की मिट्टी से उठी खुशबू मिली।

वो चौखट, वो नीम की ठंडी छाँव,
गलियों में बचपन के हजारों पाँव।

मायका है, जहाँ मेरी नन्ही हँसी की गूँज,
आँगन की सहेली, खिलखिलाती सुबहें अनूठी।

शामें अलबेली, छत के नीचे बातें,
बचपन के नन्हे सपनों संग धड़कती प्रीतें।

यादों के पन्नों पर सजी तस्वीरें,
हर कोने में छुपी अनगिनत तहरीरें।

चाय के प्यालों संग माँ की डाँट-फटकार,
और दुआओं की छाँव, जैसे परम उपहार।

मेरी अलमारी के कोनों में अब भी बसा है,
बचपन का छोटा सा प्यारा किस्सा।

पुराने कपड़े, अधूरी डायरी के पन्ने,
और माँ की चुनरी—अनमोल नज़ाने।

भाई की शरारतें, झगड़े और रुठना,
फिर मुस्कुराकर एक-दूसरे को मनाना।

बहन संग छोटी-छोटी मीठी बातें,
वो रिश्ते ही तो असली दौलत कहलाते।

पापा का वह स्नेह, माँ का वह दुलार,
हर लम्हे का जहाँ दिल से जुड़ा संसार।

वक़्त ने थाम ली रिश्तों की डोर,
और जिम्मेदारियों ने खींचा एक और ओर।

छोटे से आँगन को छोड़कर,
सपनों का नया संसार जोड़कर,
निकली मैं जीवन की राहों पर,
पर दिल आज भी लौटना चाहता है बार-बार
अपने मायके की गलियों की ओर।

Feedback and Complaint Redressal

Grievance Redressal

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

Information Dissemination

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

Seminars and Workshops conducted by NPPA and by PMRUs

Collaboration with State Governments

PMRU: To help NPPA to monitor notified prices and ensure availability of medicines.

To spread awareness regarding the pricing of drugs, etc.

NPPA
AFFORDABLE MEDICINES FOR ALL
सभी के लिए वहनीय दवाईयाँ

NATIONAL PHARMACEUTICAL PRICING AUTHORITY

3rd / 5th Floor, YMCA Cultural Center Building 1, Jai Singh Road, New Delhi, India

www.nppa.gov.in | Helpline No.: 1800 111 255 (10 am to 6 pm on working days)