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RATIONAL DRUG USE IN INDIA: GENERIC PRESCRIBING AND REGULATION OF FIXED-DOSE COMBINATIONS

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ABSTRACT

India's healthcare system is witnessing a significant transition toward affordability, safety, and rational drug use, driven by growing concerns over high out-of-pocket expenditure, irrational prescribing, and the widespread availability of unsafe fixed-dose combinations (FDCs). Generic prescribing has emerged as a key strategy to improve access to essential medicines, reduce treatment costs, and support universal health coverage initiatives such as Ayushman Bharat – Pradhan Mantri Jan Arogya Yojana (PMJAY) and Pradhan Mantri Jan Aushadhi Pariyojana (PMJP). Alongside this, regulatory authorities have taken decisive actions to prohibit irrational FDCs that lacked scientific justification and posed risks of adverse drug reactions and antimicrobial resistance. This review critically examines the current landscape of generic prescribing and FDC regulation in India, emphasizing their implications for healthcare delivery, pharmacists, and rational drug use. Evidence from national and international guidelines, regulatory frameworks, and published studies highlights that generic medicines, when manufactured and regulated appropriately, offer therapeutic equivalence to branded products at substantially lower costs. However, challenges such as prescriber bias, patient misconceptions, variable brand substitution, and weak pharmacovigilance limit their optimal utilization. The review further underscores the central role of pharmacists in promoting generic substitution, patient counselling, pharmacovigilance, and antimicrobial stewardship. Integration of World Health Organization (WHO) recommendations, Indian Council of Medical Research (ICMR) guidelines, National Pharmaceutical Pricing Authority (NPPA) pricing controls, Central Drugs Standard Control Organization (CDSCO) regulatory actions, and national health schemes provides a strong

policy foundation for rational medicine use. Strengthening regulatory enforcement, enhancing professional education, and improving public awareness are essential to fully realize the benefits of generics and ensure patient safety in India.

KEYWORDS: Generic prescribing, Fixed-dose combinations, Pharmacists, Rational drug use, India, PMJAY, NPPA, CDSCO.

INTRODUCTION

1.1 ***Background: Rational drug use and medicine policy in India:*** India's healthcare system is undergoing significant reform with a growing emphasis on affordability, safety, and rational drug use. Rising out-of-pocket expenditure and dependence on branded medicines underscore the necessity for wider adoption of generic prescribing practices [1]. Global and national regulatory authorities, including the World health organization (WHO), Indian council of medical research (ICMR), Central drugs standard control organization (CDSCO), and National pharmaceutical pricing authority (NPPA), advocate evidence-based prescribing through essential medicine frameworks, pricing regulations, and therapeutic guidelines [2,3,4]. Within this evolving landscape, generic medicines and stronger regulation of irrational fixed-dose combinations (FDCs) have emerged as crucial strategies to improve equitable access, enhance treatment outcomes, and strengthen India's public health system [5,6].

1.2 ***Scientific and regulatory rationale for the prohibition of irrational fixed-dose combinations in India:*** An investigation was carried out in 2023 on the scientific, regulatory, and clinical reasons behind India's large-scale prohibition of irrational FDCs. Their study revealed that many FDCs in the Indian market lacked pharmacological justification, contained incompatible drug pairings, or included subtherapeutic or toxic doses. They found widespread issues such as duplication of therapeutic action, increased risk of adverse drug reactions, antimicrobial resistance, and absence of supporting clinical evidence. The authors emphasized that strong CDSCO intervention, expert committee evaluations, and stricter regulatory oversight were essential to protect patient safety and promote rational drug use in India [6].

1.3 ***Regulatory evaluation and public health basis for the 2024 ban on irrational fixed-dose combinations:*** A comprehensive investigation was conducted in 2024 into India's decision to ban numerous irrational FDCs. Their analysis revealed that many formulations lacked

mandatory clinical trial data, violated pharmacokinetic and pharmacodynamic compatibility, and posed significant safety concerns. The authors highlighted that expert committee reviews found inadequate justification for combined use, poor therapeutic rationale, and heightened risk of toxicity and antimicrobial resistance. The study emphasized that CDSCO's regulatory action aligned with WHO's principles of rational drug use and represented a crucial intervention to safeguard public health and prevent irrational prescribing practices [5].

1.4 ***Generic prescribing in India: Advantages, limitations, and practice challenges:*** The advantages and limitations of prescribing medicines by their generic names was carried out in 2023. Their study highlights that generic prescribing significantly improves affordability, reduces patient financial burden, and aligns with national policies promoting rational drug use. However, they identified several barriers, including prescribers' concerns regarding generic drug quality, variable patient perceptions, and the strong influence of pharmaceutical brand promotion. The authors emphasized that pharmacists play a pivotal role in counselling, generic substitution, and addressing misconceptions. They recommended stronger regulatory communication, bioequivalence awareness, and nationwide sensitization programs to enhance generic adoption [7].

1.5 ***Comparative analysis of branded and unbranded generic medicines in India:*** The contemporary landscape of generic medicines in India through a comparative analysis of branded versus unbranded generics was carried out in 2021. Their findings show that generic medicines substantially reduce treatment costs and improve accessibility, especially for economically vulnerable populations. However, the study identified persistent challenges, including inconsistent physician preference for branded drugs, limited public awareness about generic quality, and inadequate enforcement of bioequivalence standards. The authors emphasized strengthening regulatory surveillance, expanding Jan Aushadhi availability, and enhancing pharmacist involvement to promote rational generic substitution and improve national healthcare affordability [8].

1.6 ***Role of pharmacists in strengthening India's healthcare system and rational drug use:*** Evaluation on India's healthcare structure was carried out in 2022 and highlighted the pivotal role of pharmacists in bridging gaps in medication safety, accessibility, and rational drug use. The study noted that India faces significant challenges, including high out-of-pocket expenditure, uneven access to essential medicines, and widespread preference for branded drugs. Pharmacists were identified as key contributors to generic substitution, patient

counselling, and pharmacovigilance activities. Integrating pharmacists more deeply into healthcare delivery, public health programs, and national initiatives such as Pradhan Mantri Jan Arogya Yojana (PMJAY) and Jan Aushadhi could substantially improve affordability and rational prescribing practices in India [1].

1.7 ***Pharmaceutical pricing dynamics and their impact on generic medicine affordability in India:*** The complex pricing mechanisms within India's pharmaceutical sector was carried out in 2025, highlighting how marketing strategies, brand influence, distribution margins, and prescriber behaviour collectively shape medicine affordability. The chapter explains that generic medicines significantly reduce treatment costs, yet price disparities persist due to market fragmentation and aggressive branding. Mahato emphasized the regulatory role of NPPA and Drug price control order (DPCO) in capping prices of essential medicines, improving accessibility for low-income populations. However, he noted that public awareness, prescriber adherence, and transparent pricing practices must improve to strengthen rational drug use and optimize healthcare expenditure [9].

1.8 ***Pharmacovigilance as a pillar of medicine safety and rational drug use:*** The foundational role of pharmacovigilance in ensuring the safe and effective use of medicines was emphasized in 2025, with particular relevance to generic drugs and fixed-dose combinations (FDCs). The chapter highlights that adverse drug reaction (ADR) reporting, signal detection, and post-marketing surveillance are essential to protect patients from substandard or irrational formulations. The authors identified pharmacists as central figures in pharmacovigilance systems, particularly within Pharmacovigilance program of India (PvPI), where they monitor medication safety, educate patients, and detect issues related to bioequivalence or irrational FDC use. Strengthening pharmacovigilance practices was recommended to enhance rational drug use nationally [10].

1.9 ***WHO guidelines on rational prescribing and generic medicine use:*** The World health organization in 2021 outlines a structured approach to rational prescribing, emphasizing accurate diagnosis, evidence-based drug selection, appropriate dosing, and patient-cantered communication. The guide strongly recommends prescribing medicines by generic names to ensure transparency, affordability, and standardization across healthcare systems. WHO identifies irrational FDCs, polypharmacy, and excessive antibiotic use as major threats to patient safety and global health. The document provides prescribers with step-by-step

methods to minimize medication errors, avoid unnecessary drugs, and improve therapeutic outcomes. These principles form the basis of national prescribing reforms in India [2].

1.10 ***WHO model list of essential medicines and its role in promoting rational drug use:*** The World health organization in 2022 updated the model list of essential medicines to emphasize treatments that are effective, safe, and cost-efficient for global health systems. The list prioritizes generic formulations and discourages the use of irrational FDCs that lack proven therapeutic advantage. WHO stresses that essential medicines must be affordable and supported by strong clinical evidence, forming the backbone of national drug policies. The document also guides countries like India in updating their national list of essential medicines (NLEM), shaping regulatory decisions, pricing controls, and rational prescribing frameworks [11].

1.11 ***WHO report on global challenges in rational medicine use:*** The WHO in 2023 reported persistent global challenges in rational medicine use, including unnecessary polypharmacy, inappropriate antibiotic prescribing, and widespread availability of irrational FDCs. The report highlights that more than half of all medicines worldwide are prescribed, dispensed, or sold inappropriately, leading to increased treatment failures, adverse drug reactions, and antimicrobial resistance. WHO recommends national stewardship programs, prescriber training, strict regulatory action, and promotion of generic medicines to improve affordability and safety. The findings underscore the importance of evidence-based decision-making and stronger regulatory enforcement in healthcare systems such as India's [12].

1.12 ***ICMR guidelines on antimicrobial stewardship and rational antibiotic use:*** The ICMR in 2022 emphasizes the urgent need for antimicrobial stewardship in India to counter rising antimicrobial resistance and inappropriate prescribing. The guidelines highlight irrational fixed-dose antibiotic combinations, self-medication, and unrestricted over-the-counter sales as major contributors to resistance. ICMR strongly discourages irrational FDCs and stresses that antibiotic therapy must be evidence-based, pathogen-directed, and aligned with national protocols. The report also promotes generic prescribing to improve access and affordability while ensuring treatment uniformity. Hospitals are advised to implement stewardship committees, monitor antibiotic consumption, and strengthen diagnostic stewardship [3].

1.13 ***NPPA and DPCO regulations for medicine price control and affordability:*** The NPPA in 2022 provided critical updates to the DPCO, reinforcing government control over prices of

essential medicines in India. The report highlights that regulating ceiling prices has significantly improved affordability, particularly for cardiovascular, antimicrobial, and chronic disease drugs. NPPA notes that large price gaps exist between branded and unbranded generics, and price caps help reduce patient out-of-pocket expenditure. The document also stresses the importance of monitoring trade margins, preventing unethical pricing practices, and ensuring availability of quality-assured generics to strengthen rational drug use nationwide [4].

1.14 ***CDSCO regulatory actions on irrational fixed-dose combinations:*** The CDSCO in 2023 issued comprehensive notifications banning numerous irrational FDCs after detailed scientific review. The findings revealed that many FDCs lacked clinical justification, combined pharmacologically incompatible drugs, or posed unacceptable safety risks. Expert committees identified concerns such as increased toxicity, treatment duplication, antimicrobial resistance, and absence of validated efficacy data. CDSCO emphasized that such formulations compromise patient safety and violate regulatory requirements under the Drugs and Cosmetics Act. The ban aligns with WHO recommendations, aiming to promote rational prescribing and enhance national drug safety standards [13].

1.15 ***Role of Ayushman Bharat–PMJAY in promoting access to affordable medicines:*** The National Health Authority in 2023 reported that Ayushman Bharat–Pradhan Mantri Jan Arogya Yojana (PMJAY) significantly improved access to affordable healthcare for millions of low-income families in India. The report highlights that centralized procurement of quality-assured generic medicines through state health agencies drastically reduces hospitalization costs and ensures uniform treatment standards. PMJAY promotes rational drug use by prioritizing essential medicines and discouraging irrational FDCs within empanelled hospitals. The scheme also strengthens pharmacists' roles in medication distribution and patient counselling. Overall, PMJAY enhances affordability, transparency, and equitable medicine access nationwide [14].

1.16 ***Jan Aushadhi (PMBJP) initiative for affordable and quality generic medicines:*** The Pharmaceuticals and medical devices bureau of India (PMBI) in 2023 reported substantial expansion of the Pradhan Mantri Bhartiya Jan Aushadhi Pariyojana (PMBJP), with over 9,000 functional stores supplying WHO–Good manufacturing practices (WHO-GMP) certified generic medicines at significantly lower prices. The report highlights price reductions of 50–90% compared to branded alternatives, improving access for economically

disadvantaged populations. PMBI emphasized stringent quality testing across National accreditation board for testing and calibration laboratories (NABL) accredited laboratories and consistent supply-chain monitoring to ensure reliability. The initiative strengthens rational drug use by promoting generic substitution, reducing treatment costs, and increasing public trust in generics nationwide [15].

1.17 ***Challenges to rational medicine use in India: Critical perspectives:*** India's longstanding challenges in achieving rational medicine use was critically examined in 2021. The analysis highlights pervasive issues such as irrational prescribing, excessive antibiotic use, aggressive pharmaceutical marketing, and inadequate regulatory enforcement. The author emphasized that irrational FDCs and brand-biased prescribing significantly contribute to medication misuse and patient harm. Srinivasan further identified gaps in public awareness, prescriber training, and pharmacist involvement. The study calls for stronger stewardship programs, nationwide generic promotion, and stringent regulation to align India's prescribing practices with global rational drug-use standards [16].

1.18 ***Economic burden of medicines and the need for generic adoption: World bank perspective:*** The World Bank in 2020 reported that India continues to experience one of the highest levels of out-of-pocket healthcare expenditure globally, with medicines accounting for a major share of household spending. The analysis highlights that dependence on branded medicines significantly elevates treatment costs, limiting access for low-income populations. The report emphasizes that wider adoption of generic medicines, stronger price regulation, and expansion of publicly funded schemes are essential to improving affordability. It also notes that inequitable access, variable quality perception, and fragmented insurance coverage remain major barriers to universal healthcare [17].

TABLE 1: Comparative matrix of generic medicines vs branded medicines, impact of Fixed-dose combinations (FDCs), and role of pharmacists.

Parameter	**Generic medicines**	**Branded medicines**	**Fixed-dose combinations (FDCs)**	**Role of pharmacists**
Cost & Affordability	Significantly lower cost; reduce out-of-pocket	Higher cost due to branding, marketing, and	Often more expensive without proportional	Guide patients toward cost-effective generics;

	expenditure; supported by NPPA, Jan Aushadhi, PMJAY [8,4,14]	promotion [9]	clinical benefit [6]	support affordability initiatives
Quality & Bioequivalence	Bioequivalent to branded drugs when CDSCO-approved; WHO-GMP compliant in Jan Aushadhi supply [11,15]	Perceived as superior, though not always clinically different [7]	Many banned FDCs lacked quality and efficacy data [13]	Educate patients and prescribers on bioequivalence and quality standards
Clinical Efficacy	Comparable therapeutic outcomes when appropriately prescribed [2]	Clinically effective but not superior solely due to branding	Rational FDCs may improve adherence; irrational FDCs reduce efficacy [5]	Ensure appropriate selection, dosing, and patient adherence
Safety Profile	Well-defined when used as single-drug formulations [12]	Generally safe but cost may limit adherence	Irrational FDCs linked to ADRs, toxicity, and AMR [6,3]	Monitor ADRs, report to PvPI, identify unsafe combinations
Risk of Antimicrobial Resistance (AMR)	Lower risk when prescribed rationally and singly [3]	Similar risk profile if misused	High AMR risk with irrational antibiotic FDCs [3.13]	Support antimicrobial stewardship and rational antibiotic use
Regulatory Control	Regulated by CDSCO,	Regulated but influenced by	Subject to strict scrutiny and	Ensure compliance

	NPPA, DPCO, WHO standards	market dynamics	bans by CDSCO [5]	with regulatory bans and guidelines
Prescriber Preference	Increasingly encouraged by NMC and WHO [2]	Still preferred due to brand familiarity and marketing	Previously over-prescribed due to convenience	Advocate rational prescribing and generic substitution
Patient Acceptance	Growing acceptance, especially under PMJAY and Jan Aushadhi [14]	High acceptance due to brand trust	Confusion and misuse common with irrational FDCs	Counsel patients, improve medication literacy
Public Health Impact	Improves access, equity, and sustainability of healthcare [17]	Increases financial burden	Negative impact when irrational; positive only if evidence-based	Act as frontline public health professionals
Contribution to Rational Drug Use	Strongly supports rational therapy principles	Neutral unless combined with rational prescribing	Mixed, beneficial only when rational [6]	Central to implementing rational drug use at ground level

Table 2. Role of national and international regulatory bodies and health policies in promoting rational drug use in India.

Regulatory / Policy body	**Key guidelines / Policies**	**Focus areas**	**Key contributions to rational drug use**	**Relevance to review**
World Health Organization	WHO Good Prescribing	Generic prescribing,	Promotes prescribing by	Provides global standards and

(WHO)	Guide (2021); WHO Model List of Essential Medicines (2022); Rational Use of Medicines Report (2023) [2,11,12]	essential medicines, rational therapy	generic name, discourages irrational FDCs, emphasizes evidence-based drug selection, patient-centered care	conceptual foundation for India's prescribing and FDC regulations
Indian Council of Medical Research (ICMR)	Antimicrobial Stewardship & Treatment Guidelines (2022) [3]	Antibiotic use, AMR control	Recommends rational antibiotic prescribing, discourages irrational antibiotic FDCs, supports single-drug therapy and stewardship programs	Strengthens scientific basis for banning irrational FDCs and promoting generics
Central Drugs Standard Control Organization (CDSCO)	Drugs & Cosmetics Act; FDC ban notifications (2016–2023) [13]	Drug approval, safety, efficacy	Evaluates safety and efficacy of medicines; bans irrational FDCs lacking evidence; enforces regulatory compliance	Core regulatory authority ensuring safety and rationality of medicines in India

National Pharmaceutical Pricing Authority (NPPA)	Drug Price Control Order (DPCO-2013) updates [4]	Drug pricing, affordability	Fixes ceiling prices of essential medicines; reduces price disparities between branded and generic drugs	Facilitates affordability and access to essential generic medicines
National Medical Commission (NMC)	Medical ethics & prescribing norms [18]	Prescriber behaviour	Mandates prescribing by generic name wherever possible; promotes ethical prescribing	Influences prescriber practices and supports generic adoption
National Health Authority (NHA) – PMJAY	Ayushman Bharat–PMJAY policies & annual reports [14]	Universal health coverage, affordability	Ensures access to quality-assured generic medicines through public procurement; reduces out-of-pocket expenditure	Demonstrates real-world implementation of generic medicine use
Pharmaceuticals & Medical Devices Bureau of India (PMBI)	Jan Aushadhi (PMBJP) program [15]	Generic medicine availability	Operates Jan Aushadhi stores supplying WHO-GMP generics at low	Strengthens public trust and availability of generics

			cost; ensures quality testing	
Pharmacovigilance Programme of India (PvPI)	ADR reporting guidelines [10]	Drug safety monitoring	Detects ADRs related to generics and FDCs; supports post-marketing surveillance	Ensures safety and continuous evaluation of medicines
World Bank	Healthcare expenditure & access reports (2020) [17]	Health economics	Highlights high out-of-pocket spending; supports generics for financial protection	Provides economic justification for policy reforms

CONCLUSION

Generic prescribing and the regulation of irrational FDCs represent two critical pillars of rational drug use in India. While generic medicines significantly enhance affordability and access to healthcare, their success depends on robust regulatory oversight, prescriber confidence, and informed patient acceptance. The prohibition of irrational FDCs by regulatory authorities has addressed major safety and efficacy concerns, rein-forcing evidence-based prescribing practices and reducing the risk of antimicrobial resistance. Pharmacists play a pivotal role in translating policy into practice by facilitating generic substitution, counselling patients, monitoring adverse drug reactions, and supporting pharmacovigilance systems. National initiatives such as PMJAY and Jan Aushadhi, supported by WHO and ICMR guidelines, have strengthened the foundation for rational medicine use. Moving forward, sustained collaboration among policymakers, healthcare professionals, regulators, and educators is essential to promote safe, effective, and affordable pharmacotherapy and to ensure a resilient and patient-centred healthcare system in India.

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