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A STUDY OF QUALITY ASSURANCE AND PRESCRIBING PRACTICES IN GENERIC MEDICINE USE IN INDIA

*Sankpal Shirish Vithal

Research Scholar, Department of Pharmacy, Sunrise University, Alwar, Rajasthan

**Dr. Saraswati VithalraoVijaypure

Assistant Professor, Department of Pharmacy, Sunrise University, Alwar, Rajasthan

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ABSTRACT

Generic medicines support affordable healthcare in India, but their appropriate use depends on pharmaceutical quality, regulatory oversight, and informed prescribing and dispensing practices. This study examines how quality-assurance systems and healthcare professionals' decisions influence the acceptance and use of generic medicines, with particular attention to pharmaceutical equivalence, bioequivalence, laboratory standards, and substitution practices. It employs a descriptive and analytical design based exclusively on published scientific studies, official pharmaceutical guidelines, regulatory publications, and government reports. Purposively selected documentary evidence is examined through qualitative interpretation and descriptive comparisons; no primary survey, laboratory experiment, or original inferential analysis is undertaken. The findings show that lower prices do not necessarily indicate inferior pharmaceutical quality. In a comparative investigation in Kerala, all 131 sampled branded and generic medicines satisfy the assessed pharmacopoeial parameters, while generic products cost an average of 48.6% less. However, results from selected samples cannot establish nationwide quality compliance. Evidence on prescribing reveals differences in professional confidence: approximately 84% of government physicians and 64% of private physicians in one study consider generics equally safe and effective, while substantial proportions request further information on bioequivalence. Pharmacy-level evidence highlights the importance of patient counselling, medicine availability, and coordination with prescribers. The introduction of 121 new monographs in Indian Pharmacopoeia 2026 and government-supported batch testing illustrate continuing quality-assurance efforts. The study concludes that wider, appropriate generic medicine use requires transparent product-quality evidence, stronger professional education, consistent regulatory monitoring, and legally compliant substitution practices. These measures promote clinical confidence, patient safety, and access to affordable treatment.

1. INTRODUCTION

Generic medicines constitute an essential component of India's pharmaceutical sector by improving access to affordable treatment. Their effective utilisation depends on pharmaceutical quality, safety, therapeutic performance and appropriate prescribing practices. Generic formulations contain the same active pharmaceutical ingredients as corresponding reference products, although inactive ingredients and manufacturing processes may differ. Pharmaceutical equivalence concerns comparable active ingredients, strength and dosage form, whereas bioequivalence evaluates the rate and extent of drug absorption. Therapeutic equivalence establishes the basis for expected comparable clinical performance. The World Health Organization (n.d.) emphasises appropriate quality standards and evidence of interchangeability for multisource pharmaceutical products.

The development of India's generic pharmaceutical industry is closely associated with changes in patent regulations, manufacturing capabilities and pharmaceutical quality-control systems. The Drugs and Cosmetics Act, 1940, provides an important regulatory foundation, while the Central Drugs Standard Control Organization oversees specified drug approvals and regulatory standards. Generic medicine quality is influenced by good manufacturing practices, pharmacopoeial compliance, product stability, storage conditions and professional knowledge. Prescribing by generic name, pharmacist involvement, patient counselling and pharmaceutical marketing further influence medicine selection.

Recent developments demonstrate increasing attention to pharmaceutical quality assurance. The Indian Pharmacopoeia Commission (2026) introduced the tenth edition of the Indian Pharmacopoeia, incorporating 121 new monographs and increasing the total to 3,340. Government-supported generic medicine distribution also incorporates manufacturer qualification, batch testing and accredited laboratory assessments (Ministry of Chemicals and Fertilizers, 2026).

Priyadarsini et al. (2023), in *A Comparative Study on Perception and Use of Generic Drugs Between Public and Private Health Practitioners*, examined physicians' knowledge, attitudes and prescribing practices through a cross-sectional questionnaire containing 25 closed-ended

questions.

The findings revealed that 84% of government physicians and 64% of private physicians considered generic medicines equally effective and safe. The researchers concluded that additional education concerning bioequivalence, quality assurance and therapeutic interchangeability was necessary.

Dehury et al. (2024), in *Genesis of People's Medicine Centre (PMC) for Popularisation of Generic Medicine: A Critical Qualitative Inquiry*, investigated pharmacy ownership, pharmacists' motivations, consumer confidence and operational difficulties in Odisha. Through 17 qualitative interviews, the researchers identified financial incentives, affordability and pharmacist communication as important influences on generic medicine acceptance. They concluded that geographical inequalities and unfavourable professional attitudes required institutional attention.

Philips et al. (2026), in *Pharmaceutical Quality and Cost-Effectiveness of Branded Versus Generic Medicines Across 22 Drug Types and 8 Therapeutic Categories*, evaluated 131 medicine samples through a cross-sectional laboratory investigation in Kerala. All samples satisfied the pharmacopoeial parameters examined, while generic medicines were approximately 48.6% cheaper than branded alternatives. The researchers concluded that the tested generic formulations offered comparable pharmaceutical quality at lower prices, although these results did not independently establish bioequivalence.

Despite established regulatory standards, uncertainty regarding pharmaceutical quality, bioequivalence and generic substitution continues to influence prescribing decisions. The separation between laboratory evidence and professional understanding creates a need to examine both dimensions together.

This study is aimed to examine pharmaceutical quality assurance, regulatory standards and prescribing practices influencing appropriate generic medicine use in India, while identifying opportunities for professional education and improved regulatory communication.

Thisstudy has adopted a descriptive and analytical documentary approach using published information exclusively.Information was collected from open-access scientific articles,

government publications, pharmaceutical guidelines and regulatory documents.Purposive documentary sampling was employed.

Relevant, accessible and verifiable sources were included, while duplicate, unsupported and insufficiently documented publications were excluded.Published quality assessments, prescribing practices and regulatory evidence were comparatively analysed using descriptive and qualitative documentary techniques. No primary surveys, laboratory experiments, systematic review procedures or original inferential statistical analyses were undertaken.

2. PHARMACEUTICAL QUALITY AND SCIENTIFIC STANDARDS OF GENERIC MEDICINES

2.1 Pharmaceutical Equivalence, Bioequivalence and Quality Parameters

Pharmaceutical quality assurance constitutes a fundamental requirement for ensuring the safety, efficacy, and reliability of generic medicines in India. Scientific evaluation involves three interconnected concepts: pharmaceutical equivalence, bioequivalence, and therapeutic equivalence. Pharmaceutical equivalence requires medicines to contain identical active pharmaceutical ingredients in the same strength, dosage form, and route of administration while meeting applicable quality standards. Bioequivalence establishes whether comparable formulations produce sufficiently similar rates and extents of systemic drug exposure, commonly measured through maximum plasma concentration (Cmax) and area under the concentration–time curve (AUC). Therapeutic equivalence additionally concerns the expectation of comparable clinical effectiveness and safety under appropriate conditions of use.

The U.S. Food and Drug Administration (2024), through the ICH M13A guidance, emphasises scientifically established bioequivalence requirements for immediate-release oral formulations, including tablets and capsules. These principles are particularly relevant to medicines such as metformin, amlodipine, and atorvastatin, which are commonly prescribed for chronic diseases.

Pharmaceutical quality assessment involves several laboratory parameters. Assay determination establishes active ingredient content, while dosage-unit uniformity evaluates consistency between tablets or capsules.

Dissolution testing measures drug release under specified experimental conditions, whereas impurity analysis identifies unwanted substances and degradation products. Stability assessments evaluate whether pharmaceutical products retain acceptable quality during their intended shelf life under prescribed storage conditions.

Importantly, compliance with pharmacopoeial specifications does not independently establish bioequivalence or clinical interchangeability for every formulation. Additional regulatory evidence, including pharmacokinetic investigations or scientifically justified biowaivers, may be necessary.

2.2 Evidence from Comparative Pharmaceutical Quality Investigations

Published Indian investigations provide valuable evidence concerning the pharmaceutical quality of generic and branded medicines. Singal et al. (2011) compared five pairs of branded and branded-generic formulations, including alprazolam, cetirizine, ciprofloxacin, fluoxetine, and lansoprazole. The medicines underwent identification, chemical composition, dosage uniformity, and dissolution testing according to Indian Pharmacopoeia 2007 standards. All tested formulations satisfied the applicable quality requirements, despite considerable differences in retail prices and distribution margins.

Similarly, Aivalli et al. (2018) investigated generic and branded medicines in Tumkur, Karnataka, focusing on metformin, glibenclamide, atenolol, and amlodipine obtained from government and private pharmaceutical sources. Laboratory assessments included identification, assay, weight uniformity, content uniformity, and dissolution testing. The evaluated formulations complied with applicable Indian Pharmacopoeia 2014 specifications. Nevertheless, qualitative findings indicated that patients and healthcare workers frequently expressed greater confidence in branded medicines, despite comparable laboratory results.

Recent national surveillance statistics further demonstrate the importance of continuous quality monitoring. According to the Ministry of Chemicals and Fertilizers (2026), State and Union Territory drug-control authorities reported testing 141,322 pharmaceutical samples during 2025–26, of which 3,012 were classified as not of standard quality, representing approximately 2.13% of tested samples. These surveillance findings concern sampled pharmaceutical products

generally and cannot be interpreted as the nationwide failure rate of generic medicines.

Collectively, the evidence indicates that lower pharmaceutical prices do not necessarily imply inferior product quality. However, individual investigations differ in medicine selection, laboratory methods, sampling coverage, and geographical representation.

Consequently, findings from selected locations cannot establish universal quality compliance across India's pharmaceutical market. Continued batch testing, transparent regulatory reporting, and scientifically appropriate bioequivalence assessment remain essential for strengthening confidence in generic medicines.

3. PRESCRIBING BEHAVIOUR AND GENERIC MEDICINE SUBSTITUTION

3.1 Physicians' Prescribing Practices and Generic Medicine Selection

Physicians play a central role in determining the utilisation of generic medicines within India's healthcare system. Their prescribing decisions are influenced by professional knowledge, clinical experience, perceived therapeutic reliability, medicine costs, patient preferences, pharmaceutical marketing and familiarity with manufacturers. Although generic medicines provide opportunities for affordable treatment, their acceptance depends considerably on physicians' understanding of pharmaceutical quality, bioequivalence and appropriate therapeutic substitution.

Charan et al. (2021), in a cross-sectional investigation involving 240 primary care physicians in Patan, Gujarat, observed that approximately 57% supported prescribing generic medicines exclusively, whereas 79.3% were aware of the Jan Aushadhi Scheme. Nevertheless, concerns regarding medicine quality and therapeutic effectiveness influenced prescribing preferences. The study included government and private practitioners and identified differences in attitudes towards pharmacist-led substitution, with private practitioners expressing greater reservations.

Recent evidence further demonstrates the importance of professional knowledge. Sreedevi et al. (2026) investigated 100 physicians across 21 Indian states and reported that only 16% possessed comprehensive knowledge of complex generic medicines, while 49% expressed neutral confidence regarding their quality, safety and efficacy. These findings highlight the importance of communicating scientific and regulatory evidence to healthcare professionals.

Prescribing medicines by their generic names must also be distinguished from selecting a

particular manufacturer's formulation. For example, a prescription specifying metformin 500 mg identifies the active ingredient and strength without necessarily establishing the manufacturer or product selected during dispensing. In India, the professional framework encourages generic-name prescribing and rational medicine use.

The stricter 2023 prescribing regulations were subsequently held in abeyance, restoring the applicability of the 2002 professional conduct regulations (National Medical Commission, 2023). Consequently, informed prescribing requires reliable quality information, appropriate clinical judgement and consideration of individual patient requirements.

3.2 Pharmacists' Role in Dispensing, Substitution and Patient Education

Pharmacists constitute an important link between physicians, pharmaceutical manufacturers and patients. Their responsibilities include interpreting prescriptions, verifying medicine strength and dosage form, maintaining appropriate storage conditions, assessing product availability and providing counselling regarding medicine administration, safety and affordability. Within Jan Aushadhi Kendras, pharmacists also contribute to public awareness by explaining the characteristics and economic benefits of quality-assured generic medicines.

Khandelwal and Choraria (2026) examined 100 pharmacists in Jaipur, Rajasthan, and reported that 86% had recommended generic medicines. However, 60% indicated that generics constituted less than 25% of the medicines they dispensed, while 99% expressed the need for standardised substitution guidelines. These findings reveal a considerable difference between favourable professional attitudes and actual dispensing practices.

Patient counselling provides opportunities to address misconceptions concerning generic medicines. For example, pharmacists dispensing amlodipine for hypertension or atorvastatin for cholesterol management can explain prescribed dosage schedules, medicine storage, possible adverse effects and available price information. Such communication is especially important for patients receiving prolonged treatment, where treatment adherence and financial affordability influence healthcare outcomes.

Nevertheless, generic substitution remains subject to legal and professional restrictions. Regulation 4.3 of the Pharmacy Practice Regulations, 2015, requires pharmacists to dispense medicines according to registered medical practitioners' prescriptions and prohibits independent prescription substitution (Pharmacy Council of India, n.d.). Therefore, pharmacists should clarify alternative formulations with prescribers whenever necessary rather than independently changing prescribed medicines.

Furthermore, inconsistent stock availability, branded prescribing preferences and limited patient awareness can restrict generic medicine utilisation. Effective pharmaceutical practice consequently requires cooperation among physicians, pharmacists and patients, supported by reliable medicine supplies, transparent quality-assurance information and continuing professional education. Such coordination strengthens responsible medicine selection while protecting patient safety and improving access to affordable treatment.

4. REGULATORY FRAMEWORK AND STRATEGIES FOR STRENGTHENING GENERIC MEDICINE USE

4.1 Pharmaceutical Regulation, Quality Assurance and Monitoring Mechanisms

Pharmaceutical regulation constitutes an essential foundation for ensuring the quality, safety, and therapeutic reliability of generic medicines in India. The Central Drugs Standard Control Organization (CDSCO), operating under the Ministry of Health and Family Welfare, performs central regulatory functions, while State Licensing Authorities oversee pharmaceutical manufacturing, sales, and distribution through licensing and inspections. These activities are governed primarily by the Drugs and Cosmetics Act, 1940, and Drugs Rules, 1945. The Indian Pharmacopoeia Commission (IPC), headquartered in Ghaziabad, Uttar Pradesh, establishes official pharmaceutical standards covering medicine identity, purity, strength, and quality. In January 2026, the IPC introduced the tenth edition of the Indian Pharmacopoeia, incorporating 121 new monographs and increasing the total to 3,340 (Indian Pharmacopoeia Commission, 2026).

Bioavailability and bioequivalence assessments represent another important regulatory requirement. The CDSCO's Bioavailability/Bioequivalence Division in New Delhi evaluates study protocols and oversees relevant study centres under applicable regulations. Such assessments are particularly important for systemically absorbed medicines requiring evidence of comparable drug exposure (Central Drugs Standard Control Organization, n.d.).

Regulatory improvements also include revised Schedule M requirements concerning Good Manufacturing Practices (GMP), manufacturing facilities, documentation, and quality management. According to the Ministry of Health and Family Welfare (2026), CDSCO and state authorities conducted risk-based inspections of more than 960 manufacturing premises since December 2022, resulting in over 860 regulatory actions.

Furthermore, official figures for 2025–26 recorded 141,322 pharmaceutical samples tested, of which 3,012 were declared not of standard quality, representing approximately 2.13% of tested samples (Ministry of Chemicals and Fertilizers, 2026).

Quality assurance under the Jan Aushadhiprogramme additionally involves procurement from WHO-GMP-compliant manufacturers and batch-wise testing through NABL-accredited laboratories before distribution. Post-marketing surveillance, laboratory accreditation, and adverse drug reaction monitoring complement these mechanisms. Nevertheless, sample-testing results cannot establish nationwide medicine quality prevalence or demonstrate bioequivalence independently. Transparent reporting of product-specific regulatory evidence remains essential for strengthening professional confidence.

4.2 Pharmaceutical Awareness, Professional Education and Evidence-Based Generic Prescribing

Professional education and access to reliable pharmaceutical information are important determinants of evidence-based generic prescribing. Physicians and pharmacists require an understanding of pharmaceutical equivalence, bioequivalence, therapeutic effectiveness, adverse drug reactions, and regulatory quality standards to make appropriate medicine-selection decisions.

Khanna et al. (2025), in a retrospective investigation of 300 outpatient prescriptions at a tertiary care teaching hospital in South Delhi, reported that only 14 prescriptions (4.7%) used generic medicine names. The findings demonstrate a substantial gap in generic-name prescribing within the investigated institution and support the need for prescription audits and targeted professional education.

Continuing medical education programmes, pharmacy training, and updated prescribing guidance can address such gaps. The Indian Council of Medical Research provides Standard Treatment Workflows covering several medical specialties, offering structured resources for rational clinical decisions (Indian Council of Medical Research, n.d.).

For example, professional training can demonstrate how generic-name prescriptions for metformin 500 mg or amlodipine 5 mg should be interpreted alongside dosage form, clinical suitability, and applicable substitution requirements.

Hospital drug and therapeutics committees can strengthen these practices through formulary development, prescription audits, and evaluation of pharmaceutical quality information. Similarly, medical colleges, pharmacy institutions, professional associations, and regulatory authorities can disseminate verified evidence concerning medicine quality and appropriate interchangeability.

Pharmacists should communicate medicine costs, dosage instructions, possible adverse effects, and storage requirements while ensuring that substitution remains consistent with applicable regulations and clinical instructions. Publicly accessible quality alerts and product-specific testing information can further improve professional decision-making.

Ultimately, cooperation among physicians, pharmacists, healthcare institutions, and regulatory bodies can strengthen confidence in quality-assured generic medicines. Integrating regulatory transparency, continuing education, patient counselling, and prescription monitoring provides a practical approach to promoting safe, rational, and affordable pharmaceutical treatment in India.

5. RESULTS, FINDINGS AND DISCUSSION

The integrated analysis of pharmaceutical quality, prescribing behaviour, and regulatory mechanisms has identified important relationships influencing generic medicine utilisation in India. The findings demonstrate that pharmaceutical quality assurance provides the scientific foundation for generic medicine acceptance, whereas professional knowledge, prescribing preferences, and institutional practices influence their actual utilisation. The available evidence also indicates that lower medicine prices do not necessarily imply inferior pharmaceutical quality, provided that the formulations meet applicable quality standards.

Table 1: Comparative Evidence on Pharmaceutical Quality, Professional Practices and Generic Medicine Use in India

Analytical Dimension	Documented Evidence	Relevance to the Study
Pharmaceutical quality	All 131 samples examined in a 2026 Kerala investigation satisfied the tested pharmacopoeial standards.	Demonstrates quality compliance among the specific formulations and batches examined.
Price and quality	Generic medicines in the same investigation were approximately 48.6% cheaper than branded alternatives.	Indicates potential cost advantages without inferior results in the examined quality parameters.
Physician confidence	Approximately 84% of government physicians and 64% of private physicians in a 2023 investigation considered generic medicines equally effective and safe.	Identifies differences in professional confidence across healthcare settings.
Knowledge of bioequivalence	Approximately 76% of physicians in both groups expressed a need for additional bioequivalence information.	Highlights gaps in professional knowledge and pharmaceutical education.
Pharmacy-level experience	A 2024 Odisha investigation included 17 in-depth interviews.	Provides qualitative evidence concerning pharmacists, professional attitudes, and operational challenges.
Pharmacopoeial development	The Indian Pharmacopoeia 2026 incorporated 121 new monographs.	Demonstrates continuing development of pharmaceutical quality standards.
Government-supported quality assurance	PMBJP adopted batch-wise medicine testing through accredited laboratories.	Identifies institutional mechanisms supporting pharmaceutical quality assurance.

The findings presented in Table 1 have demonstrated that pharmaceutical quality and affordability can coexist under appropriate manufacturing and regulatory conditions. The Kerala investigation identified satisfactory results across the tested pharmaceutical quality parameters despite substantial price differences between generic and branded formulations. However, laboratory compliance does not independently establish bioequivalence, therapeutic interchangeability, or universal quality compliance across India's pharmaceutical market.

The analysis of prescribing behaviour reveals a difference between documented pharmaceutical quality and professional confidence. The higher proportion of government physicians expressing confidence in generic medicines, compared with private practitioners, suggests that institutional settings may influence prescribing preferences. Furthermore, the expressed need for additional bioequivalence information indicates that professional education remains important for evidence-based medicine selection.

Pharmacy-level evidence further demonstrates that pharmacists influence medicine accessibility through dispensing practices, product availability, and patient counselling. However, their contribution depends on appropriate prescription interpretation, regulatory compliance, and coordination with physicians. Generic substitution must therefore remain consistent with applicable legal requirements and individual clinical circumstances.

The regulatory findings indicate continued institutional efforts to strengthen pharmaceutical quality through updated pharmacopoeial standards, manufacturing requirements, accredited laboratory testing, and post-marketing monitoring. Nevertheless, regulatory compliance information must be communicated effectively to healthcare professionals to support informed prescribing decisions. Overall, the findings identify three interconnected dimensions: the relationship between medicine prices and demonstrated pharmaceutical quality, the influence of professional knowledge on prescribing practices, and the contribution of regulatory oversight to confidence in generic medicines. The evidence suggests that strengthening generic medicine utilisation requires coordinated improvements in pharmaceutical quality assurance, professional education, regulatory transparency, and patient counselling. These measures can support safe, rational, and affordable medicine use across India's healthcare system.

6. CONCLUSION AND RECOMMENDATIONS

Conclusion

This study has examined the relationship between pharmaceutical quality assurance, prescribing practices and the appropriate use of generic medicines in India. It has discussed the scientific importance of pharmaceutical equivalence, bioequivalence, manufacturing standards and regulatory monitoring, alongside published evidence concerning the practices of physicians and pharmacists.

The analysis has distinguished product-quality evidence from professional perceptions and has considered how differences in knowledge, clinical circumstances and institutional practices may influence medicine selection.

The study has also examined the importance of regulatory transparency, pharmaceutical education and appropriate dispensing practices in strengthening informed generic medicine use. It has identified opportunities for better communication of quality-assurance information and improved coordination among healthcare professionals and regulatory institutions. Overall, the study has provided an evidence-based basis for discussing quality-assured generic medicine use while recognising the limitations of the available scientific and observational evidence.

Recommendations

1. Strengthening professional education on generic medicine quality

Medical and pharmacy education institutions should place greater emphasis on pharmaceutical equivalence, bioavailability, bioequivalence and the scientific requirements for generic substitution. Continuing professional development programmes should provide practical information that enables healthcare professionals to interpret regulatory and quality-control evidence correctly.

2. Improving communication of regulatory quality-assurance information

Regulatory authorities and pharmaceutical institutions should make reliable information about medicine standards, quality-testing procedures and applicable regulatory requirements more accessible. Clear communication could help professionals distinguish verified scientific information from assumptions based on branding or price.

3. Promoting evidence-based prescribing practices

Healthcare institutions should encourage medicine selection based on clinical suitability, quality assurance, evidence of interchangeability where required, patient needs and treatment affordability. Clinical guidance should help physicians identify circumstances in which generic prescribing and substitution are appropriate.

4. Strengthening the professional contribution of pharmacists

Pharmacists should receive support and training to communicate accurate information about generic medicines, explain appropriate usage instructions and assist patients in understanding available pharmaceutical options. Their responsibilities should remain consistent with applicable dispensing laws, professional standards and prescription requirements.

5. Enhancing pharmaceutical quality monitoring

Regulatory bodies and pharmaceutical suppliers should continue strengthening manufacturing compliance, batch-quality assessment and post-marketing surveillance. Monitoring systems should provide reliable mechanisms for identifying potential quality problems and ensuring that appropriate corrective action is taken when required.

6. Improving coordination among pharmaceutical stakeholders

Healthcare institutions, regulatory authorities, medical professionals, pharmacists and professional associations should strengthen information-sharing and educational cooperation. Coordinated efforts could improve understanding of generic medicine standards and support responsible medicine selection across different healthcare settings.

Areas for Further Researches

Future research may examine changes in physicians' knowledge and prescribing practices following targeted pharmaceutical education programmes, differences in generic medicine counselling practices among pharmacists, and the relationship between regulatory information and professional confidence. Laboratory-based studies may also evaluate selected formulations across manufacturers and geographical markets, while prospective clinical investigations could examine treatment outcomes following appropriately regulated generic substitution.

Additional research may explore prescribing practices in government and private institutions, patterns of patient understanding and the impact of professional training on evidence-based medicine selection.

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