

Review Article

USE OF GENERIC DRUGS IN MEDICAL PRACTICE: A REVIEW

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ABSTRACT

The escalating cost of healthcare has driven global interest in generic medicines as affordable alternatives to branded drugs. This review explores the definition, characteristics, and regulatory requirements of generics, highlighting their proven bioequivalence and safety. It examines global trends, policy frameworks, physician and pharmacist perceptions, patient acceptance, and country-specific experiences in the promotion of generics. Although generics offer significant cost savings and expanded access to essential medicines, adoption remains uneven due to regulatory gaps, stakeholder scepticism, and inconsistent public awareness. This study emphasizes the importance of harmonized regulatory standards, educational campaigns, and strong policy enforcement to improve acceptance and utilization. The future of generics, including biosimilars, appears promising with increased international collaboration and focus on quality assurance to enhance global healthcare equity.

Keywords: Generic medicines, bioequivalence, healthcare cost, regulatory policy, patient perceptions.

INTRODUCTION

The escalating cost of healthcare globally has intensified the search for cost-effective alternatives to branded medications. Pharmaceutical expenditures represent a significant proportion of healthcare budgets worldwide, often imposing financial burdens on both healthcare systems and patients. In this context, generic medicines, which offer equivalent therapeutic effects at substantially lower prices, have emerged as a cornerstone in healthcare systems aiming to optimize expenditure without compromising quality.^[1-3] Generic medicines can reduce treatment costs by up to 80% compared to their branded counterparts, thereby enhancing access to essential medicines, particularly in low- and middle-income countries.^[3,4] Despite their proven clinical equivalence, the uptake of generic drugs varies markedly across countries due to factors such as regulatory policies, market dynamics, physician and patient perceptions, and pharmaceutical industry influences.^[4-6] Additional barriers include brand loyalty, misinformation regarding the efficacy of generics, and limited physician incentives to prescribe them.^[5,6] This review aims to

comprehensively explore the use of generic drugs in medical practice, focusing on policies, challenges, perceptions, and future prospects. It further seeks to identify gaps in implementation and propose recommendations for improving the integration of generics into routine healthcare delivery.

Definition and Characteristics of Generic Drugs

Generic drugs are pharmaceutical products that are bioequivalent to branded drugs in dosage form, safety, strength, route of administration, quality, and intended use.^[1,7] According to the World Health Organization, bioequivalence is confirmed when the rate and extent of absorption of the generic drug do not show a significant difference from the innovator product.^[7,8] This ensures that patients receive the same clinical benefit when switching between branded and generic medicines. Generic manufacturers must comply with stringent regulatory standards set by national and international agencies such as the US Food and Drug Administration (FDA), the European Medicines Agency (EMA), and others.^[7,8] These standards cover product development, manufacturing processes, stability, labeling, and packaging. Additionally, generics must demonstrate consistent batch-to-batch quality and

adhere to Good Manufacturing Practices (GMP).^[1,7] Unlike branded drugs, generic medicines do not carry the costs of original research and development, which allows for their significantly lower pricing. However, they must still undergo rigorous testing and documentation to gain market approval, thus ensuring patient safety and therapeutic effectiveness.

Historical Background and Global Trends

The adoption of generics started in high-income countries with strong regulatory frameworks aimed at reducing healthcare expenditure and increasing medication accessibility. Nations like the United Kingdom and the Netherlands have led in promoting generics through favorable pharmaceutical policies, public awareness campaigns, and physician prescribing incentives.^[2,9] These countries have established strong generic substitution laws and reimbursement policies that encourage the widespread use of generics. More recently, emerging economies like Brazil and Malaysia have also made significant strides in integrating generic medicines into their national health policies.^[10,11] Brazil, for instance, launched its Generic Drugs Policy in 1999, which resulted in substantial growth in the market share of generics.^[10] Similarly, Malaysia's National Medicines Policy promotes the use of quality-assured generics to improve affordability and access.^[11] In contrast, some developing countries continue to face regulatory, infrastructural, and cultural challenges that limit the growth of their generic medicine markets. However, global initiatives, including WHO's prequalification programs and partnerships with non-governmental organizations, are working to bridge these gaps and promote the international harmonization of generic drug standards.^[2,9]

Policy Frameworks Promoting Generics

Government policies are pivotal to the success of generics. Regulatory and legislative frameworks play a crucial role in ensuring the acceptance, availability, and use of generic medicines within national healthcare systems. Many countries have implemented mandatory generic substitution, reference pricing, and incentives for prescribers and pharmacists to favor generics.^[1,9,12] For example, reference pricing establishes a maximum reimbursement level for groups of interchangeable drugs, encouraging patients and providers to opt for lower-cost generics.^[9,12] Countries such as Germany and Sweden have demonstrated the success of such policies through substantial market penetration of generics.^[12] Brazil and Iran serve as successful models of generic drug policy implementation, with Brazil's National Policy of Medicines promoting the production and use of generics since 1999, leading to a significant rise in their market share.^[11,13] Iran has adopted a Generic Medicine Scheme since the 1980s, focusing on local manufacturing and centralized procurement to enhance accessibility and affordability.^[11] Additionally, initiatives like educational campaigns for healthcare providers and the public, as well as stringent regulatory requirements, have been shown to improve

confidence in generics and enhance their utilization rates.^[1,12] However, disparities still exist across countries, with some healthcare systems lacking strong enforcement mechanisms or experiencing resistance from stakeholders influenced by branded pharmaceutical companies.

Economic Impact of Generic Medicines

Generic substitution significantly reduces healthcare costs and contributes to the sustainability of healthcare systems worldwide. By offering equivalent therapeutic benefits at a fraction of the price, generics enable health services to allocate resources more efficiently.^[3,14,15] Studies show that substituting branded drugs with generics can lower pharmaceutical expenditures by 30% to 80%, depending on the therapeutic class and market conditions, without affecting the overall health outcomes of patients.^[3,14] For example, pharmaceutical spending control has been critical to healthcare sustainability in OECD countries, where generic medicines have played a vital role in containing escalating costs.^[3] In the United States alone, the use of generics saved the healthcare system over \$300 billion annually in recent years.^[14] Similar cost-saving trends have been observed in European countries with high generic uptake, such as the Netherlands and the United Kingdom.^[3] Furthermore, increased competition from generics can drive down the prices of originator medicines, amplifying the economic benefits.^[15] Beyond direct cost savings, generics also contribute to enhanced patient access to essential medicines, which is particularly valuable in resource-constrained settings. However, the economic impact varies considerably across regions due to differences in regulatory environments, patent laws, and market dynamics.^[3,15]

Physician Perceptions and Prescribing Practices

Physician attitudes play a crucial role in generic medicine acceptance and utilization within healthcare systems. As the primary decision-makers in medication prescribing, their perceptions directly influence the extent to which generics are recommended to patients. Several studies reveal a persistent scepticism among healthcare providers regarding the efficacy, safety, and quality of generics, particularly in therapeutic areas where narrow therapeutic index drugs are involved.^[6,16-18] Concerns about bioequivalence testing, variability in excipients, and potential impacts on patient outcomes contribute to this cautious approach.^[6,17] In some regions, the lack of trust stems from inconsistent regulatory enforcement or poor-quality generics in the past, which has shaped physician hesitancy.^[16,18] Additionally, promotional activities by branded drug manufacturers can sway physician prescribing habits against generics.^[17,18] To overcome these barriers, continuous education and formulary guidance are necessary to change this mindset and promote evidence-based prescribing.^[12] Educational interventions and clinical guidelines emphasizing the safety and cost-effectiveness of generics have proven

effective in improving physician acceptance in several healthcare settings.^[12,18] Engaging physicians early in policy discussions and creating platforms for peer-to-peer sharing of positive experiences with generics can further enhance their willingness to prescribe these alternatives.

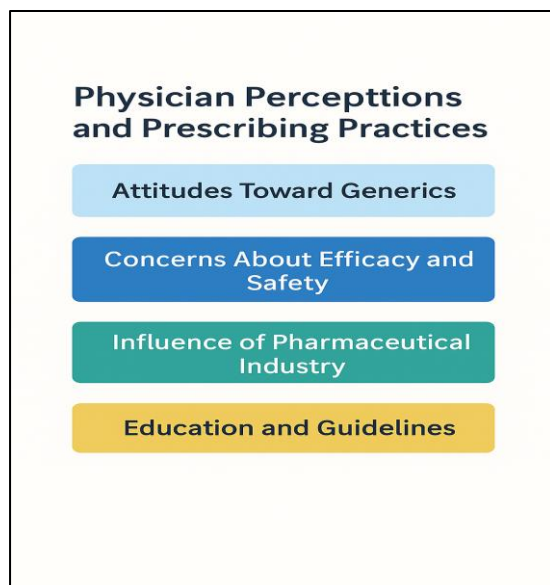


Figure 1: Physician Perceptions and Prescribing Practices

Pharmacist Perspectives on Generic Substitution

Pharmacists are key drivers of generic substitution, acting as the final point of contact before medications reach patients. Their role in counseling and guiding patient decisions makes them critical players in enhancing the acceptance of generics. However, research indicates that their practices are influenced by perceptions of quality, concerns over patient trust, and fear of liability in case of adverse drug reactions.^[17,19,20] Studies have shown that while pharmacists generally recognize the therapeutic equivalence of generics, they may hesitate to substitute branded prescriptions without physician consent, particularly in settings lacking clear substitution policies.^[17,19] Moreover, patients sometimes question the legitimacy of generics, placing pharmacists in a delicate position between patient expectations and healthcare system directives.^[20] Better pharmacist training and supportive policies can improve substitution rates and patient education efforts.^[19] National and institutional guidelines empowering pharmacists to substitute generics where appropriate, coupled with targeted education on regulatory standards and bioequivalence criteria, can mitigate hesitation and promote confidence.^[19,20] Additionally, integrating pharmacists into interdisciplinary healthcare teams and involving them in public awareness campaigns can further reinforce their role as advocates for the safe and cost-effective use of generics.

Patient Perceptions and Acceptance

Patients often harbor doubts about the quality and effectiveness of generics, mainly due to misinformation, lack of awareness, and deep-rooted loyalty to branded medications.^[4,5] Mistrust arises from misconceptions about generics being inferior or less potent than brand-name drugs, even though rigorous regulatory standards ensure therapeutic equivalence.^[5,18] Additionally, variability in pill appearance, packaging, and labeling between branded and generic products can further contribute to patient confusion and doubt.^[4,18] Such concerns can lead to poor adherence to treatment regimens or outright rejection of generic substitutions. Socioeconomic factors and education levels also play a significant role, with patients in lower-income and rural populations often less informed about the benefits and safety of generics.^[4,5] Public education campaigns and transparent regulatory assurances are essential for enhancing patient confidence and encouraging acceptance.^[4,5,18] Targeted awareness initiatives, patient counseling at the pharmacy level, and engagement through community outreach programs have shown success in some countries in improving public trust in generics.^[5,18] Clear communication regarding the regulatory oversight, clinical efficacy, and substantial cost benefits of generics can further enhance patient willingness to switch from branded medications.

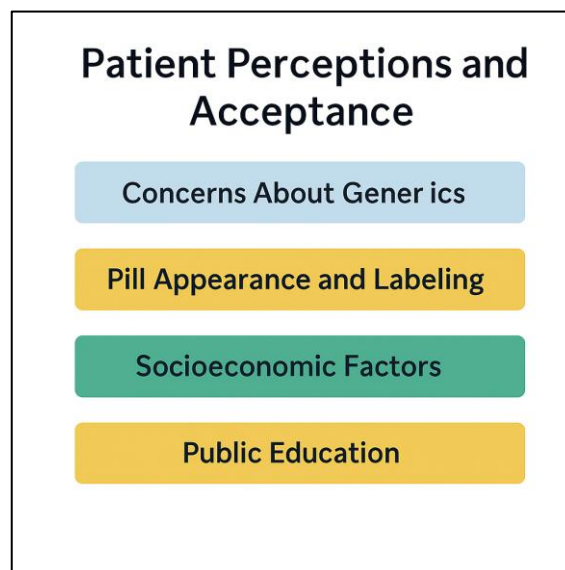


Figure. 2 Patient Perceptions and Acceptance

Country-Specific Experiences

The adoption of generics varies widely depending on national policies, healthcare infrastructure, and socio-cultural factors.

Malaysia: The country has made significant progress in promoting generics through the National Medicines Policy, yet it still faces regulatory and perception challenges. There remains a need for stronger bioequivalence enforcement and more comprehensive public and healthcare provider

education programs to dispel misconceptions about generics.^[10,21,17]

India: India's pharmaceutical landscape is dominated by branded generics rather than pure generics. This complex market structure, combined with variable pricing and quality discrepancies across manufacturers, has led to patient and physician scepticism despite the country's significant role as a global generics supplier.^[8,22] Initiatives like the Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) aim to improve access to affordable generics, but market penetration and acceptance remain inconsistent.^[8]

Iran and Brazil: Both countries have implemented robust policies that have successfully encouraged local production and wide utilization of generics. Iran's Generic Medicine Scheme, one of the oldest globally, mandates exclusive use of generics in the public sector.^[11,13] Brazil's National Generic Drugs Policy, initiated in 1999, significantly boosted domestic production and generic market share, improving patient access and reducing overall healthcare costs.^[11,13]

Pakistan: Despite having regulatory frameworks that support the use of generics, physician reluctance and patient mistrust continue to hinder widespread adoption.^[18] This is partly due to historical inconsistencies in regulatory oversight and quality assurance, highlighting the urgent need for systematic public and professional education efforts.^[18]

Pricing and Quality Comparison

Studies comparing branded and generic medicines consistently demonstrate that generic drugs meet the same stringent quality, safety, and efficacy standards as their branded counterparts, as mandated by regulatory authorities.^[8,22] Analytical testing, stability studies, and bioequivalence trials confirm that generics deliver identical therapeutic outcomes despite being produced by different manufacturers.^[8] However, significant price differences persist, often ranging from 30% to 80% less than the cost of innovator drugs.^[22] These disparities are largely attributed to the absence of research and development costs for generics and reduced marketing expenses.^[8,22] The lower pricing of generics provides a strong economic rationale for their promotion in routine medical practice, offering substantial cost savings for both healthcare systems and patients.^[8,22] For healthcare providers and policy-makers, these savings enable the reallocation of resources to other critical areas such as hospital infrastructure, diagnostics, and innovative treatments. Moreover, increased competition from generics in the marketplace has the added effect of lowering prices even for branded drugs, contributing further to healthcare affordability.^[8,22] While some concerns persist regarding batch-to-batch variability and manufacturing quality among low-cost producers, regulatory mechanisms in countries with strong pharmaceutical oversight continue to ensure that generics remain a safe and effective alternative.

Barriers to Widespread Adoption

Despite the clear benefits of generics in terms of cost and therapeutic equivalence, several barriers hinder their widespread adoption.

Regulatory gaps in some countries: Many low- and middle-income nations still face challenges in establishing and enforcing robust regulatory frameworks for generic drug approval, manufacturing, and quality assurance.^[1,2,10] These gaps can undermine public and healthcare provider trust in the quality and safety of generics.

Negative stakeholder perceptions: Misinformation, aggressive marketing by branded drug manufacturers, and scepticism among physicians and patients contribute to persistent doubts about generics' efficacy and reliability.^[5,6,17,18] Educational interventions and stronger professional guidelines are essential to counteract these perceptions and promote confidence.^[5,6] **Lack of uniform bioequivalence standards globally:** Regulatory bodies across different regions vary significantly in their requirements for bioequivalence testing and manufacturing standards, leading to inconsistency in the quality of generics entering the global market.^[9,11] This variation creates hesitancy among prescribers and pharmacists, especially when dealing with imports from countries with weaker regulatory oversight. Addressing these barriers requires a multipronged approach that includes harmonized policies, international cooperation, and the establishment of universally accepted quality benchmarks.^[1,9,11] Collaborative initiatives between regulatory agencies, healthcare organizations, and industry stakeholders can facilitate the global standardization of bioequivalence and quality assurance processes, ultimately improving access and confidence in generic medicines worldwide.

The Role of Education and Awareness

Training programs for healthcare professionals and public awareness campaigns have shown positive effects on the acceptance of generics, acting as key interventions to overcome scepticism and misinformation.^[4,16,20] Education initiatives targeted at physicians, pharmacists, and nurses have been effective in clarifying the regulatory requirements, therapeutic equivalence, and safety of generic medicines.^[16,20] These programs often include continuing medical education modules, workshops, and inclusion of generics education within medical and pharmacy curricula.^[4,16] Countries that incorporated systematic education in their healthcare policies have seen markedly improved generic utilization rates.^[1,21] For example, Sweden and the United Kingdom have achieved high generic penetration through consistent and structured education of both healthcare providers and patients.^[1,21] Public awareness campaigns using mass media, community outreach, and patient counseling at the point of dispensing have also played a critical role in reducing patient apprehension and increasing adherence to generic prescriptions.^[4,20] Furthermore, involving patient advocacy groups and professional

societies in education efforts has proven effective in building trust and promoting informed decision-making. Sustained and well-coordinated educational strategies are thus essential for maximizing the health and economic benefits of generics at a population level.

The Future of Generic Medicines

The future of generic medicines looks increasingly promising as global healthcare systems prioritize cost-containment and equitable access to essential drugs. Growing global awareness, combined with policy reforms and regulatory initiatives, has set the stage for continued expansion of the generics market.^[7,11,22] Advances in technology and manufacturing are also improving the quality and affordability of generics, making them even more attractive to healthcare providers and patients.^[22] One of the most significant developments is the rise of biosimilars, which are biologic products highly similar to already approved reference biologics, offering potential savings in the treatment of complex conditions such as cancer and autoimmune diseases.^[7,22] While biosimilars present new regulatory and clinical challenges, they represent the next frontier in the evolution of the generics market.^[7] Increased international regulatory collaboration, such as the work of the International Council for Harmonisation (ICH), is expected to foster global standardization and accelerate market approvals.^[22] Additionally, as healthcare systems continue to focus on universal health coverage, the role of generics in enhancing affordability and accessibility will remain vital. Continued investment in quality assurance, education, and public trust-building efforts will be key to realizing the full potential of generics in improving health outcomes worldwide.

CONCLUSION

Generic medicines play a vital role in improving healthcare affordability and accessibility without compromising therapeutic quality. Despite their proven clinical efficacy and significant cost-saving potential, adoption remains uneven due to regulatory gaps, stakeholder perceptions, and patient scepticism. Strong policy frameworks, consistent regulatory standards, and comprehensive education initiatives are essential to overcome these barriers. Countries that have embraced systematic generic promotion have demonstrated substantial health and economic benefits. Continued global collaboration and investment in quality assurance will be crucial to realizing the full potential of generics in advancing equitable healthcare access.

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