Casting Light on Potential: A Thorough Examination of the Effectiveness, Challenges, and Future of Generic Medicines

Rohit Shivcharan Patil, Swati Samadhan Patil, Kaveri Pradiprao Borse, Dishant Sunil Chaudhari, Mayuri Arun Chaudhari, Komal Yuvraj Chaudhari, Pratiksha Bhaiyyasaheb Patil
Pharmacy, Smt. Sharadchandrika Suresh Patil

Abstract: Generic drugs, mirroring brand-name counterparts in composition and efficacy, offer substantial cost savings by circumventing expenses associated with research, development, and marketing. In India, despite economic advantages, challenges persist due to limited awareness of regulatory standards. However, initiatives promoting generic substitution are gaining traction among healthcare providers. Globally, the introduction of generics has revolutionized healthcare accessibility, especially benefiting marginalized populations. Governments advocate for generic use, emphasizing comparable clinical benefits to brand-name drugs at reduced costs, enabled by streamlined regulatory pathways prioritizing bioequivalence.

***Index Terms*: ANDA, Brand drugs, Drug approval, FDA, Generic drugs, NDA.**

INTRODUCTION

Generic drugs are pharmaceutical products that closely resemble brand-name counterparts in dosage, strength, administration route, quality, performance, and intended use, containing the same active ingredients. The primary advantage of generics lies in their significant cost savings, avoiding the expenses of research, development, and extensive marketing associated with brand-name drugs. Despite economic benefits, India faces challenges in adopting generic prescriptions due to limited awareness of regulatory standards in drug manufacturing. Nonetheless, there is strong support for substituting brand-name drugs with generics, prompting initiatives to encourage their use by healthcare providers.

The introduction of generic drugs has transformed healthcare by enhancing access to reliable, safe, and affordable medications, particularly benefiting underserved communities. Governments worldwide are promoting generic accessibility while educating the public about their efficacy and safety standards. In the United States, for instance, generic drugs, once approved by the FDA, offer comparable clinical benefits to brand-name drugs at a fraction of the cost. This affordability stems from streamlined regulatory requirements prioritizing bioequivalence over duplicating expensive clinical trials conducted for original drugs.

Legislation like the Hatch–Waxman Act has historically played a crucial role in expanding generic drug availability. This act streamlined the approval process for generics after patent expiry, fostering competition that significantly reduces prices—often up to 85% lower than brand-name equivalents. Moreover, generics constitute a substantial portion of prescriptions dispensed in the U.S., contributing to substantial savings in overall healthcare expenditures.

Regarding patent challenges, generic manufacturers consult the FDA's Orange Book to identify patents held by innovator companies. Challenges to these patents trigger legal processes, including potential patent infringement lawsuits delaying generic approvals by up to 30 months. However, certain provisions, such as the 180-day market exclusivity granted to the first generic challenger, incentivize competition and further reduce drug costs.

In conclusion, the widespread availability of generic drugs underscores their crucial role in improving healthcare affordability and accessibility globally. By leveraging regulatory frameworks that prioritize safety and efficacy while encouraging competition, governments can continue to promote the widespread adoption of generics, ensuring sustainable healthcare solutions for diverse populations.

- ❖ Fundamental Requirements of Generic Pharmaceuticals:

The development of generic medications is governed by strict regulations that require alignment with the parameters of the innovator drug. Key requirements include:

1. Active Pharmaceutical Ingredient (API) and its Application: Generic drugs must contain the same active ingredient as the innovator drug, ensuring therapeutic equivalence.

2. Dosage and Potency: The dosage strength of generic drugs must be comparable to that of the brand-name product, ensuring consistent therapeutic outcomes.
3. Method of Administration: Generic drugs must be administered using the same route and method as the innovator drug to ensure similar bioavailability and efficacy.

These parameters ensure that generic medications provide the same clinical benefits as brand-name drugs, while typically being more affordable due to streamlined development processes after patent expiry. Regulatory bodies such as the FDA in the United States enforce these standards to guarantee the safety, efficacy, and quality of generic pharmaceuticals.

❖ Advantages of Generic Pharmaceuticals:

Generic medicines offer numerous advantages that make them a practical choice for treating various health conditions. Understanding these benefits helps individuals make informed decisions about their healthcare options. Here are the key advantages:

1. Cost-Effectiveness: Generic medications are significantly cheaper, typically reducing costs by 80% to 85% compared to branded medications. This affordability is due to streamlined development processes and lower marketing expenses.
2. Comparable Effectiveness and Safety: Generic drugs are considered equally effective and safe as their branded counterparts. They undergo rigorous testing and must meet the same regulatory standards for quality, efficacy, and safety.
3. Regulatory Alignment: Both generic and branded medications adhere to identical regulatory frameworks and quality standards. This ensures that generic drugs provide the same therapeutic benefits as brand-name drugs.
4. Availability After Patent Expiry: When patents for branded drugs expire, generic alternatives can be produced by any pharmaceutical manufacturer. This fosters competition and further reduces prices, benefiting consumers.
5. Widespread Availability: Generic medicines are widely accessible, offering patients easy access to affordable alternatives without compromising on quality. Initiatives like the Pradhan Mantri Bhartiya Janaushadhi Pariyojna (PMBJP) in India promote the availability and affordability of generic medicines.
6. Safety and Quality Assurance: Generic medicines are manufactured under strict guidelines enforced by regulatory authorities like the Central Drugs Standard Control Organization (CDSCO) in India. They undergo rigorous testing to ensure they meet stringent quality standards, ensuring safety and efficacy.
7. Insurance Coverage: Generic medicines are typically covered favorably by insurance companies due to their cost-effectiveness. This coverage helps reduce out-of-pocket expenses for patients, making healthcare more affordable.

In conclusion, the advantages of generic medicines extend beyond cost savings to encompass safety, efficacy, and accessibility. They play a crucial role in providing affordable healthcare solutions globally, ensuring that patients have access to high-quality medications without financial barriers.

❖ Generic Drug Approval Process:

The approval process for generic drugs differs significantly from that of new chemical entities, leveraging an Abbreviated New Drug Application (ANDA) pathway that does not require submitting clinical data on safety and efficacy. Instead, generic manufacturers demonstrate bioequivalence to the pioneer product, leveraging existing safety and efficacy data.

To obtain marketing approval, generic drugs must meet stringent criteria:

1. Identity, Strength, Purity, and Quality: Generic drugs must meet identical batch requirements to the branded product in terms of identity, strength, purity, and quality.
2. Therapeutic Equivalence: Generic drugs must demonstrate therapeutic equivalence to the branded product through:
   - Pharmaceutical Equivalence: Matching active ingredients, dose form, route of administration, and strength.
   - Bioequivalence: Showing similar bioavailability compared to the branded product under equivalent conditions.
3. Compliance with Good Manufacturing Practices (GMP): Manufacturers must adhere to FDA's GMP regulations throughout the manufacturing process to ensure consistent quality and safety.

The ANDA process enables generic drugs to enter the market efficiently after the expiration of patents

held by the innovator. By demonstrating bioequivalence and meeting stringent quality standards, generic drugs provide affordable alternatives while maintaining comparable safety and efficacy to their branded counterparts. This streamlined approval process fosters competition, driving down healthcare costs and expanding patient access to essential medications

Types of Applications:
1. Investigational New Drug (IND)
2. New Drug Application (NDA)
3. Abbreviated New Drug Application (ANDA)
4. Biologic License Application (BLA)

Abbreviated New Drug Application (ANDA) Review Process:
1. Purpose and Scope: An ANDA is submitted to the FDA to gain approval for marketing a generic drug product that is comparable to an innovator (brand-name) drug listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book). The generic product must match the innovator drug in dosage form, strength, route of administration, quality, performance characteristics, and intended use.
2. Regulatory Basis: Unlike New Drug Applications (NDAs) for new chemical entities, ANDAs are abbreviated because they do not require submitting clinical data to establish safety and efficacy. This is because these parameters have already been established through the approval of the innovator drug.
3. Submission Requirements: The ANDA submission includes various sections and documents, as outlined in the submission form:
    - Basis for Submission: Describes how the generic drug compares to the reference listed drug (RLD).
    - Request for Waiver: If applicable, requests for waiver of in vivo bioavailability/ bioequivalence (BA/BE) studies.
    - Labeling: Includes proposed labeling for the generic drug product.
    - Summary: Summarizes the key aspects of the ANDA submission.
    - Chemistry: Details on the chemistry of the generic drug product.
    - Human Pharmacokinetics and Bioavailability: Studies demonstrating bioequivalence to the RLD.
    - Patent Information: Includes information on patents associated with the RLD and certifications related to patent challenges.
    - Establishment Description: Information about manufacturing facilities where the generic drug will be produced.
    - Debarment Certification: Certification that the applicant and related parties are not debarred from federal programs.
    - User Fee Cover Sheet and Financial Information: Required fees and financial details related to the ANDA submission.
4. Review and Approval: The FDA reviews the ANDA to ensure that the generic drug product meets all regulatory requirements for safety, efficacy, and quality. Once approved, the applicant can manufacture and market the generic drug product after all patent protections and exclusivities associated with the RLD have expired.

This process allows for the efficient entry of generic drugs into the market, promoting competition and reducing healthcare costs while ensuring that patients have access to safe and effective alternatives to brand-name medications.

❖ Brand vs Generic Medicine:
1. Cost Savings: Generic drugs offer substantial financial relief for patients with chronic illnesses due to their lower prices compared to branded medications. This cost-effectiveness is a key driver for the widespread adoption of generic drugs in many countries.
2. Global Acceptance and Practices: Generic substitution is a common practice globally, driven primarily by economic factors. It involves replacing brand-name prescriptions with equivalent generic alternatives to reduce healthcare expenditures.
3. Challenges in India: Despite the global trend, India faces challenges in embracing generic substitution universally. Factors contributing to this include:
    - Limited Availability: Some generic formulations may not be widely available.
    - Healthcare Provider Skepticism: Concerns about perceived differences in quality between generic and brand-name medications.
    - Counterfeit Drugs: The presence of counterfeit medicines undermines trust in generic alternatives.

4. Progressive Adoption: Despite these challenges, there is gradual progress in adopting generic prescribing policies in institutional settings where medications are procured in bulk and stringent quality controls are in place.

❖ Bioequivalence and Bioavailability:

Bioequivalence and bioavailability are crucial concepts in comparing generic medicines to innovator (brand-name) medicines. Here's an in-depth look at these concepts and their implications:

1. Formulation and Active Ingredients: Generic medicines contain the same active ingredient(s) in the same proportions as the innovator medicine, including different salts. This replication allows generic medicines to reach a broader population, providing access to essential pharmaceuticals once the innovator medicine's patent has expired.
2. Quality and Regulatory Standards: Generic medicines adhere to stringent international quality standards and Good Manufacturing Practice (GMP) regulations, ensuring their quality and efficacy are equivalent to innovator products.
3. Clinical Trials vs. Bioequivalence Studies: Unlike innovator medicines, generic drugs do not require costly and time-consuming clinical trials to establish safety and efficacy. Instead, they undergo bioequivalence studies, following standards set by regulatory authorities like Medsafe. These studies compare the rate and extent of absorption (bioavailability) of the active ingredient in generic and innovator medicines.
4. Bioequivalence Definition and Studies: Bioequivalence ensures that generic medicines achieve similar levels of the active ingredient in the bloodstream as the innovator product. Key pharmacokinetic parameters studied include maximum plasma concentration (Cmax) and area under the plasma concentration-time curve (AUC). The acceptance criteria for bioequivalence typically require that the 90% confidence intervals for the ratio of the means of Cmax and AUC (generic/innovator) fall within 0.80-1.25, indicating no clinically significant differences.
5. Pharmacokinetic Parameters: Studies show that differences in exposure to the active ingredient between generic and innovator medicines are usually less than 5%. For drugs with a narrow therapeutic range, stricter bioequivalence criteria (e.g., 0.90-1.11) may apply due to the sensitivity of therapeutic and toxic concentrations.
6. Clinical Considerations: Despite meeting bioequivalence criteria, caution is advised when switching between different brands of medications, especially for drugs like levothyroxine and warfarin. Factors such as incomplete absorption or varying clinical effects may require additional clinical evaluation before substitution.
7. Regulatory Oversight: Regulatory bodies like Medsafe mandate detailed product information to guide healthcare providers on the interchangeability of medicines. This includes warnings against freely switching certain medications despite bioequivalence.

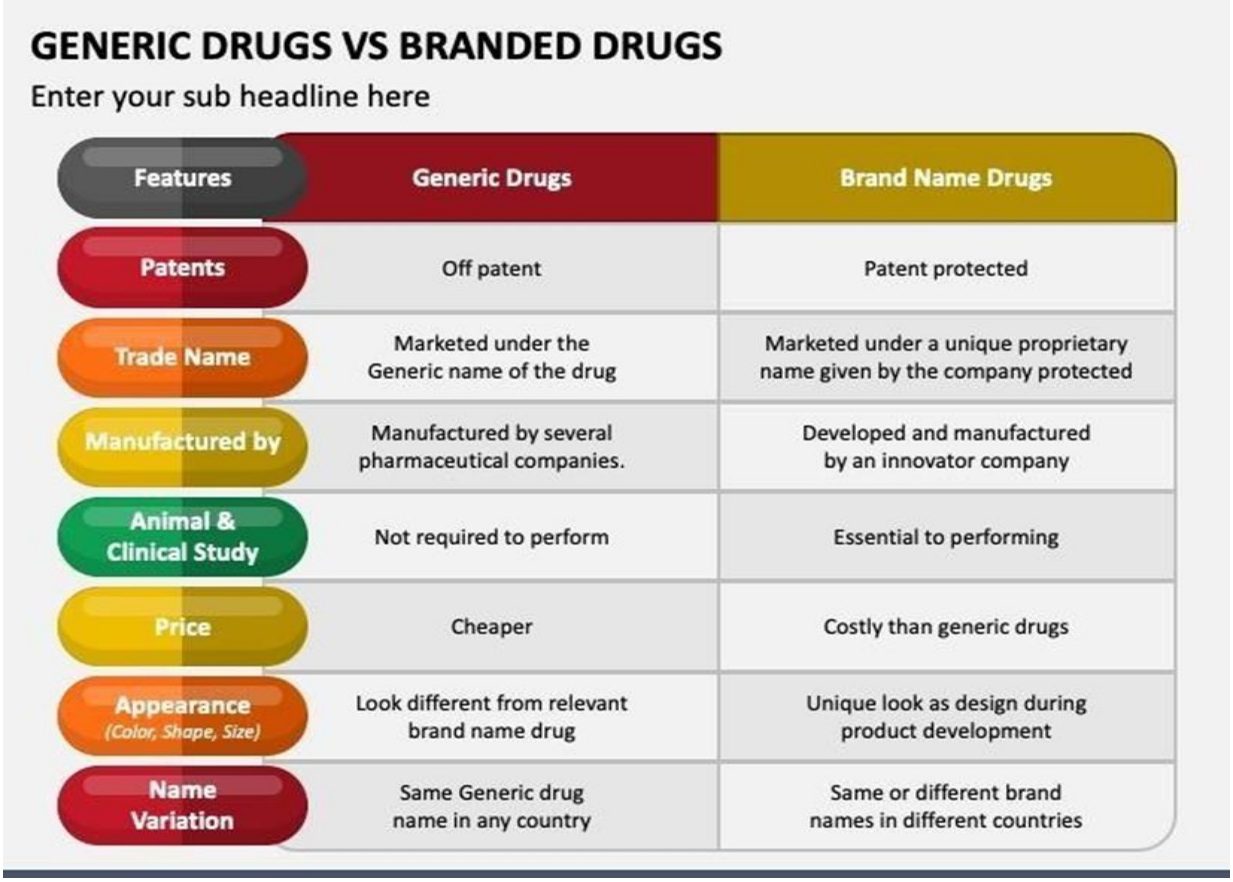
❖ Current Situation in India:

India faces significant healthcare expenses, with a notable reliance on out-of-pocket spending, placing it among countries with high per capita healthcare costs. The widespread use of generic medications in India presents a promising opportunity to redirect saved funds towards other healthcare needs. Globally, there has been an increasing trend in the adoption of generic drugs, with regulatory frameworks for generic drug approval showing overall consistency, albeit with minor variations particularly seen in developing nations.

In India, unlike the United States where bioequivalence (BE) studies are mandatory, they are not obligatory under current regulations. The Indian Government, through the Department of Pharmaceuticals, launched the "Jan Aushadhi" program in 2008. This initiative aims to provide high-quality unbranded medicines at affordable prices to underserved populations through government-supported retail outlets known as Jan Aushadhi stores. As of March 15, 2018, there were over 3200 operational Jan Aushadhi stores across more than 33 states and union territories in India.

Despite this progress, the number of Jan Aushadhi stores remains insufficient compared to the widespread presence of over 8 lakh retail pharmacies, particularly affecting rural areas. To promote the use of generic medications, the Medical Council of India revised the physicians' code of conduct in October 2016. The revision encourages doctors to prescribe drugs using generic names, promoting rational prescriptions that prioritize the use of generic medicines.

Looking ahead, there are expectations that the Government of India may introduce a legal framework mandating doctors to prescribe generic drugs to patients. This initiative aims to further enhance access to affordable medications and streamline healthcare delivery across the country.



❖ Patient Perception or Consumer Perception:

When your pharmacist asks about your preference for the generic version of a prescribed medication, several considerations should guide your decision:

1. Cost and Effectiveness: Opting for a generic medication often means lower costs without sacrificing effectiveness compared to the original product. Many patients find this option economically advantageous.
2. Brand Recognition and Avoiding Confusion: Some individuals prefer to stick with the brand-name medication they are familiar with to avoid potential confusion, especially when managing multiple prescriptions concurrently.
3. Allergies and Ingredients: Generic medications may contain different fillers, binding agents, flavors, or other components compared to the brand-name version. If you have known allergies, it is crucial to verify whether the generic alternative includes any ingredients to which you are allergic.
4. Healthcare Provider Recommendations: In certain cases, healthcare providers may recommend a specific brand-name medication based on the patient's medical history or the nature of their condition.
5. Seeking Guidance: If you have questions or concerns about generic medications, it is advisable to consult your healthcare provider or pharmacist for personalized advice.

Ultimately, the decision between choosing a brand-name medication or its generic equivalent, if available, rests with the patient. Understanding these factors allows patients to make informed choices that align with their healthcare needs and preferences.

❖ The Indian Pharmaceutical Industry:

The Indian pharmaceutical industry's diversity of brands and manufacturers poses a challenge in grasping its true market dynamics and structural complexities. Characterized by intense competition, India has emerged as a global hub for the production of generic medications, earning recognition as the "pharmacy of the developing world." Supported by favorable governmental policies, India competes

directly with major multinational pharmaceutical companies headquartered in developed countries.

Key governmental bodies such as the Indian Patents Office and the Supreme Court of India have strategically utilized flexibilities within the Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement of the World Trade Organization. Additionally, protective measures outlined in the Indian Patents Act have been pivotal. Notable decisions include the granting of compulsory licensing for Sorafenib, a treatment for advanced liver and renal cancer, and the rejection of a patent application for Imatinib, used in leukemia treatment. These decisions mark significant milestones applauded by various stakeholders, including governmental bodies and non-governmental organizations active in the pharmaceutical sector.

- Future of Generic Pharmaceuticals in India and the US:

The generic pharmaceutical market is on a robust growth trajectory, poised to outpace overall drug market expansion by threefold, having previously achieved a valuation of $100 billion. The upcoming patent expirations for blockbuster drugs between 2013 and 2015 are expected to catalyze the availability of more affordable generic alternatives, with market projections soaring into the billions of dollars. In the United States, the market share of generic drugs is projected to increase significantly from 14% to 21%, highlighting substantial export opportunities for India.

India, recognized for its cost-effective workforce and innovation prowess, stands to benefit from this growth trend. Recent advancements in manufacturing facilities, stringent testing protocols, quality assurance measures, research initiatives, clinical trials, and biotechnological innovations have played pivotal roles in driving this upward trajectory. Indian pharmaceutical companies holding USFDA affiliations and approvals for Abbreviated New Drug Applications (ANDA) are strategically positioned to capitalize on these opportunities. Currently, India commands a notable 35% share of the global generic market.Table 3 outlines drugs expected to lose their patents in 2015, further bolstering prospects for generic pharmaceuticals. Moreover, the Indian government's initiatives, such as the distribution of generic drugs through Jan Aushadhi Kendra (Facilitation Centers) in healthcare facilities, aim to enhance domestic and global access.

Looking ahead, both India and the US foresee a promising future for generics, underscoring their pivotal role in healthcare landscapes. Market Exclusivity Periods (MEPs) have become crucial in evaluating the economics of brand-name drugs, influencing revenue streams for future research and development. The escalating competition among generics underscores their growing significance in healthcare cost containment efforts advocated by payers and governments worldwide.

- Upcoming Challenges for Indian Generic Manufacturers in the Global Market:

The Indian generic pharmaceutical sector, characterized by a diverse array of companies leveraging advanced technologies and a strong market presence, is poised for continued growth as numerous patents approach expiration. These companies' scientific expertise in manufacturing and supplying generic drugs positions them favorably as major players in the global generics market. India's rich pool of subject matter expertise also attracts foreign investment, contributing positively to the economic landscape. Optimism regarding fundamental research and exploration of new pharmaceuticals further enhances industry dynamics.

However, sustaining this growth trajectory requires navigating fiercely competitive markets, particularly in developed nations. Indian generic manufacturers face several formidable challenges, foremost among them strengthening the regulatory framework. There is a critical need for a refined and universally applicable classification system for drugs and chemicals, distinguishing between branded generics and their generic equivalents.

Additionally, the high costs associated with research and development present significant hurdles for progress and innovation. Heavy investments are necessary in these areas to enhance capabilities and maintain competitiveness on a global scale. Balancing these challenges with regulatory compliance and market demands will be crucial for Indian generics manufacturers aiming to sustain and expand their presence in the international pharmaceutical landscape.

DISCUSSION

This review synthesized findings from 20 studies exploring consumers' perceptions and attitudes

towards both prescription and non-prescription generic medicines. The collective evidence indicates that consumer acceptance of generic medications is varied and influenced by several factors. While a significant proportion (approximately 40–60%) of consumers hold favourable views towards generic drugs, this positive attitude does not always translate into increased utilization.

A Florida-based study highlighted that despite cost savings, 66% of older respondents, including those with lower incomes, preferred brand-name medications, citing perceived lower effectiveness of generics. Such findings underscore the complexity of consumer preferences, which can vary based on economic development levels, such as between developed and developing countries. Notably, only two studies from Brazil and Malaysia were identified regarding consumer views on generic medications in developing nations, revealing a gap in literature from these regions where out-of-pocket expenditures for medicines are high.

The review contributes valuable insights into global consumer perspectives on generic medicines, emphasizing diversity across countries and highlighting gaps in existing research. While comprehensive, the review acknowledges limitations, including restricted access to databases and exclusion of non-English language studies, which may have resulted in overlooking pertinent research.

The role of pharmaceutical reimbursement systems emerged as crucial in shaping consumer behaviour towards generic drugs. Studies indicated that when third-party payers cover medication costs or when co-payments for generics are comparable to branded products, consumers often prefer branded drugs. Financial incentives were identified as strong motivators for generic drug use, underscoring the influence of healthcare policies and pharmacist-led patient education in promoting acceptance of generics.

Policy changes, such as those observed in Spain and Brazil regarding drug patenting and generic drug policies, were found to positively impact consumer perceptions towards generic medications. Similarly, demographic and socioeconomic factors such as income, education, ethnicity, age, gender, and chronic medical conditions significantly influenced attitudes towards generics. Lower-income and less educated individuals tended to hold more negative views towards generics, whereas positive past experiences and discussions with healthcare professionals about generics fostered acceptance.

Moreover, consumer perceptions of generic drugs were influenced by attributes such as price, perceived quality, effectiveness, and the reputation of manufacturers. The affordability of generics initially attracts consumers, while perceptions of quality and safety, along with past experiences and professional recommendations, contribute to sustained usage.

In conclusion, while generic drugs offer substantial cost savings and potential benefits, consumer acceptance remains nuanced and influenced by various personal, economic, and healthcare system factors. Addressing these complexities through targeted education, policy support, and enhancing research accessibility could further promote the adoption of generic medications worldwide.

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