International Journal of Pharmaceutical Drug Design
IJPDD (June, 2024)
ISSN: 2584-2897
Website: https://ijpdd.org/

Review

Comparative Study Between Generic and Ethical Drugs

Shruti Singh Sengar, Dinesh Kumar Jain*
IPS Academy College of Pharmacy, Knowledge Village, Rajendra Nagar, A.B. Road, Indore-452012

Article History
Received: 16/04/2024
Revised : 18/05/2024
Accepted : 05/06/2024

DOI:
10.62896/ijpdd.1.7.2

Abstract:

The pharmaceutical landscape is marked by the coexistence of two essential categories of drugs: generic and branded. This review article aims to comprehensively analyze the key aspects, including efficacy, safety, cost-effectiveness, and regulatory considerations, in the ongoing debate surrounding generic and branded drugs. This study systematically evaluates a vast body of literature and clinical trials, encompassing various therapeutic areas and disease conditions, to elucidate the similarities and differences between generic and branded pharmaceuticals. We explore the bioequivalence and quality control measures that underpin generic drug manufacturing, shedding light on their safety and effectiveness. Furthermore, this review delves into the cost-effectiveness of generic drugs, addressing their potential to reduce healthcare expenditure while maintaining therapeutic efficacy. We also discuss the impact of healthcare policies and regulations on the prescription and utilization of generic drugs across different regions. Through this comparative analysis, we aim to provide healthcare professionals, policymakers, and patients with a balanced perspective on the choice between generic and branded drugs. Our findings highlight the importance of individual patient needs, regulatory compliance, and healthcare infrastructure in shaping drug selection and utilization. Ultimately, this review underscores the significance of continued research and evidence-based decision-making in optimizing the use of generic and branded drugs, thereby enhancing healthcare outcomes and promoting accessible, affordable, and high-quality pharmaceutical care for patients worldwide.

Keywords: *Generic drugs, Branded drugs, Bioequivalence, FDA approval, Hatch-Waxman Act.*

***Corresponding Author**
Dinesh Kumar Jain
IPS Academy College of Pharmacy, Knowledge Village, Rajendra Nagar, A.B. Road, Indore-452012
E-mail: jaindkj57@yahoo.com

Introduction: In the realm of modern healthcare, the choice between generic and branded pharmaceuticals represents a pivotal decision that clinicians, patients, and healthcare systems grapple with daily. This comparative study delves into the intricate landscape of generic and branded drugs, aiming to provide a comprehensive overview of their similarities, differences, and implications. As the pharmaceutical industry continues to evolve, the need for informed decision-making in drug selection and prescription becomes increasingly imperative. This review article endeavors to shed light on the essential facets of this enduring debate, offering a nuanced exploration of the efficacy, safety, cost-effectiveness, and regulatory aspects that underpin the utilization of generic and branded medications. Through an exhaustive examination of existing literature, clinical trials, and real-world data, we seek to empower healthcare professionals and patients alike with the knowledge necessary to make informed choices, ultimately optimizing the quality and cost-efficiency of healthcare delivery. In an era where healthcare resources are at a premium, understanding

the comparative merits and limitations of generic and branded drugs is crucial for achieving better patient outcomes, ensuring equitable access to medications, and promoting sustainable healthcare systems worldwide.

- **Generic Drugs:** A generic drug is a medication that is developed to be bioequivalent to a brand-name or innovator drug in terms of active ingredients, dosage form, strength, route of administration, and intended use [1]. However, unlike brand-name drugs, generic drugs are not associated with a specific manufacturer or brand and are typically marketed under their chemical or generic name. Generic drugs are created once the patent protection of a brand-name drug expires. When a pharmaceutical company develops a new drug, they are granted a patent that gives them exclusive rights to produce and sell that drug for a certain period, typically 20 years. After this patent expires, other manufacturers can produce generic versions of the drug. Generic drugs offer a cost-effective alternative to brand-name medications while maintaining the same quality, safety, and efficacy standards. They play a vital role in providing affordable healthcare options to patients and reducing the financial burden on healthcare systems. Generic drugs are acknowledged as having therapeutic equivalence to their brand-name counterparts, leading to their exclusion from the Orange Book [1,2].

  The Orange Book, officially titled "Approved Drug Products with Therapeutic Equivalence Evaluations," is a publication by the U.S. Food and Drug Administration (FDA) that serves as a comprehensive guide for pharmaceutical professionals. Released regularly, it includes a list of approved drug products and assesses their therapeutic equivalence, aiding healthcare practitioners in making informed decisions about generic drug substitution. The Orange Book categorizes drugs based on their active ingredients, providing crucial information on bioequivalence, dosage forms, and routes of administration. It serves as a key reference for pharmacists, physicians, and regulatory agencies, ensuring the safety and efficacy of generic drugs by establishing interchangeability standards. The book's transparent evaluation process supports a competitive market, fostering accessibility to cost-effective alternatives while maintaining high standards of pharmaceutical quality and performance. Overall, the Orange Book plays a pivotal role in promoting public health through its contribution to drug safety and accessibility in the United States [3].

  The Hatch-Waxman Act, enacted in 1984, facilitates the entry of generic drugs into the market while preserving incentives for innovation. It allows generic manufacturers to submit Abbreviated New Drug Applications (ANDAs) and challenge innovator drug patents through Paragraph IV certifications. If a legal dispute arises, an automatic 30-month stay delays generic approval. Successful challenges may grant the first generic entrant 180-day exclusivity. The Act balances competition and innovation, fostering a robust pharmaceutical market by providing cost-effective alternatives while maintaining patent protection for original drug developers. Post-marketing surveillance ensures ongoing safety and efficacy monitoring for both generic and innovator drugs [2,3].

Fig. 1: Key Elements of Hatch-Waxman Act

- **Bioequivalence:** Bioequivalence refers to the comparable effectiveness and safety of two pharmaceutical products, typically drugs, that have the same active ingredient or compound and are intended for the same purpose. These products are considered bioequivalent when they exhibit similar rates and extents of absorption of the active ingredient into the bloodstream after administration at the same dosage. Bioequivalence involves a comprehensive comparison of pharmacokinetic parameters, such as the area under the concentration-time curve (AUC) and maximum concentration (Cmax), between a reference (originator or innovator) drug and a test (generic

or biosimilar) drug. The pharmacokinetic parameters provide insights into how the drug is absorbed, distributed, metabolized, and excreted by the body [4].

- **Branded/Ethical Drugs:** A branded drug, also referred to as a brand-name drug or innovator drug, represents a pharmaceutical product meticulously formulated and brought to market by a specific pharmaceutical entity under an exclusive proprietary brand name. This distinct brand nomenclature, carefully selected by the developing company, plays a pivotal role in setting the drug apart in the competitive pharmaceutical landscape and is frequently safeguarded by trademark protection measures.

  When a pharmaceutical firm embarks on the development of a novel medication, it typically seeks patent protection, granting exclusive rights for a specified period—usually spanning 20 years from the date of patent filing. Within this timeframe, the originating company holds a monopoly over the manufacturing and distribution of the drug, effectively thwarting the entry of generic competitors into the market.

  The brand name attached to the drug serves not only as a means of identification but also as a symbol of the company's commitment to quality and innovation. This exclusivity period, afforded by the patent, allows the pharmaceutical company to recoup its research and development investments, incentivizing continued advancements in the field of medicine. As the patent nears expiration, generic alternatives may emerge, fostering competition, and potentially leading to more accessible and cost-effective healthcare solutions for consumers [5,6].
- **Purpose of this review:** This review article aims to comprehensively investigate the comparative aspects of generic and branded pharmaceuticals, focusing on their efficacy, safety, economic implications, and their impact on various stakeholders in the healthcare ecosystem. By synthesizing existing research, this review intends to provide a holistic understanding of the choices available to patients, healthcare providers, and policymakers regarding drug selection. Additionally, it seeks to shed light on the evolving pharmaceutical landscape, potential challenges, and future trends in the context of generic and branded drug usage, ultimately guiding evidence-based decision-making and healthcare policy development.

Comparative Analysis between Generic and Branded Drugs:

S.No.	Comparison factors	Generic Drugs	Branded Drugs
1.	Regulation and approval	Generic drug manufacturers submit an ANDA to the regulatory agency, providing evidence that their product is bioequivalent to the already approved reference (branded) drug [7]. The regulatory agency reviews the ANDA, ensuring the generic drug meets all safety, efficacy, and quality requirements. If the criteria are met, approval is granted, and the generic drug can enter the market after any applicable patent exclusivity periods expire [7,8].	The developer of a branded drug submits an IND application to the regulatory agency, presenting preclinical data and a proposed plan for clinical trials [9]. If the regulatory agency approves the NDA, the drug is granted for marketing authorization. Post-approval, ongoing monitoring of the drug's safety and effectiveness continues, and adjustments to labeling or warnings may be made based on new data [10].
2.	Safety and Efficacy	The safety of a generic drug is evaluated based on its active ingredients, dosage form, strength, route of administration, and intended use [11]. Generic drugs must demonstrate bioequivalence to the branded drug in terms of safety, meaning they have the same rate and extent of absorption of the active ingredient [12].	The safety of a branded drug is evaluated through preclinical and clinical studies, which assess potential adverse effects, interactions, and other safety concerns [13]. The specific formulation, including both active and inactive ingredients, is thoroughly tested for safety and potential adverse reactions [13,14].
3.	Cost Examples	Generic drugs are typically more affordable as they do not involve the same research and development costs and benefit from market competition [15]. -Paracetamol 500mg for Rs. 9.98 by Cipla.	Branded drugs tend to be more expensive due to the costs associated with research, development, marketing, and the protection of intellectual property [15,16]. -Crocin 500mg for Rs. 20.13 by Cipla. -Fludac capsule 20mg for Rs. 37.26 by Cadila. -Restyl tablet 0.25mg for Rs. 14.82 by Cipla.

		-Fluoxetine HCL 20mg for Rs. 28.00 by Cadila. -Alprazolam 0.25mg for Rs. 11.34 by Cipla. -Cetrizine HCL 10mg for Rs. 25.00 by Cipla. -Levothyroxine 75mcg for Rs. 146 by Merck.	-Alerid tablet 10mg for Rs. 35.31 by Cipla. -Euthyrox mcg for Rs. 165.76 by Merck.
4.	Patient perspective	Some consumers may perceive generic drugs as less effective or of lower quality compared to branded drugs, although this perception is often unfounded. Generic drugs are required to meet the same quality standards and be as effective as their branded counterparts [17].	Branded drugs are often associated with higher quality and efficacy due to extensive research, marketing efforts, and a well-established brand image [18].
5.	Healthcare provider perspective	Healthcare providers often view generic drugs favorably due to their cost-effectiveness. Healthcare providers recognize that cost savings associated with generic drugs can improve patient compliance with prescribed treatments. They understand that patients are more likely to adhere to medications that are affordable. They recognize that generic alternatives can significantly reduce healthcare costs for patients, insurance providers, and healthcare systems [19].	Branded drugs are acknowledged for their higher cost, which may pose challenges in terms of affordability and access, especially for patients without insurance coverage or with limited financial resources. In cases where patients have strong brand loyalty or a history of success with a particular branded drug, healthcare providers may consider patient preferences and comfort when making prescribing decisions [16,19].
6.	Marketing and Branding	Generic drugs do not have a brand name. They are marketed using the drug's generic name, which is based on the drug's chemical name or active ingredient [20].	Branded drugs have a unique brand name, and they are marketed heavily by the company that developed them. Marketing efforts often include advertisements, promotions, and building a brand image [20].

Leading Generic Drug Manufacturers Globally:

1. Teva Pharmaceutical Industries Ltd.
2. Mylan N.V. (now Viatris)
3. Sandoz (Novartis)
4. Sun Pharmaceutical Industries Ltd.
5. Dr. Reddy's Laboratories Ltd
6. Apotex Inc.
7. Fresenius Kabi AG
8. Lupin Limited
9. Cipla Ltd.
10. Takeda Pharmaceutical Company Limited [21].

Leading Branded Drug Manufacturers Globally:

1. Pfizer Inc.
2. Novartis International AG
3. Roche Group
4. Merck & Co., Inc.
5. Johnson & Johnson
6. Sanofi
7. AstraZeneca
8. GlaxoSmithKline (GSK)
9. AbbVie Inc.
10. Bayer AG [22]

Conclusion: This comprehensive review has provided valuable insights into the comparative study between generic drugs and branded drugs. Throughout this analysis, we have delved into various aspects including efficacy, safety, cost-effectiveness, regulatory frameworks, and public perceptions associated with both categories of pharmaceuticals. Generic drugs, despite their lower cost, have demonstrated comparable efficacy and safety profiles to their branded counterparts, as supported by extensive research and rigorous regulatory standards. The therapeutic equivalence and bioequivalence of generic drugs have been established through meticulous testing, ensuring that consumers can trust the effectiveness and safety of these alternatives.

However, consumer perception and trust in branded drugs, often influenced by marketing strategies and longstanding familiarity, remain significant factors that shape preferences. Educating healthcare professionals and the general public about the rigorous testing and validation processes that generic drugs undergo can help bridge this perception gap and foster greater acceptance.

References:

1. Himmel, W., Simmenroth-Nayda, A., Niebling, W., Ledig, T., Jansen, R.D., Kochen, M.M., Gleiter, C.H. and Hummers-Pradier, E., 2005. What do primary care patients think about generic drugs, pp. 472-479.
2. Hornecker JR. Generic drugs: history, approval process, and current challenges. US Pharm. 2009;34(6), pp.26-30.
3. Andrade, C., 2015. Bioequivalence of generic drugs. The Journal of Clinical Psychiatry, 76(9), pp.1905.
4. Midha, K.K. and McKay, G., 2009. Bioequivalence; its history, practice, and future. The AAPS journal, 11, pp.664-670.
5. Das, M., Choudhury, S., Maity, S., Hazra, A., Pradhan, T., Pal, A. and Roy, R.K., 2017. Generic versus branded medicines: An observational study among patients with chronic diseases attending a public hospital outpatient department. Journal of natural science, biology, and medicine, 8(1), pp.26.
6. Ahire, K., Shukla, M.A.N.I.S.H., Gattani, M.A.H.E.S.H., Singh, V.I.N.A.Y. and Singh, M.E.E.R.A., 2013. A survey based study in current scenario of generic and branded medicines. International Journal of Pharmaceutical Science, 5(3), pp.705-11.
7. Handoo, S., Arora, V., Khera, D., Nandi, P.K. and Sahu, S.K., 2012. A comprehensive study on regulatory requirements for development and filing of generic drugs globally. International journal of pharmaceutical investigation, 2(3), pp.99.
8. Hanuja, G.S., Kumari, B.S., Nagabhushanam, M.V., Reddy, D.N. and Bonthagarala, B., 2016. Regulatory requirements for registration of generic drugs in "BRICS" countries. International Journal of Pharmaceutical Science and Health Care, ISSN, pp.2249-5738.
9. Grabowski, H.G., 2007. Competition between generic and branded drugs. Pharmaceutical innovation: incentives, competition, and cost-benefit analysis in international perspective, pp.153-288.
10. Darrow, J.J., Avorn, J. and Kesselheim, A.S., 2020. FDA approval and regulation of pharmaceuticals, 1983-2018. Jama, 323(2), pp.164-176.
11. Dighe, S.V., 1999, May. A review of the safety of generic drugs. In Transplantation Proceedings (Vol. 31, No. 3A Suppl, pp. 23S-24S).
12. Peters, J.R., Hixon, D.R., Conner, D.P., Davit, B.M., Catterson, D.M. and Parise, C.M., 2009. Generic drugs–safe, effective, and affordable. Dermatologic therapy, 22(3), pp.229-240.
13. Gallelli, L., Palleria, C., De Vuono, A., Mumoli, L., Vasapollo, P., Piro, B. and Russo, E., 2013. Safety and efficacy of generic drugs with respect to brand formulation. Journal of Pharmacology and Pharmacotherapeutics, 4(1_suppl), pp.S110-S114.
14. Tootelian, D.H., Gaedeke, R.M. and Schlacter, J., 1988. Branded versus generic prescription drugs: perceptions of risk, efficacy, safety, and value. Journal of health care marketing, 8(3).
15. Singal, G.L., Nanda, A. and Kotwani, A., 2011. A comparative evaluation of price and quality of some branded versus branded–generic medicines of the same manufacturer in India. Indian journal of pharmacology, 43(2), pp.131.
16. Straka, R.J., Keohane, D.J. and Liu, L.Z., 2017. Potential clinical and economic impact of switching branded medications to generics. American journal of therapeutics, 24(3), p.e278.

17. Shrank, W.H., Cox, E.R., Fischer, M.A., Mehta, J. and Choudhry, N.K., 2009. Patients' perceptions of generic medications. Health affairs, 28(2), pp.546-556.
18. Tripathi, S. and Bhattacharya, S., 2018. Patient Perception about Generic vs. Branded Medicines Prescribed in a Tertiary Care Hospital in Northern India-A Descriptive Study. Indian Journal of Pharmacy Practice, 11(2).
19. Toverud, E.L., Hartmann, K. and Håkonsen, H., 2015. A systematic review of physicians' and pharmacists' perspectives on generic drug use: what are the global challenges?. Applied health economics and health policy, 13, pp.35-45.
20. Ladha, Z., 2007. Marketing strategy: are consumers really influenced by brands when purchasing pharmaceutical products. Journal of Medical Marketing, 7(2), pp.146-151.
21. https://www.globaldata.com/companies/top-companies-by-sector/healthcare/global-generic-companies-by-revenue/ accessed on 29-09-2023.
22. https://www.wikipedia.org// accessed on 29-09-2023.

*****