

Understanding Generic Drugs and their Impact on Healthcare

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DESCRIPTION

The pharmaceutical industry plays a vital role in modern healthcare, providing patients with life-saving medications and treatments for a wide range of medical conditions. However, the cost of brand-name drugs can be prohibitively high for many patients, creating barriers to access and affordability. This is where generic drugs step in as a game changer, offering safe, effective, and more affordable alternatives to their brand-name counterparts [1]. In this article, we will explore the world of generic drugs, their significance in healthcare, how they are developed, and the regulatory framework that ensures their safety and efficacy [2,3]. Drugs are identical, or bioequivalent, versions of brand-name drugs that have the same active ingredients, strength, dosage form, and route of administration. They offer the same quality, safety, and efficacy as their brand-name counterparts but at a fraction of the cost. This competition in the marketplace is what drives down the cost of medications and makes healthcare more affordable for patients [4,5]. One of the most significant benefits of generic drugs is their cost-effectiveness. Because generic manufacturers do not have to invest in the study and development of a new drug, their production costs are substantially lower. This cost advantage is passed on to patients, resulting in lower drug price [6]. This increased access to essential treatments can have a positive impact on public health by helping patients better manage their conditions and prevent serious complications. The introduction of generic drugs into the market encourages competition, which benefits both patients and the healthcare system [7]. Competition forces drug prices down and motivates pharmaceutical companies to continually innovate and develop new, more effective treatments. Generic drugs often come in various forms, such as tablets, capsules, and liquid formulations, providing patients with more treatment options to suit their individual needs and preferences. Generic drug manufacturers must conduct to identify an equivalent active ingredient and formulation to the brand-name drug. They analyse the chemical structure, pharmacological properties, and therapeutic effects to ensure that the generic drug will be bioequivalent to the brand-name product. These trials involve human participants and are designed to prove that the generic drug has the same therapeutic effects and is absorbed in the body at the same rate as the brand-

name drug. After regulatory approval, the generic drug manufacturer begins mass production. They must adhere to strict quality control standards to ensure the safety, purity, and efficacy of the product. To gain approval for a generic drug, manufacturers submit an Abbreviated New Drug Application (ANDA) to the Food and Drug Administration (FDA). This application includes data on the drug's safety, efficacy, and bioequivalence to the brand-name drug [8,9]. If the Food and Drug Administration (FDA) determines that the generic drug is therapeutically equivalent to the brand-name product, it is granted approval for marketing and sale.

The Food and Drug Administration (FDA) maintains a list of therapeutic equivalence evaluations for generic drugs. This publication helps healthcare professionals and patients identify generic drugs that are considered equivalent to their brand-name counterparts. Generic drug manufacturers must conduct bioequivalence studies to demonstrate that their product is absorbed into the bloodstream at the same rate and to the same extent as the brand-name drug [10].

CONCLUSION

Generic drug manufacturers are required to follow Good Manufacturing Practices to ensure the quality and consistency of their products. These regulations cover various aspects of drug production, including facility cleanliness, equipment calibration, and product labelling. The Food and Drug Administration (FDA) continues to monitor generic drugs after they enter the market. In some cases, the availability of generic drugs may be limited due to manufacturing issues, supply chain disruptions, or lack of competition. These disputes can delay the introduction of generic alternatives to the market. Some patients and healthcare professionals may have concerns about the perceived differences between brand-name and generic drugs, leading to questions about the effectiveness and safety of generic options. Generic drugs have transformed the healthcare landscape by providing safe, effective, and affordable alternatives to brand-name medications. They play a crucial role in increasing access to essential treatments, promoting healthy competition, and lowering the overall cost of healthcare. However, it is essential to maintain a robust regulatory framework to ensure the quality and safety of generic drugs.

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REFERENCES

1. Tang T, Winberg D, Stoecker C, Li J, Shao H, Cong M, et al. RWD77 \$0 Drug Copay Program Increases Generic Drug Use Among Members with Diabetes in Louisiana: Six-Month Outcomes Analysis. *JAMA Netw Open*. 2023;26(6):S374-85.
2. Algabbani AM, Alkeridy WA, Alessa MA, Alrwisan AA. The inadvertent consequences of drug recalls: A case study of a recall of pantoprazole generics from the markets. *Saudi Pharm J*. 2023;31(7):1181-85.
3. McElwee NE. Does the United States Need Better Policies Governing Generic Drug Use. *Value Health*. 2023;26(3):392-93.
4. Beechinor RJ, Mohyuddin GR, Mitchell DE, Aaron D, Mahmoudjafari Z. The story of the development of generic lenalidomide: How one company thwarted the Waxman-Hatch Act to generate billions of dollars in revenue. *J Cancer Policy*. 2023:1004-46.
5. Bergmann F, Nussbaumer-Pröll A, Wulkersdorfer B, Eberl S, Ruppitsch W, Lepuschitz S, et al. Antimicrobial activity and pathogen mutation prevention of originator and generics of cefepime, linezolid and piperacillin/tazobactam against clinical isolates of *Staphylococcus aureus*. *J Glob Antimicrob Resist*. 2023;34:179-85.
6. Rome BN, Egilman AC, Patel NG, Kesselheim AS. Using multiple authorized generics to maintain high prices: the example of entacapone. *Value Health*. 2023;26(3):370-7.
7. Ray SE, Boudewyns V, Oguntimein O, Conti D, Malik R, Srivastava I, et al. Generic Substitution of Epinephrine Auto-injectors: Patient and Caregiver Perceptions and Attitudes. *J Allergy Clin Immunol Glob: Global*. 2023:1001-70.
8. Ma P, Shang S, Feng W, Liu C, Liu F, Xiong L, et al. Pharmacokinetic/pharmacodynamic comparison between generic and brand-name levofloxacin based on Monte Carlo simulation. *J Glob Antimicrob Resist*. 2023;33:120-29.
9. Menendez L, Osherov M, Nitsan Z, Alkrenawi M, Gelfand A, Hovel N, et al. The consequences of switching from Gilenya® to generics for fingolimod. *Mult Scler Relat Disord*. 2023;74:1046-92.
10. ALRabeeh D, Almomen A, Alzoman N, Arafah M. Evaluating the bioequivalence of levetiracetam brand and generic oral tablets available in the Saudi market in vivo. *Saudi Pharm J*. 2023;31(10):1017-58.