



THE BENEFIT OF GENERIC SUBSTITUTION ON HEALTH & ECONOMICAL OUTCOME

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Article Received on 28/01/2019

Article Revised on 16/02/2019

Article Accepted on 08/03/2019

ABSTRACT

Medicines have an important role in our routine life. Drug are available in two forms-branded and generic drug. A generic drug is a medication that have exactly the same active ingredients as the branded drug and give the same therapeutic effect, it is the same in dosing, safety, strength, quality, the way it works the way it is taken should be used. However, a generic drug can only be marketed after the branded drugs patent has expired which may take up to 20 years or up to the patent life.

KEYWORDS: Generic drugs, Branded drugs, Generic name, innovator drugs, ANDA, FDA etc.

INTRODUCTION

A generic drug is a drug defined as “a drug product that is comparable to a generic drug brand/reference listed drug product in dosage form. Strength, quality and performance characteristics, and intended use. “It has also been defined as a term referring to any drug marketed under its chemical name without advertising. A generic medicine works in the same way and provides the same clinical benefit as its brand-name version. This standard applies to all FDA-approved generic medicines. A generic medicine is the same as a brand-name medicine in dosage, safety, effectiveness, strength, stability, and quality, as well as in the way it is taken and should be used. Manufacturers simply “borrow their neighbor’s homework” and don’t have to spend the time or money to do their own. Since they can produce the medication at a much lower cost, it stands to reason that they can sell it at a lower cost and still make a profit. When several companies begin to manufacture the same generic medication, competition further keeps the price down. That’s why nearly 8 of 10 prescriptions in the United States are filled with generics.

Why do brand name drugs cost more than generics?

1. Brand name drugs take several years, costly scientific development and may clinical studies to get market approval.
2. Manufacturers of brand name/innovator drugs usually take on the research and development cost for new medications.
3. These research and development costs, along with marketing costs, account for most of the higher prices pay most brand name drug.
4. In contract, generic drug have less research and development costs since the original manufacturer has already done many studies, to make sure the drug is safe.
5. Thesesavings are passed on to the customer.

Benefit of buying generic drugs online

1. Totally hassle free
2. Need not enter any crowded medical store.
3. Order from your home
4. Make payment by your debit or credit card
5. You can ask anything if you have any doubts - get quick response
6. 100% money back guarantee

Table 1: Some example of generic and branded drug with their price.

Category	Generic drug	price	Branded drug	price
Analgesic	paracetamol	Rs2.45	Crocin	Rs 11
	Diclofenac sodium + paracetamol	Rs 4.4	Diclogesic	Rs 19.40
Antibiotic	Amoxyclin	Rs 13.2	LMX	Rs 40
			Remox	Rs 38.7

	Azihromycin	Rs 41.8	Azee	Rs 107
			Azithral	Rs 128.55
Vitamin	Folic acid	Rs 2.8	follvite	Rs 11.8
	B-complex	Rs 1.8	becosul	Rs 11.0
Cardiovascular Drug	Atenolol	Rs 7.0	Aten	Rs 23.8

Generic drugs must meet high standards to receive FDA approval

FDA requires drug companies to demonstrate that the generic medicine can be effectively substituted and provide the same clinical benefit as the brand-name medicine that it copies. The abbreviated new drug application (ANDA) submitted by drug companies must show the generic medicine is the same as the brand-name version in the following ways.

- The active ingredient in the generic medicine is the same as in the brand-name drug/innovator drug.
- The generic medicine has the same strength, use indications, form (such as a tablet or an injectable), and route of administration (such as oral or topical).
- The inactive ingredients of the generic medicine are acceptable.
- The generic medicine is manufactured under the same strict standards as the brand-name medicine.
- The container in which the medicine will be shipped and sold is appropriate, and the label is the same as the brand-name medicine's label.

Why are generic drugs cheaper than brand name drugs?

Manufacturers of generic drugs do not have to repeat the years of costly laboratory and clinical trials that the developing company invested in to gain FDA approval. Generic manufacturers simply “borrow their neighbor’s homework” and don’t have to spend the time or money to do their own. Since they can produce the medication at a much lower cost, it stands to reason that they can sell it at a lower cost and still make a profit. When several companies begin to manufacture the same generic medication, competition further keeps the price down. That’s why nearly 8 of 10 prescriptions in the United States are filled with generics. Generic drugs are copies of brand-name drugs that have exactly the same dosage, intended use, effects, side effects, route of administration, risks, safety, and strength as the original drug. In other words, their pharmacological effects are exactly the same as those of their brand-name counterparts.

REFERENCES

1. Ahire, Kishor. "A survey based study in current scenario of generic and branded medicines." *International Journal of Pharmacy and Pharmaceutical Sciences*, 19 Apr. 2013. Web. 7 Mar. 2016.
2. Consumer Reports Best Buy Drugs. (2011, February 1). Retrieved October 3, 2015.
3. Criscely, Go. "Generic versus Branded Pharmacotherapy in Parkinson’s Disease: Does It Matter? A Review." *Science Direct*. 4 Feb. 2011. Web. 28 Oct. 2015.
4. Dunne, Suzanne, and Colum Dunne. "What Do People Really Think of Generic Medicines? A Systematic Review and Critical Appraisal of Literature on Stakeholder Perceptions of Generic Drugs." *BMC Medicine*. 29 July 2015. Web. 27 Oct. 2015.
5. "Facts about Generic Drugs." U.S. Food and Drug Administration Protecting and Promoting Your Health. 19 Sept. 2012. Web. 17 Feb. 2015.
6. Friedman, Lauren. "Here's Why You Should Always Buy Generic Drugs." *Business Insider*. 6 May 2014. Web. 3 Oct. 2015.
7. Gagne JJ, Choudhry NK, Kesselheim AS, Polinski JM, Hutchins D, Matlin OS, et al. Comparative Effectiveness of Generic and Brand-Name Statins on Patient Outcomes: A Cohort Study. *Ann Intern Med*, 2014; 161: 400-407. doi:10.7326/M13-2942.
8. Gavura, Scott. "Generic Drugs: Are They Equivalent?" *Science -Based Medicine*. 5 Jan. 2012. Web. 17 Feb. 2016. Graedon, Joe. "Why Pharmacists Are Wrong About Generic Drugs." *The People's Pharmacist*. 11 Apr. 2011. Web. 14 Mar. 2016. Keenum, Amy. *Generic Medications for You, but Brand-name Medications for Me.* *Science Direct*. 1 Nov. 2012. Web. 27 Oct. 2015.
9. Kesselheim, Aaron S. et al. "Clinical Equivalence of Generic and Brand-Name Drugs Used in Cardiovascular Disease: A Systematic Review and Meta-Analysis." *JAMA: the journal of the American Medical Association* 300.21 (2008): 2514–2526. PMC. Web. 23 Sept. 2015.
10. Kohli, Erol. "Factors Influencing Consumer Purchasing Patterns of Generic Versus Brand Name Over-the-Counter Drugs." & Factors Influencing Consumer Purchasing Patterns. Feb. 2013. Web. 7 Mar. 2016.
11. Levine, Beth. "Generic Meds Vs. Brand Name: Which Is Better?" *Grandparents*. 17 Feb. 2015. Web. 22 Mar. 2016. <<http://www.grandparents.com/health-and-wellbeing/health/generic-vs-brand-name-drugs>>.
12. Orszag, Peter. "Sometimes Brand-Name Drugs Really Are Better." *Bloombergview*. 22 Apr. 2014. Web. 6 Oct. 2015. <<http://www.bloombergview.com/articles/2014-04-22/sometimes-brand-name-drugs-really-are-better>>.
13. Panahi, Yunes et al. "Efficacy and Safety of Dorocontin® versus Sustac® in the Treatment of Stable Angina Pectoris: A Randomized, Double-Blind Comparative Trial." *Scientia Pharmaceutica*, 2014; 82.4: 815–824. PMC. Web. 22 Sept. 2015.

14. Pollack, Hannah. "Preference Towards Generic Prescription Drugs Shows A Four-to-One Lead Over Brand Name Medications." Harris. 17 Mar. 2015. Web. 6 Oct. 2015.
15. Shrank, William. "Patients' Perceptions Of Generic Medications." Health Affairs. Mar.-Apr. 2009. Web. 5 Mar. 2016.
16. Sicras-Mainar, Antoni, Javier Rejas-Gutiérrez, and Ruth Navarro-Artieda. "Comparative Effectiveness and Costs of Generic and Brand-Name Gabapentin and Venlafaxine in Patients with Neuropathic Pain or Generalized Anxiety Disorder in Spain." Clinico Economics and Outcomes Research: CEOR, 2015; 7: 299–312. PMC. Web. 22 Sept. 2015.
17. Steinman, Michael. What's in a Name? Use of Brand versus Generic Drug Names in United States Outpatient Practice. Springer International Publishing, 1 May 2007. Web. 10 Nov. 2015.
18. "Survey of Consumer Attitudes Toward Generic Drugs SUMMARY REPORT." Excellusbcb. Mar. 2007. Web. Mar. 2016.
19. What's the difference between brand-name and generic prescription drugs? (2004). Scientific American. Retrieved February 17, 2015, from <http://www.scientificamerican.com/article/whats-the-difference-betw-2004-12-1>.