SUMMARY

A generic drug is a copy (of an approved drug, innovator / branded product) that is the same as a branded drug, in dosage, safety, strength, how it is taken, quality, performance and intended use. All over the world, regulatory agencies require that all drugs be safe and effective. Since generics use the same active ingredients and are shown to work the same way in the body, they have the same risks and benefits as their branded counterparts. Regulatory agencies also require the generic drugs to have the same quality, strength, purity and stability, as branded products.

Generic drugs are less expensive because generic manufacturers do not have the investment costs of the developer of a new drug. Generally, new drugs are developed under patent protection. The patent protects the investment— including research, development, marketing and promotion — by giving the company the sole right to sell the drug while patent life is in force. As patents near expiration, manufacturers can apply to the regulatory agencies to sell generic versions. Because the generic manufacturers do not have the same development costs, they can sell their product at substantial discounts. Also, once generic drugs are approved, there is greater competition, which keeps the price down.

Worldwide, generics have the potential to provide substantial reduction in costs of health care, to the government, insurance agencies, hospitals, and most important, patients. However, there exist many myths / misconceptions regarding the generics, some of which are discussed below:

- The quality and effectiveness of generics have been compromised to make the less expensive products.
- Generics take longer time to work.
Generics have different (reduced) efficacy than the branded products, since they may have different colors, flavors or combination of inactive ingredients than the branded products.

This research work is aimed towards exploring the truths behind these myths / misconceptions. The work is aimed specifically towards exploring the regulatory guidelines concerning the use of branded versus generic drugs, with a specific focus on USA and India. Further, attention has been focused in the State of Haryana, wherein the prescribing habits of physicians have been explored, with a view to seek their views on the generics versus branded products. The role of retail pharmacists, who act as direct sellers to the patients, has also been explored, in a survey in the State of Haryana, in the area of generic versus branded products. To actually verify the truth behind the above mentioned myths / misconceptions, marketed samples of some generics / branded products were picked up, from the market, and tested as per pharmacopoeial standards. Lastly, samples of some generics from “Jan Aushdhi Stores”, promoted by Government of India for selling generics, were also picked up and tested as per pharmacopoeial standards, comparing them with their branded counterparts. The results conclusively disapprove the above myths / misconceptions and strongly substantiate the quality of generic products, in spite of their lower costs. Regulatory guidelines of several countries have been analyzed, with a view to provide useful recommendations, for improvement in the Indian laws, regarding the use of generic drugs.
VS GENERIC BRAND NAME DRUGS

the idiocy of paying more for the same thing

Generic. It’s not a very sexy word, and at the grocery store generic products can be of inferior quality to their brand counterparts. But in the pharmacy aisle, the rules are different.

Generic pharmaceuticals must be identical in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use.

Well, generics are almost identical. There is one major difference. Generics are 80% CHEAPER on average.

Let’s meet a familiar friend...

HELLO
my name is
isobutylpropanoic phenolic acid
The process for creating Ibuprofen was patented in 1961 (3,385,886) and was available for prescription in 1974 and over the counter in 1984.

The patent expired two years later.

So why is Wyeth, a subsidiary of Pfizer, and owner of the Advil brand, spending $114 million a year in advertising trying to sell a product whose only unique feature is its higher price?

Because there is an off chance that you may be a moron.

Generics may seem like the obvious choice but there are powerful emotional attachments (branding) at work.

Let’s try an experiment. You have a migraine. Which would you rather buy?

**Advil Migraine**
- Liquid Filled Capsules
- 200mg 40qty
- $12.99

**Ibuprofen Capsules**
- 200mg 40qty
- $4.75

Now what if there was a sale.

**Advil Migraine**
- Liquid Filled Capsules
- 200mg 40qty
- $10.99 BOX OUT

**Ibuprofen Capsules**
- 200mg 40qty
- $4.75