

BRAND NAME AND GENERIC DRUGS

The rapid rise in prescription drug costs requires a close look at the factors propelling that rise. That increase is about 15% yearly, which is 5 times the rate of inflation. The costs involved in developing new and effective drugs are great. These are ‘Brand Name’ drugs. The option of using equivalent and effective generic drugs in substitution for brand name drugs allows for greater access to effective medications.

BRAND NAME DRUGS (INNOVATOR DRUGS)

The process of gaining the Food and Drug Administration’s (FDA) approval to market a “new chemical entity” (prescription drug) is long and demanding. They include:

- Chemical Review – FDA reviewers look at manufacturing process to ensure the compound is stable and reproducible (same chemical identity with each manufacture)
- Animal Testing – to measure how much of the drug is absorbed into the blood stream and how it is broken down in the body.
- Clinical (Human) Studies – the compound is administered to humans for safety and effectiveness in treating a specific condition.
- A patent is provided to the developer for 17 years. It is issued at the time of application to the FDA.
- Promotion and distribution to allow general availability of the product.

GENERIC DRUGS

When the patent for an approved brand name product is about to expire generic drug firms can apply to the FDA to produce and market that drug. This requires submission of an abbreviated New Drug Application. This includes proof that:

- The generic drug contains the same active ingredients as the innovator drug.
- The generic drug is identical in strength dosage form and route of administration.
- They are used for the same medical conditions.
- They are manufactured under the same strict standards that the FDA requires for innovator products.
- The FDA scientists do periodic checks of both Brand and generic manufactured drugs to test for potency and safety.

On the basis of this careful approach the FDA has stated to prescribing physicians that approved generic drugs are “therapeutically equivalent “ to the ‘Brand Name’ products. The FDA

has issued letters to physicians and pharmacists stating that no special measures (e.g. lab testing) are needed when a patient's prescription changes from brand name to generic of the same drug.

HOW DOES THIS AFFECT MPI HEALTH PLAN?

Currently about 40% of all prescription drugs dispensed are generic and 60% are brand names. Reasons for the high percentage of brand names are:

- More brand name drugs are receiving FDA approval in recent years
- The effect of TV advertising
- The effectiveness of some newer brand name drugs over older brand name drugs.
- Perception of generics being less potent or less effective.

With clearer understanding of the careful oversight of generic manufactured drugs we may address some of the rising costs of medication for this Plan.

CENTER FOR DRUG EVALUATION AND RESEARCH

GENERIC DRUGS: QUESTIONS AND ANSWER

Frequently Asked Questions about Generic Drugs

1. What are generic drugs?

A generic drug is a copy that is the same as a brand-name drug in dosage, safety, strength, how it is taken, quality, performance and intended use.

2. Are generic drugs as safe as brand-name drugs?

Yes. FDA requires 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 brand-name counterparts.

3. Are generic drugs as strong as brand-name drugs?

Yes. FDA requires generic drugs to have the same quality, strength, purity and stability as brand-name drugs.

4. Do generic drugs take longer to work in the body?

No. Generic drugs work in the same way and in the same amount of time as brand-name drugs.

5. Why are generic drugs less expensive?

Generic drugs are less expensive because generic manufacturers don't have the investment costs of the developer of a new drug. 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 it is in effect. As patents near expiration, manufacturers can apply to the FDA to sell generic versions. Because those manufacturers don't 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. Today, almost half of all prescriptions are filled with generic drugs.

6. Are brand-name drugs made in more modern facilities than generic drugs?

No. Both brand name and generic drug facilities must meet the same standards of good manufacturing practices. FDA won't permit drugs to be made in substandard facilities. FDA conducts about 3,500 inspections a year to ensure standards are met. Generic firms have facilities comparable to those of brand-name firms. In fact, brand-name firms are linked to an estimated 50 percent of generic drug production. They frequently make copies of their own or other brand-name drugs but sell them without the brand name.

7. If brand-name drugs and generic drugs have the same active ingredients, why do they look different?

In the United States, trademark laws do not allow a generic drug to look exactly like the brand-name drug. However, a generic drug must duplicate the active ingredient. Colors, flavors, and certain other inactive ingredients may be different.

8. Does every brand-name drug have a generic counterpart?

No. Brand-name drugs are generally given patent protection for 20 years from the date of submission of the patent. This provides protection for the innovator who laid out the initial costs (including research, development, and marketing expenses) to develop the new drug. However, when the patent expires, other drug companies can introduce competitive generic versions, but only after they have been thoroughly tested by the manufacturer and approved by the FDA.

9. What is the best source of information about generic drugs?

Contact your physician, pharmacist, or insurance company for information on your generic drugs. You can also visit the FDA website at <http://www.fda.gov/cder/ogd/index.htm> for more information.