

Pamlico News Article

Susan Koepp,

Nurse Practitioner, Partners in Health, PC



Generic and Brand name drugs

Are they the same?

A brand name drug (for example Coumadin) is a drug that has a trade name and is protected by a patent. Patent laws vary from country to country. In the United States, drug patents are held for twenty years and ensure that the drug can be produced and sold only by the company holding the patent. This creates a monopoly, and the company holding the patent sets the price for the drugs. It is expensive to develop new medicines but comparatively much less expensive to manufacture the medicines. Generic drugs (for example warfarin, a generic for Coumadin) may have a patent on the formulation of a drug but not the active ingredient of the drug. The manufacturing of generic drugs opens the market to competition and lowers the price. Generic drugs are produced in laboratories world-wide. India is the leading manufacturer of generic drugs. Pharmaceutical companies seek to protect their patents from generic competition, for instance this can be done by licensing a subsidiary to sell generics under the original patent. In fact, the FDA estimates that 50% of generic drug production is by name-brand companies. The FDA applies the same standards for all facilities that manufacture both generic and brand-name drugs.

That's the economics, but are generics the same? According to the U.S. Food and Drug Administration (FDA), generic drugs are "identical". However, the definition of "identical" is left to interpretation. Yes, the dose, strength, route of administration, safety, efficacy and intended use is the same but the colors, flavors and more importantly the combinations of inactive ingredients differ from the original medications. Trademark laws in the United States do not allow the generic drugs to look exactly like the brand-name drug. This brings us to the *bioequivalence* of preparations. Bioequivalence as defined by the United States

FDA, “is the absence of a significant difference in the rate and extent to which the active ingredient becomes available at the site of the drug action when given at the same dose in the same conditions.” Most countries require generic drug manufacturers to prove their formulation exhibits bioequivalence to the brand-name drug. The US FDA requires the bioequivalence of the generic product to be between 80% and 125% of that of the brand-name product. This variance may not be statistically significant for most drugs but there are a few medications that have a narrow therapeutic window, which means there is little difference between a sub-therapeutic dose and a toxic dose.

Do you have a choice on whether you receive a generic or brand-name drug? Yes, but be your own advocate. Your insurance company often predicts whether you receive a generic or a brand-name drug, they set the “Tiers and co-payments” for the pharmaceutical coverage in your plan, they may require a pre-authorization before they will pay for a specific drug; it is your responsibility to know your plan’s coverage. Talk to your healthcare provider. When a prescription is written, it is signed to authorize a generic or brand-name drug. Brand-name drugs are usually easier to say and write and out of habit the prescription may be written for the more expensive alternative. A pharmacist and their staff are excellent resources and avail themselves to answer questions about prescription (generic and brand-name drugs) and non-prescription drugs. If you are taking a brand-name drug, for instance Glucophage (for diabetes) and switch to the generic (metformin) see if you notice if your blood sugars are affected. I have seen this clinically and this difference may speak to the bioequivalence range of 80-125% in YOUR body (this may or may not apply to any generic and brand name drug you are taking).

There is no question that generic drugs are cost effective for patients and insurance companies alike costing about 30-80% less than brand-name drugs. It is important to remember that while they must be approved to be produced and manufactured; there may be a bioequivalent variance between generic and brand-name drugs. As with all aspects of your healthcare, be informed and discuss any concerns you have with your provider.