Generics: What you need to know

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New drugs are developed under patent protection. The patent protects the investment in the drug's development by giving the company the sole right to sell the drug while the patent is in effect. After patent expiration of a brand drug product, a generic drug product may be marketed. **A generic drug product must be bioequivalent to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteritistics and intended use.**

Although generic drugs are chemically identical to their branded counterparts, they are sold at much lower price. The reason behind the fact that generics are much cheaper than the brand drug products is that drug companies only need to submit an Abbreviated New Drug Application (ANDA) for approval to market their generic product; this application includes only human bioequivalence studies, whereas the marketing of a brand new drug product necessitates pre-clinical safety and efficacy studies as well as costly clinical trials. In the United States and according to the congressional Budget Office, generic drugs save consumers an estimated $8 to $10 billion a year at retail pharmacies. Even more billions are saved when hospitals use generics. Today, nearly 8 in 10 prescriptions filled in the United States are for generic drugs.

Cheaper does not mean lower quality; Generic drugs are as effective as brand-name drugs and the chemistry, manufacturing and controls requirements for the generic drug product are similar to those for the brand name drug product. A study conducted by Kesselheim et al. and published in the JAMA evaluated the results of 38 published clinical trials that compared cardiovascular generic drugs to their brand name counterparts. There was no evidence that brand name heart drugs worked any better than generic heart drugs.

Health professionals and consumers can be confident that in order to gain market approval, a generic drug must meet all the following standards:

- Contain the same active ingredients as the brand-name drug.
- Be identical in strength, dosage form, and route of administration.
- Have the **same use** indications.
- Be **bioequivalent**.
- Meet the same batch requirements for identity, strength, purity and quality
- Be manufactured under the same strict standards of Good Manufacturing Practice (GMP) regulations required for innovator products.