# MPR Concise Consult

The Role of Generic Drugs in Patient Care and the Healthcare System



# For the Healthcare Professional

- Overview of the generic drug approval process
- Impact of generics in the healthcare system

# For the Patient

Myths and facts about generic drugs

## UNDERSTANDING THE GENERIC DRUG APPROVAL PROCESS

#### **GENERIC DRUG APPROVAL PROCESS**

- Generics undergo a rigorous review process by the United States Food and Drug Administration (FDA) to ensure their quality prior to becoming available to patients<sup>1</sup>
- Generic drug manufacturers must submit an Abbreviated New Drug Application (ANDA) to the FDA for review and approval<sup>2</sup>



including drug components, drug stability, packaging, manufacturing processes, and facility descriptions<sup>1</sup>

Source: Adapted from Buehler 2007.1

#### **REQUIREMENTS FOR GENERIC DRUG APPROVAL**

Contains the same active ingredient(s), same dosage form, and route of administration

Meets same batch requirements for strength, quality, purity, and identity

Be therapeutically bioequivalent to a reference product

Manufactured in compliance with current Good Manufacturing Practice regulations

Source: Davit 2009.3

# BIOEQUIVALENCE

The primary difference between a generic drug approval and a brand-name drug approval is the requirement for bioequivalence data for the generic drug.<sup>1</sup>

Bioequivalence can be defined as the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study<sup>4</sup>



Proving that the generic is bioequivalent to the brand assures that it will perform in the same manner as the brand<sup>2</sup>

#### STATISTICAL CRITERIA

- The standard bioequivalence study is conducted using pharmacokinetic parameters<sup>5</sup>
  - Upon calculating a 90% confidence interval (CI) for the AUC (amount absorbed) and C<sub>max</sub> (peak concentration), the CI for the AUC and C<sub>max</sub> for the generic drug must fall within an 80% to 125% bioequivalence limit<sup>5</sup>
- Nearly 98% of bioequivalence studies conducted during a 12-year period demonstrated a <10% difference in the extent of absorption between a generic and brand-name drug<sup>3</sup>
- The observed average difference in absorption into the body between a generic and brand-name drug was about 3.5%<sup>3,5</sup>
  - This is the result one would expect if 2 different lots of the brand-name drug were tested against each other<sup>6</sup>
- Generally, the requirement to submit bioequivalence data for a generic injectable drug approval may be waived because an injectable<sup>8</sup>
  - Has in vivo bioavailability or bioequivalence that is self-evident, as it is only administered by injection, and
  - Contains the same active and inactive ingredients in the same concentration as the already-approved brand-name drug



# **IMPACT OF GENERICS**

#### PATIENT ADHERENCE

Prescription affordability affects patient adherence

- Cost issues may lead patients to take prescribed medication inappropriately to make it last longer<sup>9</sup>
- In a national survey of commercially insured adults (N=1,047), more than 27% reported not filling or refilling their medication due to cost<sup>10</sup>
- Patients fill their maintenance medications more frequently when a generic is available and a "dispense as written" is not designated<sup>11</sup>
- In a retrospective analysis of claims from a 3-tier pharmacy benefit plan, patients who received tier 1 generic medications had 62% greater odds of achieving adequate adherence (>80% of days covered) than those who received nonpreferred tier 3 branded medications<sup>12</sup>

PATIENT ADHERENCE FAVORS GENERICS OVER PREFERRED AND NONPREFERRED BRANDS



#### **GENERIC UTILIZATION**

- Approximately 80% of prescriptions filled in the US are with generic drugs<sup>6</sup>
- On average, the cost of a generic drug is 80% to 85% lower than the brand-name drug<sup>6</sup>
- Generic drug use has saved the US healthcare system approximately \$1.2 trillion between 2003 and 2012<sup>13</sup>
- Generic drug discount programs (GDDPs) are an option to provide affordable prescription medication to low-income individuals<sup>14</sup>

#### MAKE A DIFFERENCE WITH GENERICS

Talking about generics with your patients has an impact

- In a national survey of commercially insured adults, 53.7% of patients (N=1,047) indicated that their healthcare provider seldom or never discussed generic drugs with them<sup>10</sup>
- Patients who talked with their healthcare provider about generics were more likely to fill their prescriptions with a generic drug than those who did not<sup>15</sup>
- In a survey of low-income adults using community healthcare services, the use of GDDPs was 4 times more likely when a physician or pharmacist talked to them about it<sup>14</sup>
- For patients enrolled in tiered pharmacy benefit plans, clinicians can influence long-term adherence by prescribing generics when initiating chronic therapy<sup>12</sup>

#### **ABOUT TEVA GENERICS**

As the world's leading provider of generic drugs, Teva understands the importance of making safe, quality medications accessible—and affordable. Teva manufactures and markets the most expansive portfolio of prescription generic drugs in the United States. In fact, one in eight of the 3.4 billion generic prescriptions written in the United States is filled with a Teva product.<sup>16</sup>

Teva's extensive generic portfolio covers all major therapeutic categories, including cardiovascular, anti-infective, central nervous system, anti-inflammatory, oncolytic, anti-diabetic, analgesic, dermatologic, respiratory, and women's health.

Teva Pharmaceuticals USA is a wholly owned subsidiary of Israeli-based Teva Pharmaceutical Industries Ltd., the global leader in generics and one of the top 10 pharmaceutical companies in the world. Our US operations are headquartered outside of Philadelphia, PA and include more than 7,000 employees in more than 30 facilities across North America.<sup>17</sup>

#### **ADDITIONAL RESOURCES**

#### Food and Drug Administration (FDA)

www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/ UnderstandingGenericDrugs/default.htm

#### **Generic Pharmaceutical Association**

www.gphaonline.org

Teva Generics

www.tevagenerics.com



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# **For the Patient**

## **GENERIC DRUG MYTHS VS FACTS**

# Myth: Generic drugs do not have to be approved by the Food and Drug Administration (FDA).

**Fact:** All generic prescription drugs must be reviewed and approved by the FDA before becoming available on the market. Like brand-name drugs, generics undergo an extensive evaluation. The FDA evaluates clinical and product performance data for a generic drug to ensure it has the same qualities of the brand-name drug. The FDA decides if a generic can be used by patients by evaluating the items listed in **Figure 1**.<sup>1</sup>



#### Myth: Generic drugs aren't as effective as brand name drugs.

**Fact:** FDA approval indicates that generics work just as well as brand-name drugs. To be approved by the FDA, manufacturers have to show that the generic drug works the same way in the body as the brand-name drug. This is known as *bioequivalence*.<sup>1</sup>

# Myth: Generic drugs look and act differently than the brand-name drugs.

**Fact:** Generic drugs look different because certain inactive ingredients, such as colors and flavorings, may be different. These ingredients do not affect how the drug works in the body or its safety. Trademark laws in the United States do not allow a generic drug to look exactly like other drugs already on the market.<sup>2</sup>

# Myth: Generic drugs are less expensive because they have quality problems.

**Fact:** Generic companies can sell their products at lower prices because they do not have to spend significant amounts of time or money conducting drug development studies, clinical trials, advertising, or promotion. Generic companies produce a drug with the same active ingredient as the brand-name drug at a lower price.<sup>1</sup>

(continued on next page)

## **GENERIC DRUG MYTHS VS FACTS** (continued)

#### Myth: Generic drugs are not as safe as brand-name drugs.

**Fact:** Most reported side effects generally describe a known reaction to a drug's active ingredient, which is found in both brand name and generic versions of the medication. The FDA reviews the safety of both brand and generic prescription drugs before approval and continues to monitor safety when they are available to patients.<sup>1</sup>

## DID YOU KNOW...

- Approximately 80% of prescriptions filled in the US are with generic drugs<sup>1</sup>
- On average, the cost of a generic drug is 80% to 85% lower than the brand name drug<sup>1</sup>
- Generic drug use has saved the US healthcare system approximately \$1.2 trillion between 2003-2012<sup>3</sup>

## **ABOUT TEVA PHARMACEUTICALS**

Teva understands the importance of safe and quality medications for you and your family, and that those medications need to be affordable and accessible. As the largest generic pharmaceutical manufacturer, Teva is committed to developing and manufacturing products that meet the highest standards of quality. Teva offers more generic prescription medications than any other company. In fact, one out of every seven generic prescriptions in the US is filled with a Teva product!<sup>4</sup>

Learn more about Teva's quality generic medicines at TevaGenerics.com.



#### REFERENCES

1. US Food and Drug Administration. Facts about Generic Drugs. Updated September 19, 2012. http:// www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGeneric Drugs/ucm167991.htm. Accessed March 3, 2014. 2. US Food and Drug Administration. You know the questions that go through your mind when you take your generic drug? Here are the answers. DHHS Publication No. (FDA) 02-3243. http://www.fda.gov/downloads/Drugs/ResourcesForYou/UCM133888.pdf. Accessed March 3, 2014. 3. Generic Pharmaceutical Association. 2013 Generic Drug Savings in the U.S. Report. http://www.gphaonline.org/gpha-media/gpha-resources/2013-generic-drug-savings-in-the-u-sreport. Accessed March 3, 2014. 4. IMS Health NPA Data as of MAT December 2013.

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