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What is a Generic Medication?

The World Health Organization Definition of a Generic Medication

A generic drug is a pharmaceutical product, usually intended to be interchangeable with an innovator product, that is manufactured without a licence from the innovator company and marketed after the expiry date of the patent or other exclusive rights.

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Source World Health Organization, accessed 04 17 2015
http://www.who.int/trade/glossary/story034/en/

What is a Generic Medication?

A generic drug is identical -- or bioequivalent -- to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use.

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Source: US Food and Drug Administration http://www.fda.gov/drugs/resourcesforyou/consumers/questionsanswers/ucm100100.htm, accessed 04 17 2015

What is a Generic Medication?

Generic drugs are marketed under a non-proprietary or approved name rather than a proprietary or brand name.

For example, paracetamol is a chemical ingredient found in a number of brand-name painkillers, but is also sold as a generic drug (not under a brand name).

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Source World Health Organization, accessed 04 17 2015
http://www.who.int/trade/glossary/story034/en/

What Are the Advantages of a Generic Medication?

Although generic drugs are chemically identical to their branded counterparts, they are typically sold at substantial discounts from the branded price.

Cost to the consumer is typically 20% to 90% less than the brand-name original with the same safety, quality and efficacy.

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Source: US Food and Drug Administration http://www.fda.gov/drugs/resourcesforyou/consumers/questionsanswers/ucm100100.htm,accessed 04 17 2015

What is the Primary Driver to Reducing the Cost of Generic Medications?

Generic drugs do not have to undergo the large, expensive clinical trials that are required for approval of brand-name medications.

Strict standards exist to guarantee the quality of generic drugs through a process known as an abbreviated new drug application (ANDA), and bioequivalence studies.

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Source: Pawel Lewek and Przemyslaw Kardas, The Journal of Family Practice, Vol 59 No. 11, 2010

How is a Generic Medication Determined Equivalent to Brand Name Drug?

The active pharmaceutical ingredient (API) is the chemical that has the desired biological effect in a medication and **is the same** in both branded and generic medications.

The ANDA process does not require costly animal and clinical research on ingredients or dosage forms already approved for safety and effectiveness.

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http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003519.pdf Accessed 04 17 2015

How is a Generic Medication Determined Equivalent to Brand Name Drug?

Therapeutic equivalence of a generic drug is based on pharmacokinetic parameters, most notably, the area under the plasma concentration curve (AUC)—a measure of overall drug exposure—and the maximal plasma concentration (Cmax).

The process for new generic medication approval is clear, following a well-defined roadmap

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http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003519.pdf Accessed 04 17 2015

Setting the Bar for Successful Approval: Standards for Generic Medications

1. Contain the same active ingredients as the innovator drug (inactive ingredients may vary)
2. Identical in treatment indications, strength, dosage form, route of administration and bioequivalence
3. Meet the same batch requirements for identity, strength, purity, and quality
4. Manufactured under the same strict standards of FDA and EMA good manufacturing practice regulations required for innovator products

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Source: US Food and Drug Administration http://www.fda.gov/drugs/resourcesforyou/consumers/questionsanswers/ucm100100.htm, accessed 04 17 2015

Summary

Generic drugs offer identical quality, benefit and safety when compared to branded medications, with significant cost savings for product development and to the consumer.

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