Generic Drugs

The Academy of Managed Care Pharmacy (AMCP) encourages the use of generic drugs[1] as safe, cost- effective alternatives to the equivalent brand-name products.[2] Generic drugs are approved by the U.S. Food and Drug Administration (FDA). When a generic drug is used, patients and health care professionals can expect to see a clinical result and safety profile equal to that of the brand-name drug. Generics are usually available at a significant cost-savings compared to the brand-name drug. At a time when health care expenditures are escalating at alarming rates, greater access to safe and effective generic drugs can aid in reducing prescription drug expenditures for patients and payers.

In approving a generic drug, the FDA requires many rigorous tests and procedures to assure that the generic drug is interchangeable with its brand-name counterpart. The FDA publishes a listing of approved generic drugs in the *Approved Drug Products with Therapeutic Equivalence Evaluations*, also known as the "Orange Book." FDA- approved drugs with an AB rating[3] may be substituted for the brand-name counterpart without the need for additional clinical tests or examinations. Practitioners and patients can also expect to achieve the same clinical results with a listed generic drug that would be obtained with the drug's brand-name counterpart.[3] Generic drugs are considered safe and appropriate alternatives, and can reduce costs without compromising quality of care.

In addition to interchangeability between a generic drug recognized as therapeutically equivalent by FDA to its brand-name counterpart, a generic drug may also be safer than a newer medication in the same therapeutic class. Generic drugs typically are versions of brand-name drugs that have been available in the marketplace for many years. The longer a drug has been available, the more health care practitioners know about possible side effects and treatment outcome expectations. Promotion of generic drugs can not only lower overall prescription drug spending, but could also prevent unnecessary and unknown side effects from newer treatments.

AMCP supports legislative and regulatory changes that would promote the development and use of safe, efficacious and equivalent generic drugs and eliminate barriers to the entry of generic drugs into the marketplace. Most health plans and pharmacy benefit managers structure their prescription drug coverage to promote the use of generic drugs because they usually offer greater value to payers and patients. This is often achieved by using a tiered co-payment structure, where generic drugs have a lower co-payment than brand-name drugs, as well as by encouraging prescribers to consider drugs in a therapeutic class that have a generic alternative instead of a newer, single-source therapy.[5] Health plans and pharmacy benefit managers have also been successful in working with payers to develop programs designed to promote the use of generic drugs. Financial incentives to use generic drugs instead of brand-name drugs should be considered as part of any program designed to increase the use of and access to generic drugs.

The Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act," P.L. 98-417) streamlined the process by which the FDA approved generic versions of brand-name drugs and in many cases expedited the arrival of generic drugs in the marketplace.

However, certain provisions of the law are susceptible to strategies that can delay the entry of generic drugs into the marketplace for reasons other than safety and efficacy. While AMCP realizes that appropriate incentives must be retained in order for brand-name manufacturers to recoup their investment in research and development of brand-name drugs, the use of strategies that can unnecessarily delay the entry of generic drugs into the marketplace for reasons other than safety and efficacy must be prohibited. AMCP supports efforts to prohibit patent settlement agreements between brand-name and generic manufacturers that result in the generic manufacturer delaying market entry of a generic drug, as well as authorized generics, which are intended to discourage generic competition. AMCP believes these strategies must be addressed in order to streamline the generic approval process and allow patients greater access to generic drugs.

In addition to removing ambiguity in current patent law, Congress also needs to ensure that the FDA has access to adequate resources in order to review and process applications for generic drugs. The FDA is an agency that has been chronically underfunded for many years, and the lack of available funding has led to unnecessary delays in approval of generic drugs. AMCP believes that Congress must provide adequate funding to the FDA each budget year.

AMCP supports legislation that would increase consumer access to generic drugs and promote generic drug use. AMCP believes that pharmacists, in consultation with patients and prescribers, can achieve substantial cost-savings for patients and payers without compromising quality of care by promoting generic drugs as safe, cost-effective alternatives to their brand-name counterparts.

See also: AMCP's *Where We Stand on Biosimilar Drug Therapies*

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AMCP *Where We Stand* series: www.amcp.org/positionstatements.

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[1] Generic drugs are clinically equivalent to brand name drugs; they contain the same active ingredient(s), are of the same dosage form, have the same route of administration, are identical in strength or concentration, and can be expected to have the same effect and safety profile when administered to patients under the conditions specified in the labeling.

[2] A brand name drug is a patented drug marketed by the original drug manufacturer following its FDA approval. The manufacturer receives a patent on the drug giving it the right to make that drug without any competition. When a patent expires on a brand name drug, other companies can start making the drug after receiving FDA approval. A brand name drug is usually known by its trade name, (e.g., "Motrin®") rather than by its chemical (i.e., generic) name (e.g., "ibuprofen").

[3] The rating system used by the FDA for therapeutic equivalence evaluations is constructed to allow users to determine quickly whether the Agency has evaluated a particular approved product as equivalent to other pharmaceutically equivalent products (first letter) and to provide additional information on the drug (second letter). Drug products with a first-letter rating of A are considered to be therapeutically equivalent to other pharmaceutically equivalent drugs. The second letter in a drug's rating refers to the dosage form of the particular drug (i.e., solid oral, oral liquid).

[4] Letter from the U.S. Food and Drug Administration to the National Association of Chain Drug Stores (April 16, 2007).

[5] As defined in Section 1927(k)(7)(A)(iv) of the Social Security Act, a covered outpatient drug which is produced or distributed under an original new drug application approved by the Food and Drug Administration, including a drug product marketed by any cross-licensed producers or distributors operating under the New Drug Application (NDA). A single-source drug has no generic counterpart.