The Interchange of Narrow Therapeutic Index (NTI) Drugs

The Academy of Managed Care Pharmacy (AMCP) opposes legislation that restricts the appropriate generic substitution of narrow therapeutic index (NTI) drugs. A drug is commonly referred to as having a narrow therapeutic index when small variances in blood levels cause changes in the effectiveness or toxicity of that drug. AMCP supports allowing pharmacists, in consultation with prescribers, to exercise professional judgment, based on scientific information, when determining whether a generic drug is an appropriate substitute for its brand name equivalent.

When the patent or exclusivity protection on a brand name drug expires, drug manufacturers may gain approval to market a generic version. Generic products are commonly substituted for brand name drugs as permitted by state law. The practice of dispensing generic drugs is a substantial cost-saving measure for patients and payers while retaining the clinical effectiveness of the branded medication.

Using a rigorous review process, the Food and Drug Administration (FDA) reviews drug applications to assure that generic drugs are pharmaceutically and therapeutically equivalent to the brand name product. An FDA approved generic product must be produced in accord with good manufacturing practices, and must contain the same active ingredients as its brand name equivalent.

Safe and effective use of NTI drugs requires careful dosage adjustment and patient monitoring, regardless of generic or brand name product use. Due to its strict generic approval process, the FDA does not consider NTI drugs as separate from any other generic drug substitution. The FDA has stated that it has not received data suggesting clinical problems with the use of approved NTI generic drugs, which would support proposed state NTI legislation. Consequently, the FDA has taken the position that when an FDA approved and therapeutically equivalent generic drug is selected, patients, physicians, and pharmacists can be assured that they will obtain the same clinical results and safety profile as would be expected from the equivalent brand name product.[1]

AMCP believes pharmacists and prescribers, not legislative entities, are in the best position to evaluate the appropriateness of generic drug interchange, both in general and on a case-by-case basis. AMCP opposes legislation that is designed to restrict the generic interchange of NTI drugs. AMCP believes pharmacists, in consultation with prescribers, should have the right to use their professional judgment and knowledge of the available scientific information in determining the appropriateness of generic substitution.

For more information please see AMCP's *Where We Stand on Generic Drugs* and *Where We Stand on Therapeutic Interchange* at www.amcp.org/positionstatements.

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Please see AMCP's website for revisions and updates to our *Where We Stand* series: www.amcp.org/positionstatements.

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