

**Position Statement
on
Generic Therapeutic & Biosimilar Substitution
(Approved by the Board of Directors: March 29, 1992;
Reviewed by the Board of Directors: August 5, 2007;
Amended by the Board of Directors: November 3, 2012;
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Generic therapeutic substitution is the replacement at dispensation of an alternative, therapeutically equivalent drug than what was originally prescribed by a physician. Drugs are considered to be therapeutically equivalent even if they are chemically different but hold the same pharmacokinetic properties.

Biologics are large, complex molecules derived from living cells using recombinant DNA technology. Due to their inherent variability, biologics can never be exactly replicated. Because of these differences in biosimilars, it cannot be assumed that they will be equally effective and have the same side effects and safety profile. Therefore, biosimilars must be carefully evaluated by a patient's physician and health care team to determine the benefits and risks of a biosimilar substitution. It is imperative that data be collected regarding efficacy and safety, and that these products have different names so that medical records can fully reflect the exact medication prescribed and taken.

Therefore, in order to ensure patient safety, the American Academy of Dermatology Association supports a prohibition on generic therapeutic and biosimilar substitution unless all of the following minimal thresholds are met:

- (1) in the case of biosimilars, the biosimilar has a unique nonproprietary name to eliminate confusion, to allow providers to accurately track the therapeutic effect in a patient's permanent record, and to allow for the collection of adverse event information;
- (2) in the case of biosimilars, the biosimilar has been designated by the Food and Drug Administration as interchangeable¹ with the prescribed biologic for the specified indicated use;
- (3) the prescribing physician provides explicit permission to the pharmacist that a generic therapeutic or biosimilar may be used as a substitute to the original therapeutic or biologic medication;

¹ Interchangeability is defined in the Patient Protection and Affordable Care Act (ACA) as a biosimilar product that shows sufficient data to demonstrate that the product: 1) is a biosimilar to the reference product, 2) can be expected to produce the same clinical result as the reference product in any given patient, and 3) would have no enhanced risk in terms of safety and efficacy when switching or alternating between a biosimilar and reference product, when compared to the risk and effectiveness profile of the reference product.

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- (4) the patient (or patient's authorized representative) must be informed and educated about a generic therapeutic or biosimilar substitution at the point of sale;
- (5) the pharmacist notifies the prescriber in writing or electronic communication by the time of dispensing; and
- (6) upon notification of a substitution, the pharmacy and the prescribing physician are encouraged to retain a permanent record in the patient's medical record of the generic therapeutic or biosimilar substitution and document any adverse events.