American Heart Association Statement on Drug Formularies

1. The AHA opposes therapeutic substitution in any patient care setting.

2. When necessary, the AHA supports therapeutic interchange, including the practice of generic substitution, in designated circumstances.

3. The AHA supports a formulary system that:
   - Is under the supervision of qualified physicians, pharmacists, and other appropriate health professionals;
   - Provides protocols for the procurement, storage, distribution, and safe use of formulary and non-formulary drug products;
   - Has policies for the development, maintenance, approval and dissemination of the drug formulary, and for periodic - at least yearly - comprehensive review of formulary drugs; and
   - Provides active surveillance mechanisms to regularly monitor both compliance with these standards and safety outcomes where substitution has occurred, and to intercede where indicated.

4. When developing the formulary, the AHA supports the use of methods and criteria that are open and transparent and objectively evaluate all available pharmaceuticals, taking the following factors into account:
   - Level and strength of evidence;
   - Potential differences in patients’ medical conditions;
   - Patient-specific information (e.g., pediatric patients, pregnant women, elderly patients, transplant patients, immuno-compromised patients);
   - FDA’s Orange book guidance; and
   - Economic factors, although their consideration should not be a primary factor.

5. The AHA supports formularies’ permission of special dosage/delivery products which, while a generic or less expensive version might exist for substitution, can be shown to significantly improve compliance or lower ongoing medical care costs because of improved outcomes.

6. The AHA supports the notification of the patient and, if appropriate, the prescriber, verbally and/or in writing, at the point of distribution when therapeutic interchange has occurred.

7. The AHA supports the prescriber’s ability to override, without undue administrative burden, the substitution of, or allowance for, a restricted/non-formulary drug when necessary for an individual patient.

8. AHA recognizes the role of economic considerations in developing a formulary. Any changes to a formulary (e.g., mid-year tier switches) should balance access and cost considerations and

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1 Available at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm
must be made known to prescriber and patient with adequate time (minimum of 60 days) for appropriate therapeutic interchange to occur.

9. In the case of narrow therapeutic index drugs, the AHA does not support generic-to-generic interchange.

10. Biosimilars do not require demonstration of efficacy and safety in clinical outcomes trials and whether meaningful differences may exist regarding impact on clinical outcomes is uncertain. With these safety issues in mind, as new biosimilars appear on the market, close pharmacovigilance should be considered to completely characterize the drug risk and efficacy profile.

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Definitions

Biosimilars: “Generic” biologics that are copies of a therapeutic protein, not manufactured by an innovator company, and approved through an abbreviated process. Biosimilars are also known as biogenerics, post-patent biologics, and follow-on biologics.

Formulary: A compilation of drugs or drug products in a drug inventory list. Formularies may be created by a healthcare facility, healthcare system, payer, or a third party.

Formulary system: A method whereby members of the healthcare system, working through the pharmacy and therapeutics committee, evaluate, appraise, and select from among the numerous available drug entities and drug products those that are considered most cost-effective in patient care.

Generic substitution: The act of switching between a branded drug and its therapeutically equivalent generic version.

Narrow therapeutic index drugs: Drugs identified as having less than a 2-fold difference between the median lethal and the median effective dose or having less than a 2-fold difference between the minimum toxic and minimum effective concentrations in the blood and where safe and effective use of the drug requires careful titration and patient monitoring (e.g., warfarin, cyclosporine, digoxin).

Therapeutic equivalent, therapeutic alternate: Drug products with different chemical structures but which are of the same pharmacological and/or therapeutic class, and usually can be expected to have similar therapeutic effects and adverse reaction profiles when administered to patients in therapeutically equivalent doses.

Therapeutic interchange: The act of dispensing, with the authorization of the initial prescriber, an alternative drug that is believed to be therapeutically similar but may be chemically different, in a different category, with different pharmacokinetic properties. This interchange is based on the premise that the substituted drug will provide similar clinical efficacy, desired outcomes, and safety profile.

Therapeutic substitution: Therapeutic interchange that occurs without the prior authorization of the prescriber.

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- Sana Al-Khatib, MD, MHS, Duke University Medical Center, Duke Clinical Research Institute, Durham, NC
- Robert Lee Page II, PharmD, MSPH, BCPS, University of Colorado Anschutz Medical Campus, Schools of Pharmacy and Medicine, Aurora, CO
- Brent N. Reed, PharmD, BCPS, University of North Carolina Hospitals and Clinics, Chapel Hill, NC
- Michael W. Rich, MD, Washington University School of Medicine, Saint Louis, MO
- William H. Roach, Jr., Chairman of the Board, American Heart Association, Retired Partner, McDermott Will & Emery LLP, Chicago, IL
- Joseph Saseen, PharmD, BCPS, University of Colorado Anschutz Medical Campus, Schools of Pharmacy and Medicine, Aurora, CO
- Jeffrey B. Washam, PharmD, BCPS, Duke Heart Center, Duke University Medical Center, Durham, NC