THERAPEUTIC EQUIVALENCE AND GENERIC DRUG PRODUCTS

Multisource drug products are drug products that are marketed by more than one manufacturer, contain the same active pharmaceutical ingredient (API) or drug substance, in the same dosage form, and are given by the same route of administration. Multisource drug products contain identical drug substances and may meet compendial (e.g., United States Pharmacopeia [USP]-National Formulary monograph) standards of strength, quality, purity, and identity. However, multisource drug products should not be considered automatically as interchangeable or therapeutic equivalent, generic drug products. The term "generic product" has somewhat different meanings in different jurisdictions [1]. Regulatory approval for interchangeable multisource products may differ somewhat in each country. To be considered as an interchangeable generic drug product, the product must be approved by the relevant regulatory agency as a therapeutic equivalent. A therapeutic equivalent, generic drug product must have the same performance characteristics and is expected to have the same clinical effect and safety profile as the reference product when administered to patients under the conditions specified in the labeling. Because the reference product (generally the brand's or innovator's product) sold in different countries may not be bioequivalent to each other, each domestic market has regulations that decide which reference product should be used during generic drug product development and approval. International regulatory requirements for generic drug products are discussed in another book in this series [2].

Pharmaceutical Equivalents and Pharmaceutical Alternatives

Pharmaceutical equivalents are drug products that contain the same active ingredient(s), are of the same dosage form and route of administration, and are identical in strength or concentration (e.g., chlordiazepoxide hydrochloride, 5 mg capsules). Pharmaceutically equivalent drug products are formulated to contain the same amount of active ingredient in the same dosage form and to meet the same or compendial or other applicable standards (i.e., strength, quality, purity, and identity), but they may differ in characteristics such as shape, scoring, configuration, release mechanisms, packaging, excipients (including colors, flavors, and preservatives), expiration time, and, within certain limits, labeling [3]. Pharmaceutical alternatives are drug products that contain the same therapeutic moiety, but are different salts, esters, or complexes of that moiety, or are different dosage forms or strengths (e.g., tetracycline hydrochloride, 250 mg capsules vs. tetracycline phosphate complex, 250 mg capsules; quinidine sulfate, 200 mg tablets vs. quinidine sulfate, 200 mg capsules) [3]. The U.S. Food and Drug Administration (FDA) considers tablets and capsules as pharmaceutical alternatives even if the same API in each is bioequivalent. Other countries may accept bioequivalent capsules and capsules of the same drug as interchangeable drug products. Pharmaceutical alternatives may also be different dosage forms and strengths within a product line by a single manufacturer such as extended-release products compared with immediate-release or standard-release formulations of the same active ingredient [3].