ARCHIVED: WMA STATEMENT ON GENERIC DRUG SUBSTITUTION

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Definition

Generic substitution is herein defined as the dispensing of a different brand or an unbranded drug product for the drug product prescribed; i.e., the exact same chemical entity in the same dosage form but distributed by a different company.

Preamble

If drug products are not bioequivalent because of different manufacturing processes and/or the presence of different biologically inactive excipients, anticipated therapeutic equivalence among such drug product may also change. Therefore, when substitution occurs among drug products that are not bioequivalent and chemically and therapeutically equivalent, the patient may be adversely affected; i.e, suffer an adverse drug reaction or a therapeutic failure. For these reasons, the physician should be assured by national regulatory authorities of the bioequivalence and the chemical and therapeutic equivalence of prescription drug products from multiple sources. This principle is also desirable in the case of single-source drug products. Quality assurance procedures should be in place to ensure their lot-to-lot bioequivalence and their chemical and therapeutic equivalence.

In the drug selection process, many medical considerations should be addressed before prescribing the drug of choice for a particular indication in any given patient. Once these primary considerations are met, the physician should then consider comparative costs of similar drug products available to best serve all of the patient's needs. The physician has both the right and the obligation to exercise his/her best judgment on behalf of the patient; therefore, the physician should select the type and quantity of drug product that he or she considers to be in the best medical and financial interest of the patient. Once the patient gives his consent on the drug selected that drug should not be changed without the consent of the patient and his or her physician. Even when third-party carriers mandate generic drug substitution, every effort must be made to preserve the prescribing authority of the physician. Failure to follow these principles can result in harm to patients, and physicians can be held liable for such harmful consequences. On behalf of patients and physicians alike, national medical associations should do everything possible to uphold these precepts.

Recommendations

1. Physicians should become familiar with specific laws and/or regulations governing generic drug substitution in locals where they practice.

2. On initiation of treatment, physicians should carefully determine the dose of any medication for optimum efficacy and safety, especially in patients with chronic disorders who require prolonged therapy or patients in special population groups not expected to respond to a drug in the normal manner.

3. Once medication for chronic diseases has been prescribed and begun, no substitution of either generic or brand-name drug products should be made without the attending physician's permission. If generic or brand-name substitution of a drug product occurs, the physician should carefully monitor and adjust the dose to ensure therapeutic equivalence of the drug products.

4. The physician has the duty to report serious adverse drug reactions or therapeutic failures that may be related to drug substitution; the finding should be documented and reported to appropriate drug regulatory authorities, including the appropriate national medical association.

5. National medical associations should regularly monitor generic drug substitution issues and keep their members advised on developments that have special relevance for patient's care. When appropriate, information reports on significant developments should be made available to physicians.

6. National medical associations, in collaboration with other appropriate drug regulatory bodies, should

evaluate and ensure the bioequivalence and the chemical and therapeutic equivalence of all similar drug products, whether generic or brand-name manufactured, in order to ensure safe and effective treatment.

7. National medical associations should oppose any action to restrict the freedom and the responsibility of the physician to prescribe in the best medical and financial interest of the patient.