WMA STATEMENT ON DRUG SUBSTITUTION

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and reaffirmed by the 200th WMA Council Session, Oslo, Norway, April 2015

INTRODUCTION

1. The prescription of a drug represents the culmination of a careful deliberative process between physician and patient aimed at the prevention, amelioration or cure of a disease or problem. This deliberative process requires that the physician evaluate a variety of scientific and other data including costs and make an individualized choice of therapy for the patient. Sometimes, however, a pharmacist is required to substitute a different drug for the one prescribed by the physician. The World Medical Association has serious concerns about this practice.

2. Drug substitution can take two forms: generic substitution and therapeutic substitution.

3. In generic substitution, a generic drug is substituted for a brand name drug. However, both drugs have the same active chemical ingredient, same dosage strength, and same dosage form.

4. Therapeutic substitution occurs when a pharmacist substitutes a chemically different drug for the drug that the physician prescribed. The drug substituted by the pharmacist belongs to the same pharmacologic class and/or to the same therapeutic class. However since the two drugs have different chemical structures, adverse outcomes for the patient can occur.

5. The respective roles of physicians and pharmacists in serving the patient's need for optimal drug therapy are outlined in the WMA Statement on the Working Relationship between Physicians and Pharmacists in Medicinal Therapy.

6. The physician should be assured by national regulatory authorities of the bioequivalence and the chemical and therapeutic equivalence of prescription drug products from both multiple and single sources. Quality assurance procedures should be in place to ensure their lot-to-lot bioequivalence and their chemical and therapeutic equivalence.

7. Many considerations should be addressed before prescribing the drug of choice for a particular indication in any given patient. Drug therapy should be individualized based on a complete clinical patient history, current physical findings, all relevant laboratory data, and psychosocial factors. Once these primary considerations are met, the physician should then consider comparative costs of similar drug products available to best serve the patient's needs. 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.

8. Once the patient gives his or her consent to the drug selected, that drug should not be changed without the consent of the patient and his or her physician. Failure to follow this principle can result in harm to patients. On behalf of patients and physicians alike, National Medical Associations should do everything possible to ensure the implementation of the following recommendations:

RECOMMENDATIONS

1. Physicians should become familiar with specific laws and/or regulations governing drug substitution where they practise.

2. Pharmacists should be required to dispense the exact chemical, dose, and dosage form prescribed by the physician. Once medication has been prescribed and begun, no drug substitution should be made without the prescribing physician's permission.

3. If substitution of a drug product occurs, the physician should carefully monitor and adjust the dose to ensure therapeutic equivalence of the drug products.

4. If drug substitution leads to serious adverse drug reaction or therapeutic failure, the physician should document this finding and report it to appropriate drug regulatory authorities.

5. National Medical Associations should regularly monitor drug substitution issues and keep their members advised on developments that have special relevance for patient care. Collection and evaluation of information reports on significant developments in this area is encouraged.

6. 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, 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.

8. National Medical Associations should urge national regulatory authorities to declare therapeutic substitution illegal, unless such substitution has the immediate prior consent of the prescribing physician.