Senate
Office of the Secretary

SIXTEENTH CONGRESS OF THE REPUBLIC)
OF THE PHILIPPINES)
First Regular Session)

'13 SEP 26 P3 :58

SENATE
S. No. 1737

RECEIVED BY:

Introduced by Senator Miriam Defensor Santiago

EXPLANATORY NOTE

The Constitution, Article 2, Section 13 provides that:

> "The State shall establish and maintain an effective food and drug regulatory system and undertake appropriate health manpower development and research, responsive to the country's health needs and problems."

Republic Act No. 6675, also known as the Generics Act of 1998, requires the use of generic terminologies in prescription of drugs. However, such requirement is not sufficient, as drugs having the same generic term may have different active ingredients.

This bill aims to establish therapeutic equivalence requirements for generic drugs, to ensure that drug products with similar generic name also contain the same chemical components responsible for the claimed therapeutic effect.*

MIRIAM DEFENSOR SANTIAGO

* This bill was re-filed during the Thirteenth Congress, First Regular Session.

Senate
Office of the Secretary

SIXTEENTH CONGRESS OF THE REPUBLIC)
OF THE PHILIPPINES)
First Regular Session)

'13 SEP 26 P3 :58

SENATE
S. No. 1737

RECEIVED BY:

Introduced by Senator Miriam Defensor Santiago

AN ACT
ESTABLISHING THERAPEUTIC EQUIVALENCE REQUIREMENTS
FOR GENERIC DRUGS

Be it enacted by the Senate and House of Representatives of the Philippines in Congress assembled:

SECTION 1. *Short Title.* – This Act shall be known as the "Generic Drug Uniformity Act."

SECTION 2. *Declaration of Policy.* – It is the policy of the State to ensure safe and good quality of drugs, and regulate their production, in order to protect the health of the consumer.

SECTION 3. *Definition of Terms.* - For purposes of this Act, the term:

(A) "Generic Drugs" means drugs not covered by patent protection and which are labeled solely by their international non-proprietary or generic name.

(B) "Generic Name or Generic Terminology" means the identification of drugs and medicines by their scientifically and internationally recognized active ingredients or by their official generic name as determined by the Bureau of Food and Drugs of the Department of Health.

(C) "Active Ingredient" means the chemical component responsible for the claimed therapeutic effect of the pharmaceutical product.

(D) "Essential Drugs List" or "National Drug Formulary" is a list of drugs prepared and periodically updated by the Department of Health on the basis of health conditions obtaining in the Philippines, as well as on internationally accepted criteria. It shall consist of a core list and a complementary list.

(E) "Core List" is a list of drugs that meets the health care needs of the majority of the population.

(F) "Complementary List" is a list of alternative drugs used when there is no response to the core essential drug or when there is a hypersensitivity reaction to the core essential drug or when, for one reason or another, the core essential drug cannot be given.

(G) "Drug Establishment" means any organization or company involved in the manufacture, importation, repacking and/or distribution of drugs or medicines.

SECTION 4. *Therapeutic Equivalence.* – A drug is the therapeutic equivalent of a drug listed in the essential drugs list or National Drug Formulary when, with respect to the listed drug—

(A) All of its active ingredients are the same, it is of the same dosage form, it has the same route of administration, it is identical in strength or concentration, and it meets the same compendial or other applicable standard, except that it may differ in shape, scoring, configuration, packaging, expiration time or labeling;

(B) It is expected to have the same clinical effect and safety profile when administered to patients under conditions specified in the labeling; and

(C) It either does not present a known or potential bioequivalence problem and meets an acceptable in vitro standard or if it does present such a problem, is shown to meet an appropriate bioequivalence standard.

If a drug meets the requirements of paragraphs (A), (B) and (C), with respect to an essential drugs list, the Secretary of Health shall include in the approval of the application for the drug that it is the therapeutic equivalent the listed drug involved.

SECTION 5. *Licensing of Drug Establishment.* – When the Secretary approves an application for the licensing of drug establishments, he shall include in such approval a finding that the drug for which the application is approved is or is not the therapeutic equivalent of the listed drug involved.

SECTION 6. *Separability Clause.* – If any provision or part hereof is held invalid or unconstitutional, the remainder of the Act or the provision not otherwise affected shall remain valid and subsisting.

SECTION 7. *Repealing Clause.* – Any law, presidential decree or issuance, executive order, letter of instruction, administrative order, rule, or regulation contrary to or inconsistent with the provisions of this Act is hereby repealed, modified, or amended accordingly.

SECTION 8. *Effectivity Clause.* – This Act shall take effect fifteen (15) days after its publication in at least two (2) newspapers of general circulation.

Approved,