[REPUBLIC ACT 6675]

"AN ACT TO PROMOTE, REQUIRE AND ENSURE THE PRODUCTION OF AN ADEQUATE SUPPLY, DISTRIBUTION, USE AND ACCEPTANCE OF DRUGS AND MEDICINES IDENTIFIED BY THEIR GENERIC NAMES"

Section. 1. *Title*. - This Act shall be known as the Generics Act of 1988.

Sec. 2. *Statement of Policy.* - It hereby declared the policy of the State:

To promote, encourage and require the use of generic terminology in the importation, manufacture, distribution, marketing, advertising and promotion, prescription and dispensing of drugs;

To ensure the adequate supply of drugs with generic names at the lowest possible cost and endeavour to make them available free for indigent patients;

To encourage the extensive use of drugs with generic names through a national system of procurement and distribution;

To emphasize the scientific basis for the use of drugs, in order that health professionals may become more aware and cognisant of the therapeutic effectiveness; and;

To promote drug safety by minimizing duplication in medications and/or use of drugs with potentially adverse drug interactions.

Sec. 3. *Definition of Terms.* - The following terms are herein defined for purposes of this Act;

"Generic Name or Generic Terminology" is the identification of drugs and medicines by their scientifically and internationally recognized active ingredients or by their generic names as determined by the Bureau of Food and Drugs of the Department of Health.

1. "Active Ingredient" is the chemical component responsible for the claimed therapeutic effect of the pharmaceutical product.

2. "Chemical Name" is the description of the chemical structure of the drugs and medicine and serves as the complete identification of the compound.

3. "Drug Product" is the finished product form that contains the active ingredients, generally but not necessarily in association with inactive ingredients.

4. “Drug Establishment” is any organization or company involved in the manufacture, importation, repacking and/or distribution of drugs or medicines.

5. “Drug Outlets” means drugstores, pharmacist, and any other business establishment which sell drugs or medicines.

6. “Essential Drug 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 in the internationally accepted criteria. It shall consist of a core list or a complimentary list.

7. “Core List” is the list of drugs that meet the health care needs hundred eighty days upon the approval of this Act.

8. “Complimentary List” is a list of alternative drugs used wherein no response to the core essential drug or where there is hypersensitivity reaction to the core essential drug or when, for one reason or another, the core essential drugs cannot be given.

9. “Brand Name” is the proprietary name given by the manufacture to distinguish its product from those of competitors.

10. “Generic Drugs” are not covered by the patent protection and which are labelled solely by their international non-proprietary or generic name.

Sec. 4. *The Use of Generic Terminology for Essential Drugs and Promotional Incentives.* - (a) In the promotion of the generic names for pharmaceutical products, special consideration shall be given to drugs and medicines which are included in the Essential Drug List to be prepared within one hundred eighty (180) days from approval of this Act and updated quarterly by the Department of Health conditions obtaining in the Philippines as well as in the internationally accepted criteria.

a. The exclusive use of generic terminology in the manufacture, marketing and sales of drugs and medicines, particularly those in the Essential Drug List, shall be promoted through such a system of Incentive as the Board of Investments jointly with the Department of Health and other government agencies as maybe authorized by laws, within one hundred eighty (180) days after approval of this Act.

Sec. 5. *Posting and Publication.* - The Department of Health shall publish annually in at least two newspapers of general circulation in the Philippines the generic names, and the corresponding brand name under which they are marketed, of all drugs and medicines available in the Philippines.

Sec. 6 *Who shall use generic Terminology.* - (a) All government agencies and their personnel as well as other government agencies shall use generic terminology or generic names in all transactions related to purchasing, prescribing, dispensing and administering of all drugs and medicines.

a. All medical, dental and veterinary practitioners, including private practitioners, shall write prescriptions using generic name. The brand name maybe included if so desired.

b. Any organization or company involved in the manufacture, importation, repacking, marketing and/or distribution of drugs and medicine shall indicate prominently the generic name of the product labels as well as in advertising and other promotional materials.

c. Drug Outlets, including drugstores, hospital and non-hospital pharmacies and non-traditional outlets such as supermarkets and stores shall inform any buyer about all other drug products having the same generic name, together with their corresponding prices so that the buyer may adequately exercise his option. Within one (1) year after approval of this Act, the drug outlets referred to herein. Shall post in conspicuous places in their establishment, a list of drug products with the same generic name and their corresponding prices.

Sec. 7. *Provision on Quality, Manufacturer's Identity and Responsibility*. - In order to assure responsibility of drug quality in all instances, the label of drugs and medicine shall have the following: name and country of manufacture, dates of manufacture and expiration. The quality of such generically labelled drugs and medicines shall be duly certified by the Department of Health.

Sec. 8. *Required Production*. - Subject to the rules and regulations promulgated by the Secretary of Health, every drug manufacturing company operating in the Philippines shall be required to produce, distribute and make available to the general public the medicine it produces, in the form of generic drug.

Sec. 9. *Rules and Regulation.* - The implementation of the provision of this Act shall be in accordance with the rules and regulations to be promulgated by the Department of Health. Rules and regulations with penal sanctions shall be promulgated within hundred eighty (180) days after approval of this Act.

Sec. 10. *Authority to Import.* - Within three (3) years from the effectivity of this Act, extendible by the president for another two (2) years and during periods of critical shortage and absolute necessity, the Department of Health is hereby authorized to import raw materials of which there is a shortage for the use of Filipino-owned or controlled drug establishments to be marketed and sold exclusively under generic nomenclature. The President may authorize the importation of raw materials tax and duty-free. The Secretary of Health shall ensure that the imported raw materials are allocated fairly and efficiently among Filipino-owned or controlled drug establishment. He shall submit to the office of the President and to the Congress a quarterly report of the quantity, kind and value of the raw materials imported.

Sec. 11. *Education Drive.* - The Department of Health jointly with the Department of Education, Culture and Sports, Philippine Information Agency and the

Department of Local Government shall conduct a continuous information campaign for the public and a continuing education and training for the medical and allied medical professions on drugs with generic names as an alternative of equal efficacy to the more expensive brand name drug. Such educational campaign shall include information on the illnesses or symptoms which each generically named drug is suppose to cure or alleviate, as well as its contradiction. The Department of Health with assistance of the Department of Local Government and the Philippine Information Agency shall monitor the progress of the education drive, and shall submit regular reports to Congress.

Sec. 12. *Penalty.* - A) Any person who shall violate Section 6(a), or 6(b) of this Act shall suffer the penalty graduated hereunder, viz:

a. For the first conviction, he shall suffer the penalty of reprimand, which shall be officially recorded in the appropriate books of the Professional Regulation Commission.

b. The second conviction, the penalty of fine in the amount of not less than two thousand pesos (₱2,000).

c. For the third conviction, the penalty of fine in the amount of not less than five thousand pesos (₱5,000) but not exceeding ten thousand pesos (₱10, 000) and suspension of his license to practice his profession for thirty days at the discretion of the court.

d. For the fourth subsequent convictions, the penalty of fine not less than ten thousand pesos (₱10, 000) and suspension of his license to practice his profession one year or longer at the discretion of the court.

A. Any juridical person violates Section 6(c), 6 (d), 7 or 8 shall suffer the penalty of a fine of not less than five thousand pesos (₱5, 000) nor more than ten thousand pesos (₱10,000) and suspension or revocation of license to operate such drug establishment or drug outlet at the discretion of the Court : Provide, that its officers directly responsible for the violation shall suffer the penalty of fine and suspension or revocation of license to practice profession, if applicable, and by imprisonment of not less than six (6) months nor more than one (1) year or both fine and imprisonment at the discretion of the Court: and *Provided, further* that if the guilty party is an alien, he shall be *ipso facto* deported after service of sentence without need of further proceedings.

B. The Secretary of Health shall have the authority to impose administrative sanctions such as suspension or cancellation of license to practice profession to the Professional Regulation Commission as the case may be for the violation of the Act.

Sec. 13. *Separability Clause.* - If any provision of this Act is declared invalid, the remainder of any provision hereof not affected thereby shall remain in force and effect.

Sec. 14. *Repealing Clause.* - The provisions of any law, executive order, presidential decree or other issuance inconsistent with this Act are hereby repealed or modified accordingly.

Sec. 15. *Effectivity*. - This Act shall effect fifteen (15) days after its complete publication in the *Official Gazette* or two (2) newspapers of general circulation.

This Act which is a consolidation of Senate Bill No. 453 and House Bill No. 10900 was finally passed by the Senate and the House of Representative on August 25, 1988, respectively.

Approved: September 13, 1988.