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CONGRESS OF THE PHILIPPINES
First Regular Session

SENATE

S. No. 453

INTRODUCED BY SENATORS MERCADO, PIMENTEL, JR., ZIGA, ROMULO AND ANGARA

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

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

SECTION 1. *Title.*—This Act shall be known as the "Generic Drugs Act of 1988."

SEC. 2. *Statement of Policy.*—It is hereby declared the policy of the State:

(1) To promote the use of generic terminology (names) in the importation, manufacture, distribution, marketing and promotion, prescription and dispensing of drugs;

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

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(3) To encourage the extensive use of drugs with generic names through a rational system of procurement and prescription;

(4) To emphasize the scientific basis for the use of drugs, in order that health professionals may become more aware and cognizant of their therapeutic effectiveness; and

(5) 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:

(1) "Generic name" is the shortened scientific name based on the active ingredient, also known as the International Non-proprietary Nomenclature (INN), as recommended by the World Health Organization (WHO), in contrast to proprietary name or brand name given by the manufacturers to distinguish their products from competitors. The generic name may or may not be the abbreviated form of the chemical name.

(2) "Chemical name" is the description of the chemical structure of the drug or medicine and serves as the complete identification of a compound.

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

(4) "Active ingredient" is the chemical component responsible for the claimed therapeutic effect of the pharmaceutical product.

(5) "Drug establishment" is any organization or company involved in the process of manufacturing, importation, repacking and/or distribution of drugs or medicines.

(6) "Drug outlets" means drugstores, pharmacies, and any other business establishments which sell drugs or medicines.

(7) "List of Essential Drugs" is a list of drugs which are needed to diagnose, prevent or cure most of the common diseases or ailments of a vast majority of the population.

SEC. 4. *Use of Generic Terminology/Name for Essential Drugs.*—The Department of Health shall, within sixty (60) days from the approval of this Act and quarterly or as often thereafter as the Department of Health may deem appropriate and with the assistance of an expert committee which it shall constitute pursuant to the objectives of this Act, draw up a list of essential drugs, using generic terminology/name and in accordance with

internationally established criteria as well as, considering prevalent health problems in the country, a list of generic drugs in the manufacture of which the raw materials are derived completely from indigenous sources, and a list of manufacturers of generic drugs duly recognized and certified by the Department of Health as authorized to manufacture and sell generic drugs.

The Department of Health shall publish in at least two (2) newspapers of general circulation in the Philippines the aforementioned lists.

SEC. 5. *Incentives.*—The use of generic terminology/name in the importation, manufacture, labeling, distribution, prescription, dispensing and sales of drugs in the said lists shall be promoted through such a system of incentives as the Department of Health, the Board of Investments or other government agencies shall jointly promulgate in accordance with incentives provided by existing law.

SEC. 6. *Government Health Agencies to Use and Make Available Generic Drugs.*—All government physicians and dentists shall purchase, prescribe, dispense, administer and use whenever appropriate, and all pharmacists, nurses, nursing aides, and other persons employed in the field of public health services shall dispense, administer and

use generic drugs found in the certified lists referred to in Section 4 hereof, as prescribed by a physician or dentist, in ministering to the needs of patients in public hospitals, clinics, health centers and other health delivery outlets.

SEC. 7. *Government Purchases of Drugs with Generic Names.*—All purchases of medicines by the Department of Health and/or any other government entity shall be in the form of generic drugs, whenever and wherever available.

SEC. 8. *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 shortages and absolute necessity, the Department of Health is hereby authorized to import raw materials of which there is a shortage for the use of local Filipino manufacturers of drugs 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 the local Filipino manufacturers. He shall submit to the Office of the President a quarterly report on the quantity, kind and value of the raw materials imported.

SEC. 9. *Private Medical and Dental Practitioners.*—Private physicians and dentists, in giving out prescrip-

tions, must indicate the generic name of the drug: *Provided,* That for Medicare patients generic drugs shall be prescribed without prejudice to their right to information about the availability of branded drugs.

SEC. 10. *Drug Manufacturers, Importers, Repackers and Distributors.*—No manufacturer, importer, repacker, distributor or outlet of brand name drugs included in the lists referred to in Section 4 hereof, shall sell and/or advertise such drugs unless the generic name including indications thereof in bold letters is placed prominently above the brand name.

SEC. 11. *Contents of Label of Generic Drugs.*—The label of every generic drug shall contain the following: name and country of origin of the generic drug, name of the manufacturer, date of manufacture and expiration period.

SEC. 12. *Drugstores.*—Subject to the rules and regulations promulgated by the Secretary of Health, drugstores shall, within one year from the approval of this Act, include generic drugs in their stock in trade and shall make them regularly available to the public: *Provided,* That drugstores shall post in conspicuous places in their business establishments the lists referred to in Section 4 hereof, and which lists shall include the selling prices of such drugs both generic and branded.

SEC. 13. *Required Production.*—Subject to the rules and regulations promulgated by the Secretary of Health, every drug manufacturing company operating in the Philippines shall distribute and make available to the general public the medicine it produces in the form of generic drugs.

SEC. 14. *Education Drive.*—The Department of Health shall conduct a continuous information campaign to make the public aware of generic drugs as an alternative of equal efficacy to the more expensive brand name drugs. Such educational campaign shall include information on the illnesses or symptoms which each generic drug is supposed to cure or alleviate, as well as it's contra-indications. The Department of Health shall establish a feedback and evaluation mechanism that shall monitor the progress of the education drive, and shall submit regular reports to Congress.

SEC. 15. *Rules and Regulations.*—The Secretary of Health shall, within six (6) months from the effectivity of this Act, promulgate rules and regulations to implement the objectives of this Act with special emphasis on monitoring strict compliance therewith. The rules and regulations may include the prohibition of use in any drug marketed in the Philippines of ingredients whose

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use has been banned, withdrawn or restricted in other countries. Rules and regulations with penal sanctions shall take effect fifteen (15) days after completion of its publication in the *Official Gazette* or in two (2) newspapers of general circulation.

SEC. 16. *Sanctions.*—Any person who violates any provision of this Act or any regulation issued by the Secretary of Health to carry out the purposes of this Act shall be required to render *pro bono* community service in health or sanitation for a period of not less than thirty (30) days but not more than six (6) months in areas, whether rural or urban, to be designated by the Secretary of Health or by a fine of not less than five thousand pesos (₱5,000) but not more than fifteen thousand pesos (₱15,000), or both such fine and community service at the discretion of the court. In the first case, the offender shall report to the city or municipal health officer for the purpose of serving his sentence: *Provided,* That the sanction of community service shall apply for the first offense and the sanction of either community service or fine, or both, shall apply for a second or subsequent offense. In case of corporations or juridical persons, the president or the manager thereof shall render the community service required and the fine shall be paid by the

corporation or the juridical person: *Provided,* That a failure of the manufacturer, importer, repacker, distributor or outlet to comply with the requirements contained in Sections 10, 11 or 13 hereof, will cause the suspension or forfeiture of its license to do business in addition to the sanctions imposed in this section.

SEC. 17. *Separability Clause.*—If any provision of this Act is declared invalid, the remainder of this Act or any provision not affected thereby shall remain in force and effect.

SEC. 18. *Repealing Clause.*—The provisions of any law, executive order, presidential decree, or other issuances inconsistent with this Act are hereby repealed or modified accordingly.

SEC. 19. *Effectivity.*—This Act shall take effect fifteen (15) days after its complete publication in the *Official Gazette* or two (2) newspapers of general circulation.

Approved,

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