

Republic of the Philippines
HOUSE OF REPRESENTATIVES
Quezon City

19TH CONGRESS
Third Regular Session

HOUSE BILL NO. 10590



Introduced by Representative Michael L. Romero

EXPLANATORY NOTE

The **1987 Constitution** mandates the state to support **generics medicine** through appropriate technology and research, adequate financial services and other support services.

Generic Name or Generic medicine is the identification of drugs and medicines by their scientifically and internationally recognize active ingredients or by their official generic name as determined by the **Department of Health**.

(a) All government health 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 drugs and medicines.

(b) All medical, dental and veterinary practitioners, including private practitioners, shall write prescriptions using the generic name. The brand name may be included if so desired.

(c) Any organization or company involved in the manufacture, importation, repacking, marketing and/or distribution of drugs and medicines shall indicate prominently the generic name of the product. In the case of brand name products, the generic name shall appear prominently and immediately above the brand name in all product labels as well as in advertising and other promotional materials.

(d) Drug outlets, including drugstores, hospital and non-hospital pharmacies and non-traditional outlets such as supermarkets and stores, shall inform any buyer about any and all other drug products having the same generic name, together with their corresponding prices so that the buyer may adequately exercise, his option.

This House Bill seeks to achieve and attain a higher degree of efficiency in the organization, administration, and distribution of **generic drugs** with the end view that harmony and order shall be maintained more effectively, and the laws enforced with more impartiality.

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

Thus, the early passage of this bill is earnestly requested.

A handwritten signature in black ink, appearing to read 'Michael L. Romero', with a long horizontal flourish extending to the right.

MICHAEL L. ROMERO Ph.D.

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AN ACT

AMENDING **REPUBLIC ACT NO. 6675, “GENERIC ACT OF 1988”**, TO
ENSURE THE ADEQUATE SUPPLY OF GENERIC MEDICINES AT
THE LOWEST POSSIBLE COST, PROVIDING FOR STIFFER
PENALTIES AND SANCTIONS, APPROPRIATING FUNDS
THEREFOR, AND FOR OTHER PURPOSES

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

SECTION 1. DECLARATION OF POLICY — It is hereby a declared 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 endeavor to make them available for free to
indigent patients;

To encourage the extensive use of drugs with generic names through a rational 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 cognizant of their therapeutic effectiveness; and

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

The state recognizes the important role of **generic drugs** for nation-building and promotes the sustained development of reservoir of **generic drugs** whose prescription have been determined by honest and credible licensure examinations whose standards of professional practice and service are world-class and internationally recognized, globally competitive through preventive regulatory measures, programs and activities that foster their continuing professional development.

It shall be imperative for the state to promote and make quality health services and support accessible to all Filipino citizens.

For these purposes, the state shall provide the mechanisms to improve our health sector by maximizing the use of existing resources of all government agencies and branches, recognizing in the process the government's responsibility to provide a wholistic approach as having priority over its other functions.

It is a declared policy of the state in conformity with the mandate of the Constitution, to promote and make quality **generic drugs** accessible to all Filipino citizens. The state hereby recognizes the complementary roles of **generic drugs** and the invaluable contribution that they have made and will make to the state.

For these purposes, the state shall provide the mechanisms to improve generic drugs distribution status by maximizing the use of existing resources, recognizing in the process the government's responsibility to provide as having priority over its other functions.

SECTION 2. Budgetary Assistance - The **Secretary of DOH** shall submit annually the necessary budgetary estimates to implement the provisions of this Act.

Budgetary assistance for the succeeding years should be reviewed and increased accordingly by the **Secretary of DOH** in consultation with the **Department of Budget and Management (DBM)**.

The amount needed to implement these programs shall be provided for in the annual General Appropriations Act. The appropriation of Two **billion (P2,000,000,000.00)** already appropriated under the General Appropriations Act shall be used for this purpose.

Thereafter, such amount as is necessary to carry out the provisions of this Act shall be included in the **annual General Appropriations Act (GAA)**.

The **Department of Budget and Management (DBM)** shall rationalize the existing organizational structure and staffing pattern of the **DOH** in accordance with the prevailing provisions and relevant compensation and position classification laws, rules and regulations.

The Fund shall be chargeable against funds for the purpose and other sources recommended by the **Department of Budget and Management (DBM)**

Thereafter, the amount needed for the continued implementation of this act shall be included in the annual **General Appropriations Act (GAA)**

The Fund shall be administered by the **Secretary of DOH** in accordance with existing government budgeting, accounting, and auditing rules and regulations.

SECTION 3. section 12 of RA6675 is hereby amended to read as follows:

Section 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/she shall suffer the penalty of reprimand which shall be officially recorded in the appropriate books of the Professional Regulation Commission.

(b) for the second conviction, the penalty of fine in the amount of not less than one hundred thousand pesos **(P100,000.00)** but not exceeding two hundred thousand pesos **(200,000.00)** at the discretion of the court.

(c) for the third conviction, the penalty of fine in the amount of not less than two hundred fifty thousand pesos **(P250,000.00)** but not exceeding four hundred thousand pesos **(P300,000.00)** and suspension of his license to practice his profession for thirty (30) days at the discretion of the court.

(d) for the fourth and subsequent convictions, the penalty of fine of not less than five hundred thousand pesos **(P500,000.00)** and suspension of his/her license to practice his profession for two **(2) years** or longer at the discretion of the court.

B) Any juridical person who violates Section 6(c), 6(d), 7 or 8 shall suffer the penalty of a fine of not less than One hundred fifty thousand pesos **(P150,000.00)** nor more than three thousand pesos **(P300,000.00)** and suspension or revocation of license to operate such drug establishment or drug outlet at the discretion of the Court: Provided, 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 two **(2) years** nor more than six **(6) years** 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. C) The Secretary of Health shall have the authority to impose administrative sanctions such as suspension or cancellation of license to operate or recommend suspension of license to practice profession to the Professional Regulation Commission as the case may be for the violation of this Act. Section 13. Separability Clause – If any provision of this Act is declared invalid, the remainder or any provision hereof not affected thereby shall remain in force and effect.

SECTION 4. POSTING AND PUBLICATION – The Department of Health shall publish annually in at least two (2) newspapers of general circulation in the Philippines the generic names, and the corresponding brand names under which they are marketed, of all drugs and medicines available in the Philippines.

SECTION 5. GENERIC TERMINOLOGY:

(a) All government health 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 drugs and medicines.

(b) All medical, dental and veterinary practitioners, including private practitioners, shall write prescriptions using the generic name. The brand name may be included if so desired.

(c) Any organization or company involved in the manufacture, importation, repacking, marketing and/or distribution of drugs and medicines shall indicate prominently the generic name of the product. In the case of brand name products, the generic name shall appear prominently and immediately above the brand name in all product labels as well as in advertising and other promotional materials.

(d) Drug outlets, including drugstores, hospital and non-hospital pharmacies and non-traditional outlets such as supermarkets and stores, shall inform any buyer about any and 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 establishments a list of drug products with the same generic name and their corresponding prices.

SECTION 6. PROVISION ON QUALITY, MANUFACTURER'S IDENTITY AND RESPONSIBILITY – In order to assure responsibility for drug quality in all instances, the label of all drugs and medicines shall have the following: name and country of manufacture, dates of manufacture and expiration. The quality of such generically labeled drugs and medicines shall be duly certified by the **DOH**.

SECTION 7. REQUIRED PRODUCTION – Subject to the rules and regulations promulgated by the **DOH**, 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 drugs.

SECTION 8. PRESCRIPTION OF CRIMES. – The crime punishable under this act shall be prescribed in twenty **(20)** years.

SECTION 9. TRANSITORY PROVISION – Existing industries, businesses and offices affected by the implementation of this Act shall be given six **(6)** months transitory period from the effectivity of the IRR or such other period as may be determined, to comply with the requirements of this Act.

SECTION 10. IMPLEMENTING RULES AND REGULATIONS. – The departments and agencies charged with carrying out the provisions of this Act shall, within sixty **(60)** days after the effectivity of this Act, formulate the necessary rules and regulations for its effective implementation.

implementation of the provisions of this Act shall be in accordance with the rules and regulations to be promulgated by the **DOH**.

Upon approval of this Act, funding assistance shall be given Provided, That the present allocation of **DOH** shall be used at the same proportion and allocation as provided by law.

in accordance with **Republic Act No. 6675**, subject to compliance with the requirements prescribed by the **DOH** and **FDA**

Any unethical practice as may be defined in a **Code of ethics and Code of Technical Standards** to be prepared by the **DOH**, is prohibited

SECTION 11. INCREASE OF PERSONNEL. – The **DOH** shall maintain a sufficient staffing pattern. Hence, it is authorized to increase its manpower to meet such required and may continue to increase personnel per percentage rate increase of committed mandates annually or as the need arises

SECTION 12. REPEALING CLAUSE. – All laws, decrees, executive orders, rules and regulations, or parts thereof inconsistent with the provisions of this Act are hereby repealed or modified accordingly.

SECTION 13. SEPARABILITY CLAUSE. – If, for any reason, any section or provision of this Act is held unconstitutional or invalid, the other sections or provisions hereof shall not be affected thereby.

SECTION 14. EFFECTIVITY CLAUSE. – This Act shall take effect after fifteen (15) days from its publication in the Official Gazette or in at least two (2) national newspapers of general circulation, whichever comes earlier.

Approved,