

Republic of the Philippines
HOUSE OF REPRESENTATIVES
Quezon City

18TH CONGRESS
First Regular Session

HOUSE BILL NO. 993



Introduced by Representative MICHAEL L. ROMERO

EXPLANATORY NOTE

A **generic drug** is equivalent to its brand name counterpart, but is usually less expensive. A generic drug must have the same active ingredients, route of administration, dosage form, strength, and indications as the original brand product. Generic drugs are approved, and are deemed to be as safe and effective as the brand name product.

Generics cannot be sold until after the drug patent expires on the original brand name product. A drug manufacturer applies for a patent to protect their drug from being copied and sold by another company and losing profits.

During the period of patent protection, only the original manufacturer can research, develop and sell the brand name drug. When the patent expires, other manufacturers can submit an abbreviated new drug application for approval to market the generic version.

Generics have lower research costs and higher market competition and those substantial savings are passed on to the patient. However, generic drugs still must meet strict FDA requirements with respect to quality, performance, labeling, manufacturing, and bioequivalence.

This House Bill seeks to promote drug safety by minimizing duplication in medications and/or use of drugs with potentially adverse drug interactions.

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


MICHAEL L. ROMERO Ph.D.

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AN ACT

AMENDING **REPUBLIC ACT 6675**, OTHERWISE KNOWN AS
THE "**GENERIC ACT OF 1988**" TO PROMOTE THE
EXTENSIVE USE OF GENERIC DRUGS THROUGH A RATIONAL
SYSTEM OF PROCUREMENT AND DISTRIBUTION, PROVIDING
STIFFER PENALTIES AND SANCTIONS, AND FOR OTHER
PURPOSES

*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 "**Generics Act of
2019.**"

SECTION 2.

Section 12 of Republic Act No. 6675 is hereby amended to read:

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 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 twenty thousand pesos **(P20,000.00)** but not exceeding fifty thousand pesos **(P50,000.00)** at the discretion of the court.

(c) for the third conviction, the penalty of fine in the amount of not less than fifty thousand pesos **(P50,000.00)** but not exceeding one hundred thousand pesos **(P100,000.00)** and suspension of his license to practice his profession for one **(1)** year at the discretion of the court.

(d) for the fourth and subsequent convictions, the penalty of fine of not less than fifty thousand pesos **(P50,000.00)** and the **revocation** of his license to practice his profession 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 thousand pesos **(P100,000.00)** nor more than Five hundred thousand pesos **(P500,000.00)** and 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 one **(1)** year 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 3. 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 4. IMPLEMENTING RULES AND REGULATIONS – The departments and agencies charged, to be led by the Department of Health (**DOH**) 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.

SECTION 5. 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 6. 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 7. 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,