

Republic of the Philippines
HOUSE OF REPRESENTATIVES
Quezon City

FIFTEENTH CONGRESS
Second Regular Session

HOUSE BILL NO. 5027

Introduced by Honorable ALFREDO D. MARAÑON III

EXPLANATORY NOTE

The Medical profession admits that every medicine has both beneficial effects and adverse reactions.

In view of this, there's a need for the adverse reactions to be explained by the drug manufacturers, the physicians who dispense the medicines and pharmaceutical outlets that sell the medicines.

This bill is being filed to assist and inform the buyers and users of medicines to enable them to get desired benefits from the medicines.

Approval of this Bill is urgent.


ALFREDO D. MARAÑON III

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AN ACT
TO ENSURE THE SAFETY AND EFFICACY OF DRUGS AND MEDICINES BY
EDUCATING THE CONSUMERS ON EFFECTS THEREOF, AND FOR OTHER
PURPOSES

*Be it enacted by the Senate of the Philippines and the House of Representatives
In Congress assembled.*

SECTION 1. – Short Title – This Act shall be known as “The Safe Medication Act of 2011

SECTION 2. – State Policy – It is the policy of the State to provide and ensure the good health of the people, by prescribing rules on the proper use and prescription of medicines, in order that the State can promote and maintain good health of the people in accordance with mandate of the Constitution.

SECTION 3. – Definition of Terms – The following terms as used in this Act, shall have the following meaning:

- a. ADR – Adverse drug reactions which drugs may have on the person taking the drug, other than the intended cure for certain ailment.
- b. Allergic reaction – any adverse result that may occur from taking a drug;
- c. FDA – the Food and Drugs Administration which regulates the pharmaceutical industry.
- d. DOH – Department of Health. The government agency which sets the health policies of the government and regulates the health aspects of the people.
- e. Drug – A substance that is used as a medicine or narcotic.

- f. Ethical Drug – A drug that is available only with written instructions thru prescription from a doctor or dentist to pharmacist.
- g. Medicine – Something that treats or prevents or alleviates the symptoms of disease.
- h. Medical Practitioner - Someone who is authorized to practice medicine.
- i. Over-the-Counter Drug – A drug that is sold without prescription.
- j. Pharmaceutical Industry – The business sector engaged in the manufacture and marketing of drugs and medicines.
- k. Pharmacovigilance – A new discipline that addresses the science and activities relating to the detection, evaluation, understanding and prevention of adverse drug reaction or any other drug-related problems.

SECTION 4. – State Responsibility – It is the responsibility of the State as provided in the Constitution to maintain the good and healthy condition of the people, through the regulation of drug manufacturing, marketing and dispensing. In pursuance to this responsibility, the State shall:

- A. Require drug manufacturers, in addition to observing good manufacturing practices in manufacturing drugs, to explain in detail the therapeutic values, functions and uses, and the possible adverse effects of the medicines they manufacture, through printed literatures, for the education and information of the public;

The printed literature shall be more in detail in the case of the over-the-counter drugs (OTC), because such drugs are available to the public without the need for a prescription from medical practitioner and because these are the out-of-patent medicines, that are sold in their generic names;

- B. Require the medical practitioner to explain to their patients, in addition to the instructions in the prescription, the therapeutic values of the medicines, the intended effect of the medicines and the possible adverse reactions of such medicines and the proper actions to take if such adverse drug reactions do appear;
- C. Require pharmaceutical retail outlets, drugstores and other retail outlets for medicines, to inquire from buyers if they have been provided by the doctors who prescribed the ethical medicines, the necessary information regarding the medicines they are buying as requires in sub-section B; and in the case of over-the counter (OTC) medicines, the pharmaceutical outlets of drugstores shall provide the buyers the literature prepared by the drug manufacturers for the

information of medicine buyers, as provided in the second paragraph of sub-section A;

- D. Require drug manufacturers to provide the Food and Drugs Administration (FDA) copies of the drug literatures they manufacture, for file and reference;
- E. Require the Department of Health to issue the necessary guidelines, rules and regulations regarding the implementation of the provisions of this Act, and to issue orders, circulars and other documents regarding this Act.

SECTION 5. – Private Sector Cooperation – The private sector, the pharmaceutical industry, the medical practitioners and organizations that are concerned with the adverse reactions to users of the medicines, shall cooperate with the Department of Health and the Bureau of Food and Drugs Administration in the implementation of this Act.

SECTION 6. - Appropriations – The amount necessary for the initial implementation of this Act shall be taken from the current appropriations of the Department of Health and the subsequent appropriations shall be included in the General Appropriations Act for the year following its enactment and every year thereafter.

SECTION 7. – Implementing Rules and Regulations – The rules necessary for the implementation of this Act shall be promulgated by the Department of Health through the assistance of the Food and Drugs Administration and the participation of the associations in the Pharmaceutical Industry, the association of Medical Practitioners and association of those involved in the study of adverse reaction of drugs and medicines.

SECTION 8. – Amendatory Clause – Any law, decree or ordinance whose provisions are inconsistent with the provisions of this Act, shall be deemed repealed, amended or modified, accordingly.

SECTION 9. – Separability Clause – In the event that this Act or any provision of it is declared unconstitutional or unlawful, the remaining provisions shall remain valid and in force and effect.

SECTION 10. – Effectivity Clause – This Act shall take effect after 15 days from publication in at least one newspaper of general circulation or Official Gazette whichever comes first.

Approved.

ALFREDO D. MARAÑON III