

Republic of the Philippines
HOUSE OF REPRESENTATIVES
Quezon City



THIRTEENTH CONGRESS

First Regular Session

HOUSE BILL NO. 3463

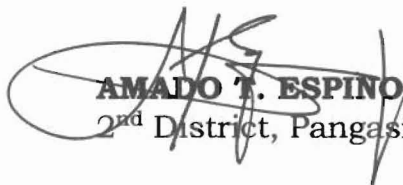
Introduced by HON. AMADO T. ESPINO, JR.

EXPLANATORY NOTE

This bill proposes to require all manufacturers and distributors to provide a parallel translation in the Filipino language, the labels, instructions and literatures in the bottles, boxes or packs of drugs and medicines before being sold to the public.

Due to the scientific and medical terms used by the drug manufacturers in the labels and literatures of drugs and medicines, ordinary folks and laymen cannot proficiently understand what these are conveying especially on the drug's effects, use and dosage since these are usually in the English language. Advanced countries have their mandatory labeling laws translated in their own language, like Japan, China, Taiwan, Mexico, South Korea, the Czech Republic, Saudi Arabia, Russia and the countries of the European Union. Our own neighbor, Indonesia have a mandatory labeling law. It is high time that the Philippines should also require mandatory labeling.

Considering the merits of this proposed measure, its early approval is earnestly requested.


AMADO T. ESPINO, JR.
2nd District, Pangasinan

Republic of the Philippines
HOUSE OF REPRESENTATIVES
Quezon City

THIRTEENTH CONGRESS

First Regular Session

HOUSE BILL NO. 3463

Introduced by HON. AMADO T. ESPINO, JR.

AN ACT
REQUIRING THE PARALLEL TRANSLATION IN THE
FILIPINO LANGUAGE OF THE LABELS, INSTRUCTIONS AND
LITERATURES OF DRUGS AND MEDICINES
MANUFACTURED, DISTRIBUTED OR SOLD IN THE
PHILIPPINES AND PROVIDING PENALTIES FOR
VIOLATIONS THEREOF.

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

SECTION 1. Scope - This Act shall cover all the drugs and medicines that are manufactured, distributed or sold within the territory of the Republic of the Philippines.

SECTION 2. Translation in the Filipino Language – It shall be mandatory for all manufacturers and distributors in the Philippines to provide a parallel translation in the Filipino language of all the labels, instructions and literatures in the bottles, boxes or packs of drugs and medicines before sale to the public..

SECTION 3. Ban on All Non-Complying Manufacturers and Distributors – All distribution outlets or wholesale or retail drugstores shall be prohibited from selling, distributing or storing any bottle, box or pack of drugs or medicines that does not comply with the requirements of this Act.

SECTION 4 Implementing Agency – The lead agency in the implementation of this Act shall be the Department of Trade and Industry. It shall determine, define and disseminate information regarding the requirements of this Act. The Department shall also be responsible for the monitoring compliance of this act and in supporting and coordinating with the police agencies in apprehending and prosecuting violators of this Act.

SECTION 5. Penalties – A fine of Ten Thousand Pesos (P 10,000.00) shall be imposed on any manufacturer, distributor, distribution outlet, wholesale or retail drugstore for every count of violation of the provision of this Act. For this purpose, every bottle, box or pack of drugs or medicine found without the required information shall be considered one count of the violation. Any finished bottle, box or pack of drugs or medicine found without the required translation shall constitute *prima facie* evidence of the violation of the provisions of this Act.

SECTION 6. Transitory Provisions – All concerned manufacturers and distributors shall be allowed a period of one (1) year from the effectivity of this Act to comply with its provisions. All distribution outlets, wholesale and retail drugstores shall be allowed a period of one (1) year and six (6) months from the effectivity of this Act to exhaust its inventory of non-complying bottles, boxes and packs of drugs and medicines after which period the ban shall take effect.

SECTION 7. Effectivity – This act shall take effect immediately upon its approval.

Approved,
