

Republic of the Philippines
HOUSE OF REPRESENTATIVES
Quezon City, Metro Manila

13th CONGRESS

First Regular Session

HOUSE BILL NO. **3830**



INTRODUCED BY **HON. ROLEX T. SUPLICO; HON. FERJENEL G. BIRON, MD;
HON. RODLOFO G. PLAZA; AND HON. JANETTE L. GARIN**

EXPLANATORY NOTE

This bill seeks to impose price controls on medicines in the Philippines in order to bring down the presently anomalous costing of medicines to reasonable and affordable levels and save the lives of millions of Filipinos in our generation and beyond.

There is no doubt that millions of Filipino are grieving and literally bleeding their hearts out by each passing day as they unavoidably contend with the astronomic cost of medicines in this country.

As outrageous and scandalous enough the prices of medicines are, what is even worse is that government is helpless amid, pardon the pun, the killing by our drug manufacturing firms in the uncontrolled, unhampered prices of their products.

Is it not shocking that the level of prices of medicines in the Philippines is comparatively the highest in Asia?

Is it not insulting to the Filipino people that some medicines that are being sold in the market today are five times costlier compared to other Asian countries?

It is interesting to note that competition as we know it in the Philippine pharmaceutical industry does not necessarily translate to cheaper products for the Filipinos. There are more than 300 pharmaceutical firms in the Philippines that either manufacture or import some 25,000 registered drugs. Yet the level of prices of medicines in our country persistently remains to be the highest in the world.

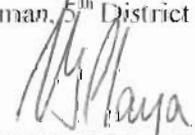
It is simply because the drug manufacturers are having a field day jacking up their prices as much as they wanted – in the absence of government intervention and control.

Nowadays, overpricing of medicines is the name of the game in the Philippines to the shock and horror of foreigners and the suppressed wrath and anger of a severely-abused and helpless nation.

Hence, approval of this bill is urgently requested.


HON. ROLEX T. SUPLICO
Congressman, 5th District of Iloilo


HON. FERJENEL G. BIRON, MD
Congressman, 4th District of Iloilo


HON. RODOLFO G. PLAZA
Congressman, Lone District Agusan del Sur


HON. JANETTE L. GARIN
Congressman, 1st District of Iloilo

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AN ACT
REGULATING DRUG PRICES, CREATING FOR THE PURPOSE THE DRUG PRICES
REGULATION BOARD, DEFINING ITS POWERS AND FUNCTIONS, AND
PROVIDING FUNDS THEREFOR.

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

SECTION 1. Short Title. – This Act shall be known as “Drug Prices Regulation Act of 2005.”

SEC. 2. Policy Statement. – It is hereby declared the policy of the State to protect and promote the right to health of the people and instill health consciousness among them. Pursuant thereto, the State shall regulate control the prices of medicines in order to make them affordable to everyone.

SEC. 3. Definition of Terms. – As used in this Act, the following terms are hereby defined as follows:

- (a) “Board” means the Drug Prices Regulation Board.
- (b) “Bulk drug” means any pharmaceutical, chemical, biological or plant product including its salts, esters, stereo-isomers and derivatives, conforming to pharmacopoeial or other standards and used as such or as an ingredient in any formulation.
- (c) “Capital employed” means net fixed assets plus working capital of a manufacturer in relation to manufacture of pharmaceutical formulations.
- (d) “Importer” means any establishment that imports raw materials, active ingredients and/or finished products for its own use or for wholesale distribution to other drug establishments or outlets.
- (e) “Drug” includes –
 - (i) all medicines for internal or external use of human beings and all substances intended to be used for, or in the diagnosis, treatment, mitigation, or prevention of any disease or disorder in human beings;
 - (ii) such substances, intended to affect the structure or any function of the human body or intended to be used for the destruction of vermin or insects which cause disease in human beings, as may be specified from time to time by the Bureau of Food and Drugs and the Department of Health; and
 - (iii) bulk drugs and formulations.
- (f) “Formulation” means a medicine processed out of, or containing one or more

bulk drugs with or without the use of any pharmaceutical aids, for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease in human beings.

- (g) "Fund" means the Drug Prices Equalization Fund.
- (h) "Manufacture" in relation to any drug, includes any process or part of a process for making, altering, finishing, packing, labeling, breaking or otherwise treating or adapting any drug with a view to its sale and distribution, but does not include the compounding or dispensing of any drug or the packing of any drug in the ordinary course of retail business, and "to manufacture" shall be construed accordingly.
- (i) "Manufacturer" means any establishment engaged in operations involved in the production of a drug with the end view of storage, distribution or sale of the product.
- (j) "National pharmaceutical company" means any establishment whose capital structure is majority-owned by Filipino citizens. Any other establishment that does not fall under the definition of a National pharmaceutical company is a "Multinational pharmaceutical company".
- (k) "Publication" means publication once a week for three (3) consecutive weeks in a newspaper of general circulation.
- (l) "Retailer" means an establishment carrying on the retail business of sale of drugs to customers.
- (m) "Trader" means any establishment which is a registered owner of the drug product; procures the materials and packaging components, and provides the production monographs, quality control standards and procedures, but sub-contracts the manufacture of such product to a licensed manufacturer.
- (n) "Wholesaler" means an establishment that procures raw materials, active ingredients and/or finished products from local establishments for local distribution on wholesale basis.

SEC. 4. Creation and Composition of the Drug Prices Regulation Board. – (a) In pursuance of the aforementioned policy, there is hereby created the Drug Prices Regulation Board, which shall be attached to the Department of Trade and Industry and composed of the following:

1. *Ex-officio* Chairman – Secretary of Trade and Industry
2. *Ex-officio* Vice Chairman – Secretary of Health
3. *Ex-officio* Member – Director, Bureau of Food and Drugs

(b) The Board shall have as many members as maybe recommended by the Secretary of Trade and Industry and appointed by the President of the Philippines; Provided that, consumers, pharmaceutical companies whether National or Multinational, pharmacists, physicians, And hospitals shall be duly represented from among the reputable associations nationwide; Provided further, that the total membership of the Board, including the *ex-officio* members, shall not exceed ten (10).

SEC. 5. The Secretariat of the Drug Prices Regulation Board. – (a) The Undersecretary for Consumer Welfare & Trade Regulation of the Department of Trade and Industry shall be the Board's *ex-officio* secretary.

(b) Within thirty (30) days from the effectivity of this Act, the Board's *ex-officio* secretary shall prepare a *plantilla* of positions for the Secretariat of the Board for the approval of the Secretary of the Department of Trade and Industry. It shall be ratified by a majority of the members of the Board in its first meeting which shall be called within ten (10) days from the approval thereof of the Secretary of Trade and Industry.

SEC. 6. Powers of the Board. – The Board shall have the following powers:

(a) Power to Fix the Maximum Retail Prices of Formulations Included in the List of Regulated Drugs. – (1) Upon application or *motu proprio* when the public interest so requires, the Board shall have the power to regulate the retail prices of formulations included in the List of Regulated Drugs, including their dosage and packing, and, in order that they shall be made publicly available at affordable retail price from the different manufacturers, importers, distributors, wholesalers or retailers and after a proper determination as the Board may deem fit, fix from time to time, by publication the maximum retail price at which such formulations shall be sold:

(2) No retailer shall sell a formulation at a retail price exceeding the maximum retail price fixed by the Board: Provided that, until the maximum retail price of a formulation is fixed by the Board, the retail price thereof shall be the price which prevailed immediately before the effectivity of this Act and no manufacturer, importer, distributor, wholesaler or retailer of such formulation shall sell the same at a retail price exceeding the price prevailing immediately before the effectivity of the Act; and

For purposes hereof, formulations include single- and multi-ingredient formulations included in the List of Regulated Drugs and sold under their generic and brand names.

(b) Power to Include Formulations in the List of Regulated Drugs. – Upon application or *motu proprio* when the public interest so requires and after proper determination, the Board may order the inclusion in the List of Regulated Drugs of any formulation excluded therefrom.

(c) Power to Direct Manufacturers of Bulk Drugs of Formulations Included in the List of Regulated Drugs to Sell Such Bulk Drugs to Other Manufacturers of Formulations. – Upon application or *motu proprio* when the public interest so requires, the Board may direct any manufacturer of any bulk drug of formulations included in the List of Regulated Drugs to sell such bulk drug to such other manufacturer of formulations: Provided that, any or all of the following shall be considered:

- (i) the requirements for captive consumption of such manufacturer; and
- (ii) the requirements of other manufacturers.

(d) Power to Recover Overcharged Amount and Establishment of Drug Prices Equalization Fund. – (1) Upon application or *motu proprio* when public interest so requires, the Board may order manufacturers, importers, distributors, wholesalers or retailers, as the case may be, to deposit the amount accrued due to the charging of retail prices formulations included in the List of Regulated Drugs higher than the maximum retail prices fixed by the Board, including any imposable penalty, to the Drug Prices Equalization Fund, which is hereby established under the supervision of the Board.

(2) Every retailer shall remit to the Board one-half of one percent of every sale inclusive of the fixed retail price, which shall be deposited in the Fund.

(3) The Fund shall be utilized for:

- (i) Securing the equitable distribution and availability at fair prices of drugs or subsidizing the cost of drugs in order to make them affordable;
- (ii) Meeting the expenses incurred by the Board in discharging its functions;
- (iii) Promoting higher education and research in Pharmaceutical sciences and technology; and

- (iv) Any similar or analogous uses in consonance with the purposes of this Act.

SEC. 7. Display of Prices Fixed by the Board for Formulations Included in the List of Regulated Drugs. – (a) Within a reasonable period as may be determined by the Board, and provided that it conforms to existing drug product labeling requirements, every manufacturer, importer, distributor, wholesaler or retailer of a formulation intended for sale shall display the retail price of a formulation included in the List of Regulated Drugs which shall not exceed the maximum retail price fixed by the Board. The maximum retail price shall be printed on the label of the container of the formulation and the minimum pack thereof offered for retail sale with the words “retail price not to exceed” preceding it, and “Under Drugs Prices Regulation Board” on a red strip provided that, in the case of a container consisting of smaller saleable packs, the retail price of such smaller pack shall also be displayed on the label of each smaller pack and such price shall not be more than the *pro-rata* retail price of the main pack rounded off to the nearest centavo.

(b) Within a period as may be determined by the Board from time to time, every manufacturer or importer shall issue a price list to distributors, wholesalers, retailers and the Board, indicating the retail prices and the maximum retail price and such other information as may be required by the Board.

SEC. 8. Prices of Formulation Included in the List of Regulated Drugs and Sold to the Retailer. – (a) No manufacturer, importer, distributor or wholesaler shall sell a formulation included in the List of Regulated Drugs to a retailer at a retail price exceeding the maximum retail price fixed by the Board, minus fifteen percent (15%).

(b) Upon application or *motu proprio* when the public interest so requires and after proper determination, including the conduct of public hearings whenever necessary, the Board may allow a higher or lower retailer’s margin than the fifteen percent (15%) provided above.

SEC. 9. The List of Regulated Drugs. The List of Regulated Drugs shall include (1) all formulations indicated for treatment of chronic illnesses and life-threatening conditions such as, but not limited to, Endocrine Disorders, e.g., Diabetes Mellitus; Gastrointestinal Disorders, e.g., Peptic Ulcer; Urologic Disorders, e.g., BPH; Cardiovascular Diseases, e.g., Hypertension; Pulmonary Diseases, e.g., PTB, Asthma; Autoimmune Diseases, e.g., SLE; Skin Diseases, e.g., Psoriasis; Neuro-Psychiatric Disorders; Other Infectious Diseases, e.g., HIV-AIDS; and Other Conditions such as Organ Transplants and Neoplasms (2) formulations indicated for prevention of diseases, e.g., Vaccines, Immunoglobulins, Anti-sera (3) formulations indicated for prevention of pregnancy, e.g., oral contraceptives, and (4) Anesthetic Agents.

SEC. 10. Information to be Furnished by Manufacturers or Importers of Formulations Included and Excluded from the List of Regulated Drugs. – Within thirty (30) days after the effectivity of this Act and every December 31st of every year thereafter, every manufacturer or importer of a formulation whether included in or excluded from the List of Regulated Drugs shall furnish the Board a list of all formulations it produces or imports, and any necessary information that the Board may require.

SEC. 11. Display of Prices and Price List of Formulations Excluded from the List of Regulated Drugs. – (a) Every manufacturer, importer, distributor, wholesaler or retailer of a formulation excluded from the List of Regulated Drugs shall display in indelible print mark on the label of container of the formulation and the minimum pack thereof offered for retail sale, the words “Not Under Price Regulation” on a green strip.

(b) If required by the Board, every manufacturer, importer, wholesaler, distributor, or retailer shall issue a price list of formulations excluded from the List of Controlled Drugs, indicating changes from time to time.

SEC. 12. Manufacturers, Importers, Distributors and Retailers Not to Refuse Sale of Drug. – (a) No manufacturer, importer or distributor shall withhold from sale or refuse to sell to a wholesaler or retailer any drug without good and sufficient reasons.

(b) No retailer shall withhold from sale or refuse to sell any available drug to any customer.

SEC. 13. Maintenance of Records and Production Thereof For Inspection of Formulations Included in and Excluded from the List of Regulated Drugs. – Every manufacturer, importer, distributor, wholesaler or retailer shall maintain records containing information on sales or formulations included in and excluded from the List of Regulated Drugs and such other information as may be required by the Board from time to time. Whenever public interest so requires, the Board shall have the power to call for and inspect such records at the premises of any manufacturer, importer, distributor, wholesaler or retailer.

SEC. 14. Power to Exempt. – (a) Notwithstanding any other provisions of this Act, and taking into consideration the factors enumerated in sub-paragraph (b) below, subject to such conditions as it may specify by an order duly published and upon application or *motu proprio* when public interest so requires, the Board may exempt any manufacturer from the coverage of any or all the provisions of this Act.

(b) In the grant of exemptions under sub-paragraph (a) above, the Board shall consider any or all of the following factors:

- (i) production of bulk drugs from basic stage by a process developed through indigenous research and development, and which is significantly different from known processes and results in cost reduction; and
- (ii) production of a new drug, which has not been produced elsewhere, if developed through indigenous research and development.

SEC. 15. Power to Review. – (a) Any person aggrieved by any order, resolution or decision made by the Board may file a motion for reconsideration or review of such order, resolution or decision within fifteen (15) days from the date of the publication or receipt thereof: Provided that, pending a resolution or decision by the Board of such motion for reconsideration or review, no manufacturer, importer, distributor, wholesaler or retailer shall sell a formulation included in the List of Regulated Drugs, at a price exceeding the maximum retail price fixed by the Board.

(b) The resolution of the foregoing motion for reconsideration or review may be further reviewed by the President of the Philippines with finality.

SEC. 16. Penalties. – In addition to the penalties that may be imposed by Republic Act No. 3720, as amended, and other laws, decrees, rules and regulations and other issuances, the penalty of life imprisonment and a fine of Five Hundred Thousand pesos (P500,000.00) to Five Million pesos (P5,000,000.00), shall be imposed upon the owner, president, manager, director, or other responsible officer of any public or private firm, company, corporation, or entity, who shall willfully or knowingly violate any of the provisions of this Act including the defacing or altering of the printed price tag label.

SEC. 17. Rules and Regulations. – The Board shall issue rules and regulations necessary for the effective implementation of this Act.

SEC. 18. Appropriations. – Any amount necessary for the initial implementation of this Act shall be taken from the current appropriations of the Department of Trade and Industry. Thereafter, such sums as may be necessary for its continued implementation shall be included in the annual General Appropriations Act.

SEC. 19. Saving Clause. – In case any provision of this Act shall be declared invalid or unconstitutional, the other provisions not affected thereby shall remain in full force and effect.

SEC. 20. Repealing Clause. – All laws, decrees, orders, rules and regulations and other issuances or parts thereof, inconsistent with this Act, are hereby repealed or amended accordingly.

SEC. 21. Effectivity. – This Act takes effect two (2) weeks after its publication in two (2) newspapers of general circulation.

Approved.