THIRTEENTH CONGRESS OF THE
REPUBLIC OF THE PHILIPPINES
First Regular Session

SENATE

S. No. 608

INTRODUCED BY HON. MANUEL B. VILLAR JR.

EXPLANATORY NOTE

Medicines are vital to a patients' well-being. But if these medicines cost too much for the ordinary Filipino, a graver illness or even death becomes imminent.

Drug prices in the Philippines are among the highest in Asia – five (5) times higher than its Asian neighbors. This comes as a surprise, since we have over 300 pharmaceutical firms in the country, manufacturing and importing some 25,000 registered drugs. This only shows that competition does not translate to cheaper medicines in our country.

This bill seeks to regulate drug prices in the Philippines and bring them to affordable levels. The creation of a Drug Prices Control Board will ensure an affordable retail price of drugs from the different manufacturers, importers, distributors, or retailers. The Board also has the power to recover any overcharged amount in the prices of medicines, and deposit it to the Drug Prices Equalization Fund. The Fund shall be utilized to ensure equitable distribution and availability of drugs at fair prices, to subsidize the cost of medicines to make them affordable, and to promote higher education and research in pharmaceutical sciences and technology.

Regulating drug prices will help save lives.

The passage of this bill, therefore, is fervently called for.

MANUEL B. VILLAR, JR.
Senator

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AN ACT
REGULATING DRUG PRICES, CREATING FOR THE PURPOSE THE DRUG PRICES CONTROL 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 Control Act of 2004."

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

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

(a) ***Board*** – means the Drug Prices Control Board
(b) ***Bulk drug*** - means any pharmaceutical, chemical, biological or plant product including its salts, esters, stereo-isomers and derivatives conforming to pharmacopeial 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 and pharmaceutical formulations
(d) ***Distributor*** – means any establishment that imports raw materials, active ingredients and/or finished products for its own use 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, in the diagnosis, treatment, mitigation , or prevention of any disease or disorder in human beings, including

preparations applied on the human body for the purpose of repelling insects like mosquitoes;

ii. such substances, intended to affect the structure or any function of the human body or intended to be used for the destruction or 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 our 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 but shall not include –

i. any medicine included or external the Homoeopathic system of medicine; and

ii. any substance to which the provisions of Republic Act No. 3720, as amended, do not apply.

(g) ***Fund*** – means the Drug Prices Equalization Fund

(h) ***Import*** – with its grammatical variations and cognate expressions means bringing to the Philippines, and "Importer", in relation to goods at any time between their importation and consumption, includes any establishment/entity holding itself out to be the importer.

(i) ***Manufacture*** – in relation to any drug, includes any process or part of a process for making, altering, fishing, 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 in the ordinary course of retail business, and "to manufacture" shall be construed accordingly.

(j) ***Manufacturer*** – means any establishment which manufactures a bulk drug or formulation.

(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) ***Sales Turn Over*** – means the product of units of formulations sold by a manufacturer or importer in an accounting year multiplied by the retail price inclusive of sales tax, if any paid on direct taxes by the manufacturer or importer but does not include excise duty or local taxes, if any.

(n) ***Wholesaler*** – means an establishment that procures raw materials, active ingredients and/or finished products from local establishments for local distribution on wholesale basis.

SECTION 4. ***Creation and Composition of the Drug Prices Control Board*** - (a) In pursuance of the aforementioned policy , there is hereby created the Drug Prices Control 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, 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).

SECTION 5. ***Secretariat of the Drug Prices Control Board*** – (a) The concerned Assistant Secretary for Domestic Trade or the officer occupying an equivalent rank and position in 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 Trade and Industry.

SECTION 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 Controlled Drugs***

1. Upon application or *motu propio* when the public interest so requires, the Board shall have the power to control the retail prices of formulations included in the List of Controlled Drugs, including their dosage and packing, and in order that they shall be made publicly available a affordable retail price at which such formulations shall be sold;

2. When fixing the maximum retail price of formulations, the Board shall take into consideration a post-tax return of fourteen percent (14%) on net worth or a return of twenty-two percent (22%) on capital employed or in respect of a new plant an internal rate of return to fourteen percent (14%) based on long term marginal costing depending upon the option for any of the specified rates of return that may be exercised by a manufacturer of a pharmaceutical formulation; Provided that, where the production is from the basic stage, the Board shall take into consideration a post–tax return of eighteen percent (18%) on net worth or a return of twenty-six percent (26%) on capital employed; Provided further, that the option with regard to the rate of return once exercised by a manufacturer shall be final and no change of rates shall be made prior approval of the Board;

3. 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

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

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

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

i. the requirement for captive consumption of such manufacturer; and
ii. the requirement of other manufacturers.

(d) ***Power to Recover Overcharged Amount and Establishment of Drug Prices Equalization Fund*** –

1. Upon application or *motu propio* when the public interest so requires, the Board may order manufacturers, importers, distributors, wholesalers and retailers, as the case may be, to deposit the amount accrued due to the charging of retail of prices of formulations included in the List of Controlled 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 two percent (2%) 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 in order to make them affordable;
   ii. Meeting the expenses incurred in 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 purpose of this Act.

SECTION 7. ***Display of Prices Fixed by the Board of Formulations Included in the List of Controlled Drugs*** – (a) Within a reasonable period as may be determined by the Board, every manufacture, importer, distributor, wholesaler or retailer of a formulation intended for sale shall display the retail price of a formulation included in the List of Controlled 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 or the formulation and the minimum pack thereof offered for a retail sale with the words "retail price not to exceed" preceding it, and "Under Drug Prices Control Board" on a red strip; Provided that, in the case of 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 the 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.

SECTION 8. ***Prices of Formulations Included in the List of Controlled Drugs and Sold to the Retailer*** – (a) No manufacturer, importer, distributor or wholesaler shall sell a formulation included in the List of Controlled Drugs to a retailer at a retail price exceeding the maximum retail price fixed by the Board, minus twelve percent (12%).

(b) Upon application or *motu propio* 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 twelve percent (12%) provided above.

SECTION 9. ***The List of Controlled Drgus*** – The List of Controlled Drugs shall be as follows:

LIST OF CONTROLLED DRUGS

1. **ALIMENTARY SYSTEM**
   a. Antacids, Antiulcerants
   b. GIT Regulators, Antiflatulents and Anti-inflammatories
   c. Antispasmodics
   d. Antidiarrheals
   e. Laxatives, Purgatives
   f. Digestives
   g. Chlolagogues, Chlolelitholytics and Hepatic Protectors
2. **CARDIOVASCULAR & HEMATOPEOITIC SYSTEM**
   a. Cardiac Drugs
   b. Anti-Anginal Drugs
   c. ACE-Inhibitors/Other Antihypertensives
   d. Beta blockers
   e. Calcium Antagonists
   f. Diuretics
   g. Antidiuretics
   h. Peripheral Vasodilators and Cerebral Activators
   i. Vasoconstrictors
   j. Migraine Drugs
   k. Haemostatics
   l. Anticoagulants, Antithrombotics, and Fibrinolytics
   m. Haemorrhoidal, Phlebbitis and Varicose Preparations
   n. Haemorrheologicals
   o. Hematopoeitic Agents
   p. Other Cardiovascular Drugs

3. **RESPIRATORY SYSTEM**
   a. Respiratory Stimulants
   b. Antiasthmatic Preparations
   c. Cough and Cold Remedies
   d. Decongestants and Other Nasal Preparations
   e. Other Drugs Acting on Respiratory System
4. **NEURO-MUSCULAR SYSTEM**
   a. Anti-inflammatory Enzymes
   b. Analgesics and Antipyretics
   c. Anti-rheumatic, Anti-inflammatory Analgesics
   d. Gout Preparations
   e. Minor Tranquilizers
   f. Major Tranquilizers
   g. Hypnotics and Sedatives
   h. Anticonvulsants
   i. Antidepressants
   j. CNS Stimulants
   k. Nootropics and Neurotics
   l. Antiemetics and Antivertigo Drugs
   m. Neurodegenerative Disease Drugs
   n. Antiparknisonism Preparation
   o. Neuromuscular Disorder Drugs
   p. Muscle Relaxants
5. **HORMONES**
   a. Androgens and Related Synthetic Drugs
   b. Oestrogens and Progesterones and Related Synthetic Drugs

c. Combined Sex Hormones
d. Corticosteroid Hormones
e. Trophic Hormones and Related Synthetic Drugs
f. Anabolic Agents
g. Other Hormone Related Drugs

6. CONTRACEPTIVES AGENTS

a. Depot Contraceptives
b. Oral Contraceptive
c. Other Contraceptives

7. ANTIBIOTICS

a. Aminoglycosides
b. Cephalosporins
c. Chlorampenicols
d. Macrolides
e. Penicillins
f. Quinolones
g. Tetracyclines
h. Antibacterial Combinations
i. Other Antibiotics

8. OTHER CHEMOTHERAPEUTICS

a. Antituberculous Agents
b. Sulphonamides
c. Antiamoebics
d. Antihelmintics
e. Antileprotics
f. Antivirals
g. Antineoplastics
h. Antimalarials
i. Antifungals
j. Leishmaniacides, Trypanocides
k. Filaricides

9. GENITO-URINARY SYSTEM

a. Preparations for Vaginal Conditions
b. Urinary Antiseptics
c. Drug Acting on Uterus
d. Other Drugs Acting Genito-Urinary System

10. METABOLISM

a. Insulin
b. Oral Hypoglycaemic Agents
c. Thyroid Preparations
d. Antithyroids
e. Antihyperlipidaemic Agents
f. Other Agents Affecting Metabolism

11. NUTRITION

a. Parental Nutrition

12. EYE AND EAR PREPARATIONS

a. Eye Anti-infectives and Antiseptics
b. Eye Corticosteroids
c. Eye Antiseptics with Corticosteroids
d. Mydriatics Drugs
e. Myotic Drugs
f. Glaucoma Preparations
g. Other Eye Preparations
h. Ear Anti-infectives and Antiseptics
i. Ear Corticosteroids

j. Ear Antiseptics and Corticosteroids
k. Other Ear Preparations

13. DERMATOLOGICALS

a. Anti-infectives
b. Anti-infectives with Corticosteroids
c. Topical Corticosteroids
d. Acne Treatment Preparations
e. Antiseptics and disinfectants
f. Medicated Surgical Dressings
g. Fungicides and Antiparasites
h. Psoriasis, Seborrhea and Ichthyosis
i. Topical Antivirals
j. Keratolytics
k. Skin Protectives
l. Antihistamines/Antipruritics
m. Analgesics and Anti-inflammatories
n. Other Dermatologicals

14. ANAESTHETICS

15. ALLERGY AND IMMUNE SYSTEM

a. Antihistamines and Antiallergics
b. Vaccines, Antisera and Immunoligicals
c. Immunosuppressants

16. ANTIDOTES & DETOXIFYING AGENTS

17. INTRAVENOUS & OTHER STERILE SOLUTIONS

SECTION 10. ***Calculation of the Maximum Retail price of Formulations Included in the List of Controlled Drugs*** - (a) The maximum retail price of a locally-manufactured formulation included in the List of Controlled Drugs shall be calculated by the Board in accordance with the following formula:

M.R.P.=(M.C.+C.C+P.M.+P.C.) x (1+MAPE/200)+VAT

Where:

M.R.P. – means maximum retail price;

M.C. – means material cost and includes the cost of drugs and other pharmaceutical aids used including overages, generally accepted process loss as determined by the Board from time to time, input VAT, and import duty, if any;

C.C.- means conversion cost worked out in accordance with established procedures of costing and shall be fixed as a norm by the Board;

P.M. – means cost of the packing material used in the packing of concerned formulation including process lost, and shall be fixed as a norm by the Board;

P.C. – means packing charges worked out in accordance with established procedures of costing and shall be fixed as a norm every year by the Board;

MAPE (*Maximum Allowable Post-Manufacturing Expenses*) – means all costs incurred by a manufacturer from the stage of ex-factory cost to retailing includes trade margin and margin for the manufacturer and shall not exceed two hundred percent (200%) for manufactured formulations included in the List of Controlled Drugs; and

VAT – means output value added tax.

(b) In the case of an imported formulation, the maximum retail price thereof shall be calculated as follows:

M.R.P. = L.C. x (1+MAPE/100)+VAT

Where:

L.C. – means landed cost consisting of FOB cost, insurance, freight and other miscellaneous expenses multiplied by the applicable duty and input VAT, if payable, as follows:

L.C. = (FOB+Insurance cost+Freight cost+Misc.expenses) x D x Input VAT

MAPE (*Maximum Allowable Post-Manufacturing Expenses*) – means all costs incurred by a manufacturer from the stage of ex-landed cost to retailing and includes trade margin and margin for the importer and shall not exceed one hundred percent (100%) for imported formulations included in the List of Controlled Drugs.

SECTION 11. ***Information to be Furnished by Manufacturers or Importers of Formulations Included in and Excluded from the List of Controlled 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 Controlled Drugs shall furnish the Board of a list of all formulations it produces or imports, indicating the details of the cost of each, including any necessary information that the Board may require.

SECTION 12. ***Display of Prices and Price List of Formulation Excluded from the List of Controlled Drugs*** – Every manufacturer, importer, distributor, wholesaler or retailer of a formulation excluded from the List of Controlled Drugs shall display in indelible print mark on the label of the container of the formulation and minimum pack thereof offered for retail sale, the words "Not Under Price Control" on a green strip.

SECTION 13. ***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.

SECTION 14. ***Maintenance of Records and Production Thereof for Inspection of Formulations Included in and Excluded from the List of Controlled Drugs.*** – Every manufacturer, importer, distributor, wholesaler or retailer shall maintain records containing information on sales of formulations included in or excluded form the List of Controlled 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.

SECTION 15. ***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 propio* 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 the sub-paragraph (a) above, the Board shall consider any or all of the following factors:

i. level of technology utilized
ii. numbers of workers employed;
iii. amount of capital invested;
iv. range/group and type of products manufactured;
v. sales turn-over
vi. 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

vii. production of a new drug, which has not been produced elsewhere, if developed through indigenous research and development

SECTION 16. ***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 publication or receipt thereof; Provided that, pending a resolution or decision by the Board on such motion for reconsideration or review, no manufacturer, importer, distributor, wholesaler or retailer shall sell a formulation included in the List of Controlled 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 not be further reviewed by the President of the Philippines with finality.

SECTION 17. ***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 *reclusion temporal* in it is maximum period to *reclusion perpetua*, and a fine not less One hundred thousand pesos (100,000.00) but shall not exceed Ten million pesos (10,000,000.00), 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.

SECTION 18. ***Rules and Regulations*** – The Board shall issue the rules and regulations necessary for the effective implementation of this Act.

SECTION 19. ***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.

SECTION 20. ***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.

SECTION 21. ***Repealing Clause*** – Executive Order NO. 776 dated February 24, 1982, Letter of Instructions No. 1225 dated July 14, 1982 and all laws, decrees, orders, rules, and regulations and other issuances or parts thereof, inconsistent with this Act, are hereby repealed or modified.

SECTION 22. ***Effectivity*** - This Act takes effect after fifteen (15) days following its publication in the least two (2) national newspapers of national circulation.

Approved,