NINETEENTH CONGRESS OF THE)
REPUBLIC OF THE PHILIPPINES)
First Regular Session)

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RECEIVED BY:

SENATE

S.B. No. 1305

Introduced by **SENATOR IMEE R. MARCOS**

AN ACT
ESTABLISHING THE DRUG PRICE REGULATORY BOARD TO REGULATE THE PRICES OF DRUGS AND MEDICINES IN THE PHILIPPINES AMENDING FOR THE PURPOSE REPUBLIC ACT NO. 9502, OTHERWISE KNOWN AS THE "UNIVERSALLY ACCESSIBLE CHEAPER AND QUALITY MEDICINES ACT OF 2008" AND FOR OTHER PURPOSES

EXPLANATORY NOTE

Article II, Section 15 of the 1987 Constitution provides that the State shall protect and promote the right to health of the people and instill health consciousness among them.

Article XIII, Sections 11 and 12 of the Constitution further mandate that the State shall adopt an integrated and comprehensive approach to health development which shall endeavor to make essential goods, health and other social services available to all the people at affordable cost. There shall be priority for the needs of the under-privileged, sick, elderly, disabled, women, and children. The State shall endeavor to provide free medical care to paupers. It is further provided that the State shall establish and maintain an effective food and drug regulatory system and undertake appropriate health manpower development and research, responsive to the country's health needs and problems.

The enactment of Republic Act No. 9502, otherwise known as the Universally Accessible Cheaper and Quality Medicines Act of 2008 has lowered the prices of medicines in the country. However, the Department of Health admitted that while the general trend in the prices of generic essential medicines have gone down in recent years, the Philippines is still paying higher prices when compared internationally.

Generic drugs are still sold up to four times the international reference prices whereas branded innovator products are sold up to 22 times higher, especially in private hospitals and pharmacies.

This bill seeks to create an inter-agency Drug Price Regulatory Board (hereafter referred as the Board) to regulate the prices of drugs and medicines in the Philippines, in lieu of the Drugs and Medicines Price Monitoring and Regulation Authority of the Secretary of the Department of Health. The inter-agency composition of the Board ensures a broad spectrum of ideas, viewpoints and administrative powers in addressing the issue of affordability and accessibility of drugs and medicines in the country.

The bill also seeks to strengthen the procurement of cheaper drugs and medicines by the government through the creation of a trust fund to be utilized for parallel drug importation and other procurement arrangements. The Board is empowered to require pharmaceutical distributors to buy or obtain under any other form of arrangement, reasonable quantity of drugs and medicines procured by the government. The Board can also mandate up to 15% of a drug or medicine procurement of large pharmaceutical distributors to be allotted to a particular generic drug and medicine, thereby ensuring affordability and accessibility of medicines for our countrymen.

In view of the foregoing, the passage of this bill is earnestly sought.

Imee R. Marcos

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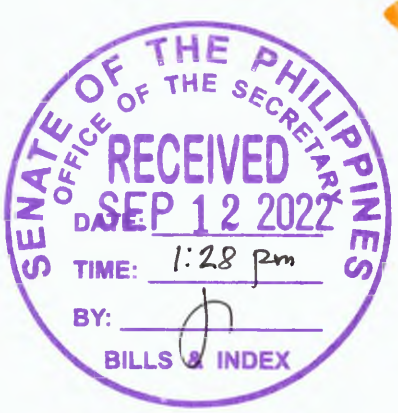

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Be it enacted by the Senate and House of Representatives of the Philippines in Congress assembled:

SECTION 1. Chapter 3 of Republic Act No. 9502 will now be titled "*Drugs and Medicines Price Regulatory Board.*"

SEC. 2. Section 17 of Republic Act No. 9502 is hereby deleted and a new Section 17 is hereby inserted to read as follows:

"SEC. 17. *CREATION AND COMPOSITION OF THE DRUG PRICES REGULATION BOARD.*

a) THERE IS HEREBY CREATED THE DRUGS PRICES REGULATION BOARD, WHICH SHALL BE ATTACHED TO THE DEPARTMENT OF HEALTH AND COMPOSED OF SEVEN (7) MEMBERS AS FOLLOWS:

1) SECRETARY OF HEALTH OR HIS DULY DESIGNATED REPRESENTATIVE AS CHAIRPERSON;
2) SECRETARY OF TRADE AND INDUSTRY OR HIS DULY DESIGNATED REPRESENTATIVE AS VICE-CHAIRPERSON;

3) **DIRECTOR, FOOD AND DRUGS ADMINISTRATION OR HIS DULY DESIGNATED REPRESENTATIVE AS MEMBER;**
4) **CHAIRMAN, PHILIPPINE HEALTH INSURANCE CORPORATION AS MEMBER;**
5) **ONE (1) ECONOMIST FROM THE ACADEME AS MEMBER; AND**
6) **TWO (2) REPRESENTATIVES FROM THE CONSUMERS' SECTOR AS MEMBERS**

b) THE MEMBERS OF THE BOARD REPRESENTING THE ACADEME AND THE CONSUMERS' SECTOR SHALL BE APPOINTED BY THE PRESIDENT OF THE PHILIPPINES AND SHALL SERVE FOR A TERM OF TWO (2) YEARS: *PROVIDED*, THAT THE REPRESENTATIVES FROM THE CONSUMERS' SECTOR SHALL NOT BE ELIGIBLE FOR REAPPOINTMENT FOR ANOTHER TERM."

SEC. 3. Section 18 of Republic Act No. 9502 is hereby deleted and a new Section 18 is hereby inserted to read as follows:

"SEC. 18. *POWERS OF THE BOARD*. -THE BOARD SHALL HAVE THE FOLLOWING POWERS:

a) *POWER TO DETERMINE THE MAXIMUM RETAIL PRICE OF DRUGS OR MEDICINES SUBJECT TO PRICE REGULATION.–*

(1) UPON APPLICATION OR *MOTU PROPIO* WHEN THE PUBLIC INTEREST SO REQUIRES, THE BOARD SHALL HAVE THE POWER TO REGULATE THE RETAIL PRICES OF DRUGS AND MEDICINES LISTED UNDER SECTION 26 HEREOF, INCLUDING THEIR DOSAGE FORM AND PACKING, AND, IN ORDER THAT THEY SHALL BE MADE AVAILABLE TO THE PUBLIC AT AFFORDABLE RETAIL PRICE FROM THE DIFFERENT MANUFACTURERS, IMPORTERS, TRADERS, 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 DRUGS AND MEDICINES AT A RETAIL PRICE EXCEEDING THE MAXIMUM RETAIL PRICE FIXED BY THE BOARD: PROVIDED, THAT UNTIL THE MAXIMUM RETAIL PRICE OF DRUGS AND MEDICINES

SUBJECT TO PRICE REGULATION IS FIXED BY THE BOARD, THE RETAIL PRICE THEREOF SHALL BE THE PRICE WHICH PREVAILED IMMEDIATELY BEFORE THE EFFECTIVTTY OF THIS ACT AND NO MANUFACTURER, IMPORTER, TRADER, DISTRIBUTOR, WHOLESALER OR RETAILER OF SUCH DRUG OR MEDICINE SHALL SELL THE SAME AT A RETAIL PRICE EXCEEDING THE PRICE PREVAILING IMMEDIATELY BEFORE THE EFFECTIVITY OF THIS ACT.

FOR PURPOSES HEREOF, DRUGS AND MEDICINES SHALL INCLUDE BUT IS NOT LIMITED TO SINGLE- AND MULTI-INGREDIENT MEDICINES INCLUDED IN THE PHILIPPINE NATIONAL DRUG FORMULARY (PNDF) ESSENTIAL DRUG LIST AND SOLD UNDER THEIR GENERIC AND BRAND NAMES.

b) ***POWER TO INCLUDE OTHER DRUGSOR MEDICINES IN THE LIST SUBJECT TO PRICE REGULATION.*** **- UPON APPLICATION OR *MOTU PROPIO* WHEN THE PUBLIC INTEREST SO REQUIRES AND AFTER PROPER DETERMINATION, THE BOARD MAY ORDER THE INCLUSION OF DRUGS AND MEDICINES TO THE LIST SUBJECT TO PRICE REGULATION UNDER SECTION 26 HEREOF.**

c) ***POWER TO IMPLEMENT COST-CONTAINMENT AND OTHER MEASURES –***

1) **THE BOARD SHALL HAVE THE POWER TO DETERMINE THE FAIR PRICE OF DRUGS OR MEDICINES FOR PURPOSES OF PUBLIC HEALTH INSURANCE AND GOVERNMENT PROCUREMENT; AND**

2) **THE BOARD SHALL HAVE THE POWER TO IMPLEMENT ANY OTHER MEASURES THAT THE GOVERNMENT MAY AVAIL OF TO EFFECTIVELY REDUCE THE COST OF DRUGS OR MEDICINES THAT SHALL INCLUDE, BUT NOT LIMITED TO, COMPETITIVE BIDDING, PRICE-VOLUME NEGOTIATIONS, PARALLEL DRUG IMPORTATION AND OTHER APPROPRIATE MECHANISMS THAT INFLUENCE SUPPLY, DEMAND, AND EXPENDITURES ON DRUGS AND MEDICINES.**

3) **THE BOARD SHALL HAVE THE POWER TO MANDATE UP TO FIFTEEN PERCENT (15%) OF A DRUG OR MEDICINE PROCUREMENT OF LARGE PHARMACEUTICAL DISTRIBUTORS TO BE ALLOTTED TO A PARTICULAR GENERIC DRUG AND MEDICINE AND/OR REQUIRE PHARMACEUTICAL DISTRIBUTORS TO BUY OR OBTAIN UNDER ANY OTHER FORM OF ARRANGEMENTS, REASONABLE QUANTITY OF DRUGS AND MEDICINES PROCURED BY THE PHILIPPINE PHARMA PROCUREMENT, INC. SUCH DRUGS AND MEDICINES SHALL BE MADE AVAILABLE TO ALL BRANCHES OF THE SAID DISTRIBUTOR WHICH SHALL INFORM ANY BUYER OF THE AVAILABILITY, WITH CORRESPONDING PRICES, OF THESE DRUGS AND MEDICINES SO THAT THE BUYER MAY ADEQUATELY EXERCISE HIS/HER OPTION. THE LIST OF THESE DRUGS AND MEDICINES SHALL BE POSTED IN A CONSPICUOUS PLACE IN THE SAID BRANCHES.**

d) ***POWER TO IMPOSE ADMINISTRATIVE FINES AND PENALTIES.–*** **AFTER DUE NOTICE AND HEARING, THE BOARD SHALL HAVE THE POWER TO SUSPEND OR REVOKE THE LICENSE TO OPERATE (LTO), PROFESSIONAL OR BUSINESS LICENSE, AS THE CASE MAY BE, OF ANY PERSON, MANUFACTURER, IMPORTER, TRADER, DISTRIBUTOR, WHOLESALER, RETAILER, OR ANY OTHER ENTITY, AND IMPOSE ADMINISTRATIVE FINES IN SUCH AMOUNT AS IT MAY DEEM REASONABLE WHICH SHALL IN NO CASE BE LESS THAN TWO HUNDRED THOUSAND PESOS (P200,000.00) NOR MORE THAN FIVE MILLION PESOS (P5,000,000.00) FOR VIOLATIONS OF THE MAXIMUM RETAIL PRICE FIXED PURSUANT TO THIS SECTION.**

e) ***OTHER POWERS NECESSARY TO IMPLEMENT PROVISIONS OF THIS CHAPTER.*** **– THE BOARD SHALL EXERCISE SUCH POWERS AND FUNCTIONS AS MAY BE NECESSARY TO IMPLEMENT AND ENFORCE THE PROVISIONS OF THIS CHAPTER OF THIS ACT, INCLUDING THE POWER TO REQUIRE THE PRODUCTION AND SUBMISSION OF RECORDS, DOCUMENTS, BOOKS OF ACCOUNT, BILLS OF LADING, INPUT DOCUMENTS, RECORDS OF PURCHASE AND SALE, FINANCIAL STATEMENTS, AND SUCH OTHER DOCUMENTS,**

INFORMATION AND PAPERS AS MAY BE NECESSARY TO ENABLE THE BOARD TO CARRY OUT ITS FUNCTIONS, DUTIES AND RESPONSIBILITIES. ACCORDINGLY, EVERY DECEMBER 31st OF EVERY YEAR, EVERY MANUFACTURER, IMPORTER, TRADER, DISTRIBUTOR, WHOLESALER, AND RETAILER OF DRUG AND MEDICINE WHETHER INCLUDED IN OR EXCLUDED FROM THE LIST OF DRUGS AND MEDICINES THAT ARE SUBJECT TO PRICE REGULATION SHALL FURNISH THE BOARD A LIST, CONTAINING ON THE MINIMUM THE CORRESPONDING PRICES AND INVENTORY, OF ALL DRUGS AND MEDICINES IT MANUFACTURES, IMPORTS, TRADES, DISTRIBUTES, WHOLESALES, OR RETAILS AND ALL NECESSARY INFORMATION THAT THE BOARD MAY REQUIRE."

SEC. 4. Section 19 of Republic Act No. 9502 is hereby deleted and a new Section 19 is hereby Inserted to read as follows:

"SEC. 19. *MEETINGS OF THE BOARD* - THE BOARD SHALL HOLD REGULAR MEETING EVERY QUARTER AND SUCH SPECIAL MEETINGS AS MAY BE NECESSARY UPON THE REQUEST OF THE CHAIRMAN OR UPON THE REQUEST OF AT LEAST TWO (2) OF ITS MEMBERS. THE BOARD MAY INVITE CONCERNED PUBLIC AND PRIVATE AGENCIES OR ENUTIES TO PARTICIPATE, COMPLEMENT, AND ASSIST IN THE PERFORMANCE OF ITS FUNCTIONS."

SEC. 5. Section 20 of Republic Act No. 9502 is hereby deleted and a new Section 20 is hereby inserted to read as follows:

"SEC. 20. *CREATION OF A SECRETARIAT.* – THERE IS HEREBY CREATED A SECRETARIAT TO BE HEADED BY AN EXECUTIVE DIRECTOR TO SUPPORT THE BOARD IN CARRYING OUT ITS FUNCTIONS. THE BOARD SHALL PROVIDE FOR THE INSTITUTIONAL SETUP, QUALIFICATIONS, AND COMPENSATION OF THE EMPLOYEES COMPOSING THE SECRETARIAT IN ACCORDANCE WITH EXISTING CIVIL SERVICE AND CAREER EXECUTIVE SERVICE RULES AND REGULATIONS AND CONSISTENT WITH THE PROVISION OF THE SALARY

STANDARDIZATION LAW FOR GOVERNMENT PERSONNEL, AND DETERMINE THE SIZE AND COMPOSITION OF THE SECRETARIAT."

SEC. 6. Section 21 of Republic Act No. 9502 is hereby deleted and a new Section 21 Is hereby inserted to read as follows:

"SEC. 21. *PROCEDURES FOR INQUIRIES, STUDIES, HEARINGS, INVESTIGATIONS, AND PROCEEDINGS.* —ALL INQUIRIES, STUDIES, HEARINGS, INVESTIGATIONS AND PROCEEDINGS CONDUCTED BY THE BOARD SHALL BE GOVERNED BY THE RULES ADOPTED BY THE BOARD, AND IN THE CONDUCT THEREOF SHALL NOT BE BOUND BY THE TECHNICAL RULES OF EVIDENCE."

SEC. 7. Section 22 of Republic Act No. 9502 is hereby deleted and a new Section 22 is hereby inserted to read as follows:

"SEC. 22. *EFFECIVITY AND REVIEW OF THE DECISIONS OR ORDERS OF THE BOARD.* — ALL DECISIONS OR ORDERS OF THE BOARD PURSUANT TO SECTION 18 HEREOF, SHALL BE IMMEDIATELY OPERATIVE.

A PARTY ADVERSELY AFFECTED BY A DECISION, ORDER OR RULING OF THE BOARD MAY, WITHIN THIRTY (30) DAYS FROM NOTICE OF SUCH DECISION, ORDER OR RULING, OR IN CASE OF A DENIAL OF A MOTION FOR RECONSIDERATION THEREOF, WITHIN FIFTEEN (15) DAYS AFTER NOTICE OF SUCH DENIAL, FILE AN APPEAL WITH THE COURT OF APPEALS, WHICH SHALL HAVE JURISDICTION TO REVIEW SUCH DECISION, ORDER OR RULING.

THE FILING OF A PETITION FOR A WRIT OF CERTIORARI OR OTHER SPECIAL REMEDIES IN THE SUPREME COURT SHALL IN NO CASE SUPERSEDE OR STAY ANY DECISION, ORDER OR RULING OF THE BOARD, UNLESS THE SUPREME COURT SHALL SO DIRECT, AND THE PETITIONER MAY BE REQUIRED BY THE

SUPREME COURT TO GIVE BOND IN SUCH FORM AND OF SUCH AMOUNT AS MAY BE DEEMED PROPER."

SEC. 8. Section 26 of Republic Act No. 9502 is hereby amended to read as follows:

"SECTION 26. ***Display of Maximum Retail Price Fixed [and approved by order of the President of the Philippines] by the BOARD for Drugs or Medicines Subject to Price Regulation.*** – (a) Within a reasonable period as may be determined by the [Secretary of the Department of Health] BOARD, and: *Provided*, That it conforms to existing drug product labeling requirements, every manufacturer, importer, distributor, wholesaler, trader, or retailer of a drug and medicine Intended for sale shall display the retail price which shall not exceed the maximum retail price fixed by the Board. The maximum retail price shall be printed on the label of the immediate container of the drug and medicine and the minimum pack thereof offered for retail sale with the words **"RETAIL PRICE NOT TO EXCEED"** preceding It, and **"UNDER DRUG PRICE REGULATION"** on a red strip **PROVIDED THAT IN 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 [Secretary of the Department of Health] **BOARD** from time to time, every manufacturer, importer, or trader shall issue a price list to wholesalers, distributors, retailers and to the [Secretary of the Department of Health] **BOARD**, indicating the retail price, the maximum retail price, and such other information as may be required by the [Secretary of the Department of Health] **BOARD**.

SEC. 9. A new Section 26-A is hereby inserted to read as follows:

"SECTION 26-A. ***Display of Price and Price List of Drugs or Medicines Excluded from the List Subject to Price Regulation.*** – Every manufacturer. Importer, trader, distributor, wholesaler, or retailer of

a drug or medicine excluded from the list subject to price regulation under Section 23 hereof shall display in indelible print mark on the label of the immediate container of the drug or medicine and the minimum pack thereof offered for retail sale, the words **"NOT UNDER PRICE REGULATION"** on green strip.

SEC. 10. Section 28 of R.A 9502 is hereby deleted and a new Section 28 is hereby inserted to read as follows:

"Sec. 28. ***Creation of a Trust Fund*** - A trust fund in the amount of Five Hundred Million Pesos (P 500,000,000.00) is hereby established to be administered by the Board. The fund shall serve as revolving fund to be utilized for parallel drug importation and other procurement arrangements to lower the cost of drugs and medicines through the Philippine Pharma Procurement, Inc."

SEC. 11. Section 30 of R.A. 9502 is hereby amended to read as follows:

"SEC. 30. Reportorial and Public Notice Requirements. — (a) The [Secretary of the Department of Health] **BOARD** shall submit a bi-annual Monitoring Report of its performance on the implementation of this Act to the Office of the President. This report submitted to the Office of the President shall be published in a newspaper of general circulation within thirty (30) days upon submission.

xxx

(c) The order of the [President of the Philippines] **BOARD** imposing maximum retail prices on drugs and medicines, including the conditions implementing it, shall be published within fifteen (15) days from issuance in at least two (2) newspapers of general circulation. All wholesalers, manufacturers, distributors, importers, or traders shall have a copy of the order of the [President of the Philippines] **BOARD** and provide the same to their clients and customers for every transaction.

xxx"

SEC. 12. *Appropriations*. – The amount of Five Hundred Million Pesos (P500,000,000.00) as a trust fund under Section 28 hereof and the amount necessary

to carry out the functions of the Board shall be included in the annual General Appropriations Act.

SEC. 13. *Separability Clause*. – Should any provision herein be declared unconstitutional, the same shall not affect the validity of other provisions of this Act.

SEC. 14. *Repealing Clause*. – All laws, decrees, orders, rules and regulations or other issuances or parts thereof inconsistent with the provisions of this Act are hereby repealed or modified accordingly.

SEC. 15. *Effectivity*. – This Act shall take effect fifteen (15) days after its publication in the *Official Gazette* or in any two (2) newspapers of general circulation in the Philippines.

Approved,