FOURTEENTH CONGRESS OF THE)
REPUBLIC OF THE PHILIPPINES)
First Regular Session **)**

SENATE

S. BILL NO. 755

Introduced by Senator Antonio F. Trillanes IV

EXPLANATORY NOTE

The very high cost of medicines in the Philippines is a common complaint of citizens from all walks of life and a perennial issue among policy makers, local and foreign drug companies and medical practitioners. A comparison of the prices of medicines obtained from the Department of Health (DOH) reveals that retail prices of commonly-used drugs in the Philippines are one of the highest, if not the highest, in Asia.

One of the major factors affecting the cost of medicines in the Philippines is the country's heavy dependence on imported basic raw materials. Our drug industry does not have the sufficient capacity to produce the active substances or basic raw materials used in drug manufacture. Except for a few firms, most of the players in the industry merely buy finished bulk chemicals from abroad and re-compound, reformulate and/or repackage them into finished products.

Another related factor is the common and well-known practice of *"transfer pricing"* prevailing in the industry that begins from the moment raw materials are acquired until the phase finished products are distributed in the market. Under this practice, a multinational company inflates the cost of raw materials and sells the to another drug company, either a subsidiary or a holder of a voluntary or compulsory license, at a price higher than that prevailing in the world market. Almost fifty percent (50%) of the cost of branded drugs in the local market are artificially inflated due to *"transfer pricing"*.

Republic Act No. 8203, otherwise known as the *"Special Law on Counterfeit Drugs"*, classifies, among others, an unregistered imported drug product, except drugs brought into the country for personal use, as counterfeit drugs. Because of this, drug distributors, specifically drug importers, resort to exclusive distributorship that prevents importation of the same brand by companies other than those that have Foreign Agency Agreement with multinational suppliers (BFAD Administrative (Order 56, 1989). The Bureau of Food and Drug's (BFAD) exclusive distributorship policy allows drug manufacturers to dictate drug prices, enabling them to monopolize the market by preventing parallel importation by other companies.

Under present conditions, Filipinos also do not have much choice as to what drugs to buy because drug companies have found a way to go around the *"Generics Law"* (RA 6675). Drug companies, who have recognized a long time ago the significant role of the *prescribers* in their marketing strategies, offer doctors attractive incentives in exchange for pushing their products to the consumers. No penal sanction in R.A. 6675 or even from the Professional Regulation Commission (PRC) is meted for the highly unethical practice of accepting gifts, rewards and incentives by medical practitioners for prescribing certain drugs.

The industry players' high expenditures on marketing, advertising and promotion all the more contribute to the high cost of medicines. The Generics Law has become ineffective in the sense that it fails to give consumers any choice or alternative of cheaper drugs because compliance to generic prescription is not strictly enforced and/or monitored.

Another factor that slows down the full implementation of the Generics Law is the long period that drug manufacturers have to wait for a patent to expire before it is allowed to manufacture cheaper drug products. R.A. 8293 otherwise known as the *"Intellectual Property Code of the Philippines"*, sets the term of potential in twenty (20) years from the filing of the application, in the Philippines. Amending the law by exempting pharmaceutical products will shorten the patent period and once those brand names become off patent, compulsory licensing should allowed.

Moreover, there is that prevailing perception among consumers of the low quality - as to safety and efficacy - of generic products in the local market. The proliferation of sub-standard and fake drugs, and the lack of administrative and technical capability and/or sufficient resources of the Department of Health (DOH) and Bureau of Food and Drug (BFAD) to conduct laboratory tests on newly produced drugs have raised doubts on the efficacy of generic drugs. This puts the consumers at the mercy of expensive branded products.

The *Pharmacy Law* as amended in 1978 needs to be reviewed to make it more relevant to present times. Liberalization of trade outlets will allow the selling of over-the-counter drugs in supermarkets and other similar establishments thereby making them accessible to the masses. As it is now, going to an accredited drug outlet (which could be few and far between, particularly in the rural areas) entails transportation expenses that add up to the total cost of the machine.

In the meantime, thousands of Filipinos there are literally dying without receiving proper medication and treatment because the medicines they need have been priced out of their reach.

There are, however, simple measures that could be adopted which, together, could significantly lower the cost of medicines. These include setting stiffer penalty for non-compliance to generic prescription, multinational corporations (MNC's) mandatory disclosure of selling prices in different countries, liberalization of trade outlets, amending the policy on granting distributorship, amending the provision on patents, and conducting congressional oversight on the implementation of the Generics Law and the National Drug Policy.

This bill is being filed to put into place these small measures which, together, are intended to significantly bring down the price of medicines. It is the earnest belief of the author that the passage of this bill will greatly contribute to the reduction of the price of pharmaceutical products in the country to more realistic and affordable levels.

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

ANTONIO F. TRILLANES IV

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

SENATE

S. BILL NO. 755

Introduced by Senator Antonio F. Trillanes IV

AN ACT
PRESCRIBING SPECIAL MEASURES TO LOWER THE PRICE OF MEDICINES AND OTHER RELATED PURPOSES.

BE IT ENACTED by the Senate and the House of Representatives of the Philippines in Congress assembled.

SECTION 1. *Short Title*. – This Act shall be known as the *"Affordable Medicines Act"*.

SEC. 2. *Declaration of Policy*. - It is hereby declared the policy of the State:

a. To promote, encourage and require the use of generic terminology in the importation, manufacture, distribution, marketing, advertising and promotion, prescription, and dispensing of drugs;

b. To emphasize the moral obligation of medical and para-medical practitioners relative to their prescription of drugs and/or medical advise;

c. To ensure the adequate supply of drugs with generic names at the lowest possible cost and the availability of over-the- counter drugs in establishments other than accredited drug outlets;

d. To promote drug safety and efficacy simultaneous with the full implementation of the Generics Law (RA 6675);

e. To set the patent period for pharmaceutical products at twenty (20) years from date of the filing of the original application, regardless of the place of application; and

f. To amend the policy on granting distributorship to allow parallel imports of pharmaceutical products.

SEC. 2. ***Strengthening the Generics Law.*** - Section 12 of Republic Act No. 6675 otherwise known as the *"Generics Act of 1988"* is hereby amended to read as follows:

"Sec. 12. Penalty. - A) Any person who shall violate Section 6 (a) or 6(b) of this Act shall suffer penalty graduated hereunder, viz:

a. for the first conviction, he shall suffer the penalty of reprimand which shall be officially recorded in the appropriate books of the Professional Regulation Com-mission.

b. for the second conviction, the penalty of fine in the amount of not less than [two thousand pesos] TEN THOUSAND PESOS (P10,000.00) but not exceeding [five thousand pesos] TWENTY FIVE THOUSAND PESOS (P25,000.00) at the discretion of the court.

c. for the third conviction, the penalty of fine in the amount of not less than [five thousand pesos] twenty five thousand (P25,000.00) but not exceeding [ten thousand pesos] FIFTY THOUSAND PESOS (P50,000.00) and suspension of his license to practice his profession for SIXTY (60) days at the discretion of the court.

d. for the fourth and subsequent convictions, the penalty of fine of not less than [ten thousand pesos] ONE HUNDRED THOUSAND PESOS (P100,000.00) and suspension of his license to practice his profession for one year or longer at the discretion of the court."

SEC. 4. ***Amending the Pharmacy Law.*** - Section 2 of PD 1363 is hereby amended to read as follows:

"Sec. 25. Sale of medicine, pharmaceuticals, drugs and devices. -- No medicine, pharmaceutical or drug, except for those which are non-prescription or over-the-counter of whatever nature and kind, or device shall be compounded, dispensed, sold or resold, or otherwise be made available to the

consuming public except through a prescription drugstore or hospital pharmacy, duly established in accordance with the provisions of this Act. ***NON-PRESCRIPTION OR OVER-THE-COUNTER DRUGS MAY BE SOLD IN THEIR ORIGINAL PACKAGES, BOTTLES OR CONTAINERS OR IN SMALL QUANTITIES NOT ON THEIR ORIGINAL CONTAINERS TO THE CONSUMING PUBLIC THROUGH SUPERMARKETS, CONVENIENCE STORES AND OTHER RETAIL ESTABLISHMENTS.***

"Pharmaceutical, drug or biological manufacturing establishment, importers and wholesalers of drugs, medicines or biological products, shall not sell their products for re-sale except only to retail drugstores, hospital pharmacies or to other drug wholesalers under the supervision of registered pharmacists, AND SUPERMARKETS, CONVENIENCE STORES AND OTHER RETAIL ESTABLISHMENTS FOR OVER-THE-COUNTER DRUGS duly established and licensed under the Retail Trade Law."

SEC. 5. ***Disclosure of Selling Prices by Multinational Corporations (MNCs).*** - The Department of Health (DOH) shall issue an administrative order requiring multi-national drug companies and/or their local subsidiaries, agents, licensees or representatives to disclose on a semestral basis the selling prices of the drug they manufacture and/or distribute in the Philippines vis-a-vis prices in other countries. Sanctions for non-compliance shall be provided for in the DOH administrative order.

SEC. 6. ***Parallel importation and distribution.*** - Parallel importation shall be allowed by allowing more than one (1) Philippine importer enter into a Foreign Agency Agreement with a foreign supplier. BFAD Administrative Order No. 56, Series of 1989 shall be amended to conform to the requirement of this provision. In cases when the price difference between the local selling price of a drug or pharmaceutical product exceeds by twenty percent (20%) the selling price of the same product in another country, the DOH is mandated and authorized to import and/or authorize the importation of the said drug or pharmaceutical product by a duly licensed distributor. The DOH and/or said drug distributor may then distribute said drug or pharmaceutical product all over the country in the same manner as distributor authorized by the manufacturer/patentee of said products may do so.

SEC. 7. *Patents for Pharmaceutical Products.* - Section 54 of R.A. 8293, otherwise known as the *"Intellectual Property Code of the Philippines"*, is hereby amended as follows:

> *"Sec. 54. Term of Patent. - The term of a patent shall be twenty (20) years from the filing date of the application EXCEPT IN THE CASE OF PHARMACEUTICAL PRODUCTS WHICH SHALL BE TWENTY (20) YEARS FROM THE DATE OF FILING OF THE ORIGINAL APPLICATION FOR THE SAME, BE IT HERE IN THE PHILIPPINES OR OUTSIDE THE PHILIPPINES."*

SEC. 8. *Congressional Oversight on Implementation of Generics Law and National Drug Policy.* - Congress shall constitute an Oversight Committee to assess and monitor the implementation of the Generics Law and National Drug Policy and to recommend measures that would strengthen and enforce the same. Evaluation and assessment of the implementation of National Drug Policy shall beef up the administrative and technical capability of Department of Health (DOH) and Bureau of Food and Drugs (BFAD) in conducting laboratory tests to minimize, if not totally erase, doubts on the efficacy of generic drugs resulting to their low utilization.

SEC. 9. *Implementing Agency.* - The Department of Health shall be the main agency to enforce the provisions of this Act. It shall likewise promulgate the rules and regulations necessary to effectively implement the provisions of this Act.

SEC. 10. *Separability Clause.* - If for any reason any provision of this Act is declared unconstitutional or invalid, the remainder or any provisions hereof not affected thereby shall remain in force and effect.

Sec. 11. *Repealing Clause.* - The provisions of any law, executive orders presidential decrees or other issuance inconsistent with this Act are hereby repealed or modified accordingly.

Sec. 12. *Effectivity.* - This Act shall stake effect fifteen (15) days after its complete publication in two (2) newspapers of general circulation.

Approved,