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

S E N A T E
S. NO. 1

Introduced by Senator Flavier

EXPLANATORY NOTE

The high cost of drugs 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 drug prices obtained from the Department of Health (DOH) reveals that retail prices of commonly used drugs are much higher in the Philippines than in most Asian countries

One of the major factors affecting the cost of drugs in the Philippines is the heavy dependence on imports. Our drug industry does not yet have sufficient capacity to produce the active substances of basic raw materials used in drug manufacture except for a few firms. Most of the players in the industry merely buy finish bulk chemicals from abroad and then re-compound, reformulate and/or package them into finish 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 and sells them to a drug company, either a subsidiary or a holder of a voluntary or compulsory license, at a price higher that that prevailing in the world market. Almost fifty percent (50%) of the cost of branded drugs in the local market are "transferred price".

R.A.8203, otherwise known as the "Special Law on Counterfeit Drugs" classifies, among others, an unregistered imported drug product, except drugs brought into this country for personal use, as counterfeit drugs. Because of this drug distributors specifically drug importers resort to exclusive distributorship that prevents importations of the same brand by companies other than those that have foreign Agency Agreements transnational suppliers (BFAD Administrative order 56.S. 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.

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 Generic Law (R.A.6675). Drug companies, recognizing the significant role of the prescribers in their marketing strategies, offer doctors attractive incentives in exchange for pushing their product to the consumers. No penal sanctions on R.A. 6675 on either from the professional Regulation Commission (PRC) is meted for the highly unethical practice of accepting gifts, rewards and incentives by medical practitioner for prescribing certain drugs. The industry player's high expenditure on marketing advertising and promotion all the more contribute to the high cost of drugs. The Generic Law has been ineffective in a sense that it has failed to give consumers any choice

or alternative because compliance with generic prescription is not strictly enforced and 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" grant the term of a patent twenty (20) years from the filing of the application of the Philippines. Amending the law exempting pharmaceutical products will shorten the patent period and once these brand names become off patent, compulsory licensing should be allowed.

Moreover, there is that prevailing perception among consumers of the low quality- as to safety and efficacy-of generic products of the local market. The proliferation of sub-standard and fake drugs, and the lack of administrative and technical capability of the Department of Health (DOH) and Bureau of Food and Drug (BFAD) to conduct laboratory tests on newly-produced drugs have raised doubts as to 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. Liberation 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 entails transportation expenses that add up to the total cost of the medicine.

The World Health Organization identifies the determinant of drug pricing as cost of production, discovery, distribution and dispensation. These are mostly given factors that we can do nothing about. Yet there are special measures that would lower the cost of medicines. These include setting stiffer penalty for non-compliance with generic prescription requirements, multinational corporations (MNCs) disclosure of selling prices in different countries, liberation of trade outlets, amending the policy on granting distributorship, amending the provision on patents and conducting congressional oversight on the implementation of the Generic Law and national drug policy.

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

JUAN M. FLAVIER
SENATOR

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

S E N A T E

S. NO. 1

Introduce by Senator Flavier

AN ACT
PRESCRIBING SPECIAL MEASURES TO LOWER THE COST OF MEDICINES, AND FOR OTHER PURPOSES

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

SECTION 1 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 and other drug preparations;

b) To emphasize the moral obligation of medical and para-medical practitioners relative to their drug prescription or 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 Generic Law;

e) To set the patent for pharmaceutical products at twenty (20) years from application, regardless of the place of application; and to amend the policy on granting distributorship to allow parallel imports.

SEC. 2. Strengthening the Generic Law. – Section 12 of the Generic Act of 1998 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 fist conviction, he shall suffer the penalty of reprimand, which shall be officially recorded in the appropriate books of the Professional Regulation Commission;

b) For the second conviction, the penalty of fine in the amount of not less than [two thousand pesos] TWENTY FIVE THOUSAND PESOS, at the discretion of the courts;

c) For the third conviction, the penalty of fine in the amount of not less than [five thousand pesos] TWENTY FIVE THOUSAND PESOS and suspension of his license to practice his profession for [thirty] SIXTY days at the discretion of the courts;

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

SEC. 3. Amending the Pharmacy Law. Section 2 of P.D. 1363 is hereby amended to read as follows:

"Sec. 25. Sale of medicines, 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 provision of this Act. NON-PRESCRIPTION OR OVER-THE-COUNTER DRUGS MAY BE SOLD IN THEIR ORIGINAL PACKAGES BOTTLES CONTAINERS OR IN SMALL QUANTITIES NOT IN THEIR ORIGINAL CONTAINERS TO THE CONSUMING PUBLIC THROUGH SUPERMARKETS AND OTHER ESTABLISHMENT.

"Pharmaceutical, drug or biological manufacturing establishments, importers and wholesalers of drugs, medicine or biological products, shall not sell their products for re-sale except only to retail drugstore, hospital pharmacies or to other drug wholesalers under the supervision of registered pharmacist, and supermarkets and small stores for over-the counter drugs, duly establish and licensed under the retail Trade Law.

SEC. 4. Drug Price Selling Index –The Department of Health (DOH) shall issue an Administrative Order requiring drug companies to disclose the manufacturing cost and selling price of pharmaceutical products listed in the National Drug Formulary. The DOH will include the declared costs and prices in an annual bulletin with price comparisons from other ASEAN Countries. *Sanction for non-compliance* shall be provided for in the DOH administrative order.

The Drug Price Selling Index will serve as the Philippine Health Insurance Corporation's and other national and local government agencies' reference for the official price of pharmaceutical products listed in the National Drug Formulary. It is also mandated to serve as the official reference for the pharmaceutical purchases of all government agencies and basis for the COA (Commission on Audit) in auditing of all state supported medicine expenditures.

SEC. 5. Distributorship – parallel importation shall be allowed by allowing *more than one (1) Philippine importer* to enter into foreign Agency Agreement with a foreign supplier. BBFAD Administrative Order No. 56, Series of 1989 shall be amended to conform to the requirement of this provision.

SEC. 6. 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 patent shall be twenty (20) years from the filing date of application. EXCEPT FOR PHARMACEUTICAL PRODUCTS WHICH SHALL BE TWENTY (20) YEARS FROM THE FILING DATE OF APPLICATION. BE IT HERE IN THE PHILIPPINES OR OUTSIDE THE PHILIPPINES."

Sec. 7. False claims to promote food supplements. -Any law to the contrary notwithstanding, any product approve by BFAD as food supplement shall carry the words as "AS FOOD SUPPLEMENTS ONLY" printed in parenthesis below the BFAD Registration Number, in all its advertisements, whether print, electronic or broadcast.

In addition, in cases where unfounded claims are being publicly made regarding such food supplement, the BFAD may also require all its advertisement to carry other specific disclaimer, for the protection and information of the public.

SEC. 8. Congressional Oversight on Implementation of Generics Law and National Drug Policy- Congress shall constitute an Oversight Committee to assess and monitor the implement of the Generic Law and National Drug Policy, and to recommend measures that would strengthen and enforce the same. Evaluation and assessment of the implementation of the National Drug Policy shall beef up the administrative and technical capabilities of the Department of Health and Bureau of Food and Drugs (BFAD) in the conduct of laboratory test to minimize, if not erase, doubts on the efficacy of generic drugs.

SEC. 9. Implementing Agency. – The Department of Health (DOH) shall be the main agency tasked to enforce the provision of this Act. It shall, likewise promulgate the rules and regulation necessary to effectively implement the provision of this Act.

SEC. 10. Separability Clause. – If any provision of this Act is declared invalid the remainder or any provision hereof not affected thereby shall remain in full force and effect.

SEC. 11. – Repealing Clause. – The provision of any law, Executive Orders, Presidential Decrees, and other issuance inconsistent with this Act are hereby repealed on modified accordingly.

SEC. 12. – This Act shall take effect fifteen (15) days after its complete publication in the Official Gazette or in at least two national newspapers of general circulation, which ever comes first.

Approved,