

Republic of the Philippines
HOUSE OF REPRESENTATIVES
Quezon City

FOURTEENTH CONGRESS
First Regular Session

HOUSE BILL No. 2492

Introduced by Representatives SATUR C. OCAMPO, TEODORO A. CASIÑO, LIZA L. MAZA,
CRISPIN B. BELTRAN and LUZVIMINDA C. ILAGAN

EXPLANATORY NOTE

Health is a basic human right. The Constitution mandates the State “to adopt an integrated and comprehensive approach to health development which shall endeavor to make essential foods, health and other social services available to all the people at affordable cost.” Providing for the health of the people is the responsibility of the State.

The exorbitant medicine prices exacerbate the deplorable condition of the country’s health care system. While essential and life-saving drugs exist and more are being discovered to treat emerging and re-emerging diseases, millions of Filipinos die due to infectious but treatable diseases.

Medicines should be within everyone’s reach. But safe, affordable, necessary and essential medicines remain out of reach to millions of people. There are about 25,000 medicines in the market yet more than 70% of the Filipino population have no access to them. Based on the studies conducted by the National Drug Policy Program group of the Department of Health (NDPP-DOH), prices of medicines in the Philippines are the highest in the ASEAN region, which are 250% to 1,600% higher than in other countries as of 2002.

The domestic drug industry is controlled by profit-oriented transnational drug cartels. Transnational corporations (TNCs) command 72% to 80% of the market to a high of 75% to 90%. The remaining 32% is shared by both foreign and local players of the industry, only 12% to 15% of which is Filipino-owned. *However, a full-fledged Filipino drug industry does not exist since it does not have a petrochemical industry to process the basic raw materials for medicines. The local drug industry does not manufacture finished products from raw materials but is limited to formulating, processing, packaging and distributing the drug products of TNCs, with some firms functioning merely as product licensees of the multinationals.* It is only in retailing that Filipino-owned companies top the chart.

Additionally, the heavy dependence on imported raw materials of local manufacturers in the Philippines contributes to the exorbitant prices of drug products. Under the World Trade Organization’s (WTO) trade liberalization scheme, production quality standards have been “globalized” to facilitate smoother trade between countries, including medicines and drug products. The latter has spawned problems of substandard and fake drugs, and influx of cheaper imports and toll-manufactured

products that virtually kill local industries as it has become more viable to import than manufacture.

Government aggravates the problem of lack of safe, affordable and accessible medicines by not controlling the prices of drugs, leaving profit-oriented TNC drug companies to dictate prices. The government's lack of political will to effectively implement the already weakened Generics Law or RA 6675 further makes affordable medicine inaccessible.

Graft and corruption also contribute to high prices and unavailability of drugs. According to Philippine Center for Investigative Journalism (PCIJ), about 70% of local health funds go to corruption.

TNCs are allowed by government to dictate the prices of medicines through transfer pricing and price fixing by selling raw materials to a local firm at a price higher than the prevailing price in the world market (transfer pricing) and by conniving with each other in selling their products at an agreed price (price fixing). Transnational drug companies also spend more on advertising and promotion than on research and development (R&D) accounting for 40% to 60% of sales while research and development (R&D) only accounts for 10% to 20% of the same. Local firms also pay royalties to their mother companies aside from dividends, and technical and other fees.

Based on the above, a price regulatory body, with active consultation of and participation from stakeholders becomes imperative.

The WTO agreement on Trade Related Intellectual Property Rights (TRIPS) sets enforceable global rules affecting the protection of patents, copyright and trademarks for drugs, international pharmaceutical trade, regulatory requirements, access to information and prices of drugs. Its effects as perpetrated by TNCs extend to new areas, such as living things virtually legalizing bio-piracy or the theft of biodiversity denying the Filipinos their own biological resources, and undermining the indigenous knowledge, bio-safety and access to health care of developing countries. TRIPS enforce the patenting of all medicines from 17 to 20 years. According to the World Health Organization (WHO), increased patent protection leads to higher drug prices. Until the patents expire, people have no choice but to buy medicines monopolized by TNCs, denying patients cheaper alternatives. This assures the TNCs' acquisition of super profits and ensures the patent holder will recover its investments. Patents allow TNCs to obtain exclusive rights to market their products at prices they dictate.

Government should immediately address the problem of making medicines available to the public in sufficient quantities and quality, and at lower and affordable prices. The government must provide greater support to local drug companies by giving them incentives such as tax holidays, and reduction of taxes leading to its 100% elimination to lower their production costs and assure an adequate level of price competition. It should also enforce outright price control of essential drugs, impose sanctions and penalties on firms overpricing their medicines, and insist on the inspection of accounting books of TNCs and local drug companies to protect the consumers instead of abolishing price controls. The pharmaceutical industry must not be left to market forces because medicines are integral aspects of the health service system.

Compulsory licensing for medicines must be part of the patent law. The government compels a company to grant license to non-patent holders to produce the drug even if it is still under patent when public interest and public health requires so. The patent holder receives adequate remuneration for the license and is assured that distribution of the drug is limited to the domestic market. This will ensure affordability and availability of essential drugs.

Parallel importation of medicines is a scheme where similarly branded drugs that are cheaper in other countries are imported and introduced in the local market. It temporarily responds to one of the problems in the pharmaceutical sector – i.e. exorbitant prices of medicines – and temporarily makes certain highly priced medicines available to the people. However, it is a palliative measure and a stop-gap response that does not answer the real problem of the local drug industry. It deepens the local industry's dependence on importation, which, in the first place, is one of the reasons why prices are high. The monopoly of transnational drug companies over the Philippine pharmaceutical market, the country's scant resources and the absence of a genuine national industrialization program will eventually make importation of even low-cost generic drugs difficult. Hence, parallel importation should not be the primary strategy in making essential and life-saving medicines affordable and accessible to the public, especially to the poorer segments of the society.

The key to safe and affordable medicines is a nationalized drug industry, an industry based on the willingness to serve the people and not satisfy the thirst for profit. A local industry that can manufacture its own products is the only way to lower the prices of medicines.

TNC monopoly control in the local drug industry must end. The government must assist local drug manufacturers build up their research and development capabilities in providing cheaper alternative medicines to tap abundant indigenous plants as raw materials, and improve productivity, efficiency and sustainability of Philippine pharmaceutical manufacturing sector. Instead of promoting importation and liberalization, the government must work towards a self-reliant drug industry, and strengthen the production and manufacturing capabilities of the national drug industry that is responsive to the medical and health needs of the people and where service to the needy takes precedence over profit.

The bill provides for the creation of a Drug Regulatory Board which shall have the power to fix the maximum retail prices formulation of drugs, direct manufacturers of bulk drugs formulations to sell bulk drugs to other manufacturers, and determine the list of selected essential medicines for selective parallel importation. Compulsory licensing is allowed by amending sections of Republic Act 8293 or the Intellectual Property Code of the Philippines. The bill likewise grants incentives to the local pharmaceutical industry through productivity support, tax incentives, and technical assistance, among others, as initial measures in laying the ground for the development of the country's own pharmaceutical industry.

In view of the foregoing, approval of this bill is immediately sought.

Approved,

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Bayan Muna Party-List

TEODORO A. CASIÑO
Bayan Muna Party-List

LIZA L. MAZA
Gabriela Women's Party

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Introduced by Representatives SATUR C. OCAMPO, TEODORO A. CASIÑO, LIZA L. MAZA,
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**AN ACT REGULATING DRUG PRICES AND PROVIDING SUPPORT FOR LOCAL DRUG
MANUFACTURERS FOR THE PRODUCTION OF LOW COST, SAFE AND QUALITY MEDICINE, AND
FOR OTHER PURPOSES**

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

**ARTICLE I
GENERAL PROVISIONS**

SECTION 1. *Short Title.* – This Act shall be known as the “Low Cost, Safe and Effective Medicines Act of 2007.”

SEC. 2. *Declaration of Policy.* – The Philippine Constitution declares as policy of the State to “adopt an integrated and comprehensive approach to health development which shall endeavor to make essential goods, health and other social services available to all people at affordable cost,” (Article XIII, Sec. 11) and to “protect and promote the right to health of the people and instill health consciousness among them.” (Article II, Sec. 15).

Article II, Section 19 of the Constitution further stipulates that “the State shall develop a self-reliant and independent national economy effectively controlled by Filipinos”.

Article XII, Section 1 elaborates on the economic objectives of the Constitution: “The State shall promote industrialization and full employment based on sound agricultural development and agrarian reform, through industries that make full and efficient use of human and natural resources, and which are competitive in both domestic and foreign markets. However, the State shall protect Filipino enterprises against unfair foreign competition and trade practices”.

In addition, Article II, Section 20 of the Charter states that the “State recognizes the indispensable role of the private sector, encourages private enterprise, and provides incentives to needed investments.” Article XII, Section 12 qualifies such government support to the private sector in terms of preferential treatment for local and Filipino industries: “the State shall promote the preferential use of Filipino labor, domestic materials and locally produced goods, and adopt measures that help make them competitive”. The State should likewise “regulate or prohibit monopolies when the public

interest so requires. No combination in restraint of trade or unfair competition shall be allowed.” (Article XII, Section 19).

It is hereby declared the policy of the State to:

- (a) Protect, promote and ensure availability of health services to all the people at affordable cost;
- (b) Strengthen the local drug industry by giving incentives and developing a self-reliant and independent drug and pharmaceutical industry effectively controlled by Filipinos;
- (c) Prioritize research and development (R&D) for new medicines for tropical, infectious diseases, and maintenance medicines for chronic diseases;
- (d) Adopt and implement economic and fiscal policies that shall strengthen the position and enhance the competitiveness of locally-owned drug establishments;
- (e) Establish and maintain an effective drug regulatory system responsive to the country’s health needs and problems;
- (f) Ensure the strict and full implementation of the Generics Act of 1998, from prescribing, dispensing, manufacturing and advertising, and particularly the compliance of key players in the pharmaceutical industry and in the health delivery system of the country;
- (g) Institute appropriate penalties for illegal price manipulation and other violations of this Act;
- (h) Embark on short-term doable options to ease the immediate problem of making medicines available to the public in sufficient quantities and quality, and at lower and affordable prices; and
- (i) Provide technological and infrastructure assistance to local pharmaceutical establishments to develop a truly Filipino drug industry responsive to the medical and health needs of the people.

SEC. 3. *Definition of Terms.* – For purposes of this Act, the term:

- (a) “Local Pharmaceutical Industry” means any establishment involved in the manufacture, importation, repacking and/or distribution of drugs or medicines whose capital structure is 100% Filipino owned;
- (b) “Drug Establishment” means any organization or company involved in the manufacture, importation, repacking and/or distribution of drugs or medicines;
- (c) “Pharmaceutical Product” means any pharmaceutical or biological product containing active ingredients responsible for its desired effect intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease or to

affect the structure or function of the body of man or animal or substances intended for use as a component of the same;

- (d) “Essential Drugs” means selected drugs and medicines listed in the Essential Drugs List or National Drug Formulary prepared and periodically updated by the Department of Health on the basis of health conditions in the Philippines, as well as internationally accepted criteria;
- (e) “Generic Drugs” are drugs not covered by patent protection and which are labeled solely by their international nonproprietary or generic names;
- (f) “Bulk Drug” means any pharmaceutical, chemical, biological or plant product including its salts, esters, stereoisomer, and derivatives, conforming to pharmacopoeia or other standards and used as such or as an ingredient in any formulation;
- (g) “Brand Name” refers to the proprietary/trade name assigned to the product by the drug establishment;
- (h) “Generic Name” refers to the identification of drugs and medicines by their scientifically and internationally recognized active ingredient as determined by the Bureau of Food and Drugs;
- (i) “Drug Manufacturer” means any establishment engaged in operations involved in the production of a drug, including propagation, processing, compounding, finishing, filling, packing, repacking, altering, ornamenting and labeling with the end in view of storage, distribution or sale of the product;
- (j) “Drug Trader” means any establishment, which is a registered owner of the drug product, procures the materials and packing components and provides the production monographs, quality control standards and procedures, but sub-contracts the manufacture of such product to a licensed manufacturer. In addition, a trader may also engage in distribution and/or marketing of its products;
- (k) “Drug Distributor/Importer” means any drug 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;
- (l) “Drug Distributor/Exporter” means any drug establishment that exports raw materials, active ingredients and/or finished products to another country;
- (m) “Drug Distributor/Wholesaler” means any drug establishment that procures raw materials, active ingredients and/or finished products from local establishments for local distribution on wholesale basis;
- (n) “Drug Distributor/Retailer” means any establishment carrying on the retail business of sale of drugs to customers;

(o) Drug Outlets:

(o.1) "Drugstore, Pharmacy or Botica" means a drug outlet including hospital pharmacy or dispensary where registered drugs, chemical products, active principles, proprietary medicines or pharmaceutical specialties and dental medicines, galenical or veterinary preparations are compounded and/or dispensed ;

(o.2) "Retail Outlet" for non-prescription drugs, including non-traditional outlets such as supermarkets and stores, means a drug outlet where registered non-prescription or over-the-counter drugs are sold in their original packages, bottles or containers or in smaller quantities not in their original containers;

(p) "Board" means the Drug Prices Regulatory Board;

(q) "Capital Employed" means net fixed assets plus working capital of a manufacturer in relation to manufacture of pharmaceutical formulations;

(r) "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;

(s) "Parallel Importation" refers to the importation, without authorization of the patent holder, into a country of a product from a third country, where this product has been marketed by the patent holder or in another legitimate manner. It is mainly used when the price in the third country is considerably lower than the price the patent holder charges in the country concerned;

(t) "Fund" means Pharmaceutical Tariff, Productivity, and Price Support Fund;

ARTICLE II DRUG PRICES REGULATORY BOARD

SEC. 4. Creation and Composition of the Drug Prices Regulatory Board.

(a) There is hereby created the Drug Prices Regulatory Board, hereinafter referred to as the Board, which shall be attached to the Department of Health. The Board shall be composed of the following members:

1. Secretary of the Department of Health who shall act as the Chairperson of the Board;
2. Secretary of the Department of Trade and Industry who shall act as the Vice-Chairperson of the Board;
3. Director of the Bureau of Food and Drugs who shall act as member;
4. One (1) representative from the manufacturing sector of the pharmaceutical industry;
5. One (1) representative from the consumer's sector;
6. One (1) representative from the drugstore's association of the country;

7. One (1) representative from the Non-Government Organizations with health concerns;
8. Two (2) representatives from healthcare service providers – one physician and one pharmacist;
9. One (1) representative from the hospital association of the country;
10. One (1) representative from the academe.

Provided, that the Chairperson, Vice-Chairperson and the member from BFAD shall select the other members of the Board representing the various sectors from a list of names submitted or recommended by each sector which a particular member represents;

- (b) The Board shall convene every quarter of the year and whenever the Chairman of the Board deems necessary. *Provided*, that each Board shall operate for a span of three (3) to five (5) years, beginning 60 days after the approval of this Act.
- (c) All the members of the Board shall receive honoraria and allowances based on existing government accounting and auditing rules and regulations.
- (d) The Board shall conduct public hearings in considering the approval/disapproval of an increase in drug prices.

SEC. 5. 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 Drugs* to be determined by the National Drug Committee (NDC).
 - (i) Upon application or *motu proprio* when the public interest so requires, the Board shall have the power to regulate and set the maximum retail prices of formulations
 - (ii) 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 Drugs to be determined by the NDC, and sold under their generic and brand names.

- (b) *Power to Direct Manufacturers of Bulk Drugs of Formulations to Sell 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 Drugs to

be determined by the NDC 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.

(c) *Power to determine the list of selected essential medicines for selective parallel importation.*

ARTICLE III IMPLEMENTATION OF THE NATIONAL DRUG POLICY AND THE GENERICS ACT OF 1998

SEC. 6. *Implementation of the National Drug Policy.* – The Department of Health (DOH) shall immediately undertake a full implementation of the National Drug Policy pursuant to the issuance of the E.O. Nos. 174 and 175 amendments to R.A. 5921 or the Pharmacy Law, and R.A. 3720 or the Food, Drug and Cosmetic Act respectively, so as to provide guidelines for rational use of quality drugs. *Provided*, that the implementation of the National Drug Policy together with the five pillars designed for the Philippine National Drug Policy (PNDP) to ensure the availability and affordability of safe, effective and good quality drugs or medicines, shall strictly and comprehensively monitor the regulations of the importation, manufacture, marketing, and consumer utilization of all drugs or medicines and their intermediates. *Provided further*, that the Philippine National Drug Formulary (PNDF) shall continuously monitor and print updates on the list of drugs or medicines that are most essential for the diseases and conditions encountered in the Philippines, and describing the appropriate use of these essential drugs or medicines.

ARTICLE IV SELECTIVE PARALLEL IMPORTATION

SEC. 7. *Limitation of Patent Rights.* – Other than the instances in Section 72 of Republic Act No. 8293, otherwise known as the “Intellectual Property Code of the Philippines,” the owner of a patent to drugs or medicines shall likewise be prevented from exercising his rights under Section 71, under the following circumstances:

- (i) USING, OFFERING FOR SALE, SELLING OR IMPORTING A PATENTED PRODUCT WHEN IT HAS BEEN INTRODUCED ANYWHERE IN THE WORLD BY THE PATENT OWNER OR ANY PART AUTHORIZED TO USE THE INVENTION: PROVIDED, THAT A PATENTED PRODUCT SHALL MEAN A PATENTED ACTIVE PHARMACEUTICAL INGREDIENT (API), DRUGS OR MEDICINES: PROVIDED, FURTHER, THAT SUCH IMPORTED PATENTED PRODUCTS SHALL CLEARLY INDICATE ITS COUNTRY OF ORIGIN AND MANUFACTURE AND BE CLEARLY DISTINGUISHED FROM THE SAME PRODUCT MANUFACTURED WITH LICENSE IN THE PHILIPPINES.
- (ii) WHERE THE ACT CONSISTS OF MAKING OR USING EXCLUSIVELY FOR EXPERIMENTAL USE OF THE INVENTION FOR SCIENTIFIC PURPOSES OR EDUCATIONAL PURPOSES AND SUCH

OTHER ACTIVITIES DIRECTLY RELATED TO SUCH SCIENTIFIC OR EDUCATIONAL EXPERIMENTAL USE.

SEC. 8. *Selective Parallel Importation.* – Any selected drug or medicine procured shall be evaluated and approved for the public consumption by BFAD after extensive laboratory testing for safety, efficacy and quality. It is provided, further, that the sale and distribution of such drugs or medicines shall only be made by drug outlets, including drugstores, hospital and non-hospital pharmacies and non-traditional outlets such as supermarkets and stores and any other juridical persons who are duly licensed by both the DOH to engage in the sale and distribution of drugs or medicines and authorized by the DTI to be official distributors or retailers of the drugs or medicines subject of the said procurement. Provided, further, that selected drugs or medicines for parallel importation are life-saving drugs or medicines that the local manufacturers can not afford to produce.

ARTICLE V COMPULSORY LICENSING

SEC. 9. *Patents of Pharmaceutical Products.* – Section 54 of Republic Act No. 8293, otherwise known as the “Intellectual Property Code of the Philippines,” is hereby amended to read as follows:

SEC. 54. *Term of Patent.* – The term of patent shall be twenty (20) years from the filing date of application, EXCEPT FOR DRUG AND PHARMACEUTICAL PRODUCTS WHICH SHALL BE TEN (10) YEARS FROM THE FILING DATE OF APPLICATION.

SEC. 10. *Compulsory Licensing.* – Sections 93 and 95 of R.A. 8293 are hereby amended to read as follows:

SEC. 93. *Grounds for Compulsory Licensing.* – The Director of Legal Affairs OR THE SECRETARY OF THE DEPARTMENT OF HEALTH, IN CASES OF DRUG OR PHARMACEUTICAL PRODUCTS, may grant a license to exploit a patented invention, even without the agreement of the patent owner, in favor of any person who has shown his capability to exploit the invention, under any of the following circumstances.

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93.2. Where the public interest, in particular, national security, nutrition, health or the development if other vital sectors of the national economy WHICH SHALL INCLUDE THE NATIONAL PHARMACEUTICAL INDUSTRY as determined by the appropriate agency of the Government, so requires [or];

IN PARTICULAR, PATENTED DRUGS AND PHARMACEUTICAL PRODUCTS SHALL NOW BE SUBJECT TO COMPULSORY LICENSING.

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SEC. 95. *Requirement to Obtain a License on Reasonable Commercial Terms.* –

95.1. The license will only be granted after the petitioner shall have made efforts to obtain authorization from the patent owner on reasonable commercial terms and conditions but such efforts have not been successful within a reasonable period of time.

95.2. The requirement under Subsection 95.1. shall not apply in the following cases:

- (a) XXX
- (b) XXX
- (c) XXX
- (d) IN CASES OF PRODUCTION OF DRUGS AND PHARMACEUTICAL PRODUCTS AS CARRIED OUT BY THE STATE THROUGH ACCREDITED LOCAL DRUG ESTABLISHMENTS.

SEC. 11. *Implementing Agency.* – The DOH, in coordination with the DTI, shall be the main body to enforce this Act. It shall likewise, promulgate the rules and regulations necessary to implement the provisions of this Act within sixty (60) days from its passage.

ARTICLE VI INCENTIVES TO THE LOCAL PHARMACEUTICAL INDUSTRY

SEC. 12. *Incentives to the Local Pharmaceutical Industry.* – Pursuant to the state policy of developing the national drug industry, all 100% Filipino-owned drug industries shall be granted the following incentives:

- a) Tax Incentives. Section 108 [B] of Republic Act 9337 is hereby amended to include:
 - (8) THE SALE OR IMPORTATION BY LOCAL PHARMACEUTICAL INDUSTRY, OF BULK DRUGS OR MEDICINES, INCLUDING THE CHEMICAL OR PREPARATIONS FOR THE FORMULATION OF MEDICINES, AND RAW MATERIALS THEREOF.
- b) Productivity Support. The government shall give high priority to the development of the technology of local pharmaceutical industry, especially research and development (R&D) for new medicines for tropical, infectious diseases.
 - (i) Local drug companies shall enjoy tax credits as may be deemed by the Department of Finance (DOF).
- c) Technical Assistance. Technical assistance shall be extended on the following areas:
 - (i) Repacking of drugs and pharmaceutical products and other operational processes if available and within the expertise of any government agency or corporation;

- (ii) Research, training and developmental skills to be provided by reputable state universities and government experts at reasonable and discounted rates;
 - (iii) Information dissemination campaigns and entrepreneurship education; and;
 - (iv) Establishment of regional branches or centers.
- c) Credit Assistance. Loan applications and credit assistance and stronger linkages with the government banks and financing institutions.
- d) Allocation of Credit Resources. The locally-owned drug establishments are guaranteed access to a fair share of government contracts and related incentives and preferences. The local production of raw materials for essential drugs and medicines shall be eligible for government assistance and mandatory allocation of credit resources to small and medium enterprises, as provided for in Republic Act No. 6977, otherwise known as "Magna Carta for Small Enterprises," as amended by Republic Act No. 8289.
- e) Preference for Filipino Pharmaceutical Producers. In line with the Philippine Constitution, additional rights, privileges, and incentives in terms of further tax exemptions and priority access to concessional government loans shall be granted to local drug companies that are majority or wholly-owned by Filipino citizens.
- f) Other Incentives for Local Drug Companies. Other incentives for local drug companies may be determined by the Board as needed.

ARTICLE VII PENALTIES

SEC.13. Penalties. –

- (a) Any organization or company involved in the manufacture, importation, repacking, marketing and/or distribution of drugs and medicines or any drug outlets, including drugstores, hospital and non-hospital pharmacies and non-traditional outlets such as supermarkets and stores and any other juridical person who shall violate any of the provisions of this Act shall suffer the following penalties;
 - a. For the first offense, the penalty of a fine not less than One Hundred Thousand Pesos (P100,000.00) nor more than Five Hundred Thousand Pesos (P500,000.00) and suspension of at least one (1) year of license to operate such drug establishment or drug outlet at the discretion of the court;
 - b. For the second succeeding offense, the penalty shall but not less than One Million Pesos (P1,000,000.00) but not more than Five Million Pesos (5,000,000.00) at the discretion of the court, plus the

revocation of license to operate such drug establishment or drug outlet at the discretion of the court.

Provided, That its officers directly responsible for the violation shall suffer the penalty of fine and suspension or revocation of license to practice profession, if applicable, and by imprisonment of not less than six (6) months nor more than one (1) year or both fine and imprisonment at the discretion of the court: *Provided, further*, That if the guilty party is and alien, he shall be *ipso facto* deported after service of sentence without need of further proceedings.

ARTICLE VIII OTHER PROVISIONS

SEC. 14. Appropriations. – The amount of Three Million Pesos (P3,000,000.00) shall be taken from the current appropriations of the Department of Health for the initial implementation of this Act. Thereafter, such sums as may be necessary for its continued implementation shall be included in the annual General Appropriations Act.

SEC. 15. Implementing Rules and Regulations. – The Board shall formulate and issue the implementing rules and guidelines of this Act within sixty (60) days after the passage of this Act.

SEC. 16. Repealing Clause. – All laws, decrees, executive orders, rules and regulations and other issuances or parts thereof, which are inconsistent with this Act, are hereby repealed or modified accordingly.

SEC. 17. Separability Clause. – If any provision of this Act is declared unconstitutional and the application thereof to any person, circumstance or transaction is held invalid, the validity of the remaining provisions of this Act or the applicability of such provision to other persons, circumstances or transactions shall not be affected hereby.

SEC. 18. Effectivity Clause. – This Act shall take effect fifteen (15) days after its publication in at least two (2) newspapers of general circulation.

Approved,