

Republic of the Philippines
HOUSE OF REPRESENTATIVES
Quezon City

SEVENTEENTH CONGRESS
Second Regular Session

HOUSE BILL NO. **7127**



Introduced by Representative MICHAEL L. ROMERO

EXPLANATORY NOTE

The "**Universally Accessible Cheaper and Quality Medicines Act**" or **Republic Act 9502** was in place since June 2008.

There are several programs that should make medicines more affordable under the new law.

These are the intensification of competition through "parallel importation" of patented cheaper medicine; increased production of generic medicine, compulsory licensing of patented drugs, reimbursement by the Philippine Health Insurance Corp. (**Philhealth**) of money spent by consumers on drugs, imposition of a maximum retail price (MRP) on drugs, and a drug consignment selling scheme.

There are other systems that will be in place to help accelerate reduction in price and encourage consumption of cheap drugs.

These are the early working provision (**EWP**) of the law, strengthening of the Bureau of Food and Drugs (**BFAD**), and generic drug awareness.

Competition through parallel importation. Competition is really recognized to bring down the cost of a product or service.

This is why RA 9502's Implementing Rules and Regulations (**IRR**) encourages competition at each level of the pharmaceutical supply chain.

Patents are territorial. Under the old system, a company holding a patent in the Philippines is fully protected and can sell the drug at any price it wants,

even at an unaffordable level. A competitor company cannot import the same drug that is patented locally. The exception now is in medicine.

Even if a drug is patented, an importer that has a contact abroad for the same drug of the same brand and quality may bring in that drug as allowed under Section 72.1 of RA 9502. "With 'international exhaustion,' once a product is introduced anywhere-else in the world, anyone can import this.

International exhaustion is accepted under the Trade-Related Aspects of Intellectual Property Rights **(TRIPS)** Agreement between World Trade Organization member-countries.

Since 2001, state-owned Philippine International Trading Corp. (PITC) has been allowed to import medicine in order to cut local medicine costs. Unfortunately, PITC's mandate until RA 9502 was ratified was only to import off-patent drugs, those not protected by a Philippine patent. PITC's importation of off-patent drugs was just about P90 million in 2007,

Allowing importation only of off-patent drugs must be illogical since the real way to cut price is to provide drugs that can compete with high-priced patented drugs that carry brands offered by multinational companies that once heavily dominated the Filipino market. With the law, anyone can import from any country a branded drug in the Philippines that is also produced in another country (same manufacturer, same quality, same brand), only with a cheaper price.

Pfizer that offers a more expensive drug in the Philippines may be producing the same drug at a cheaper price in India. So, importing this from India, known to be one of the world's cheapest source of medicine, may substantially cut price.

One of the reasons why India may have cheaper medicine, according to pharmaceutical suppliers, may be due to Indian firms' not having to pay for research and development **(R&D)**.

With **RA 9502**, drug importation may actually be done in bulk by the PITC even for the private sector in order to bring down cost through economies of scale.

The Department of Health (DOH) said government also plans to carry out collective importation for all government agencies' drug requirements in order to consolidate volume and bring down import cost. The real long-term factor to cutting medicine price will really be the production of generic medicine.

The expansion of generic medicine manufacturing will be the key to the long-term cut-down on local drug price. Importation will only be a stop-gap measure.

Filipinos are brand-conscious. That's why we came up with parallel importation. But eventually, when Filipinos get used to generic, parallel importation will generally die because why will we import if there's generic counterpart that is cheap (that's equal in quality).

DOH said that once a drug becomes off-patent, or its 20-year protection expires, then the original company that developed it, the innovator, will be compelled to manufacture a generic of that medicine. "Innovator companies that have already earned a lot from their patents over a long time are required to produce generic counterpart of their drugs once the patent expires.

DOH officials assure that both imported and locally-manufactured generic medicine will be strictly monitored for quality.

BFAD said that once an import shipment arrives, drug samples are sent to BFAD laboratory for testing.

We collect samples and undergo additional test. So we're very assured of quality of medicine brought in through parallel importation.

Similarly, generic drugs are tested by BFAD. These drugs are also tested from samples that are already in the market.

Prior to the importation of a drug, Rule 74 of the Implementing Rules and Regulation (IRR) indicated that the World Health Organization should certify that imported products in finished dosage forms should conform with international purity and quality standards as established in the **International Pharmacopoeia**.

As part of widening generic drug consumption, all government health agencies and government-owned and controlled corporations (GOCC) are required to use generic names in all transactions.

For private medical practitioners, they are required to prescribe a medicine using the generic name of a drug. However, they can include a drug's brand name as an option.

Compulsory Licensing. When a national emergency situation arises, a patented invention may be opened by the government for licensing to other manufacturers even without the consent of the patent holder.

Where the public interest, in particular, national security, nutrition, health or the development of other vital sectors of the national economy requires, the Intellectual Property Office (**IPO**) may grant a license to exploit a patented invention.

Reimbursement by Philhealth of money spent on medicine. Since the major objective of RA 9502 is to "eliminate out-of-pocket expenses" of patients and promote social health welfare, Philhealth is mandated to make cheaper drugs available to the public.

Philhealth will help implement the following:

- Setting up of an Outpatient Drug Benefit Package,
- Accreditation of all health-related units—hospital and commercial pharmacies, DOH-recognized drug outlets, and
- Penalty imposition for medical professionals failing to use generic medicine on their prescription.

Philhealth's reimbursement of drugs will be through hospital pharmacies. Primarily, it will reimburse a Philhealth member's expense for drugs covered by prescriptions in generic names based on the list of drugs under the Philippine National Drug Formulary System (**PNDF**).

The PNDF will be set up by the DOH and will be updated quarterly. It is a list of drugs that are used often by the public. Drug list will be based on mortality and morbidity rates.

DOH said reimbursement by Philhealth will only be valid for PNDF drugs. This PNDF list will also be the basis for procurement of medicines by all government agencies and local government units.

Consignment of drugs and medicines. Philhealth will also set up a consignment program under which drug producers will be allowed to display their products on consignment basis or payable only once the drugs are sold.

DOH already accredits drug outlets called *Botika ng Barangays* which improves people's access to important drugs.

BFAD will further issue guidelines for the licensing of drug distribution through non-traditional outlets. Moreover, DOH has released guidelines for this consignment system

Maximum Retail Price. This may be a difficult measure, but the imposition of an MRP on drug manufacturers is one of the strongest provisions of **RA 9502**.

Under this, the Philippine president may impose MRP on any drug or all drugs or medicines under a national emergency situation. Imposition of the MRP may be issued by the president anytime when this is needed.

The goal is to bring down the price of medicine by not lower than 50 percent (from 2003 drug prices).

The MRP may be imposed on all levels of the supply chain—the manufacturer, trader, distributor, wholesaler, and retailer.

To be subjected under MRP are drugs in PNDF's Essential Drug List, all drugs for chronic illnesses and life-threatening conditions, disease-preventing drugs (vaccines, immunoglobulin, anti-sera), pregnancy-preventing drugs, anesthetic agents, and intravenous fluids.

DOH will consider the following factors in setting the maximum price— retail price of drugs, supply availability, cost to each level of the supply chain, foreign exchange rate, labor costs, transport and distribution costs, and costs on research, promotion, advertising, and taxes.

When price manipulation is suspected in the market, hoarding may be investigated based on a person's or entity's accumulation of drugs beyond his normal inventory level (50 % higher), unreasonable limitation or refusal to dispose this drug, and unjustifiable withdrawal of a drug from channels of production.

RA 9502 may also rule profiteering of traders if a product has no price tag, if it is misrepresented as to weight or other measurement forms, and is adulterated or diluted. It can also charge cartel against two or more enterprises if they perform uniform acts to increase price for competing products that are pharmaceutically the same.

Senior Citizen Law and People with Disability Law. With **RA 9502** and provisions like the MRP already in place, government will still recognize rights of senior citizens and the disabled.

If MRP will have to be imposed, we'll continue to honor the senior citizen law and people with disability law. So even if the price is already low, price will continue to go down.

Early Working Provision in the Intellectual Property Code. Since patents carry a lengthy 20-year protection during which no one can manufacture the same drug formulation, an early working provision (EWP) allows for a preparatory period by which any future generic drug manufacturer can begin registration and experimentation of the product.

Three to five years before a patent of a drug expires, a generic manufacturer can begin these processes including manufacturing of this drug, provided this is not yet sold in the market. EWP's aim is by Day One after the patent expires, this drug can immediately be distributed to the market.

They can already stockpile, although they cannot sell it yet. This will improve competition because under the old regime, a generic company cannot begin developing a drug until the drug patent expires.

With the permit to start developing the drugs, generic companies can carry out reverse engineering in developing an equivalent drug as permitted under the EWP as stated under the "Limitation of Patent Rights" of the RA 9502.

Generic companies can do reverse engineering. But information disclosed (by patent holders) with BFAD like pre-clinical trial and pre-clinical tests are (usually) trade secrets. So those are protected and BFAD won't give that.

Strengthening of BFAD. To effectively implement RA 9502, BFAD's operation will be strengthened through the retention of its income. BFAD does not need to remit its income to the national government.

The fees, fines, royalties, and other charges that BFAD collects from its services will be used to fund upgrading of facilities and investments in equipment and human resource development. The national government has already supported the beefing up of BFAD's workforce:

Generic Drug Awareness. When a patented product becomes off patent, Section 39n of RA 9502 indicates that manufacturing companies will be required by DOH to manufacture their generic counterparts. Priority for this are PNDP drugs. The awareness of the equal quality of generics medicine is really envisioned to make cheap generics medicine replace high-priced medicine manufactured by multinational firms.

Even now, the Philippine Chamber of Pharmaceutical Industry (**PCPI**) reports that generic drugs that are beginning to be recognized as having an equal quality as those of branded drugs have already gained a foothold on a substantial 40 percent of the ₱107 billion industry.

Quality assurance is also given by DOH to generic products as it has been imposing on local companies the adoption of Good Manufacturing Practices. To create generic awareness, both the government and Filipino generic companies inevitably have to invest in spreading information about generic medicine's good quality.

The local industry has to come out with generic counterpart. That is why DOH is doing generic awareness. This has made a big dent on information. When

the buying public are aware of the generic product, they will naturally buy the lower-priced generic product compared to the branded ones.

International monitoring of drug price. One way to ensure that local drugs will remain cheap is the active monitoring of international price. Aside from DOH, the Department of Trade and Industry (DTI) has the mandate to monitor international price. This can be through Philippine Health attaches and Philippine Missions.

This House Bill seeks to protect public health, public interest and circumstances of extreme urgency so requires, it shall adopt more appropriate measures to promote and ensure access to affordable quality drugs and medicines for everyone.

Thus, the early passage of this bill is earnestly requested.



MICHAEL L. ROMERO Ph.D.

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AN ACT

**AMENDING REPUBLIC ACT 9502, OTHERWISE KNOWN AS THE
“UNIVERSALLY ACCESSIBLE CHEAPER AND QUALITY
MEDICINES ACT OF 2008” TO FOSTER THE IMPOSITION OF ALL
EXISTING POLICIES AND GUIDELINES, PROVIDING STIFFER
PENALTIES AND SANCTIONS, AND FOR OTHER PURPOSES**

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

SECTION 1.

Section 19, Chapter 3 of Republic Act No. 9502 is hereby amended to read:

**SEC. 19. Functions and Responsibilities of the Secretary of the
Department of Health.** - Pursuant to Section 18 of this Act, the Secretary
of the Department of Health shall have the following powers:

(A) Power to Recommend the Maximum Retail Price of Drugs
and Medicines Subject to Price Regulation - (1) Upon application
or motu proprio when the public interest so requires, the
Secretary of the Department of Health shall have the power to
determine the maximum retail prices of drugs and medicines

which shall be recommended to the President of the Philippines for approval. In order that affordable prices of drugs and medicines from the different manufacturers, importers, traders, distributors, wholesalers, or retailers shall be made available to the public, the Secretary of the Department of Health, as he/she may deem fit and after a proper determination, shall have such approved maximum retail prices of drugs and medicines published;

(2) In recommending the maximum retail price, the Secretary of the Department of Health shall consider the following factors:

(a) Retail prices of drugs and medicines that are subject to regulation in the Philippines and in other countries;

(b) The supply available in the market;

(c) The cost to the manufacturer, importer, trader, distributor, wholesaler or retailer of the following, but not limited to:

(i) The exchange rate of the peso to the foreign currency with which the drug or any of its component, ingredient or raw material was paid for;

(ii) Any change in the amortization cost of machinery brought about by any change in the exchange rate of the peso to the foreign currency with which the machinery was bought through credit facilities;

(iii) Any change in the cost of labor brought about by a change in minimum wage; or

(iv) Any change in the cost of transporting or distributing the medicines to the area of destination;

(d) Such other factors or conditions which will aid in arriving at a just and reasonable maximum price; and

(3) No retailer shall sell drugs and medicines at a retail price exceeding the maximum retail price approved by the President of the Philippines as provided in Section 17 of this Act: Provided, That, the Secretary of the Department of Health shall immediately undertake a study on the prevailing prices of drugs and medicines subject to price regulation and provide an initial list of drugs and medicines, which maximum retail prices he/she shall recommend to the President of the Philippines.

(B) Power to Include Other Drugs and Medicines in the List Subject to Price Regulation - Upon application or *motu proprio* when the public interest so requires and after proper determination, the Secretary of the Department of Health may order the inclusion of drugs and medicines to the list subject of price regulation under Section 23 hereof.

(C) Power to Implement Cost-Containment and Other Measures - (1) The Secretary of the Department of Health shall have the power to implement the fair price of drugs and medicines for purposes of public health insurance and government procurement based on the order of the President of the Philippines imposing maximum retail prices; and

(2) The Secretary of the Department of Health shall have the power to implement any other measures that the government may avail of to effectively reduce the cost of drugs and medicines that shall include, but not limited to, competitive bidding, price volume negotiations, and other appropriate mechanisms that influence supply, demand and expenditures on drugs and medicines.

(D) Power to Impose Administrative Fines and Penalties - After due notice and hearing, the Secretary of the Department of Health shall have the power to impose administrative fines against any person, manufacturer, importer, trader, distributor, wholesaler, retailer, or any other entity, in such amount as it may deem reasonable, which in no case shall be less than Two hundred Fifty thousand pesos (**Php250,000.00**) nor more than Five million pesos (Php5,000,000.00) for violations of the maximum retail price approved by the President of the Philippines pursuant to the provisions of this Chapter.

(E) Power to Deputize Government Entities - The Secretary of the Department of Health shall have the power to call upon and deputize any official, agent, employee, agency, or instrumentality of the national and local government for any assistance that it may deem necessary to carry out the purposes of this Chapter.

(F) Other Powers Necessary to Implement Provisions of this Chapter - The Secretary of the Department of Health 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 Secretary of the Department of Health to carry out its functions, duties, and responsibilities. Accordingly, within thirty (30) days from the effectivity of this Act and every December 31st of every year thereafter, every manufacturer, importer, trader, distributor, wholesaler, and retailer of a drug and medicine whether included in or excluded from the list of drugs and medicines that are subject to price regulation shall furnish the Secretary of the Department of Health a list, containing on the minimum the corresponding prices and inventory, of all drugs and medicines it manufactures, imports, trades, distributes, wholesales, or retails, data pertaining to the factors enumerated under Section 19(A)(2), and any and all necessary information that the Secretary of the Department of Health may require.

SECTION 2.

Section 25, Chapter 3 of Republic Act No. 9502 is hereby amended to read:

SEC. 25. *Penalty for Illegal Acts of Price Manipulation.* - Any person or entity who commits any act of illegal price manipulation of any drug and medicine subject to price regulation shall suffer the penalty of imprisonment for a period of not less than five (5) years nor more than fifteen (15) years or shall be imposed a fine of not less than Two hundred Fifty thousand pesos (**Php250,000.00**) nor more than Ten million pesos (Php10,000,000.00), at the discretion of the court. The court may

also order the suspension or revocation of its license to operate (LTO), professional or business license.

SECTION 3.

Section 35, Chapter 5 of Republic Act No. 9502 is hereby amended to read:

SEC. 35. Penalties. - Any person or entity who shall refuse to carry or sell drugs and medicines pursuant to the provisions of this Chapter shall be punished with a fine of not less than Two hundred Fifty thousand pesos (**Php250,000.00**) but not more than Five hundred thousand pesos (Php500,000.00), at the discretion of the court. For the succeeding offense, the penalties shall not be less than Five hundred thousand pesos (Php500,000.00) but not more than Two million pesos (**Php2,000,000.00**), at the discretion of the court, and suspension or revocation of its license to operate (LTO), business or professional license, as the case may be.

SECTION 4.

Section 41, Chapter 6 of Republic Act No. 9502 is hereby amended to read:

SEC. 41. 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 the 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 Commission.

"(b) for the second conviction, the penalty of fine in the amount of not less than Twenty-five thousand pesos

(Php25,000.00) but not exceeding Fifty thousand pesos **(Php50,000.00)**, at the discretion of the court.

"(c) for the third conviction, the penalty of fine in the amount of not less than Fifty thousand pesos **(Php50,000.00)** but not exceeding One hundred thousand pesos **(Php100,000.00)** and suspension of his license to practice his profession for One hundred twenty **(120)** days at the discretion of the court.

"(d) for the fourth and subsequent convictions, the penalty of fine of not less than Two hundred Fifty thousand pesos **(Php250,000.00)** and suspension of his license to practice his profession for two **(2)** years or longer at the discretion of the court.

"(B) Any juridical person who violates Sections 6(c), 6(d), 7 or 8 shall suffer the penalty of a fine of not less than Two hundred Fifty thousand pesos **(Php250,000.00)** and suspension or 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 of at least One hundred thousand pesos **(Php100,000.00)** and suspension or revocation of license to practice profession, if applicable, and by imprisonment of not less than one (1) year nor more than two (2) years or both fine and imprisonment at the discretion of the court: and, a list of drug products with the same generic name and their corresponding prices.

Provided, further, That if the guilty party is an alien, he shall be ipso facto deported after service of sentence without need of further proceedings.

"(C) The Secretary of Health shall have the authority to impose administrative sanctions such as suspension or cancellation of license to operate or recommend suspension of license to practice profession to the Professional Regulation Commission as the case may be for the violation of this Act.

"The administrative sanctions that shall be imposed by the Secretary of the Department of Health shall be in a graduated manner in accordance with Section 12.A.

"An administrative case may be instituted independently from the criminal case: Provided, That, the dismissal of the criminal case or the withdrawal of the same shall in no instance be a ground for the dismissal of the administrative case."

SECTION 5. TRANSITORY PROVISION – Existing industries, businesses and offices affected by the implementation of this Act shall be given six **(6)** months transitory period from the effectivity of the IRR or such other period as may be determined, to comply with the requirements of this Act.

SECTION 6. IMPLEMENTING RULES AND REGULATIONS – The departments and agencies charged, to be led by the Department of Health **(DOH)** with carrying out the provisions of this Act, shall within sixty **(60)** days after the effectivity of this Act, formulate the necessary rules and regulations for its effective implementation.

SECTION 7. REPEALING CLAUSE – All laws, decrees, executive orders, rules and regulations, or parts thereof inconsistent with the provisions of this Act are hereby repealed or modified accordingly.

SECTION 8. SEPARABILITY CLAUSE – If, for any reason, any section or provision of this Act is held unconstitutional or invalid, the other sections or provisions hereof shall not be affected thereby.

SECTION 9. EFFECTIVITY CLAUSE – This Act shall take effect after fifteen (15) days from its publication in the Official Gazette or in at least two (2) national newspapers of general circulation whichever comes earlier.

Approved,