Republic of the Philippines
CONGRESS OF THE PHILIPPINES
Metro Manila

Fourteenth Congress
First Regular Session

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[Republic Act No. 9502]

AN ACT PROVIDING FOR CHEAPER AND QUALITY MEDICINES, AMENDING FOR THE PURPOSE REPUBLIC ACT NO. 8293 OR THE INTELLECTUAL PROPERTY CODE, REPUBLIC ACT NO. 6675 OR THE GENERICS ACT OF 1988, AND REPUBLIC ACT NO. 5921 OR THE PHARMACY LAW, AND FOR OTHER PURPOSES

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

CHAPTER 1
GENERAL PROVISIONS

SECTION 1. *Short Title*. — This Act shall be known as the "Universally Accessible Cheaper and Quality Medicines Act of 2008".

SECTION 2. *Declaration of Policy*. — It is the policy of the State to protect public health and, when the public interest or circumstances of extreme urgency so require, it shall adopt appropriate measures to promote and ensure access to affordable quality drugs and medicines for all. Pursuant to the attainment of this general policy, an effective competition policy in the supply and demand of quality affordable drugs and medicines is recognized by the State as a primary instrument. In the event that full competition is not effective, the State recognizes as a reserve instrument the regulation of prices of drugs and medicines, with clear accountability by the implementing authority as mandated in this Act, as one of the means to also promote and ensure access to quality affordable medicines.

SECTION 3. *Construction in Favor of Protection of Public Health*. — All doubts in the implementation and interpretation of the provisions of this Act, including its implementing rules and regulations, shall be resolved in favor of protecting public health.

SECTION 4. *Definition of Terms*. — For purposes of this Act, the following terms are to mean as follows:

(a) "Compulsory License" is a license issued by the Director General of the Intellectual Property Office to exploit a patented invention without the permission of the patent holder, either by manufacture or through parallel importation;

(b) "Drug outlet" refers to drugstores, pharmacies, and any other business establishments which sell drugs and medicines;

(c) "Drugs and medicines" refers to any chemical compound or biological substance, other than food, intended for use in the treatment, prevention or diagnosis of disease in humans or animals, including but not limited to:

(1) any article recognized in the official United States Pharmacopoeia-National Formulary (USP-NF), official Homeopathic Pharmacopoeia of the United States, Philippine Pharmacopoeia, Philippine National Drug Formulary, British Pharmacopoeia, European Pharmacopoeia, Japanese Pharmacopoeia, Indian Pharmacopoeia, any national compendium or any supplement to any of them;

(2) any article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals;

(3) any article other than food intended to affect the structure or any function of the human body or animals;

(4) any article intended for use as a component of any articles specified in clauses (1), (2), and (3) not including devices or their components, parts, or accessories;

(5) herbal and/or traditional drugs which are articles of plant or animal origin used in folk medicine which are:

(i) recognized in the Philippine National Drug Formulary;
(ii) intended for use in the treatment or cure or mitigation of disease symptoms, injury or body defects in humans;
(iii) other than food, intended to affect the structure or any function of the human body;
(iv) in finished or ready-to-use dosage form; and
(v) intended for use as a component of any of the articles specified in clauses (i), (ii), (iii), and (iv);

(d) "Essential drugs list or national drug formulary" refers to a list of drugs prepared and periodically updated by the Department of Health on the basis of health conditions obtaining in the Philippines as well as on internationally accepted criteria;

(e) "Importer" refers to any establishment that imports raw materials, active ingredients and finished products for its own use or for distribution to other drug establishments or outlets;

(f) "Manufacture" includes any process or part of a process for making, altering, finishing, packing, labeling, breaking or otherwise treating or adapting any drug with a view to its sale and distribution, but does not include the compounding or dispensing of any drug in the ordinary course of retail business;

(g) "Manufacturer" refers to any establishment engaged in the operations involved in the production of a drug with the end view of storage, distribution, or sale of the product;

(h) "Multisource pharmaceutical products" refers to pharmaceutically equivalent or pharmaceutically alternative products that may or may not be therapeutically equivalent.

Multisource pharmaceutical products that are therapeutically equivalent are inter-changeable;

(i) "Retailer" refers to a licensed establishment carrying on the retail business of sale of drugs and medicines to customers;

(j) "Trader" refers to any licensed establishment which is a registered owner of a drug product that procures the materials and packaging components, and provides the production monographs, quality control standards and procedures, but subcontracts the manufacture of such products to a licensed manufacturer;

(k) "TRIPS Agreement" or Agreement on Trade-Related Aspects of Intellectual Property Rights refers to the international agreement administered by the WTO that sets down minimum standards for many forms of intellectual property regulation; and

(l) "Wholesaler" refers to a licensed establishment or drug outlet who acts as merchant, broker or agent, who sells or distributes for resale or wholesale drugs and medicines.

CHAPTER 2
AMENDMENTS TO REPUBLIC ACT NO. 8293, OTHERWISE KNOWN AS THE INTELLECTUAL PROPERTY CODE OF THE PHILIPPINES

SECTION 5. Section 22 of Republic Act No. 8293, otherwise known as the Intellectual Property Code of the Philippines, is hereby amended to read as follows:

"SEC. 22. *Non-Patentable Inventions*. – The following shall be excluded from patent protection:

"22.1. Discoveries, scientific theories and mathematical methods, and in the case of drugs and medicines, the mere discovery of a new form or new property of a known substance which does not result in the enhancement of the known efficacy of that substance, or the mere discovery of any new property or new use for a known substance, or the mere use of a known process unless such known process results in a new product that employs at least one new reactant. "For the purpose of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations, and other derivatives of a known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy;

"22.2. x x x;
"22.3. x x x;
"22.4. x x x;
"22.5. x x x; and
"22.6. x x x."

SECTION 6. Section 26 of Republic Act No. 8293, otherwise known as the Intellectual Property Code of the Philippines, is hereby amended to read as follows:

"SEC. 26. *Inventive Step*. – 26.1. An invention involves an inventive step if, having regard to

prior art, it is not obvious to a person skilled in the art at the time of the filing date or priority date of the application claiming the invention. *(n)*

"26.2. In the case of drugs and medicines, there is no inventive step if the invention results from the mere discovery of a new form or new property of a known substance which does not result in the enhancement of the known efficacy of that substance, or the mere discovery of any new property or new use for a known substance, or the mere use of a known process unless such known process results in a new product that employs at least one new reactant."

SECTION 7. Section 72 of Republic Act No. 8293, otherwise known as the Intellectual Property Code of the Philippines, is hereby amended to read as follows:

"SEC. 72. *Limitations of Patent Rights* . – The owner of a patent has no right to prevent third parties from performing, without his authorization, the acts referred to in Section 71 hereof in the following circumstances:

"72.1. Using a patented product which has been put on the market in the Philippines by the owner of the product, or with his express consent, insofar as such use is performed after that product has been so put on the said market: *Provided* , That, with regard to drugs and medicines, the limitation on patent rights shall apply after a drug or medicine has been introduced in the Philippines or anywhere else in the world by the patent owner, or by any party authorized to use the invention: *Provided, further* , That the right to import the drugs and medicines contemplated in this section shall be available to any government agency or any private third party;

"72.2. Where the act is done privately and on a non-commercial scale or for a non-commercial purpose: *Provided* , That it does not significantly prejudice the economic interests of the owner of the patent;

"72.3. 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;

"72.4. In the case of drugs and medicines, where the act includes testing, using, making or selling the invention including any data related thereto, solely for purposes reasonably related to the development and submission of information and issuance of approvals by government regulatory agencies required under any law of the Philippines or of another country that regulates the manufacture, construction, use or sale of any product: *Provided* , That, in order to protect the data submitted by the original patent holder from unfair commercial use provided in Article 39.3 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), the Intellectual Property Office, in consultation with the appropriate government agencies, shall issue the appropriate rules and regulations necessary therein not later than one hundred twenty (120) days after the enactment of this law;

"72.5. Where the act consists of the preparation for individual cases, in a pharmacy or by a medical professional, of a medicine in accordance with a medical prescription or acts concerning the medicine so prepared; and

"72.6. Where the invention is used in any ship, vessel, aircraft, or land vehicle of any other country entering the territory of the Philippines temporarily or accidentally: *Provided*, That such invention is used exclusively for the needs of the ship, vessel, aircraft, or land vehicle and not used for the manufacturing of anything to be sold within the Philippines. (Secs. 38 and 39, R.A. No. 165a)"

SECTION 8. Section 74 of Republic Act No. 8293, otherwise known as the Intellectual Property Code of the Philippines, is hereby amended to read as follows:

"SEC. 74. *Use of Invention by Government*. – 74.1. A Government agency or third person authorized by the Government may exploit the invention even without agreement of the patent owner where:

"(a) The public interest, in particular, national security, nutrition, health or the development of other sectors, as determined by the appropriate agency of the government, so requires; or

"(b) A judicial or administrative body has determined that the manner of exploitation, by the owner of the patent or his licensee, is anti-competitive; or

"(c) In the case of drugs and medicines, there is a national emergency or other circumstance of extreme urgency requiring the use of the invention; or

"(d) In the case of drugs and medicines, there is public non-commercial use of the patent by the patentee, without satisfactory reason; or

"(e) In the case of drugs and medicines, the demand for the patented article in the Philippines is not being met to an adequate extent and on reasonable terms, as determined by the Secretary of the Department of Health."

"74.2. Unless otherwise provided herein, the use by the Government, or third person authorized by the Government shall be subject, where applicable, to the following provisions:

"(a) In situations of national emergency or other circumstances of extreme urgency as provided under Section 74.1 (c), the right holder shall be notified as soon as reasonably practicable;

"(b) In the case of public non-commercial use of the patent by the patentee, without satisfactory reason, as provided under Section 74.1 (d), the right holder shall be informed promptly: *Provided*, That, the Government or third person authorized by the Government, without making a patent search, knows or has demonstrable ground to know that a valid patent is or will be used by or for the Government;

"(c) If the demand for the patented article in the Philippines is not being met to an adequate extent and on reasonable terms as provided under Section 74.1 (e), the right holder shall be informed promptly;

"(d) The scope and duration of such use shall be limited to the purpose for which it was authorized;

"(e) Such use shall be non-exclusive;

"(f) The right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization; and

"(g) The existence of a national emergency or other circumstances of extreme urgency, referred to under Section 74.1 (c), shall be subject to the determination of the President of the Philippines for the purpose of determining the need for such use or other exploitation, which shall be immediately executory.

"74.3. All cases arising from the implementation of this provision shall be cognizable by courts with appropriate jurisdiction provided by law. "No court, except the Supreme Court of the Philippines, shall issue any temporary restraining order or preliminary injunction or such other provisional remedies that will prevent its immediate execution.

"74.4. The Intellectual Property Office (IPO), in consultation with the appropriate government agencies, shall issue the appropriate implementing rules and regulations for the use or exploitation of patented inventions as contemplated in this section within one hundred twenty (120) days after the effectivity of this law."

SECTION 9. Section 76.1 of Republic Act No. 8293, otherwise known as the Intellectual Property Code of the Philippines, is hereby amended to read as follows:

"SEC. 76. *Civil Action for Infringement* . – 76.1. The making, using, offering for sale, selling, or importing a patented product or a product obtained directly or indirectly from a patented process, or the use of a patented process without the authorization of the patentee constitutes patent infringement: *Provided* , That, this shall not apply to instances covered by Sections 72.1 and 72.4 (Limitations of Patent Rights); Section 74 (Use of Invention by Government); Section 93.6 (Compulsory Licensing); and Section 93-A (Procedures on Issuance of a Special Compulsory License under the TRIPS Agreement) of this Code.

"76.2. x x x;
"76.3. x x x;
"76.4. x x x;
"76.5. x x x; and
"76.6. x x x."

SECTION 10. Section 93 of Republic Act No. 8293, otherwise known as the Intellectual Property Code of the Philippines, is hereby amended to read as follows:

"SEC. 93. *Grounds for Compulsory Licensing.* – The Director General of the Intellectual Property Office 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:

"93.1. National emergency or other circumstances of extreme urgency;

"93.2. Where the public interest, in particular, national security, nutrition, health or the development of other vital sectors of the national economy as determined by the appropriate agency of the Government, so requires; or

"93.3. Where a judicial or administrative body has determined that the manner of exploitation by the owner of the patent or his licensee is anti-competitive; or

"93.4. In case of public non-commercial use of the patent by the patentee, without satisfactory reason;

"93.5. If the patented invention is not being worked in the Philippines on a commercial scale, although capable of being worked, without satisfactory reason: *Provided* , That the importation of the patented article shall constitute working or using the patent; (Secs. 34, 34-A, 34-B, R.A. No. 165a) and

"93.6. Where the demand for patented drugs and medicines is not being met to an adequate extent and on reasonable terms, as determined by the Secretary of the Department of Health."

SECTION 11. A new Section 93-A is hereby inserted after Section 93 of Republic Act No. 8293, otherwise known as the Intellectual Property Code of the Philippines, to read as follows:

"SEC. 93-A. *Procedures on Issuance of a Special Compulsory License under the TRIPS Agreement.* – 93-A.1. The Director General of the Intellectual Property Office, upon the written recommendation of the Secretary of the Department of Health, shall, upon filing of a petition, grant a special compulsory license for the importation of patented drugs and medicines.

The special compulsory license for the importation contemplated under this provision shall be an additional special alternative procedure to ensure access to quality affordable medicines and shall be primarily for domestic consumption: *Provided* , That adequate remuneration shall be paid to the patent owner either by the exporting or importing country. The compulsory license shall also contain a provision directing the grantee the license to exercise reasonable measures to prevent the re-exportation of the products imported under this provision.

"The grant of a special compulsory license under this provision shall be an exception to Sections 100.4 and 100.6 of Republic Act No. 8293 and shall be immediately executory. "No court, except the Supreme Court of the Philippines, shall issue any temporary restraining order or preliminary injunction or such other provisional remedies that will prevent the grant of the special compulsory license.

"93-A.2. A compulsory license shall also be available for the manufacture and export of drugs and medicines to any country having insufficient or no manufacturing capacity in the pharmaceutical sector to address public health problems: *Provided* , That, a compulsory license has been granted by such country or such country has, by notification or otherwise, allowed importation into its jurisdiction of the patented drugs and medicines from the Philippines in compliance with the TRIPS Agreement.

"93-A.3. The right to grant a special compulsory license under this section shall not limit or prejudice the rights, obligations and flexibilities provided under the TRIPS Agreement and under Philippine laws, particularly Section 72.1 and Section 74 of the Intellectual Property Code, as amended under this Act. It is also without prejudice to the extent to which drugs and medicines produced under a compulsory license can be exported as allowed in the TRIPS Agreement and applicable laws."

SECTION 12. Section 94 of Republic Act No. 8293, otherwise known as the Intellectual Property Code of the Philippines, is hereby amended to read as follows:

"SEC. 94. *Period for Filing a Petition for a Compulsory License.* – 94.1. A compulsory license may not be applied for on the ground stated in Subsection 93.5 before the expiration of a period of four (4) years from the date of filing of the application or three (3) years from the date of the patent whichever period expires last.

"94.2. A compulsory license which is applied for on any of the grounds stated in Subsections 93.2, 93.3, 93.4, and 93.6 and Section 97 may be applied for at any time after the grant of the patent. (Sec. 34(1), R. A. No. 165)"

SECTION 13. Section 95 of Republic Act No. 8293, otherwise known as the Intellectual Property Code of the Philippines, is hereby amended to read as follows:

"SEC. 95. *Requirement to Obtain a License on Reasonable Commercial Terms.* – 95.1. The license will only be granted after the petitioner has 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 any of the following cases:

"(a) Where the petition for compulsory license seeks to remedy a practice determined after judicial or administrative process to be anti-competitive;

"(b) In situations of national emergency or other circumstances of extreme urgency;

"(c) In cases of public non-commercial use; and

"(d) In cases where the demand for the patented drugs and medicines in the Philippines is not being met to an adequate extent and on reasonable terms, as determined by the Secretary of the Department of Health.

"95.3. In situations of national emergency or other circumstances of extreme urgency, the right holder shall be notified as soon as reasonably practicable.

"95.4. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly. (n)

"95.5. Where the demand for the patented drugs and medicines in the Philippines is not being met to an adequate extent and on reasonable terms, as determined by the Secretary of the Department of Health, the right holder shall be informed promptly."

SECTION 14. Section 147 of Republic Act No. 8293, otherwise known as the Intellectual Property Code of the Philippines, is hereby amended to read as follows:

"SEC. 147. Rights Conferred. – 147.1. Except in cases of importation of drugs and medicines allowed under Section 72.1 of this Act and of off-patent drugs and medicines, the owner of a registered mark shall have the exclusive right to prevent all third parties not having the owner's consent from using in the course of trade identical or similar signs or containers for

goods or services which are identical or similar to those in respect of which the trademark is registered where such use would result in a likelihood of confusion. In case of the use of an identical sign for identical goods or services, a likelihood of confusion shall be presumed.

"There shall be no infringement of trademarks or trade names of imported or sold patented drugs and medicines allowed under Section 72.1 of this Act, as well as imported or sold off patent drugs and medicines: *Provided*, That, said drugs and medicines bear the registered marks that have not been tampered, unlawfully modified, or infringed upon, under Section 155 of this Code.

"147.2. x x x."

SECTION 15. Section 159 of Republic Act No. 8293, otherwise known as the Intellectual Property Code of the Philippines, is hereby amended to read as follows:

"SEC. 159. *Limitations to Actions for Infringement*. – Notwithstanding any other provision of this Act, the remedies given to the owner of a right infringed under this Act shall be limited as follows:

"159.1. x x x;

"159.2. x x x;

"159.3. x x x and

"159.4 There shall be no infringement of trademarks or tradenames of imported or sold drugs and medicines allowed under Section 72.1 of this Act, as well as imported or sold off-patent drugs and medicines: *Provided*, That said drugs and medicines bear the registered marks that have not been tampered, unlawfully modified, or infringed upon as defined under Section 155 of this Code."

SECTION 16. *Implementing Rules and Regulations on Amendments to Republic Act No. 8293, otherwise known as the Intellectual Property Code of the Philippines*. – Unless otherwise provided herein, the Intellectual Property Office, in coordination with the Department of Health and the Bureau of Food and Drugs, shall issue and promulgate, within one hundred twenty (120) days after the enactment of this Act, the implementing rules and regulations to effectively implement the provisions of this Act that relate to Republic Act No. 8293, otherwise known as the Intellectual Property Code of the Philippines.

CHAPTER 3
DRUGS AND MEDICINES PRICE REGULATION

SECTION 17. *Drugs and Medicines Price Regulation Authority of the President of the Philippines*. – The President of the Philippines, upon recommendation of the Secretary of the Department of Health, shall have the power to impose maximum retail prices over any or all drugs and medicines as enumerated in Section 23. The power to impose maximum retail prices over drugs and medicines shall be exercised within such period of time as the situation may warrant as determined by the President of the Philippines. No court, except the Supreme Court of the Philippines, shall issue any temporary restraining order or preliminary injunction or preliminary mandatory injunction that will prevent the immediate execution of the exercise of this power of the President of the Philippines.

SECTION 18. *Drugs and Medicines Price Monitoring and Regulation Authority of the Secretary of the Department of Health* . – To implement the policies of this Act under this Chapter, the Secretary of the Department of Health is hereby authorized to establish and initiate a price monitoring and regulation system for drugs and medicines within one hundred twenty (120) days after the enactment of this Act. The Secretary of the Department of Health may also create such bodies, consultative councils, from which advice may be sought in the implementation of a drug or medicine price monitoring and regulation policy. Such bodies or consultative councils created by the Secretary of the Department of Health shall coordinate its efforts together with other government agencies.

SECTION 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

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 Fifty thousand pesos (Php50,000.00) 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 enume-

rated under Section 19(A)(2), and any and all necessary information that the Secretary of the Department of Health may require.

SECTION 20. *Procedures for Inquiries, Studies, Hearings, Investigations, and Proceedings*. – All inquiries, studies, hearings, investigations and proceedings conducted by the Secretary of the Department of Health shall be governed by the rules adopted by him/her, and in the conduct thereof shall not be bound by the technical rules of evidence.

SECTION 21. *Effectivity of the Decisions or Orders of the Secretary of the Department of Health*. – All decisions or orders of the Secretary of the Department of Health pursuant to Section 19 Paragraphs (A) Power to Recommend the Maximum Retail Price of Drugs and Medicines Subject to Price Regulation, (B) Power to Include Other Drugs and Medicines in the List Subject to Price Regulation, (C) Power to Implement Cost-Containment and Other Measures, (D) Power to Impose Administrative Fines and Penalties, (E) Power to Deputize Government Entities, or (F) Other Powers Necessary to Implement Provisions of this Chapter, shall be immediately operative.

SECTION 22. *Review of the Decisions or Orders of the Secretary of the Department of Health*. – A party adversely affected by a decision, order or ruling of the Secretary of the Department of Health 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 Secretary of the Department of Health, 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.

SECTION 23. *List of Drugs and Medicines that are Subject to Price Regulation*. – The list of drugs and medicines that are subject to price regulation shall include, *inter alia*:

(a) All drugs and medicines indicated for treatment of chronic illnesses and life threatening conditions, such as, but not limited to, endocrine disorders, e.g., diabetes mellitus; gastrointestinal disorders, e.g., peptic ulcer; urologic disorders, e.g., benign prostatic hyperplasia (BPH); cardiovascular diseases, e.g., hypertension; pulmonary diseases, e.g., pulmonary tuberculosis (PTB), asthma; auto-immune diseases, e.g., systemic lupus erythematosus (SLE); skin diseases, e.g., psoriasis; neuro-psychiatric disorders; other infectious diseases, e.g., human immunodeficiency virus-acquired immune deficiency syndrome (HIV-AIDS); and other conditions such as organ transplants and neoplasm;
(b) Drugs and medicines indicated for prevention of diseases, e.g., vaccines, immunoglobulin, anti-sera;
(c) Drugs and medicines indicated for prevention of pregnancy, e.g., oral contraceptives;
(d) Anesthetic agents;
(e) Intravenous fluids;
(f) Drugs and medicines that are included in the Philippine National Drug Formulary (PNDF) Essential Drug List; and

(g) All other drugs and medicines which, from time to time, the Secretary of the Department of Health determines to be in need of price regulation.

SECTION 24. *Illegal Acts of Price Manipulation* . – Without prejudice to the provisions of existing laws on goods not covered by this Act, it shall be unlawful for any manufacturer, importer, trader, distributor, wholesaler, retailer, or any person engaged in any method of disposition of drugs and medicines to engage in acts of price manipulation such as hoarding, profiteering, or illegal combination or forming cartel, as defined under Section 5 of Republic Act No. 7581, otherwise known as the Price Act, and all other acts committed in restraint of trade.

SECTION 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 One hundred thousand pesos (Php100,000.00) 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. Whenever any act of illegal price manipulation of any drug and medicine subject to price regulation is committed by a juridical person, its officials or employees, or in case of a foreign corporation or association, its agent or representative in the Philippines who are responsible for the violation, shall be held liable therefore.

SECTION 26. *Display of Maximum Retail Price Fixed and Approved by Order of the President of the Philippines for Drugs and Medicines Subject to Price Regulation* . –

(a) Within a reasonable period as may be determined by the Secretary of the Department of Health, 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 approved by order of the President of the Philippines. 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.

(b) Within a period as may be determined by the Secretary of the Department of Health 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, indicating the retail price, the maximum retail price, and such other information as may be required by the Secretary of the Department of Health.

SECTION 27. *Reports from Local Government Units (LGUs) and the Department of Trade and Industry (DTI)* . – All local government units and the Department of Trade and Industry shall help ensure the implementation of pricing policies provided under this Chapter by submitting quarterly price monitoring reports to the Secretary of the Department of Health of drugs and medicines identified by the latter, and any and all necessary information that the Secretary of the Department of Health may require.

SECTION 28. *Role of the Department of Health (DOH) and the Department of Trade and Industry (DTI)* . – The Department of Health and the Department of Trade and Industry shall conduct independent periodic surveys and studies of the selling prices of all drugs and medicines referred to in Section 23 of this Act all over the country as well as their share or effect on the family income of the different economic groups in the country for purposes of serving as data base for government efforts to promote access to more affordable medicines, as well as evaluating the effectivity of the measures undertaken to promote access to more affordable medicines. The DTI shall always officially provide the Secretary of the Department of Health copies of these independent reports.

SECTION 29. *Rules and Regulations* . – The Secretary of the Department of Health, in consultation with the Department of Trade and Industry, the Congressional Oversight Committee and other appropriate government agencies, shall, within one hundred twenty (120) days from the effectivity of this Act, promulgate the rules and regulations necessary to effectively implement the provisions of this Chapter.

SECTION 30. *Reportorial and Public Notice Requirements* . –

(a) The Secretary of the Department of Health 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.

(b) It shall also submit annually a report of its performance on the implementation of this Act to both Houses of Congress, within fifteen (15) days from the opening of the regular session. It shall also regularly report and comply immediately to any order of the Congressional Oversight Committee.

(c) The order of the President of the Philippines 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 and provide the same to their clients and customers for every transaction.

(d) All drug outlets are required to post in a conspicuous area within its premises a clear copy of the order of the President of the Philippines which shall be easily accessible to the consuming public and updated regularly as the situation may warrant.

CHAPTER 4
STRENGTHENING OF THE BUREAU OF FOOD AND DRUGS

SECTION 31. *Strengthening of the Bureau of Food and Drugs (BFAD)* . –

(a) For a more effective and expeditious implementation of this Act, the Director or head of the Bureau of Food and Drugs shall be authorized to retain, without need of a separate approval from any government agency, and subject only to existing accounting and auditing rules and regulations, all the fees, fines, royalties and other charges, collected

by the Bureau of Food and Drugs under this Act and other laws that it is mandated to administer based on the immediately prior year of operations, for use in its operations, like upgrading of its facilities, equipment outlay, human resource development and expansion, and the acquisition of the appropriate office space, among others, to improve the delivery of its services to the public. This amount, which shall be in addition to the annual budget of the Bureau of Food and Drugs, shall be deposited and maintained in a separate account or fund, which may be used or disbursed directly by the Director or head.

(b) After five (5) years from the coming into force of this Act, the Director or head of the Bureau of Food and Drugs shall, subject to the approval of the Secretary of the Department of Health, determine if the fees and charges, mentioned in Subsection (a) hereof, are sufficient to meet its budgetary requirements. If so, it shall retain all the fees and charges it shall collect under the same conditions indicated in said Subsection (a) but shall forthwith, cease to receive any funds from the annual budget of the National Government; if not, the provisions of Subsection (a) shall continue to apply until such time when the Director or head of the Bureau of Food and Drugs, subject to the approval of the Secretary of the Department of Health, certifies that the above stated fees and charges the Bureau of Food and Drugs shall collect are enough to fund its operations.

(c) The Bureau of Food and Drugs shall submit a yearly performance report to the Quality Affordable Medicines Oversight Committee, as provided in Section 45 of this Act. The report shall itemize the use of such retained funds in the past year up to the present and the budgeted use of the same in the succeeding periods.

SECTION 32. *Quality Assurance of Drugs* . – The Bureau of Food and Drugs shall take the necessary steps to ensure that all drugs authorized for marketing in the country shall conform to international standards for the content, purity and quality of pharmaceutical products as established in the International Pharmacopoeia: *Provided,* That imported products in finished dosage forms, should be certified under the World Health Organization (WHO) certification scheme on the quality of pharmaceutical products moving in international commerce: *Provided, further,* That the registration for multisource pharmaceutical products should conform to the WHO guidelines on registration requirements to establish interchangeability.

CHAPTER 5
NON-DISCRIMINATORY CLAUSE

SECTION 33. *Non-Discriminatory Clause* . – It shall be unlawful for any retail drug outlet to refuse to carry either by sale or by consignment, or offer for sale drugs and medicines brought into the country, as allowed under Section 7 of this Act which amends Section 72.1 of the Intellectual Property Code of the Philippines or Republic Act No. 8293, by the government or authorized third party which have been previously approved for distribution or sale by the Bureau of Food and Drugs. For this purpose, the said products shall be displayed with equal prominence as all other products sold in the establishment.

SECTION 34. *Refusal to Sell Drugs and Medicines* . – No manufacturer, importer, trader, distributor,

wholesaler shall withhold from sale or refuse to sell to a wholesaler or retailer any drug or medicine without good and sufficient reasons.

SECTION 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 One hundred thousand pesos (Php100,000.00) 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 One million pesos (Php1,000,000.00), 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 36. *Implementing Rules and Regulations on the Non-Discriminatory Clause.* – Within one hundred twenty (120) days from the effectivity of this Act, the Department of Health, in consultation with the Department of Trade and Industry, shall promulgate the rules and regulations necessary to effectively implement the provisions of this Chapter.

CHAPTER 6
AMENDMENTS TO REPUBLIC ACT NO. 6675, OTHERWISE KNOWN AS THE GENERICS ACT OF 1989

SECTION 37. Section 5 of Republic Act No. 6675, otherwise known as the Generics Act of 1988, is hereby amended to read as follows:

> "SEC. 5. *Posting and Publication*. – The Department of Health shall publish annually in acceptable means of public dissemination in at least two (2) newspapers of general circulation in the Philippines the generic names, and the corresponding brand names under which they are marketed, of all drugs and medicines available in the Philippines."

SECTION 38. Section 6 of Republic Act No. 6675, otherwise known as the Generics Act of 1988, is hereby amended to read as follows:

> "SEC. 6. *Who Shall Use Generic Terminology* . –
>
> (a) All government health agencies and their personnel as well as other government agencies shall use generic terminology or generic names in all transactions related to purchasing, prescribing, dispensing and administering of drugs and medicines.
>
> (b) All medical, dental and veterinary practitioners, including private practitioners, shall write prescriptions using the generic name. The brand name may be included if so desired.
>
> (c) Any organization or company involved in the manufacture, importation, repacking, marketing and/or distribution of drugs and medicines shall indicate prominently the generic name of the product. In the case of brand name products, the generic name shall appear prominently and immediately above the brand name in all product labels as well as in advertising and other promotional materials.
>
> (d) Drug outlets, including drugstores, hospital and non-hospital pharmacies and non-

traditional outlets such as supermarkets and stores, shall inform any buyer about any and all other drug products having the same generic name, together with their corresponding prices so that the buyer may adequately exercise his option. Within one (1) year after the approval of this Act, the drug outlets referred to herein shall post in conspicuous places in their establishments a list of drug products with the same generic name and their corresponding prices.

(e) There shall appear prominently on the label of a generic drug the following statement: THIS PRODUCT HAS THE SAME THERAPEUTIC EFFICACY AS ANY OTHER GENERIC PRODUCT OF THE SAME NAME. SIGNED: BFAD."

SECTION 39. Section 8 of Republic Act No. 6675, otherwise known as the Generics Act of 1988, is hereby amended to read as follows:

"SEC. 8. *Required Production*. – Subject to the rules and regulations promulgated by the Secretary of Health, every drug manufacturing company operating in the Philippines shall be required to produce, distribute and make widely available to the general public an unbranded generic counterpart of their branded product."

SECTION 40. Section 11 of Republic Act No. 6675, otherwise known as the Generics Act of 1988, is hereby amended to read as follows:

"SEC. 11. Education Drive. – The Department of Health jointly with the Philippine Information Agency and the Department of the Interior and Local Government shall conduct a continuous information campaign for the public and a continuing education and training for the medical and allied medical professions on drugs with generic names as an alternative of equal efficacy to the more expensive brand name drugs. Such educational campaign shall include information on the illnesses or symptoms which each generically named drug is supposed to cure or alleviate, as well as in contraindications. The Department of Health with the assistance of the Department of the Interior and Local Government and the Philippine Information Agency shall monitor the progress of the education drive, and shall submit regular reports to Congress."

SECTION 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 Ten thousand pesos (Php10,000.00) but not exceeding Twenty-five thousand pesos (Php25,000.00), at the discretion of the court.

(c) for the third 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)

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 One hundred thousand pesos (Php100,000.00) and suspension of his license to practice his profession for one (1) year 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 One hundred thousand pesos (Php100,000.00) 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 Forty thousand pesos (Php40,000.00) 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: and, *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."

SEC. 42. *Implementing Rules and Regulations to the Amendments to the Generics Act of 1988*. – The Department of Health, in consultation with the appropriate government agencies, shall, within one hundred twenty (120) days from the effectivity of this Act, promulgate the rules and regulations necessary to effectively implement the provisions of this Act that relate to Republic Act No. 6675, or the Generics Act of 1988.

CHAPTER 7
AMENDMENTS TO REPUBLIC ACT NO. 5921, AS AMENDED, OTHERWISE KNOWN AS THE PHARMACY LAW

SECTION 43. Section 25 of Republic Act No. 5921, as amended, otherwise known as the Pharmacy Law, 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, containers or in small quantities, not in their original containers to the consuming public through supermarkets, convenience stores and other retail establishments.

"Pharmaceutical, drug or biological manufacturing establishments, importers and wholesalers of drugs, medicines, or biologic products, shall not sell their products for re-sale except only to retail drug outlets, hospital pharmacies or to other drug wholesalers under the supervision of a registered pharmacist, and supermarkets, convenience stores, other retail establishments for over-the-counter drugs, duly licensed by the Bureau of Food and Drugs."

SECTION 44. *Implementing Rules and Regulations to the Amendments to the Pharmacy Law*. – The Department of Health, in consultation with the appropriate government agencies, within one hundred twenty (120) days from the effectivity of this Act, shall promulgate the rules and regulations necessary to effectively implement the provisions of this Chapter.

CHAPTER 8
MISCELLANEOUS PROVISIONS

SECTION 45. Congressional Oversight Committee. – For the effective implementation of this Act, there shall be created a Congressional Oversight Committee, hereinafter referred to as the Quality Affordable Medicines Oversight Committee, to be composed of five (5) members from the Senate, which shall include the Chairpersons of the Senate Committees on Trade and Commerce and Health and Demography, and, five (5) members from the House of Representatives, which shall include the Chairpersons of the House of Representatives Committees on Trade and Industry and Health. The Quality Affordable Medicines Oversight Committee shall be jointly chaired by the Chairpersons of the Senate Committee on Trade and Commerce and the House of Representatives Committee on Trade and Industry. The Vice-Chair of the oversight committee shall be jointly held by the Chairpersons of the Senate Committee on Health and Demography and the House of Representatives Committee on Health.

SECTION 46. Appropriations. – For the initial implementation of this Act, the amount of Twenty-five million pesos (Php25,000,000.00), in addition to the budget of the Department of Health, shall be provided for the operations of the Office of the Secretary of the Department of Health. The Quality Affordable Medicines Oversight Committee shall be provided an initial budget of Five million pesos (Php5,000,000.00) to perform its functions as mandated under this Act. Thereafter, such sum as may be necessary for its continued implementation shall be included in the annual General Appropriations Act.

SECTION 47. *Separability Clause*. – Any portion or provision of this Act that may be declared unconstitutional or invalid shall not have the effect of nullifying other portions and provisions hereof as long as such remaining portion or provision can still subsist and be given effect in their entirety.

SECTION 48. *Repealing Clause*. – All laws, decrees, executive orders, proclamations and administrative regulations or parts thereof inconsistent herewith are hereby repealed or modified accordingly.

SECTION 49. *Effectivity Clause* . – This Act shall take effect fifteen (15) days after its publication in at least two (2) national papers of general circulation.

Approved:

PROSPERO C. NOGRALES
Speaker of the House of Representatives

MANNY VILLAR
President of the Senate

This Act which is a consolidation of Senate Bill No. 1658 and House Bill No. 2844 was finally passed by the Senate and the House of Representatives on April 29, 2008.

MARILYN B. BARUA-YAP
Secretary General
House of Representatives

EMMA LIRIO-REYES
Secretary of the Senate

Approved: June 6, 2008

GLORIA MACAPAGAL-ARROYO
President of the Philippines