

S. No. 1658  
H. No. 2844

Republic of the Philippines  
**Congress of the Philippines**

Metro Manila

Fourteenth Congress

First Regular Session

Began and held in Metro Manila, on Monday, the twenty-third day of  
July, two thousand seven.

[ 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  
GENERIC 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".

SEC. 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.

SEC. 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.

SEC. 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; and
- (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 interchangeable;

(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

SEC. 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;