

FOURTEENTH CONGRESS OF THE )  
REPUBLIC OF THE PHILIPPINES )  
*First Regular Session* )

SENATE  
S. No. 1658

(In substitution of S.B. Nos. 90, 101, 755, 1404, 1420, 1530 and P.S. Resolution No. 49)

---

Prepared by the Committees with Senators Villar, Roxas, Trillanes IV, Cayetano, P., Zubiri,  
Legarda, Lapid and Enrile as authors thereof

---

AN ACT  
TO PROVIDE FOR QUALITY AFFORDABLE MEDICINES

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

1 SECTION 1. *Short Title.* – This Act shall be known as the “*Quality Affordable*  
2 *Medicines Act of 2007.*”

3 SECTION 2. *Declaration of Policy.* – The State recognizes as a priority national policy  
4 the protection and promotion of the right to health of the people. In protecting public  
5 health, it shall always endeavor to ensure broad access to quality affordable medicines for the  
6 benefit of the people.

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

10 SECTION 4. Section 26 of Republic Act No. 8293, otherwise known as the Intellectual  
11 Property Code of the Philippines, is hereby amended to read as follows:

12 “SEC. 26. *Inventive Step.* – 26.1. An invention involves an inventive  
13 step if, having regard to prior art, it is not obvious to a person skilled in the  
14 art at the time of the filing date or priority date of the application claiming  
15 the invention.

1           “26.2. IN THE CASE OF DRUGS OR MEDICINES, THERE IS NO  
2           INVENTIVE STEP IF THE INVENTION RESULTS FROM THE MERE  
3           DISCOVERY OF A NEW FORM OR NEW PROPERTY OF A KNOWN  
4           SUBSTANCE WHICH DOES NOT RESULT IN THE ENHANCEMENT OF  
5           THE KNOWN EFFICACY OF THAT SUBSTANCE, OR, THE MERE  
6           DISCOVERY OF ANY NEW USE FOR A KNOWN SUBSTANCE OR A  
7           KNOWN PROCESS UNLESS SUCH KNOWN PROCESS RESULTS IN A  
8           NEW PRODUCT THAT EMPLOYS AT LEAST ONE NEW REACTANT.”

9           SECTION 5. Section 72 of Republic Act No. 8293, otherwise known as the Intellectual  
10          Property Code of the Philippines, is hereby amended to read as follows:

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

14           “72.1. Using a patented product which has been put on the market in  
15          the Philippines by the owner of the product, or with his express consent,  
16          insofar as such use is performed after that product has been so put on the  
17          said market: *PROVIDED*, THAT, WITH REGARD TO DRUGS OR  
18          MEDICINES, THE LIMITATION ON PATENT RIGHTS TO THE USE,  
19          SALE, OFFERING FOR SALE OR IMPORTATION OF THE PRODUCT  
20          SHALL APPLY AFTER A DRUG OR MEDICINE HAS BEEN  
21          INTRODUCED ANYWHERE IN THE WORLD BY THE PATENT  
22          OWNER, OR BY ANY PARTY AUTHORIZED TO USE THE  
23          INVENTION.

1           “72.2. Where the act is done privately and on a non-commercial scale  
2 or for a non-commercial purpose: *Provided*, That it does not significantly  
3 prejudice the economic interests of the owner of the patent;

4           “72.3. Where the act consists of making or using exclusively for [the  
5 purpose of experiments that relate to the subject matter of the patented  
6 invention;] EXPERIMENTAL USE OF THE INVENTION FOR  
7 SCIENTIFIC PURPOSES OR EDUCATIONAL PURPOSES AND SUCH  
8 OTHER ACTIVITIES DIRECTLY RELATED TO SUCH SCIENTIFIC OR  
9 EDUCATIONAL EXPERIMENTAL USE.

10          “72.4. WHERE THE ACT INCLUDES TESTING, USING, MAKING OR  
11 SELLING THE INVENTION INCLUDING ANY DATA RELATED  
12 THERETO, SOLELY FOR PURPOSES REASONABLY RELATED TO THE  
13 DEVELOPMENT AND SUBMISSION OF INFORMATION AND  
14 ISSUANCE OF APPROVALS BY GOVERNMENT REGULATORY  
15 AGENCIES REQUIRED UNDER ANY LAW OF THE PHILIPPINES  
16 THAT REGULATES THE MANUFACTURE, CONSTRUCTION, USE OR  
17 SALE OF ANY PRODUCT: *PROVIDED*, THAT IN ORDER TO PROTECT  
18 THE DATA SUBMITTED BY THE ORIGINAL PATENT HOLDER FROM  
19 UNFAIR COMMERCIAL USE PROVIDED IN ARTICLE 39.3 OF THE  
20 TRIPS AGREEMENT, THE INTELLECTUAL PROPERTY OFFICE (IPO),  
21 IN CONSULTATION WITH THE APPROPRIATE GOVERNMENT  
22 AGENCIES, SHALL ISSUE THE APPROPRIATE RULES AND  
23 REGULATIONS NECESSARY THEREIN NOT LATER THAN ONE  
24 HUNDRED TWENTY (120) DAYS AFTER ENACTMENT OF THIS LAW.

1            “[72.4] 72.5. Where the act consists of the preparation for individual  
2 cases, in a pharmacy or by a medical professional, of a medicine in  
3 accordance with a medical prescription or acts concerning the medicine so  
4 prepared;

5            “[72.5] 72.6. Where the invention is used in any ship, vessel, aircraft,  
6 or land vehicle of any other country entering the territory of the  
7 Philippines temporarily or accidentally: Provided, That such invention is  
8 used exclusively for the needs of the ship, vessel, aircraft, or land vehicle  
9 and not used for the manufacturing of anything to be sold within the  
10 Philippines. (Secs. 38 and 39, R.A. No. 165a)”

11            SECTION 6. Section 74 of Republic Act No. 8293, otherwise known as the Intellectual  
12 Property Code of the Philippines, is hereby amended to read as follows:

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

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

19            (b) A judicial or administrative body has determined that the  
20 manner of exploitation, by the owner of the patent or his  
21 license, is anti-competitive; OR

22            (C) THERE IS PUBLIC NON-COMMERCIAL USE OF THE  
23 PATENT BY THE PATENTEE, WITHOUT SATISFACTORY  
24 REASON.

1           “74.2. UNLESS OTHERWISE PROVIDED HEREIN, [T]he use by the  
2 Government, or third person authorized by the Government shall be  
3 subject, [*mutatis mutandis*, to the conditions set forth in Sections 95 to 97  
4 and 100 to 102. (Sec. 41, R.A. No. 165a)] TO THE FOLLOWING  
5 PROVISIONS:

6           (A) IN SITUATIONS OF NATIONAL EMERGENCY OR  
7 OTHER CIRCUMSTANCES OF EXTREME URGENCY, THE  
8 RIGHT HOLDER SHALL BE NOTIFIED AS SOON AS  
9 REASONABLY PRACTICABLE;

10          (B) IN THE CASE OF PUBLIC NON-COMMERCIAL USE,  
11 WHERE THE GOVERNMENT OR CONTRACTOR,  
12 WITHOUT MAKING A PATENT SEARCH, KNOWS OR  
13 HAS DEMONSTRABLE GROUNDS TO KNOW THAT A  
14 VALID PATENT IS OR WILL BE USED BY OR FOR THE  
15 GOVERNMENT, THE RIGHT HOLDER SHALL BE  
16 INFORMED PROMPTLY;

17          (C) THE SCOPE AND DURATION OF SUCH USE SHALL BE  
18 LIMITED TO THE PURPOSE FOR WHICH IT WAS  
19 AUTHORIZED, AND IN THE CASE OF SEMI-CONDUCTOR  
20 TECHNOLOGY, SHALL ONLY BE FOR PUBLIC NON-  
21 COMMERCIAL USE OR TO REMEDY A PRACTICE  
22 DETERMINED AFTER JUDICIAL OR ADMINISTRATIVE  
23 PROCESS TO BE ANTI-COMPETITIVE;

24          (D) SUCH USE SHALL BE NON-EXCLUSIVE;

1 (E) THE RIGHT HOLDER SHALL BE PAID ADEQUATE  
2 REMUNERATION IN THE CIRCUMSTANCES OF EACH  
3 CASE, TAKING INTO ACCOUNT THE ECONOMIC VALUE  
4 OF THE AUTHORIZATION;

5 (F) THE LEGAL VALIDITY OF ANY DECISION RELATING  
6 TO THE AUTHORIZATION OF SUCH USE SHALL BE  
7 SUBJECT TO JUDICIAL REVIEW; AND

8 (G) THE USE OR OTHER EXPLOITATION BY THE  
9 GOVERNMENT OR THIRD PERSON AUTHORIZED BY  
10 THE GOVERNMENT OF DRUGS OR MEDICINES UNDER  
11 THIS SECTION SHALL BE SUBJECT TO THE EXCLUSIVE  
12 DETERMINATION OF THE PRESIDENT OF THE  
13 REPUBLIC OF THE PHILIPPINES AND SHALL BE  
14 IMMEDIATELY EXECUTORY: *PROVIDED*, THAT NO  
15 COURT, EXCEPT THE SUPREME COURT OF THE  
16 PHILIPPINES, SHALL ISSUE ANY TEMPORARY  
17 RESTRAINING ORDER OR PRELIMINARY INJUNCTION  
18 OR PRELIMINARY MANDATORY INJUNCTION THAT  
19 WILL PREVENT ITS IMMEDIATE EXECUTION. THE  
20 OFFICE OF THE PRESIDENT, IN CONSULTATION WITH  
21 THE APPROPRIATE GOVERNMENT AGENCIES, SHALL  
22 ISSUE THE APPROPRIATE IMPLEMENTING RULES AND  
23 REGULATIONS FOR THE EXERCISE OF THIS AUTHORITY  
24 WITHIN ONE HUNDRED TWENTY (120) DAYS AFTER  
25 ENACTMENT OF THIS LAW. ALL CASES ARISING FROM

1 THE IMPLEMENTATION OF THIS PROVISION SHALL BE  
2 COGNIZABLE BY COURTS WITH APPROPRIATE  
3 JURISDICTION PROVIDED BY LAW.”

4 SECTION 7. Section 159 of Republic Act No. 8293, otherwise known as the Intellectual  
5 Property Code of the Philippines, is hereby amended to read as follows:

6 “Section 159. x x x

7 “x x x

8 “x x x

9 “x x x

10 “159.4 THERE SHALL BE NO INFRINGEMENT OF TRADEMARKS  
11 OR TRADENAMES OF IMPORTED OR SOLD DRUGS OR MEDICINES  
12 ALLOWED UNDER SECTION 72.1 OF THIS ACT, AS WELL AS,  
13 IMPORTED OR SOLD OFF-PATENT DRUGS OR MEDICINES:  
14 PROVIDED, THAT SAID DRUGS OR MEDICINES BEAR THE  
15 REGISTERED MARKS THAT HAVE NOT BEEN TAMPERED,  
16 UNLAWFULLY MODIFIED, OR INFRINGED UPON AS DEFINED  
17 UNDER SECTION 155 OF THIS CODE.”

18 SECTION 8. *Implementing Rules and Regulations on Amendments to Republic Act*  
19 *No. 8293, otherwise known as the Intellectual Property Code of the Philippines.* – Unless  
20 otherwise provided herein, the Intellectual Property Office, in coordination with the  
21 Department of Health and the Bureau of Food and Drugs, shall issue the necessary  
22 implementing rules and regulations for all amendments to Republic Act No. 8293, otherwise  
23 known as the Intellectual Property Code of the Philippines, within one hundred twenty  
24 (120) days after enactment of this law.

1           **SECTION 9. *Strengthening of the Bureau of Food and Drugs (BFAD).*** – (a) For a more  
2 effective and expeditious implementation of this Act, the Director or head of the Bureau of Food  
3 and Drugs shall be authorized to retain, without need of a separate approval from any  
4 government agency, and subject only to the existing accounting and auditing rules and  
5 regulations, all the fees, fines, royalties and other charges, collected by the Bureau of Food and  
6 Drugs under this Act and other laws that it is mandated to administer based on the immediately  
7 prior year of operations, for use in its operations, like upgrading of its facilities, equipment  
8 outlay, human resource development and expansion, and the acquisition of the appropriate office  
9 space, among others, to improve the delivery of its services to the public. This amount, which  
10 shall be in addition to the Bureau of Food and Drugs’ annual budget, shall be deposited and  
11 maintained in a separate account or fund, which may be used or disbursed directly by the  
12 Director or head.

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

23           (c) The Bureau of Food and Drugs shall submit a yearly performance report to the  
24 Quality Affordable Medicines Oversight Committee, as provided in Section 11 of this Act.  
25 The report shall itemize the use of such retained funds in the past year up to the present and  
26 the budgeted use of the same in the succeeding periods.

27           **SECTION 10. *Drug or Medicine Price Regulation by the President of the Philippines.*** -

1 (a) Without prejudice to the provisions in Republic Act No. 7581, otherwise known as the  
2 Price Act, the President of the Philippines shall have the power to impose price ceilings over any  
3 or all drugs or medicines, upon joint recommendation of the Secretaries of the Department of  
4 Health and Trade and Industry, if any of the following conditions so warrant:

5 (1) The impendency, existence, or effects of a calamity that affects public health;

6 (2) The threat, existence, or effect of a public health emergency officially recognized  
7 by the Department of Health or by official Department of Health recognized non-  
8 governmental organizations;

9 (3) The prevalence of widespread acts of illegal price manipulation of any drug or  
10 medicine;

11 (4) The impendency, existence, or effect of any event that causes artificial and  
12 unreasonable increase in the prices of any drug or medicine.

13 (5) Whenever the prevailing price of any drug or medicine has risen to unreasonable  
14 levels.

15 (b) The power of the President of the Philippines to impose price ceilings shall be  
16 exercised within such period of time that the President shall deem necessary. The effectivity  
17 of this power of the President of the Philippines to impose price ceilings on drugs or  
18 medicines maybe revoked by the President of the Philippines by Executive Order. No court,  
19 except the Supreme Court of the Philippines, shall issue any temporary restraining order or  
20 preliminary injunction or preliminary mandatory injunction that will prevent the immediate  
21 execution of the exercise of this power of the President of the Republic of the Philippines.

22 (c) Any person who refuses to comply with the order of the President of the  
23 Philippines as provided herein shall be punished with an administrative fine of not less than  
24 One Hundred Thousand Pesos (Php100,000.00) but not more than Five Hundred Thousand  
25 pesos (Php500,000.00) at the discretion of the Secretary of the Department of Health for the  
26 first offense. For each of the succeeding offenses, the administrative fine shall not be less

1 than Five Hundred Thousand Pesos (Php500,000.00) but not more than One Million Pesos  
2 (Php1,000,000.00) at the discretion of the Secretary of the Department of Health plus the  
3 cancellation of the license to operate by the Bureau of Food and Drugs and/or such other  
4 appropriate government authorities.

5 (d) The Secretary of the Department of Health (DOH) shall issue the necessary  
6 implementing rules and regulations for the enforcement of the exercise of this power by the  
7 President of the Philippines. The implementing rules and regulations shall be issued by the  
8 Department of Health (DOH) within sixty (60) days from the promulgation of the order of  
9 the President of the Philippines.

10 **SECTION 11.** *Congressional Oversight Committee.* – (a) For the effective  
11 implementation of this Act, there shall be created a Congressional Oversight Committee, here-in-  
12 after to be referred to as the Quality Affordable Medicines Oversight Committee to be composed  
13 of five (5) members from the Senate, which shall include the Chairpersons of the Senate  
14 Committees on Trade and Commerce and Health and Demography, and, five (5) members from  
15 the House of Representatives, which shall include the Chairpersons of the House of  
16 Representatives Committees on Trade and Commerce and Health and Demography. The Chair  
17 of the Quality Affordable Medicines Oversight Committee shall be the Chairperson of the Senate  
18 Committee on Trade and Commerce, and, the Vice-Chair of the oversight committee shall be the  
19 Chairperson of the House of Representatives Committee on Health and Demography.

20 (b) The Quality Affordable Medicines Oversight Committee shall oversee the full  
21 implementation of the provisions of this Act.

22 **SECTION 12.** *Appropriations.* – For the initial implementation of this Act, the amount  
23 of Twenty Five Million Pesos (Php25,000,000.00) shall be provided for purposes of this Act  
24 in the current General Appropriations Act as addition to the annual budget of the  
25 Department of Health. Thereafter, such sum as may be necessary for its continued  
26 implementation shall be included in the annual general Appropriations Act.

1           SECTION 13. *Separability Clause.* – Any portion or provisions of this Act that may be  
2 declared unconstitutional or invalid shall not have the effect of nullifying other portions and  
3 provisions hereof as long as such remaining portion or provision can still subsist and be given  
4 effect in their entirety.

5           SECTION 14. *Repealing Clause.* – All laws, decrees, executive orders, proclamations  
6 and administrative regulations, or parts thereof inconsistent herewith are hereby repealed or  
7 modified accordingly.

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

Approved,