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**HOUSE OF REPRESENTATIVES**

5

H. No. 2844

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6 BY REPRESENTATIVES BIRON, LACSON, GULLAS, LOCSIN, PINGOY, TEODORO,  
7 CUA (J.), NOGRALES, HONTIVEROS-BARAQUEL, DEL ROSARIO,  
8 PUENTEVELLA, CHIPECO, DEL MAR, ROXAS, ARROYO (D.), ABAYA, CUA  
9 (G.), LIM, CHATTO, VELARDE, COSCOLLUELA, GONZALES (A.), YAP,  
10 OCAMPO, CASIÑO, SYJUCO, ALVAREZ (A.), TIENG, MAZA, BELTRAN,  
11 ILAGAN, ALMARIO, SUSANO, PABLO, BONDOC, SY-LIMKAICHONG,  
12 SINGSON (E.), SILVERIO, CAJAYON, JIKIRI, ASILO, CUENCO, FUA,  
13 LAGDAMEO, ZAMORA (M.), UMALI (C.), MANGUDADATU, BICHARA,  
14 ROMAN, ABANTE, GARCIA (A.), NICOLAS, SALIMBANGON, CAJES,  
15 ROMUALDO, EMANO, PANCRUDO, SALVACION, LAGBAS, CODILLA,  
16 FABIAN, LABADLABAD, ANGARA, BRIONES, CERILLES, UY (R.S.), TEVES,  
17 PADILLA, CLIMACO, YU, HATAMAN, FERNANDEZ, ZAMORA (R.), BINAY,  
18 ESCUDERO, MARCOS, DILANGALEN, GARAY, GATCHALIAN, MENDOZA,  
19 DANGWA, DUMPIT, UY (R.A.), BAUTISTA, HOFER, APOSTOL,  
20 BALINDONG, CABILAO, ALVAREZ (G.), JALOSJOS-CARREON, JALOSJOS,  
21 GO, AMATONG, GARCIA (V.), DAYANGHIRANG, ECLEO, DIMAPORO,  
22 CHAVEZ, BONOAN-DAVID, ROBES, SY-ALVARADO, ARBISON, JAAFAR,  
23 FUENTEBELLA, DIAZ, SINGSON (R.), UY (E.), LAPUS, SUAREZ, LAGMAN,  
24 KHO, MARAÑON, MIRAFLORES, ROMARATE, AMANTE, AQUINO,  
25 CHIONGBIAN, BAGATSING, MADRONA, LOPEZ, GONZALES (N.), PLAZA,  
26 CARI, RODRIGUEZ, DEFENSOR (M.), SANDOVAL, ROMULO, BRAVO,  
27 JOSON, DUAVIT, RODRIGUEZ-ZALDARRIAGA, CLARETE, ARENAS, PONCE-  
28 ENRILE, LAZATIN, VALENCIA, CRISOLOGO, REYES (V.), DUEÑAS, DE  
29 GUZMAN, MANDANAS, CASTELO DAZA, ARROYO (I.), ALCALA,  
30 GATLABAYAN, VALDEZ, VIOLAGO, AGGABAO, VARGAS, DOMINGUEZ,  
31 ESTRELLA (C.), DEFENSOR (A.), SANTIAGO (J.), SOLIS, MATUGAS,  
32 AGYAO, SEARES-LUNA, BARZAGA, ENVERGA, PANCHO, BULUT, REYES  
33 (C.), DOMOGAN, DURANO, ERMITA-BUHAIN, ANGPING, ALBANO,  
34 ORTEGA, COJUANGCO, DY, ABLAN, CELESTE, TAN, RAMIRO, REMULLA,  
35 SOON-RUIZ, JALA, VILLAR, AKBAR, LEDESMA, PRIETO-TEODORO,

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1 COQUILLA, MERCADO, ONG, GARIN, VILLAROSA, GUNIGUNDO,  
 2 GONZALEZ, CHONG, MAMBA, UMALI (A.), PICHAY, ARAGO, GARCIA (P.),  
 3 VINZONS-CHATO, FERRER, GARCIA (P.J.), BIAZON, MACAPAGAL-  
 4 ARROYO, MAGSAYSAY, DUMARPA, DIASNES, SAN LUIS, NAVA,  
 5 ESTRELLA (R.), MITRA, VILLANUEVA, NOEL, TAÑADA, ANTONINO-  
 6 CUSTODIO AND ZIALCITA, PER COMMITTEE REPORT NO. 3

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

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

## CHAPTER 1

### PREFATORY CHAPTER

9 SECTION 1 *Short Title.* – This Act shall be known as the “Cheaper  
 10 Medicines Act of 2007”.

11 SEC. 2 *Declaration of Policy.* – It is the policy of the State to protect  
 12 public health and, when the public interest or circumstances of extreme  
 13 urgency so require, it shall adopt appropriate measures to promote and ensure  
 14 access to affordable quality drugs and medicines for all.

15 SEC. 3 *Definition of Terms.* – For purposes of this Act, the following  
 16 terms are to mean as follows:

17 (a) “Board” refers to the Drug Price Regulation Board.

18 (b) “Bulk materials” refers to any pharmaceutical, chemical, biological  
 19 or plant product including its salts, esters, stereo-isomers and derivatives,  
 20 conforming to the Philippine Pharmacopoeia, United States Pharmacopoeia  
 21 (USP), British Pharmacopoeia, European Pharmacopoeia, Japanese  
 22 Pharmacopoeia, Indian Pharmacopoeia, or other standards, and used as such or  
 23 as an ingredient in any formulation.

1 (c) “Capital” refers to employed means net fixed assets plus working  
2 capital of a manufacturer in relation to the manufacture of pharmaceutical  
3 formulations.

4 (d) “Compulsory License” is a license issued by the Director General  
5 and the Director of Legal Affairs of the Intellectual Property Office to exploit a  
6 patented invention without the permission of the patent holder, either by  
7 manufacture or through parallel importation.

8 (e) “Drug outlet” refers to drugstores, pharmacies, and any other  
9 business establishments which sell drugs or medicines.

10 (f) “Doha Declaration” refers to the November 2001 Doha Declaration  
11 on the Agreement on Trade Related Aspects of Intellectual Property Rights  
12 (TRIPS Agreement) adopted by the World Trade Organization (WTO)  
13 Ministerial Conference of 2001 in Doha, Qatar that reaffirmed that the TRIPS  
14 Agreement “can and should be interpreted and implemented in a manner  
15 supportive of the WTO members’ right to protect public health and, in  
16 particular, to promote access to medicines for all” and reaffirms that the  
17 Agreement provides flexibility for this purpose, including identifying ways by  
18 which countries with insufficient or no pharmaceutical manufacturing  
19 capacities could make effective use of compulsory licensing under the TRIPS  
20 Agreement.

21 (g) “Drug or medicine” refers to any chemical compound or biological  
22 substance, other than food, intended for use in the treatment, prevention or  
23 diagnosis of disease in humans or animals, including but not limited to:

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

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

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

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

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

10 (i) recognized in the Philippine National Drug Formulary;

11 (ii) intended for use in the treatment or cure or mitigation of disease  
12 symptoms, injury or body defects in humans;

13 (iii) other than food, intended to affect the structure or any function of  
14 the human body;

15 (iv) in finished or ready-to-use dosage form; and

16 (v) intended for use as a component of any of the articles specified in  
17 clauses (i), (ii), (iii), and (iv).

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

22 (i) "Formulation" refers to the composition of a dosage form,  
23 including the characteristics of its raw materials.

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

27 (k) "Manufacture" includes any process or part of a process for  
28 making, altering, finishing, packing, labeling, breaking or otherwise treating or  
29 adapting any drug with a view to its sale and distribution, but does not include

1the compounding or dispensing of any drug in the ordinary course of retail  
2business.

3 (l) “Manufacturer” refers to any establishment engaged in the  
4operations involved in the production of a drug with the end view of storage,  
5distribution, or sale of the product.

6 (m) “Parallel imports” refers to products imported into a country  
7without the authorization of the right holder in that country, which have been  
8put on the market in another country by that person or with his consent or by  
9any party authorized to use the patented product.

10 (n) “Retailer” refers to a licensed establishment carrying on the retail  
11business of sale of drugs or medicines to customers.

12 (o) “Trader” refers to any licensed establishment which is a registered  
13owner of a drug product that procures the materials and packaging  
14components, and provides the production monographs, quality control  
15standards and procedures, but subcontracts the manufacture of such products to  
16a licensed manufacturer.

17 (p) “TRIPS Agreement” or Agreement on Trade Related Aspects of  
18Intellectual Property Rights refers to the international agreement administered  
19by the WTO that sets down minimum standards for many forms of intellectual  
20property regulation.

21 (q) “Wholesaler” refers to a licensed establishment or drug outlet who  
22acts as merchant, broker or agent, who sells or distributes for resale or  
23wholesale drugs or medicines.

24

## CHAPTER 2

AMENDMENTS TO REPUBLIC ACT NO. 8293, OTHERWISE KNOWN AS

25

THE INTELLECTUAL PROPERTY CODE OF THE PHILIPPINES

1        SEC. 4    Section 22 of Republic Act No. 8293 is hereby amended to  
2 read as follows:

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

5                “22.1. Discoveries, scientific theories and mathematical  
6 methods[;], AND IN THE CASE OF DRUGS OR MEDICINES, THE  
7 MERE DISCOVERY OF A NEW FORM OF A KNOWN SUBSTANCE  
8 WHICH DOES NOT RESULT IN THE ENHANCEMENT OF THE  
9 KNOWN EFFICACY, SAFETY AND PURITY OF THAT SUBSTANCE,  
10 OR THE MERE DISCOVERY OF ANY NEW PROPERTY OR NEW USE  
11 FOR A KNOWN SUBSTANCE, OR THE MERE USE OF A KNOWN  
12 PROCESS, UNLESS SUCH KNOWN PROCESS RESULTS IN A NEW  
13 PRODUCT THAT EMPLOYS AT LEAST ONE !" NEW REACTANT.

14                #FOR THE PURPOSE OF THIS CLAUSE, SALTS, ESTERS,  
15 ETHERS, POLYMORPHS, METABOLITES, PURE FORM, PARTICLE  
16 SI\$, ISOMERS, MI%TURES OF ISOMERS, COMPLE%ES,  
17 COMBINATIONS, AND OTHER DERIVATIVES OF A KNOWN  
18 SUBSTANCE SHALL BE CONSIDERED TO BE THE SAME  
19 SUBSTANCE, UNLESS THEY DIFFER SIGNIFICANTLY IN  
20 PROPERTIES WITH REGARD TO EFFICACY&

1           “22.2. Schemes, rules and methods of performing mental  
2 acts, playing games or doing business, and programs for  
3 computers;

4           “22.3. Methods for treatment of the human or animal  
5 body by surgery or therapy and diagnostic methods practiced on  
6 the human or animal body. This provision shall not apply to  
7 products and composition for use in any of these methods;

8           “22.4. Plant varieties or animal breeds or essentially  
9 biological process for the production of plants or animals. This  
10 provision shall not apply to micro-organisms and non-biological  
11 and microbiological processes.

12           “Provisions under this subsection shall not preclude  
13 Congress to consider the enactment of a law providing  
14 *sui generis* protection of plant varieties and animal breeds and a  
15 system of community intellectual rights protection;

16           “22.5. Aesthetic creations; and

17           “22.6. Anything which is contrary to public order or  
18 morality. (Sec. 8, R.A. No. 165a)”

19           SEC. 5 Section 72 of Republic Act No. 8293 is hereby amended to  
20 read as follows:

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

25           “72.1. Using a patented product which has been put on  
26 the market in the Philippines by the owner of the product, or with  
27 his express consent, insofar as such use is performed after that  
28 product has been put on the said market[;]’ **PROVIDED, THAT, IN**  
29 **THE CASE OF DRUGS OR MEDICINES, THE LIMITATION ON**

1 PATENT RIGHTS SHALL APPLY AFTER A DRUG OR MEDICINE  
2 HAS BEEN INTRODUCED ANYWHERE IN THE PHILIPPINES OR  
3 ANYWHERE ELSE IN THE WORLD BY THE PATENT OWNER OR  
4 BY ANY PARTY AUTHORIZED TO USE THE INVENTION'  
5 **PROVIDED, FURTHER,** THAT THE RIGHT TO IMPORT THE DRUGS  
6 OR MEDICINES CONTEMPLATED IN THIS SECTION SHALL BE  
7 AVAILABLE TO ANY GOVERNMENT AGENCY OR ANY DULY  
8 AUTHORIZED PRIVATE THIRD PARTY;

9 "72.2. Where the act is done privately and on a non-  
10 commercial scale or for a non-commercial purpose: *Provided,*  
11 That, it does not significantly prejudice the economic interests of  
12 the owner of the patent;

13 "72.3. Where the act consists of making or using  
14 exclusively for the purpose of experiments that relate to the  
15 subject matter of the patented invention;

16 "72.4. IN THE CASE OF DRUGS OR MEDICINES, WHERE  
17 THE ACT INCLUDES TESTING, USING, MAKING OR SELLING THE  
18 INVENTION INCLUDING ANY DATA RELATED THERETO, SOLELY  
19 FOR PURPOSES REASONABLY RELATED TO THE DEVELOPMENT  
20 AND SUBMISSION OF INFORMATION AND ISSUANCE OF  
21 APPROVALS BY GOVERNMENT REGULATORY AGENCIES  
22 RE(QUIRED UNDER ANY LAW OF THE PHILIPPINES OR OF  
23 ANOTHER COUNTRY THAT REGULATES THE MANUFACTURE,  
24 CONSTRUCTION, USE OR SALE OF ANY PRODUCT' **PROVIDED,**  
25 THAT, IN ORDER TO PROTECT THE DATA SUBMITTED BY THE  
26 ORIGINAL PATENT HOLDER FROM UNFAIR COMMERCIAL USE  
27 PROVIDED IN ARTICLE )\*(.) OF THE AGREEMENT ON TRADE+  
28 RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS  
29 TRIPS AGREEMENT", THE INTELLECTUAL PROPERTY  
30 OFFICE, IN CONSULTATION WITH THE APPROPRIATE  
31 GOVERNMENT AGENCIES, SHALL ISSUE THE APPROPRIATE

1 RULES AND REGULATIONS NECESSARY THEREIN NOT LATER  
2 THAN ONE HUNDRED TWENTY !2," DAYS AFTER THE  
3 ENACTMENT OF THIS LAW&

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

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

15 SEC. 6 Section 74 of Republic Act No. 8293 is hereby amended to  
16 read as follows:

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

21 (a) [t]The public interest, in particular, national security,  
22 nutrition, health or the development of other sectors, as  
23 determined by the appropriate agency of the government, so  
24 requires; or

25 (b) A judicial or administrative body has determined that  
26 the manner of exploitation, by the owner of the patent or his  
27 licensee, is anti-competitive[.]& OR

1 (C) THERE IS A NATIONAL EMERGENCY OR OTHER  
2 CIRCUMSTANCE OF EXTREME URGENCY REQUIRING THE USE  
3 OF THE INVENTION; OR

4 (D) THERE IS PUBLIC NON-COMMERCIAL USE OF THE  
5 PATENT BY THE PATENTEE, WITHOUT SATISFACTORY REASON;  
6 OR

7 (E) IN THE CASE OF DRUGS OR MEDICINES, THE  
8 DEMAND FOR THE PATENTED ARTICLE IN THE PHILIPPINES IS  
9 NOT BEING MET TO AN ADEQUATE EXTENT AND ON  
10 REASONABLE TERMS, AS DETERMINED BY THE DEPARTMENT  
11 OF HEALTH.”

12 “74.2. UNLESS OTHERWISE PROVIDED HEREIN, [T]he  
13 use by the Government, or third person authorized by the  
14 Government shall be subject[, *mutatis mutandis*, to the  
15 conditions set forth in Sections 95 to 97 and 100 to 102. (Sec.  
16 41, R.A. No. 165a)] TO THE FOLLOWING CONDITIONS'

17 A" IN SITUATIONS OF NATIONAL EMERGENCY OR  
18 OTHER CIRCUMSTANCES OF EXTREME URGENCY AS PROVIDED  
19 UNDER SECTION -4.1 C", THE RIGHT HOLDER SHALL BE  
20 NOTIFIED AS SOON AS REASONABLY PRACTICABLE;

21 B" IN THE CASE OF PUBLIC NON-COMMERCIAL USE  
22 OF THE PATENT BY THE PATENTEE, WITHOUT SATISFACTORY  
23 REASON, AS PROVIDED UNDER SECTION -4.1 D", THE RIGHT  
24 HOLDER SHALL BE INFORMED PROMPTLY' **PROVIDED**, THAT,  
25 THE GOVERNMENT OR THIRD PERSON AUTHORIZED BY THE  
26 GOVERNMENT, WITHOUT MAKING A PATENT SEARCH, KNOWS  
27 OR HAS DEMONSTRABLE GROUNDS TO KNOW THAT A VALID  
28 PATENT IS OR WILL BE USED BY OR FOR THE GOVERNMENT;

29 C" IF THE DEMAND FOR THE PATENTED ARTICLE IN  
30 THE PHILIPPINES IS NOT BEING MET TO AN ADEQUATE EXTENT

1 AND ON REASONABLE TERMS AS PROVIDED UNDER SECTION  
2 -4.1 E", THE RIGHT HOLDER SHALL BE INFORMED PROMPTLY&

3 D" THE SCOPE AND DURATION OF SUCH USE SHALL BE  
4 LIMITED TO THE PURPOSE FOR WHICH IT WAS AUTHORISED&

5 E" SUCH USE SHALL BE NON-EXCLUSIVE&

6 F" THE RIGHT HOLDER SHALL BE PAID ADEQUATE  
7 REMUNERATION IN THE CIRCUMSTANCES OF EACH CASE,  
8 TAKING INTO ACCOUNT THE ECONOMIC VALUE OF THE  
9 AUTHORIZATION& AND

10 G" THE EXISTENCE OF A NATIONAL EMERGENCY OR  
11 OTHER CIRCUMSTANCES OF EXTREME URGENCY, REFERRED  
12 TO UNDER SECTION -4.1 C", SHALL BE SUBJECT TO THE  
13 DETERMINATION OF THE PRESIDENT OF THE PHILIPPINES FOR  
14 THE PURPOSE OF DETERMINING THE NEED FOR SUCH USE OR  
15 OTHER EXPLOITATION, WHICH SHALL BE IMMEDIATELY  
16 EXECUTORY.

17 "NO COURT, EXCEPT THE SUPREME COURT OF THE  
18 PHILIPPINES OR THE COURT OF APPEALS, SHALL ISSUE ANY  
19 TEMPORARY RESTRAINING ORDER OR PRELIMINARY  
20 INJUNCTION OR SUCH OTHER PROVISIONAL REMEDIES THAT  
21 WILL PREVENT ITS IMMEDIATE EXECUTION.

22 "THE OFFICE OF THE PRESIDENT, IN CONSULTATION  
23 WITH THE APPROPRIATE GOVERNMENT AGENCIES, SHALL  
24 ISSUE THE APPROPRIATE IMPLEMENTING RULES AND  
25 REGULATIONS FOR THE USE OR EXPLOITATION OF PATENTED  
26 INVENTIONS AS CONTEMPLATED IN THIS SECTION WITHIN ONE  
27 HUNDRED TWENTY (20) DAYS AFTER THE EFFECTIVITY OF  
28 THIS LAW.

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

4       SEC. 7   Section 76.1 of Republic Act No. 8293 is hereby amended to  
5 read as follows:

6           “SEC. 76. *Civil Action for Infringement.* – 76.1. The  
7 making, using, offering for sale, selling, or importing a patented  
8 product or a product obtained directly or indirectly from a  
9 patented process, or the use of a patented process without the  
10 authorization of the patentee constitutes patent infringement[.]’  
11 **PROVIDED,** THAT, THIS SHALL NOT APPLY TO INSTANCES  
12 COVERED BY SECTION -2.!, -2.4 LIMITATIONS ON PATENT  
13 RIGHTS”& SUBSECTIONS C, D, AND E OF SECTION -4 USE OF  
14 INVENTION BY GOVERNMENT”& SECTION \*)./ COMPULSORY  
15 LICENSING”& AND SECTION \*)+A IMPLEMENTATION OF  
16 PARAGRAPH / OF THE DOHA DECLARATION” OF THIS CODE.”

17       SEC. 8   Section 93 of Republic Act No. 8293 is hereby amended to  
18 read as follows:

19           “SEC. 93. *Grounds for Compulsory Licensing.* – The  
20 [Director of Legal Affairs] DIRECTOR GENERAL OF THE  
21 INTELLECTUAL PROPERTY OFFICE may grant a license to  
22 exploit a patented invention, even without the agreement of the  
23 patent owner, in favor of any person who has shown his  
24 capability to exploit the invention, under any of the following  
25 circumstances:

26           “93.1. National emergency or other circumstances of  
27 extreme urgency;

28           “93.2. Where the public interest, in particular, national  
29 security, nutrition, health or the development of other vital

1 sectors of the national economy as determined by the appropriate  
2 agency of the Government, so requires; or

3 “93.3. Where a judicial or administrative body has  
4 determined that the manner of exploitation by the owner of the  
5 patent or his licensee is anti-competitive; or

6 “93.4. In case of public non-commercial use of the patent  
7 by the patentee, without satisfactory reason;

8 “93.5. If the patented invention is not being worked in  
9 the Philippines on a commercial scale, although capable of being  
10 worked, without satisfactory reason: *Provided*, That the  
11 importation of the patented article shall constitute working or  
12 using the patent. (Secs. 34, 34-A, 34-B, R.A. No. 165a)

13 “93.6. WHERE THE DEMAND FOR PATENTED DRUGS OR  
14 MEDICINES IS NOT BEING MET TO AN ADE (UATE E%TENT AND  
15 ON REASONABLE TERMS, AS DETERMINED BY THE  
16 DEPARTMENT OF HEALTH.”

17 SEC. 9 A new Section 93-A is hereby inserted after Section 93 of  
18 Republic Act No. 8293 to read as follows:

19 “SEC. \*)+A. **IMPLEMENTATION OF PARAGRAPH 6**  
20 **OF THE DOHA DECLARATION ON THE TRIPS AGREEMENT**  
21 **AND PUBLIC HEALTH WHICH RECOGNIZES THAT WORLD**  
22 **TRADE ORGANIZATION (WTO) MEMBERS WITH INSUFFICIENT**  
23 **OR NO MANUFACTURING CAPACITIES IN THE**  
24 **PHARMACEUTICAL SECTOR COULD FACE DIFFICULTIES AND**  
25 **MAKING EFFECTIVE USE OF COMPULSORY LICENSING UNDER**  
26 **THE TRIPS AGREEMENT AND THE 30 AUGUST 2003 DECISION**  
27 **OF THE WTO GENERAL COUNCIL WHICH IMPLEMENTS**  
28 **PARAGRAPH 6 OF THE DOHA DECLARATION. – \*)+A.!. THE**  
29 **DIRECTOR GENERAL OF THE INTELLECTUAL PROPERTY**

1 OFFICE, UPON THE WRITTEN RECOMMENDATION OF THE  
 2 SECRETARY OF HEALTH, SHALL, UPON FILING OF A PETITION,  
 3 GRANT A COMPULSORY LICENSE FOR THE IMPORTATION OF  
 4 PATENTED DRUGS OR MEDICINES PURSUANT TO THE  
 5 IMPLEMENTATION OF PARAGRAPH / OF THE DOHA  
 6 DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC  
 7 HEALTH AND THE ), AUGUST 2,,) DECISION OF THE WORLD  
 8 TRADE ORGANISATION WTO" GENERAL COUNCIL. THE  
 9 GRANT OF A COMPULSORY LICENSE SHALL BE AN E%CEPTION  
 10 TO SECTIONS !,,.4 AND !,,./ OF REPUBLIC ACT NO. 82\*)  
 11 AND SHALL BE IMMEDIATELY E%ECUTORY.

12 "NO COURT, E%CEPT THE SUPREME COURT OF THE  
 13 PHILIPPINES OR THE COURT OF APPEALS, SHALL ISSUE ANY  
 14 TEMPORARY RESTRAINING ORDER OR PRELIMINARY  
 15 IN.UNCTION OR SUCH OTHER PROVISIONAL REMEDIES THAT  
 16 WILL PREVENT THE GRANT OF THE COMPULSORY LICENSE.

17 "\*)+A.2. A COMPULSORY LICENSE SHALL ALSO BE  
 18 AVAILABLE FOR THE MANUFACTURE AND E%PORT OF DRUGS  
 19 OR MEDICINES TO ANY COUNTRY HAVING INSUFFICIENT OR NO  
 20 MANUFACTURING CAPACITY IN THE PHARMACEUTICAL  
 21 SECTOR TO ADDRESS PUBLIC HEALTH PROBLEMS' **PROVIDED,**  
 22 THAT, COMPULSORY LICENSE HAS BEEN GRANTED BY SUCH  
 23 COUNTRY OR SUCH COUNTRY HAS, BY NOTIFICATION OR  
 24 OTHERWISE, ALLOWED IMPORTATION OF THE PATENTED  
 25 DRUGS OR MEDICINES FROM THE PHILIPPINES.

26 #\*)+A.). THE INTELLECTUAL PROPERTY OFFICE  
 27 SHALL PROMULGATE THE RULES AND REGULATIONS FOR THE  
 28 EFFECTIVE IMPLEMENTATION OF THIS SECTION, TAKING INTO  
 29 ACCOUNT THE GUIDELINES FOR THE IMPLEMENTATION OF  
 30 PARAGRAPH / OF THE DOHA DECLARATION ON THE TRIPS

1 AGREEMENT AND PUBLIC HEALTH AND THE ), AUGUST 2,, )  
2 DECISION OF THE TRIPS GENERAL COUNCIL.”

3 SEC. 10 Section 94 of Republic Act No. 8293 is hereby amended to  
4 read as follows:

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

11 “94.2. A compulsory license which is applied for on any  
12 of the grounds stated in Subsections 93.2, 93.3, [and] 93.4, AND  
13 \*)./ and Section 97 may be applied for at any time after the  
14 grant of the patent. (Sec. 34(1), R.A. No. 165)”

15 SEC. 11 Section 95 of Republic Act No. 8293 is hereby amended to  
16 read as follows:

17 “SEC. 95. *Requirement to Obtain a License on*  
18 *Reasonable Commercial Terms.* – 95.1. The license will only  
19 be granted after the petitioner has made efforts to obtain  
20 authorization from the patent owner on reasonable commercial  
21 terms and conditions but such efforts have not been successful  
22 within a reasonable period of time.

23 “95.2. The requirement under Subsection 95.1 shall not  
24 apply in the following cases:

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

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

1 (c) In cases of public non-commercial use[.]& AND  
 2 D" IN CASES WHERE THE DEMAND FOR THE  
 3 PATENTED DRUGS OR MEDICINES IN THE PHILIPPINES IS NOT  
 4 BEING MET TO AN ADE(UATE E%TENT AND ON REASONABLE  
 5 TERMS, AS DETERMINED BY THE DEPARTMENT OF HEALTH.

6 "95.3. In situations of national emergency or other  
 7 circumstances of extreme urgency, the right holder shall be  
 8 notified as soon as reasonably practicable.

9 "95.4. In the case of public non-commercial use, where  
 10 the government or contractor, without making a patent search,  
 11 knows or has demonstrable grounds to know that a valid patent is  
 12 or will be used by or for the government, the right holder shall be  
 13 informed promptly. (n)

14 "0.0. WHERE THE DEMAND FOR THE PATENTED  
 15 DRUGS OR MEDICINES IN THE PHILIPPINES IS NOT BEING MET  
 16 TO AN ADE(UATE E%TENT AND ON REASONABLE TERMS, AS  
 17 DETERMINED BY THE DEPARTMENT OF HEALTH, THE RIGHT  
 18 HOLDER SHALL BE INFORMED PROMPTLY."

19 SEC. 12 Section 147 of Republic Act No. 8293 is hereby amended to  
 20 read as follows:

21 "SEC. 147. *Rights Conferred.* – 147.1. E%CEPT IN CASES  
 22 OF IMPORTATION OF DRUGS OR MEDICINES ALLOWED UNDER  
 23 SECTION -2.1 OF THIS ACT AND OF OFF+PATENT DRUGS OR  
 24 MEDICINES, [T]The owner of a registered mark shall have the  
 25 exclusive right to prevent all third parties not having the owner’s  
 26 consent from using in the course of trade identical or similar  
 27 signs or containers for goods or services which are identical or  
 28 similar to those in respect of which the trademark is registered  
 29 where such use would result in a likelihood of confusion. In case

1 of the use of an identical sign for identical goods or services, a  
2 likelihood of confusion shall be presumed.

3 “THERE SHALL BE NO INFRINGEMENT OF TRADEMARKS  
4 OR TRADENAMES OF IMPORTED OR SOLD PATENTED DRUGS OR  
5 MEDICINES ALLOWED UNDER SECTION -2.1 OF THIS ACT, OR  
6 OF OFF-PATENT DRUGS OR MEDICINES’ **PROVIDED**, THAT, SAID  
7 DRUGS OR MEDICINES BEAR THE REGISTERED MARKS THAT  
8 HAVE NOT BEEN TAMPERED, MODIFIED, OR INFRINGED UPON,  
9 UNDER SECTION 100 OF THIS CODE.

10 “147.2. The exclusive right of the owner of a well-known  
11 mark defined in Subsection 123.1(e) which is registered in the  
12 Philippines, shall extend to goods and services which are not  
13 similar to those in respect of which the mark is registered:  
14 *Provided*, That use of that mark in relation to those goods or  
15 services would indicate a connection between those goods or  
16 services and the owner of the registered mark: *Provided, further*,  
17 That the interests of the owner of the registered mark are likely  
18 to be damaged by such use. (n)”

19 SEC. 13 *Rules and Regulations.* – The Intellectual Property Office of  
20the Philippines shall, within one hundred twenty (120) days from the effectivity  
21of this Act, promulgate the rules and regulations necessary to effectively  
22implement the provisions of this Act that relate to the Intellectual Property  
23Code.

24 CHAPTER 3

25 CREATION AND POWERS OF THE DRUG PRICE  
26 REGULATION BOARD

27 SEC. 14 *Creation and Composition of the Drug Price Regulation*  
28*Board.* – (a) There is hereby created the Drug Price Regulation Board, which  
29shall be attached to the Department of Health, and composed of seven (7)  
30members as follows:

1 (1) Secretary of Health or his duly designated representative who shall  
2 have the rank of an undersecretary as chairperson;

3 (2) Secretary of Trade and Industry or his duly designated  
4 undersecretary as vice-chairperson;

5 (3) Director, Bureau of Food and Drugs as member;

6 (4) President, Philippine Health Insurance Corporation as member;

7 (5) One (1) faculty from the health sciences school as member; and

8 (6) Two (2) representatives from the consumers' sector as members.

9 (b) The members of the Board representing the academe and the  
10 consumers' sector shall be appointed by the President of the Philippines upon  
11 the recommendation of the Secretary of Health and shall serve for a term of  
12 two (2) years: *Provided, That*, the representatives from the consumers' sector  
13 shall not serve for more than two (2) terms.

14 (c) The Board shall be constituted within thirty (30) days after the  
15 effectivity of this Act and shall be assisted by a secretariat from the existing  
16 organizational structure of the Department of Health (DOH). The secretariat  
17 shall be headed by an executive director from among the undersecretaries or  
18 assistant secretaries of the DOH serving in an *ex officio* capacity.

19 In the implementation of this Act, the organizational structure provided  
20 under Republic Act No. 7581, otherwise known as the Price Act, shall be  
21 utilized.

22 SEC. 15 *Powers of the Board.* – The Board shall have the following  
23 powers:

24 (A) Power to Determine the Maximum Retail Price of Drugs or  
25 Medicines Subject to Price Regulation – (1) Upon application or *motu proprio*  
26 when the public interest so requires, the Board shall have the power to regulate  
27 the retail price of drugs or medicines listed under Section 19 hereof, and, in  
28 order that they shall be made widely available to the public at affordable retail  
29 price from the different manufacturers, importers, traders, distributors,

1wholesalers, or retailers and after a proper determination as the Board may  
2deem fit, fix from time to time, by publication the maximum retail price at  
3which such drugs or medicines shall be sold.

4 (2) In determining the maximum retail price, the Board shall consider  
5the following factors:

6 (a) Retail prices of the same or similar drugs and medicines in other  
7countries;

8 (b) The supply available in the market;

9 (c) The cost to the manufacturer, importer, trader, distributor,  
10wholesaler or retailer of the following but not limited to:

11 (i) The exchange rate of the peso to the foreign currency with which  
12the drug or medicine or any component, ingredient or raw material thereof was  
13paid for;

14 (ii) Any change in the amortization cost of machinery brought about by  
15any change in the exchange rate of the peso to the foreign currency with which  
16the machinery was bought through credit facilities;

17 (iii) Any change in the cost of labor brought about by a change in the  
18minimum wage; or

19 (iv) Any change in the cost of transporting or distributing the drugs or  
20medicines to the area of destination.

21 (d) Such other factors or conditions which will aid in arriving at a just  
22and reasonable maximum price.

23 (3) No retailer shall sell drugs or medicines at a retail price exceeding  
24the maximum retail price fixed by the Board: *Provided*, That, until the  
25maximum retail price of drugs or medicines subject to price regulation is fixed  
26by the Board, no manufacturer, importer, trader, distributor, wholesaler, or  
27retailer of such drug or medicine shall sell the same at a retail price exceeding  
28the price prevailing immediately before the effectivity of this Act: *Provided*,  
29*further*, That, immediately after the Drug Price Regulation Board is

1 constituted, the Board shall undertake a study on the prevailing prices of drugs  
2 or medicines subject to price regulation and immediately after the effectivity of  
3 its powers, provide an initial list of drugs or medicines whose new maximum  
4 retail prices shall be fixed by the Board.

5 (B) Power to Include Other Drugs or Medicines in the List Subject to  
6 Price Regulation – Upon application or *motu proprio* when the public interest  
7 so requires and after proper determination, the Board may order the inclusion  
8 of drugs or medicines to the list subject to price regulation under Section 19  
9 hereof.

10 (C) Power to Implement Cost-Containment and Other Measures – (1)  
11 The Board shall have the power to determine the fair price of drugs or  
12 medicines for purposes of public health insurance and government  
13 procurement; and

14 (2) The Board shall have the power to implement any other measures  
15 that the government may avail of to effectively reduce the cost of drugs or  
16 medicines that shall include, but not be limited to, competitive bidding, price-  
17 volume negotiations, and other appropriate mechanisms that influence supply,  
18 demand, and expenditures on drugs or medicines.

19 (D) Power to Impose Administrative Fines and Penalties – After due  
20 notice and hearing, the Board shall have the power to impose administrative  
21 fines against any person, manufacturer, importer, trader, distributor,  
22 wholesaler, retailer or any other entity, in such amount as it may deem  
23 reasonable, which shall in no case be less than Fifty thousand pesos  
24 (P50,000.00) nor more than Five million pesos (P5,000,000.00) for violations  
25 of the maximum retail price fixed pursuant to this Section.

26 (E) Power to Deputize Government Entities – The Board shall have the  
27 power to call upon and deputize any official, agent, employee, agency, or  
28 instrumentality of the national or local government for any assistance that it  
29 may deem necessary to carry out the purposes of this Act.

1 (F) Other Powers Necessary to Implement Provisions of This Act – The  
 2 Board shall exercise such powers and functions as may be necessary to  
 3 implement and enforce the provisions of this Chapter of the Act such as, but  
 4 not limited to, the power to issue *subpoena duces tecum* and *subpoena ad*  
 5 *testificandum*, and to require the production and submission of records,  
 6 documents, books of account, bills of lading, input documents, records of  
 7 purchase and sale, financial statements, and such other documents, information  
 8 and papers as may be necessary to enable the Board to carry out its functions,  
 9 duties and responsibilities.

10 SEC. 16 *Board Procedures*. — All inquiries, studies, hearings,  
 11 investigations and proceedings conducted by the Board shall be governed by  
 12 rules adopted by the Board, and in the conduct thereof the Board shall not be  
 13 bound by the technical rules of evidence.

14 In accordance with its power to investigate any matter before it, the  
 15 Board shall have the power to depose witnesses residing within or without the  
 16 Philippines according to its rules and regulations.

17 SEC. 17 *Effectivity of the Board's Decisions or Orders*. — All  
 18 decisions or orders of the Board pursuant to Section 15, Paragraphs (A) Power  
 19 to Determine the Maximum Retail Price of Drugs or Medicines Subject to  
 20 Price Regulation, (B) Power to Include Other Drugs or Medicines in the List  
 21 Subject to Price Regulation, (C) Power to Implement Cost-Containment and  
 22 Other Measures, (D) Power to Impose Administrative Fines and Penalties, (E)  
 23 Power to Deputize Government Entities, or (F) Other Powers Necessary to  
 24 Implement Provisions of this Act shall be immediately operative, unless  
 25 otherwise provided by the Board.

26 SEC. 18 *Review of the Board's Decisions or Orders*. — A party  
 27 adversely affected by a decision, order or ruling of the Board may, within  
 28 thirty (30) days from notice of such decision, order or ruling, or in case of a  
 29 denial of a motion for reconsideration thereof, within fifteen (15) days after

1 notice of such denial, file an appeal with the Court of Appeals, which shall  
2 have jurisdiction to review such decision, order or ruling and to modify or set  
3 aside the same when it clearly appears that there was no evidence before the  
4 Board to support reasonably such decision, order or ruling, or that the same is  
5 contrary to law, or that it was without the jurisdiction of the Board. The  
6 evidence presented to the Board, together with the record of the proceedings  
7 before the Board, shall be certified by the Board to the Court of Appeals. Said  
8 appeal shall be placed on file in the Office of the Clerk of the Court of Appeals  
9 who shall furnish copies thereof to the Board and other parties interested.

10 Any decision, order or ruling of the Board may likewise be reviewed by  
11 the Supreme Court upon a writ of certiorari in appropriate cases. The  
12 procedure for review, except as herein provided, shall be in accordance with  
13 the rules prescribed by the Supreme Court.

14 The filing of a petition for a writ of certiorari or other special remedies  
15 in the Supreme Court shall in no case supersede or stay any decision, order or  
16 ruling of the Board, unless the Supreme Court shall so direct, and the petitioner  
17 may be required by the Supreme Court to give bond in such form and of such  
18 amount as may be deemed proper.

19 SEC. 19 *List of Drugs or Medicines That are Subject to Price*  
20 *Regulation.* – The list of drugs or medicines that are subject to price regulation  
21 shall include, *inter alia*:

22 (a) All drugs or medicines indicated for treatment of chronic illnesses  
23 and life threatening conditions, such as, but not limited to, endocrine disorders,  
24 e.g., diabetes mellitus; gastrointestinal disorders, e.g., peptic ulcer; urologic  
25 disorders, e.g., benign prostatic hyperplasia (BPH); cardiovascular diseases,  
26 e.g., hypertension; pulmonary diseases, e.g., pulmonary tuberculosis (PTB),  
27 asthma; auto-immune diseases, e.g., systemic lupus erythematosus (SLE); skin  
28 diseases, e.g., psoriasis; neuro-psychiatric disorders; other infectious diseases,

1 e.g., human immunodeficiency virus-acquired immune deficiency syndrome  
2 (HIV-AIDS); and other conditions such as organ transplants and neoplasm;

3 (b) Drugs or medicines indicated for prevention of diseases, e.g.,  
4 vaccines, immunoglobulin, anti-sera;

5 (c) Drugs or medicines indicated for prevention of pregnancy, e.g., oral  
6 contraceptives;

7 (d) Anesthetic agents;

8 (e) Intravenous fluids;

9 (f) Drugs or medicines that are included in the Philippine National  
10 Drug Formulary (PNDF) Essential Drug List; and

11 (g) All other drugs or medicines which, from time to time, the Board  
12 determines to be in need of price regulation.

13 SEC. 20 *Illegal Acts of Price Manipulation.* – Without prejudice to the  
14 provisions of existing laws on goods not covered by this Act, it shall be  
15 unlawful for any manufacturer, importer, trader, distributor, wholesaler,  
16 retailer, or any person engaged in any method of disposition of drugs or  
17 medicines to engage in acts of price manipulation such as hoarding,  
18 profiteering, or illegal combination or forming cartel, as defined under Section  
19 5 of Republic Act No. 7581, otherwise known as the Price Act, and all other  
20 acts committed in restraint of trade.

21 SEC. 21 *Penalty for Illegal Acts of Price Manipulation.* – Any person  
22 or entity who commits any act of illegal price manipulation of any drug or  
23 medicine subject to price regulation shall suffer the penalty of imprisonment  
24 for a period of not less than five (5) years nor more than fifteen (15) years or  
25 shall be imposed a fine of not less than One hundred thousand pesos  
26 (P100,000.00) nor more than Ten million pesos (P10,000,000.00), at the  
27 discretion of the court. The court may also order the suspension or revocation  
28 of its license to operate (LTO), professional or business license.

1 Whenever any act of illegal price manipulation of any drug or medicine  
2 subject to price regulation is committed by a juridical person, its officials or  
3 employees, or in case of a foreign corporation or association, its agent or  
4 representative in the Philippines who are responsible for the violation, shall be  
5 held liable therefor.

6 SEC. 22 *Display of Price Fixed by the Board for Drugs or Medicines*  
7 *Subject to Price Regulation.* – (a) Within a reasonable period as may be  
8 determined by the Board, and: *Provided,* That it conforms to existing drug  
9 product labeling requirements, every manufacturer, importer, distributor,  
10 wholesaler, trader, or retailer of a drug or medicine intended for sale shall  
11 display the retail price which shall not exceed the maximum retail price fixed  
12 by the Board. The maximum retail price shall be printed on the label of the  
13 immediate container of the drug or medicine and the minimum pack thereof  
14 offered for retail sale with the words “RETAIL PRICE NOT TO EXCEED”  
15 preceding it, and “UNDER DRUG PRICE REGULATION” on a red strip:  
16 *Provided,* That, in the case of a container consisting of smaller saleable packs,  
17 the retail price of such smaller pack shall also be displayed on the label of each  
18 smaller pack and such price shall not be more than the *prorata* retail price of  
19 the main pack rounded off to the nearest centavo.

20 (b) Within a period as may be determined by the Board from time to  
21 time, every manufacturer, importer, or trader shall issue a price list to  
22 wholesalers, distributors, retailers and the Board, indicating the retail price, the  
23 maximum retail price, and such other information as may be required by the  
24 Board.

25 SEC. 23 *Display of Price and Price List of Drugs or Medicines*  
26 *Excluded From the List Subject to Price Regulation.* – (a) Every manufacturer,  
27 importer, trader, distributor, wholesaler, or retailer of a drug or medicine  
28 excluded from the list subject to price regulation under Section 19 hereof shall  
29 display in indelible print mark on the label of the immediate container of the

1 drug or medicine and the minimum pack thereof offered for retail sale, the  
2 words “NOT UNDER PRICE REGULATION” on a green strip.

3 (b) If required by the Board, every manufacturer, importer, trader,  
4 wholesaler, distributor, or retailer shall issue a price list of drugs or medicines  
5 excluded from the list subject to price regulation, indicating changes from time  
6 to time.

7 (c) Every manufacturer, importer, trader, distributor, wholesaler, or  
8 retailer shall submit periodically their prices and inventory of all the drugs or  
9 medicines they carry to the Board.

10 SEC. 24 *Reports from Local Government Units (LGUs) and the*  
11 *Department of Trade and Industry (DTI).* – All local government units (LGUs)  
12 shall help ensure the implementation of pricing policies provided under this  
13 Chapter by submitting quarterly price monitoring reports to the Board of drugs  
14 or medicines identified by the latter, and any and all necessary information that  
15 the Board may require.

16 SEC. 25 *Role of the Department of Health (DOH) and the Department*  
17 *of Trade and Industry (DTI).* – The DOH and the DTI shall jointly conduct  
18 independent periodic surveys and studies of the selling prices of all drugs and  
19 medicines referred to in Section 19 of this Act all over the country as well as  
20 their share or effect on the family income of the different economic groups in  
21 the country for purposes of serving as data base for government efforts to  
22 promote access to more affordable medicines, as well as evaluating the  
23 effectivity of the measures undertaken to promote access to more affordable  
24 medicines.

25 SEC. 26 *Rules and Regulations.* – The Board, in consultation with the  
26 DOH and the DTI, the Congressional Oversight Committee and other  
27 appropriate government agencies, shall, within one hundred twenty (120) days  
28 from the effectivity of this Act, promulgate the rules and regulations necessary  
29 to effectively implement the provisions of this chapter.

1        SEC. 27 *Annual Report.* – Within thirty (30) days from the effectivity  
 2 of this Act and every December 31<sup>st</sup> of every year thereafter, every  
 3 manufacturer, importer, trader, distributor, wholesaler, and retailer of a drug or  
 4 medicine whether included in or excluded from the list of drugs or medicines  
 5 that are subject to price regulation shall furnish the Board a list of all drugs or  
 6 medicines it manufactures, imports, trades, distributes, wholesales, or retails,  
 7 data pertaining to the factors enumerated under Section 15(A)(2), and any and  
 8 all necessary information that the Board may require.

9

CHAPTER 4

10

NON-DISCRIMINATORY CLAUSE

11        SEC. 28 *Non-Discriminatory Clause.* – It shall be unlawful for any  
 12 retail drug outlet to refuse to carry either by sale or by consignment, or offer  
 13 for sale drugs or medicines brought into the country through parallel  
 14 importation by the government or third party authorized by the government  
 15 and which have been previously approved for distribution or sale by the  
 16 Bureau of Food and Drugs. For this purpose, the said products shall be  
 17 displayed with equal prominence as all other products sold in the  
 18 establishment.

19

SEC. 29 *Refusal to Sell Drugs or Medicines.* – No manufacturer,  
 20 importer, trader, distributor, wholesaler shall withhold from sale or refuse to  
 21 sell to a wholesaler or retailer any drug or medicine without good and  
 22 sufficient reasons.

23

SEC. 30 *Penalties.* – Any person or entity who shall refuse to carry or  
 24 sell drugs or medicines pursuant to the provisions of this Chapter shall be  
 25 punished with a fine of not less than One hundred thousand pesos  
 26 (P100,000.00) but not more than Five hundred thousand pesos (P500,000.00)  
 27 at the discretion of the court. For the succeeding offense, the penalties shall  
 28 not be less than Five hundred thousand pesos (P500,000.00) but not more than  
 29 One million pesos (P1,000,000.00) at the discretion of the court, and

1 suspension or revocation of its license to operate (LTO), business or  
2 professional license, as the case may be.

3 SEC. 31 *Rules and Regulations.* – The DOH, in consultation with the  
4 DTI, shall, within one hundred twenty (120) days from the effectivity of this  
5 Act, promulgate the rules and regulations necessary to effectively implement  
6 the provisions of this Chapter.

7

CHAPTER 5

8

AMENDMENTS TO REPUBLIC ACT NO. 6675, OTHERWISE

9

KNOWN AS THE GENERICS ACT OF 1988

10 SEC. 32 Section 5 of Republic Act No. 6675 is hereby amended to  
11 read as follows:

12 “SEC. 5. *Posting and Publication.* – The Department of  
13 Health shall publish annually IN ACCEPTABLE MEANS OF  
14 PUBLIC DISSEMINATION in at least two (2) newspapers of  
15 general circulation in the Philippines the generic names, and the  
16 corresponding brand names under which they are marketed, of  
17 all drugs and medicines available in the Philippines.”

18 SEC. 33 Section 6 of Republic Act No. 6675 is hereby amended to  
19 read as follows:

20 “SEC. 6. *Who Shall Use Generic Terminology.* – “(a) All  
21 government health agencies and their personnel as well as other  
22 government agencies shall use generic terminology or generic  
23 names in all transactions related to purchasing, prescribing,  
24 dispensing and administering of drugs and medicines.

25 “(b) All medical, dental and veterinary practitioners,  
26 including private practitioners, shall write prescriptions using the  
27 generic name OF THE DRUG OR MEDICINE ONLY AND ITS BRAND  
28 NAME SHALL NOT APPEAR ON ANY PART OF THE  
29 PRESCRIPTION. [The brand name may be included if so

1 desired.]

2 “(c) Any organization or company involved in the  
3 manufacture, importation, repacking, marketing and/or  
4 distribution of drugs and medicines shall indicate prominently  
5 the generic name of the product. In the case of brand name  
6 products, the generic name shall appear prominently and  
7 immediately above the brand name in all product labels as well  
8 as in advertising and other promotional materials.

9 “(d) Drug outlets, including drugstores, hospital and non-  
10 hospital pharmacies and nontraditional outlets such as  
11 supermarkets and stores, shall inform any buyer about any and  
12 all other drug products having the same generic name, together  
13 with their corresponding prices so that the buyer may adequately  
14 exercise his option. Within one (1) year after approval of this  
15 Act, the drug outlets referred to herein shall post in conspicuous  
16 places in their establishments a list of drug products with the  
17 same generic name and their corresponding prices.

18 “ E” THERE SHALL APPEAR PROMINENTLY ON THE  
19 LABEL OF A GENERIC DRUG THE FOLLOWING STATEMENT'  
20 THIS PRODUCT HAS THE SAME THERAPEUTIC EFFICACY AS  
21 ANY OTHER GENERIC PRODUCT OF THE SAME NAME. SIGNED'  
22 BFAD.”

23 SEC. 34 Section 8 of Republic Act No. 6675 is hereby amended to  
24 read as follows:

25 “SEC. 8. *Required Production.* – Subject to the rules and  
26 regulations promulgated by the Secretary of Health, every drug  
27 manufacturing company operating in the Philippines shall be  
28 required to produce, distribute and make WIDELY available to the  
29 general public [the medicine it produces, in the form of generic

1 drugs] AN UNBRANDED GENERIC COUNTERPART OF THEIR  
2 BRANDED PRODUCT.”

3 SEC. 35 Section 11 of Republic Act No. 6675 is hereby  
4 amended to read as follows:

5 “SEC. 11. *Education Drive*. – The Department of Health  
6 jointly with the [Department of Education, Culture and Sports,]  
7 the Philippine Information Agency and the Department of THE  
8 INTERIOR AND Local Government shall conduct a continuous  
9 information campaign for the public and a continuing education  
10 and training for the medical and allied medical professions on  
11 drugs with generic names as an alternative of equal efficacy to  
12 the more expensive brand name drugs. Such educational  
13 campaign shall include information on the illnesses or symptoms  
14 which each generically named drug is supposed to cure or  
15 alleviate, as well as in contraindications. The Department of  
16 Health with the assistance of the Department of THE INTERIOR  
17 AND Local Government and the Philippine Information Agency  
18 shall monitor the progress of the education drive, and shall  
19 submit regular reports to Congress.”

20 SEC. 36 Section 12 of Republic Act No. 6675 is hereby amended to  
21 read as follows:

22 “SEC. 12. *Penalty*. – (A) Any person who shall violate  
23 Section 6(a) or 6(b) of this Act shall suffer the penalty graduated  
24 hereunder, viz:

25 (a) for the first conviction, he shall suffer the penalty of  
26 reprimand which shall be officially recorded in the appropriate  
27 books of the Professional Regulation Commission.

28 (b) for the second conviction, the penalty of fine in the  
29 amount of not less than [Two thousand pesos (P2,000.00)]

1 TWENTY-FIVE THOUSAND PESOS P20,000.00," [but not  
 2 exceeding Five thousand pesos (P5,000.00)] at the discretion of  
 3 the court.

4 (c) For the third conviction, the penalty of fine in  
 5 the amount of not less than [Five thousand pesos (P5,000.00)]  
 6 TWENTY-FIVE THOUSAND PESOS P20,000.00," but not  
 7 exceeding [Ten thousand pesos (P10,000.00)] FIFTY THOUSAND  
 8 PESOS P0,000.00," and suspension of his license to practice his  
 9 profession for [thirty (30) days] SIXTY (60) DAYS at the  
 10 discretion of the court.

11 (d) for the fourth and subsequent convictions, the penalty  
 12 of fine of not less than [Ten thousand pesos (P10,000.00)] ONE  
 13 HUNDRED THOUSAND PESOS P100,000.00," and suspension of  
 14 his license to practice his profession for one (1) year or longer at  
 15 the discretion of the court.

16 "B) Any juridical person who violates Section 6(c), 6  
 17 (d), 7 or 8 shall suffer the penalty of a fine of not less than five  
 18 thousand pesos (P5,000.00) nor more than ten thousand pesos  
 19 (P10,000.00) and suspension or revocation of license to operate  
 20 such drug establishment or drug outlet at the discretion of the  
 21 court: *Provided*, That its officers directly responsible for the  
 22 violation shall suffer the penalty of fine and suspension or  
 23 revocation of license to practice profession, if applicable, and by  
 24 imprisonment of not less than six (6) months nor more than one  
 25 (1) year or both fine and imprisonment at the discretion of the  
 26 court: and *Provided, further*, That if the guilty party is an alien,  
 27 he shall be *ipso facto* deported after service of sentence without  
 28 need of further proceedings.



1 drugstore or hospital pharmacy, duly established in accordance  
 2 with the provisions of this Act. NON+PRESCRIPTION OR OVER+  
 3 THE+COUNTER DRUGS MAY BE SOLD IN THEIR ORIGINAL  
 4 PACKAGES, BOTTLES, CONTAINERS OR IN SMALL (UANTITIES,  
 5 NOT IN THEIR ORIGINAL CONTAINERS TO THE CONSUMING  
 6 PUBLIC THROUGH SUPERMARKETS, CONVENIENCE STORES  
 7 AND OTHER RETAIL ESTABLISHMENTS.

8 “Pharmaceutical, drug or biological manufacturing  
 9 establishments, importers and wholesalers of drugs, medicines,  
 10 or biological products [are authorized to sell their products only  
 11 at wholesale to duly established retail drugstore or hospital  
 12 pharmacies], SHALL NOT SELL THEIR PRODUCTS FOR RE+SALE  
 13 E%CEPT ONLY TO RETAIL DRUGSTORE, HOSPITAL PHARMACIES  
 14 OR TO OTHER DRUG WHOLESALERS UNDER THE SUPERVISION  
 15 OF REGISTERED PHARMACIST, AND SUPERMARKETS,  
 16 CONVENIENCE STORES, OTHER RETAIL ESTABLISHMENTS FOR  
 17 OVER+THE+COUNTER DRUGS, DULY LICENSED BY THE BUREAU  
 18 OF FOOD AND DRUGS.”

19 SEC. 39 Rules and Regulations. – The Department of Health (DOH),  
 20in consultation with the appropriate government agencies, within one hundred  
 21twenty (120) days from the effectivity of this Act, shall promulgate the rules  
 22and regulations necessary to effectively implement the provisions of this  
 23Chapter.

24 SEC. 40. *Quality Assurance of Drugs.* – The Bureau of Food and Drugs  
 25shall take the necessary steps to ensure the safety and quality of drugs, whether  
 26locally produced or imported as provided herein. Bio-equivalence testing shall  
 27be made on the drugs listed in the essential drug list.

1        SEC. 41. *Congressional Oversight Committee.* – To oversee the  
2 implementation of this Act, there shall be created a Congressional Oversight  
3 Committee (COC) to be composed of the chairs of the Senate Committees on  
4 Trade and Commerce, Health and Demography, and Finance, and the House of  
5 Representatives Committees on Trade and Industry, Health, and  
6 Appropriations, and two (2) members each from the Senate and House of  
7 Representatives who shall be designated by the Senate President and the  
8 Speaker of the House of Representatives: *Provided,* That one (1) of the two (2)  
9 Senators and one (1) of the two (2) House Members shall be nominated by the  
10 respective minority leaders of the Senate and the House of Representatives.

11        The Secretariat of the COC shall be drawn from the existing Secretariat  
12 personnel of the Senate and the House of Representatives committees  
13 comprising the COC.

14        SEC. 42. *Appropriations for the Drug Price Regulation Board.* – The  
15 amount necessary for the initial implementation of Chapter 3 of this Act shall  
16 be charged against the current year’s appropriations of the DOH and the DTI.  
17 Thereafter, such amounts as may be necessary for its continued implementation  
18 shall be included in the annual General Appropriations Act.

19        SEC. 43. *Separability Clause.* – Any portion or provision of this Act  
20 that may be declared unconstitutional or invalid shall not have the effect of  
21 nullifying other portions and provisions hereof as long as such remaining  
22 portion or provision can still subsist and be given effect in their entirety.

23        SEC. 44. *Repealing Clause.* – Sections 22, 61, 71, 72, 74, 76, 93, 94,  
24 95, and 147 of Republic Act No. 8293, otherwise known as the Intellectual  
25 Property Code of the Philippines; Sections 5, 6, 8, 11, and 12 of Republic Act  
26 No. 6675, otherwise known as the Generics Act of 1988; and Section 25 of  
27 Republic Act No. 5921, as amended, otherwise known as the Pharmacy Law,  
28 are hereby amended.

1 All laws, decrees, executive orders, proclamations and administrative  
2 regulations or parts thereof inconsistent herewith are hereby repealed or  
3 modified accordingly.

4 SEC. 45. *Effectivity of Section 33 of this Act.* – The amendment to  
5 Section 6(b) of Republic Act No. 6675 referred to in Section 33 which  
6 mandates the medical, dental and veterinary practitioners, including private  
7 practitioners, to write prescriptions in generic name only shall take effect after  
8 a period of twelve (12) months from the effectivity of this Act: *Provided, That,*  
9 within this twelve (12)-month period, no prescription shall carry the words “no  
10 substitution” or a similar phrase.

11 SEC. 46. *Effectivity Clause.* – This Act shall take effect fifteen (15)  
12 days after its publication in at least two (2) national newspapers of general  
13 circulation.

14 Approved,