

### JOINT EXPLANATORY STATEMENT

The Conference Committee on the disagreeing provisions of Senate Bill No. 1658 and House Bill No. 2844, after having met and fully discussed the subject matter, hereby report to their respective Houses the following, that:

1. Both versions of the Senate and the House were adopted as the working draft;
2. For Section 1, the short title shall be known as the "*Universally Accessible Cheaper and Quality Medicines Act of 2008*." This section marks the start of Chapter 1 entitled General Provisions.
3. For Section 2 on Declaration of Policy, Section 2 (*Declaration of Policy*) of the House version was adopted with the addition of a paragraph recognizing competition policy in the supply and demand of quality affordable drugs and medicines. The State, however, will recognize as a reserve instrument the regulation of prices of drugs and medicines in the event that full competition is not effective;
4. Section 3 (*Construction in Favor of Protection of Public Health*) of the Senate version was adopted as Section 3 of the consolidated bill;
5. For Section 4 on *Definition of Terms*, Section 3 of the House version was adopted with the deletion of the terms "*Board*", "*bulk materials*", "*capital*", "*Doha Declaration*", "*formulation*" and "*parallel imports*" since these terms were not used in the final version of the bill. The term "*multisource pharmaceutical products*" was added to refer to pharmaceutically equivalent or pharmaceutically alternative products that may or may not be therapeutically equivalent. Multisource pharmaceutical products that are therapeutically equivalent are interchangeable. This section marks the end of Chapter 1 entitled General Provisions.
6. For Section 5, which involves an amendment to Section 22 of Republic Act No. 8293, otherwise known as the Intellectual Property Code of the Philippines (IPC), Section 4 of the House version was adopted with a minor modification by deleting the words "safety" and "efficacy" since these words connote terms with functional responsibilities that are not under the jurisdiction of the Intellectual Property Office but under the Bureau of Food and Drugs. Without prejudice to R.A. No. 3720, as amended, otherwise known as the "Food, Drug and Cosmetic Act," it is noted that the matter of quality assurance of drugs and medicines are provided in Chapter 4, Section 32 of the final version of the bill under the title, "Strengthening of the Bureau of Food and Drugs." Said amendment to Section 22 of the IPC provided for non-patentability of new uses, and was adopted as Section 5 of the consolidated bill, to read as follows:

SEC. 5. Section 22 of Republic Act No. 8293 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"

7. Section 4 of the Senate version pertaining to Section 26 of the Intellectual Property Code (*Inventive Step*) was likewise adopted as Section 6 of the final bill;
8. On amendments to Section 72 of the Intellectual Property Code (*Limitations of Patent Rights*), Section 5 of both the Senate and the House versions were merged and adopted as Section 7 of the final bill with some modifications. Essentially, the Bicameral Conference Committee adopted the principle of international exhaustion for drugs and medicines, which consequently allows the right of parallel importation to any government agency or any private third party. This is integrated as an amendment to Section 72.1 of the Intellectual Property Code. Further, the amendments to Section 72.3 of the Senate version on experimental use were adopted as amendments to Section 72.3 of the Intellectual Property Code. Lastly, the amendments to Section 72.4 of the House version on early working were adopted as an additional circumstance in Section 72 of the Intellectual Property Code.
9. On amendments to Section 74 of the Intellectual Property Code (*Use of Invention by Government*), Section 6 of the both the Senate and the House versions were consolidated with minor amendments and adopted as Section 8 of the consolidated bill. The amendments in Section 74.1 provided an enumeration of additional instances allowing government use of an invention, specifically in the case of drugs and medicines, such as: *a)* in cases of national emergency or other circumstances of extreme urgency; *b)* there is public non-commercial use of the patent by the patentee, without satisfactory reason; and *c)* 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.

It is also noted that for purposes of judicial review, all cases, arising from the implementation of the provisions on government use, shall be cognizable by courts with appropriate jurisdiction provided by law and that 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.

The additional amendments to Section 74.2 of the IPC were based from Article 31 of the Trade Related Aspects of Intellectual Property Rights Agreement (TRIPS Agreement) pertaining to establishment of procedures or conditions for the exercise of government use.

10. For Section 9, on amendments to Section 76 of the Intellectual Property Code (*Civil Action for Infringement*), Section 7 of the House version was adopted. It was made to clarify the non-applicability to Section 76 of the same code of the amendments made in Sections 72.1, 72.4 (*Limitations on 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*).
11. On amendments to Section 93 of the Intellectual Property Code (*Grounds for Compulsory Licensing*), Section 8 of the House version was adopted as Section 10 of the final bill.
12. For Section 11, a new section adopted as Section 93-A of the Intellectual Property Code was added which was based after Section 9 of the House version. It basically reworded the House version into plain language so that there is no attribution to the 30 August 2003 Decision of the World Trade Organization General Council as well as the DOHA Declaration on TRIPS and Public Health. The new section adding Section 93-A in the Intellectual Property Code provides an alternative procedure for the issuance of a special compulsory license under the framework of the TRIPS Agreement. As such, the Director General of the IPO, upon the written recommendation of the Secretary of the Department of Health, shall grant a special compulsory license for the importation of patented drugs and medicines to ensure access to quality affordable medicines intended for domestic consumption. Said provision shall be an additional special alternative procedure and conditions were specified for its implementation. Likewise, the provision recognizes that World Trade Organization (WTO) members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties, thus the need for member-countries to make effective use of compulsory licensing under the TRIPS Agreement and the decisions of the WTO General Council. It is noted that this procedure, as provided, does not in any manner limit or prejudice the rights, obligations and flexibilities provided under the TRIPS Agreement and under Philippines laws, particularly the Sections 72 and Section 74 of the Intellectual Property Code, as amended under this Act.
13. For Section 12, on amendments to Section 94 of the Intellectual Property Code (*Period for Filing a Petition for Compulsory License*), Section 10 of the House version was adopted.
14. For Section 13, on amendments to Section 95 of the Intellectual Property Code (*Requirement to Obtain a License on Reasonable Commercial Terms*), Section 11 of the House version was adopted.

15. On amendments to Section 147 of the Intellectual Property Code (*Rights Conferred*), Section 12 of the House version was adopted as Section 14 of the consolidated bill with a minor modification which added the word "unlawfully" before the word "modified." It is noted that Section 147 of the same code deals with the law on trademarks, service marks and trade names. The provisions shall read as follows:

"SEC. 147. *Rights Conferred.*— 147.1. EXCEPT IN CASES OF IMPORTATION OF DRUGS OR MEDICINES ALLOWED UNDER SECTION 72.1 OF THIS ACT AND OF OFF-PATENT DRUGS OR MEDICINES, [T]he 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 TRADENAMES OF IMPORTED OR SOLD PATENTED DRUGS OR MEDICINES ALLOWED UNDER SECTION 72.1 OF THIS ACT, AS WELL AS, IMPORTED OR SOLD OFF-PATENT DRUGS OR MEDICINES: *PROVIDED*, THAT, SAID DRUGS OR 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"

16. For Section 15, on amendments to Section 159 of the Intellectual Property Code (*Limitations to Actions for Infringement*), Section 7 of the Senate version was adopted. It is consistent with the amendments previously adopted on Section 147;
17. For Section 16, the provision on the Implementing Rules and Regulations on Amendments to the IPC was lifted from Section 8 of the Senate version. It is noted that Chapter 2 of this Act on amendments to R.A. No. 8293, otherwise known as the Intellectual Property Code of the Philippines, ends in this section.
18. For Sections 17 to 30, it covers all provisions on *Drugs and Medicines Price Regulation* and is entitled so under Chapter 3 of this Act. The House version on drug and medicine price regulation was used as the primary starting point and was modified during the bicameral conference and during the consultation meetings between bicameral conference conferees, as follows: (1) it changed the regulatory body and structure from a price regulatory board to one where the President of the Philippines exercises the power of drug price regulation upon recommendation of the Secretary of the Department of Health; (2) it removes a provision from the House version which provides, "*until the maximum retail price of drugs or medicines is fixed by the Board, no manufacturer, importer, trader, distributor, wholesaler, or retailer of such drug or medicine shall sell the same at a retail price exceeding the price prevailing immediately before the effectivity of this Act,*" (3) it also removed the express declaration of the power of the Secretary of the Department of Health to depose witnesses, (4) it also removed the express provisions stating the procedures once any decision of the Secretary of the Department of Health is pending before the Court of Appeals or the Supreme Court, and, (5) it also removed the House proposal which requires labeling of drugs and medicines not under price regulation with a

green strip marked "NOT UNDER PRICE REGULATION." Additional provisions requiring the Secretary of the Department of Health to report to the President of the Philippines and the Congress that status of its implementation of this Act was added. Publication of the same report to President of the Philippines and of any order of the President of the Philippines imposing maximum retail prices in a newspaper of general circulation were also required. Wholesalers, manufacturers, distributors, importers, or traders are also required to have a copy of the order of the President and provide the same to their customers and clients. Lastly, drug outlets are required to post copies of the order of the President within their stores so that the consuming public is aware of the order of the President. All the other sections contain the same wordings as the House version and were only adjusted to reflect the change in regulatory structure from a board to the President of the Philippines and accordingly, corrections to its section numbers were made.

19. For Sections 31 and 32 on *Strengthening of the Bureau of Food and Drugs* under Chapter 4, Section 9 of the Senate version was adopted as Section 31 of the final bill, with some minor amendments in style. To ensure the quality and safety of drugs and medicines, Section 40 of the House version was adopted with amendments as Section 32 of the consolidated bill, to read as follows:

"SEC. 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.*

20. For Sections 33 to 36 on *Non-Discriminatory Clause* which is now so entitled under Chapter 5, the whole Chapter 4, Sections 28 to 31, of the House version was adopted in the final bill. In particular, Sections 33 (*Non-Discriminatory Clause*); 34 (*Refusal to Sell Drugs or Medicines*); 35 (*Penalties*) and 36 (*Implementing Rules and Regulations on the Non-Discrimination Clause*) were lifted from Sections 28-31 of the House version, respectively.
21. For Sections 37 to 42 on amendments to R.A. No. 6675, otherwise known as the Generics Act of 1988, which is now so entitled under Chapter 6, Sections 32-37 of the House version were adopted in the final bill except that the proposed amendment imposing generics only prescription was removed. The present wording on prescriptions is made to revert back to its current wording under the Generics Act of 1988. It is also noted that an adjustment to the penalties of juridical persons was introduced as an amendment to reflect the same which was intended for natural persons. Everything else was adopted from the House version.
22. On Sections 43 and 44 on amendments to Republic Act No. 5921, otherwise known as the Pharmacy Act, which is now so entitled under Chapter 7, Sections 38 and 39 of the House version were adopted in the final bill. It is noted that Section 40 of the House version on quality assurance of drugs has been adopted but moved under Section 32, Chapter 4 of the consolidated bill on strengthening of the Bureau of Food

and Drugs. The amendments to the Pharmacy Act allows supermarkets, convenience stores and other retail establishments to sell non-prescription or over-the-counter drugs;

23. For Section 45 on the Congressional Oversight Committee, Sections 11 and 41 of the Senate and House versions, respectively, were merged, amended and adopted, to read as:

**"SEC. 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."

24. On appropriations, Sections 12 and 42 of the Senate and House versions, respectively, were consolidated and further amended as Section 46 of the final bill, to read as:

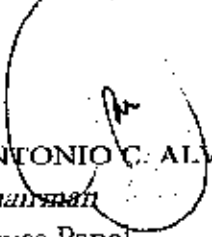
**"SEC. 46. Appropriations.** – For the initial implementation of this Act, the amount of Twenty five million pesos (Php25,000,000.00), in addition to the budget of the Department of Health, shall be provided for the operations of the Office of the Secretary of Health. The Quality Affordable Medicines 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."

25. For Section 47 on the separability clause, Sections 13 and 43 of the Senate and House versions, respectively, were adopted.
26. For Sections 48 and 49, Section 14 (*Repealing Clause*) and Section 15 (*Effectivity Clause*) of the Senate version were adopted in the consolidated bill; and
27. Finally, the title of the House version was adopted in the reconciled bill, with a minor modification which added "of 1988" after "Generics Act," to read as:

**"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"**

In case of conflict between the statements/amendments stated in this Explanatory Statement and that of the provisions of the reconciled version in the accompanying Conference Committee Report, the provisions of the latter shall prevail.

  
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House Panel

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