JOINT DOH-DTI-IPO-BFAD ADMINISTRATIVE ORDER NO. 2008-01

THE IMPLEMENTING RULES AND REGULATIONS OF REPUBLIC ACT 9502 OTHERWISE KNOWN AS THE "UNIVERSALLY ACCESSIBLE CHEAPER AND QUALITY MEDICINES ACT OF 2008"

WHEREAS, Republic Act No. 9502, otherwise known as the "Universally Accessible Cheaper and Quality Medicines Act of 2008", became effective on July 4, 2008;

WHEREAS, Republic Act No 9502 amends Republic Act No. 8293, or the Intellectual Property Code of the Philippines, Republic Act No. 6675, or the Generics Act of 1998, and Republic Act No. 5921, or the Pharmacy Law;

WHEREAS, the Department of Health, the Department of Trade and Industry, the Intellectual Property Office and the Bureau of Food and Drugs are mandated to issue and promulgate the rules and regulations to implement the provisions of Republic Act 9502;

NOW THEREFORE, the following Joint Administrative Order covering the rules and regulations implementing Republic Act 9502 are hereby adopted and prescribed for the information and guidance of all concerned.

CHAPTER I
GENERAL PROVISIONS

Rule 1. Declaration of Policy. It is the policy of the State to protect public health and, when the public interest or circumstances of extreme urgency so require, it shall adopt appropriate measures to promote and ensure access to affordable quality drugs and medicines for all.

Pursuant to the attainment of this general policy, an effective competition policy in the supply and demand of quality affordable drugs and medicines is recognized by the State as a primary instrument. In the event that full competition is not effective, the State recognizes as a reserve instrument the regulation of prices of drugs and medicines as one of the means to also promote and ensure access to quality affordable medicines. *(2)*

Rule 2. Effective Competition. Effective Competition shall encourage a milieu where there are a significant number of players at each level of the pharmaceutical supply chain that shall ensure availability and affordability of these health products. It exists in an environment where the consumers are well informed and are able to exercise their right to choose from a variety of variable options to access affordable, quality drugs and medicines. *(n)*

Rule 3. Construction in Favor of Protection of Public Health. All doubts in the implementation and interpretation of these implementing rules and regulations shall be resolved in favor of protecting public health.

Rule 4. Coverage. Unless otherwise provided by law, these Implementing Rules and Regulations shall apply to all drugs and medicines, and to all those who manufacture, trade, distribute, import, export, wholesale, retail, offer for sale, transfer, or donate drugs and medicines including medical and allied medical practitioners and to all persons, juridical or natural, involved in the provision of healthcare. *(n)*

Rule 5. Jurisdiction. The Intellectual Property Office (IPO) shall have jurisdiction over all issues concerning the requirements for patentability of drugs and medicines, infringement and/or violations of intellectual property rights, use of invention by government, compulsory licensing and special compulsory licensing. The Bureau of Food and Drugs (BFAD) shall have jurisdiction over all issues concerning the safety, quality and efficacy of drugs and medicines and procedures on parallel importation.

Rule 6. License to Import and Product Registration.

Section 1. Authority to Import. All interested parties, including government agencies must first secure a license to import from BFAD before they can import any drugs and medicines. *(n)*

Section 2. Product Registration. No drugs and medicines shall be manufactured, imported, exported, sold, offered for sale, distributed, or transferred without being registered with BFAD.

Section 3. Philippine National Drug Formulary (PNDF). Only drugs and medicines in the latest edition of the PNDF can be procured by government agencies or reimbursed by PhilHealth. *(n)*

Rule 7. Definition of Terms. The following terms as used in these Implementing Rules and Regulations shall be defined as follows:

(a) ***"Act"*** refers to Republic Act No. 9502 otherwise known as the Universally Accessible Cheaper Quality Medicines Act of 2008.

(b) ***"BFAD"*** refers to the Bureau of Food and Drugs.

(c) ***"BLA"*** refers to the Bureau of Legal Affairs of IPO.

(d) **"*Compulsory License*"** is a license issued by the Director General of the Intellectual Property Office to exploit a patented invention without the

permission of the patent holder, either by manufacture or through parallel importation;

(e) ***"Conspicuous places"*** refers to places which must be public, more or less permanently fixed, must be seen always or frequently noticeable. *(n)*

(f) ***"Director General"*** refers to the Director General of the Intellectual Property Office of the Philippines. *(n)*

(g) ***"DOH"*** refers to the Department of Health. *(n)*

(h) ***"Drug outlets"*** refers to drugstores, pharmacies, and any other business establishments duly licensed by the BFAD to sell drugs and medicines.
(AO No. 82,2000)

(i) ***"Drugs and medicines"*** refer to any chemical compound or biological substance, other than food, intended for use in the alleviation of symptoms and the treatment, prevention or diagnoses of diseases in humans or animals, including but not limited to: *(4C,n)*

(1) Articles recognized in the current official United States Pharmacopoeia-National Formulary (USP-NF), official Homeopathic Pharmacopoeia of the United States, Philippine Pharmacopoeia, official Philippine National Drug Formulary (PNDF), British Pharmacopoeia, European Pharmacopoeia, Japanese Pharmacopoeia, Indian Pharmacopoeia, any national compendium or any supplement to any of them;
(2) Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals;
(3) Articles other than food intended to affect the structure or any function of the human body or animals;
(4) Articles intended for use as a component of articles specified in clauses (1), (2), or (3) not including devices or their components, parts, or accessories; and

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

(i) Recognized in the Philippine National Drug Formulary Vol. I (Essential Drugs List);
(ii) Intended for use in the treatment, cure or mitigation of disease symptoms, injury or body defects in humans;
(iii) Other than food, intended to affect the structure or any function of the human body;
(iv) In finished or ready-to-use dosage form; and
(v) Intended for use as a component of any of the articles specified in clauses (i), (ii), (iii), and (iv). *(4c, n)*

(6) In case of conflicts, the BFAD drug classification will prevail. *(n)*

(j) ***"DTI"*** refers to the Department of Trade and Industry.

(k) ***"Essential Drugs List" or "National Drug Formulary"*** refers to a list of drugs prepared and periodically updated by the DOH on the basis of health conditions obtaining in the Philippines as well as on internationally-accepted criteria. It shall consist of a core list and a complementary list. *(4d)*

(l) ***"Fair Price"*** Unless otherwise stated by the Secretary of Health, fair price shall refer to the lowest price of an available quality, non-branded generic drug. *(n)*

(m) ***"Generic Drugs"*** refer to drugs that have the same active pharmaceutical ingredient as the innovator drugs and are not covered by patent protection. These drugs are labeled by their international non-proprietary or generic name and may or may not have brand names. *(n)*

(n) ***"Importer"*** refers to any establishment that imports raw materials, active ingredients and finished products for its own use or for distribution to other drug establishments or outlets. *(4e)*

(o) ***"Immediate container or Primary packaging"*** refers to packaging materials where the approved safe keeping units are placed. It also refers to the first pack containing the individually wrapped products such as, but not limited to, foil strips, blister packs, and sachets. *(n)*

(p) ***"Innovator or Comparator Drug"*** refers to a drug with an active pharmaceutical ingredient or molecule that was first or originally marketed anywhere in the world on the basis of documentation of quality, safety and efficacy by a specific company or an entity which is expressed in its international non-proprietary name and usually carries a brand name. Such may be patented, non-patented or off-patent. *(n)*

(q) ***"Interchangeable pharmaceutical product"*** refers to a drug which is therapeutically equivalent to an innovator drug and can be interchanged with the innovator drug in clinical practice. It does not necessarily refer to Bioavailability/Bioequivalence (BA/BE), which is not applicable to all drug products. *(n)*

(r) ***"IP Code"*** means Republic Act No. 8293 otherwise known as the Intellectual Property Code of the Philippines as amended by Republic Act 9502 or otherwise known as "Universally Accessible Cheaper and Quality Medicines Act of 2008." *(n)*

(s) **"*IPO*"** refers to the Intellectual Property Office of the Philippines *(n)*.

(t) ***"Manufacture"*** includes any process or part of a process for making, altering, finishing, packing, labeling, breaking or otherwise treating or adapting any drug with a view to its sale and distribution, but does not include the compounding or dispensing of any drug in the ordinary course of retail business. *(4f)*

(u) ***"Manufacturer"*** refers to any establishment duly licensed by the BFAD to engage in the operations involved in the production of a drug with the end view of storage, distribution, or sale of the product. *(4g)*

(v) ***"Multisource pharmaceutical products"*** refers to pharmaceutically equivalent or pharmaceutically alternative products that may or may not be therapeutically equivalent. Multisource pharmaceutical products that are therapeutically equivalent are interchangeable. *(4h)*

(w) ***"Non-traditional outlets"*** refers to supermarkets, convenience stores, other retail establishments duly licensed by the BFAD to sell over-the-counter drugs. *(n)*

(x) ***"Pharmaceutical alternative"*** refers to products that contain the same molar amount of the same active pharmaceutical moiety(s) but differ in dosage form (e.g. tablets versus capsules), and/or chemical form (e.g. different salts, different esters). Pharmaceutical alternatives deliver the same active moiety by the same route of administration but are otherwise not pharmaceutically equivalent. They may or may not be bioequivalent or therapeutically equivalent to the comparator product. *(WHO Technical Report Series no. 937, 2006)*

(y) ***"Pharmaceutical equivalence"*** refers to drug products that contain the same molar amount of the same active pharmaceutical ingredient(s) in the same dosage form, if they meet comparable standards, and if they are intended to be administered by the same route. Pharmaceutical equivalence does not necessarily imply therapeutic equivalence, as differences in the excipients and/or the manufacturing process and some other variables can lead to differences in product performance. *(WHO Technical Report Series no. 937, 2006)*

(z) ***"Pharmaceutical products"*** refer to drugs and medicines. *(n)*

(aa) ***"PPI"*** refers to Philippine International Trading Corporation Pharma Inc. *(n)*

*(*bb) ***"Retailer"*** refers to any establishment licensed by the BFAD to carry on the retail business of sale of drugs and medicines to consumers. *(4i)*

(cc) **"*Special Compulsory License*" or "*Special Compulsory Licensing*"** shall mean the import and/or export of patented drugs and medicines as referred to in Section 93-A of the IP Code. *(n)*

(dd) ***"Therapeutically equivalent"*** refers to two pharmaceutical products that are pharmaceutically equivalent or pharmaceutical alternatives and after administration in the same molar dose, their effects, with respect to both efficacy and safety, are essentially the same when administered to patients by the same route. The appropriate instruments and measures for determining such equivalence shall be those that are recognized by BFAD. *(WHO Technical Report Series no. 937, 2006, n)*

(ee) ***"Therapeutic efficacy"*** is synonymous to therapeutic equivalence with reference to their clinical effects on patients. *(n)*

(ff) ***"Trader"*** refers to any establishment licensed by the BFAD which is a registered owner of a drug product that procures the materials and packaging components, and provides the production monographs, quality control standards and procedures, but subcontracts the manufacture of such products to a licensed manufacturer; *(4j)*

(gg) **"*TRIPS Agreement*"** or Agreement on Trade-Related Aspects of Intellectual Property Rights refers to the international agreement administered by the WTO that sets down minimum standards for many forms of intellectual property regulation; *(4k)*

(hh) ***"Wholesaler"*** refers to any establishment or drug outlet licensed by the BFAD which acts as merchant, broker or agent, who sells or distributes for resale or wholesale drugs and medicines on a wholesale basis. *(4l);* and

(ii) **"*WTO*"** shall mean the World Trade Organization. *(n)*

CHAPTER II
INTELLECTUAL PROPERTY

Rule 8. Patents.

Section 1. Non-Patentable Inventions. The following shall be excluded from patent protection:

(a) Discoveries; scientific theories; 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;

(b) Schemes, rules and methods of performing mental acts, playing games or doing business, and programs for computers;

(c) Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body. This provision shall not apply to products and compositions for use in any of these methods;

(d) Plant varieties or animal breeds or essentially biological process for the production of plants or animals. This provision shall not apply to microorganisms and non-biological and microbiological processes;

(e) Aesthetic creations; and

(f) Anything which is contrary to public order or morality.

For the purposes of subsection (a) 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)*

Section 2. Inventive Step. In the case of drugs and medicines, there is no inventive step if the invention results from: (a) 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 (b) the mere discovery of any property or new use for a known substance; or (c) the mere use of a known process unless such known process results in a new product that employs at least one new reactant. *(26)*

For the purpose of this section, 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 the same substance, unless they differ significantly in properties with regard to efficacy.

Section 3. Determination of Enhanced Efficacy. When assessing the extent of enhancement in efficacy, the patent examiner may call on representatives of the BFAD and/or its delegated experts to provide an expert opinion with regard to significant enhancement of therapeutic efficacy.

The criteria for determining inventive step with respect to efficacy shall be embodied in the Manual for Substantive Examination Procedure (MSEP) of the IPO. *(n)*

Rule 9. Limitations on Patent Rights. The owner of a patent has no right to prevent third parties from performing, without his authorization, the acts referred to in Section 71 of the IP Code as enumerated hereunder:

(i) Introduction in the Philippines or Anywhere Else in the World. Using a patented product which has been put on the market in the Philippines by the owner of the product, or with his express consent, insofar as such use is performed after that product has been so put on the said market: *Provided*, That, with regard to drugs and medicines, the limitation on patent rights shall apply after a drug or medicine has been introduced in the Philippines or anywhere else in the world by the patent owner, or by any party authorized to use the invention: *Provided, further*, That the right to import the drugs and

medicines contemplated in this section shall be available to any government agency or any private third party. *(72.1)*

The drugs and medicines are deemed introduced when they have been sold or offered for sale anywhere else in the world. *(n)*

The procedures for parallel importation shall be governed by Chapter III of these rules. *(n)*

(ii). Private and Non-Commercial Scale or Purpose. Where the act is done privately and on a non-commercial scale or for a non-commercial purpose: *Provided*, that it does not significantly prejudice the economic interests of the owner of the patent. *(72.2)*

(iii). Experimental Use for Scientific or Educational Purpose. Where the act consists of making or using exclusively for experimental use of the invention for scientific purposes or educational purposes and such other activities directly related to such scientific or educational experimental use. *(72.3)*

(iv). Regulatory Evaluation and Approval. In case of drugs and medicines, where the act includes testing, using, making or selling the invention including any data related thereto, solely for purposes reasonably related to the development and submission of information and issuance of approvals by government regulatory agencies required under any law of the Philippines or of another country that regulates the manufacture, construction, use or sale of any product. *(72.4)*

(iv.a). Use of Data by BFAD. The BFAD shall not be precluded from using all data, including, but not limited to, pre-clinical and clinical trials, of an applicant when evaluating other applications. *(n)*

(iv.b). Data Protection from Unfair Commercial Use. Data submitted by the original patent holder shall be protected against unfair commercial use as provided in Article 39.3 of the TRIPS. *(72.4)*

When required as a condition of approving the marketing of drugs and medicines which utilize new chemical entities, any submitted undisclosed test or other data, the origination of which involves a considerable effort, shall be protected against unfair commercial use. In addition, such data shall be protected against disclosure, except where necessary to protect the public or unless steps are taken to ensure that the data are protected against unfair commercial use. *(39.3)*

(v). Preparation in a Pharmacy or by a Medical Professional. Where the act consists of the preparation for individual cases, in a pharmacy or by a medical professional, of a medicine in accordance with a medical prescription or acts concerning the medicine so prepared. *(72.5)*

(vi). Ship, Vessel, Aircraft or Land Vehicle Use. Where the invention is used in any ship, vessel, aircraft or land vehicle of any other country entering the territory of the Philippines temporarily or accidentally; *Provided*, that such invention is used exclusively for the needs of the ship, vessel, aircraft, or land vehicle and not used for the manufacturing of anything to be sold within the Philippines. *(72.6)*

Rule 10. Use of Invention by Government.

Section 1. Grounds for Use of Invention by Government. Any government agency or third person authorized by the government may exploit the invention even without agreement of the patent owner where:

(a) The public interest, in particular, national security, nutrition, health or the development of other sectors, as determined by the appropriate agency of the government, so requires; or
(b) A judicial or administrative body has determined that the manner of exploitation by the owner of the patent or his licensee, is anti-competitive; or
(c) In the case of drugs and medicines, there is a national emergency or other circumstances of extreme urgency requiring the use of the invention; or

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

(e) In the case of drugs and medicines, the demand for the patented article in the Philippines is not being met to an adequate extent and on reasonable terms, as determined by the Secretary of the Department of Health. *(74)*

Section 2. Authorization for the Use of Invention by the Government, or Third Person Authorized by the Government. The use of the government agency or third person authorized by the government to exploit the invention shall be covered by a written authorization to be issued by the Director General. *(n)*

Upon written request by the government agency or third person authorized by the government, the Director General shall issue a written authorization. In case of national emergency or other circumstances of extreme urgency under Section 74 of the IP Code, the Director General shall notify the patent owner of the grant of the written authorization as soon as reasonably practicable. In case of public non-commercial use of the patent by the patentee without satisfactory reason, as provided under Section 74.1(d) of the IP Code, the right holder shall be informed promptly that a valid patent will be used by or for the government, or third person authorized by the government of the grant of the written authorization. The written authorization by the Director General shall be exempted from the procedures on compulsory licensing under Rule 12. *(n)*

Section 3. Judicial Review. All cases arising from the implementation of this Rule shall be cognizable by courts with appropriate jurisdiction by law. *(74.3)*

No courts, except the Supreme Court of the Philippines, shall issue any temporary restraining order or preliminary injunction or such other provisional remedies that will prevent its immediate execution. *(74.3)*

Section 4. Conditions for Use by the Government, or Third Person Authorized by the Government. Unless otherwise provided herein, the use by the Government or third person authorized by the Government shall be subject, where applicable, to the following provisions:

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

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

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

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

(e) Such use shall be non-exclusive;

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

(g) The existence of a national emergency or other circumstance of extreme urgency, referred to under Section 74.1(c) of the IP Code, shall be subject to the determination of the President of the Philippines for the purpose of determining the need for such use or other exploitation, which shall be immediately executory. *(74.2)*

Where applicable and to the extent that the same has not been repealed by the IP Code, the other conditions for the issuance of a Compulsory License may also apply to use of Government or third person authorized by the Government. *(n)*

Rule 11. Civil Action for Infringement.

Section 1. Patent Infringement. The making, using, offering for sale, selling, or importing a patented product or a product obtained directly or indirectly from a patented process, or the use of a patented process without the authorization of the patentee constitutes patent infringement: *Provided*, That, this shall not apply to instances covered by Sections 72.1 and 72.4 (Limitations of Patent Rights); Section 74 (Use of Invention by Government); Section 93.6 (Compulsory Licensing); and Section 93-A (Procedures on Issuance of a Special Compulsory License under the TRIPS Agreement) of the IP Code. *(76.1)*

Section 2. Civil Action. Any patentee, or anyone possessing any right, title or interest in and to the patented invention, whose rights have been infringed, may bring a civil action before a court of competent jurisdiction, to recover from the infringer such damages sustained thereby, plus attorney's fees and other expenses of litigation, and to secure an injunction for the protection of his rights. *(76.2)*

Section 3. Damages. If the damages are inadequate or cannot be readily ascertained with reasonable certainty, the court may award by way of damages a sum equivalent to reasonable royalty. *(76.3)*

Section 4. Damages Over and Above Actual Damages. The court may, according to the circumstances of the case, award damages in a sum above the amount found as actual damages sustained: *Provided* that the award does not exceed three (3) times the amount of such actual damages. *(76.4)*

Section 5. Disposition or Destruction of Infringing Goods. The court may, in its discretion, order that the infringing goods, materials and implements predominantly used in the infringement be disposed of outside the channels of commerce or destroyed, without compensation. *(76.5)*

Section 6. Contributory Infringement. Anyone who actively induces the infringement of a patent or provides the infringer with a component of a patented product or of a product produced because of a patented process knowing it to be especially adopted for infringing the patented invention and not suitable for substantial non-infringing use shall be liable as a contributory infringer and shall be jointly and severally liable with the infringer. *(76.6)*

Rule 12. Compulsory Licensing.

Section 1. Applicability of Regulations on Interpartes Proceedings. The Regulations on Interpartes Proceedings, as amended by Office Order No. 79, Series of 2005 issued by the IPO, shall continue to be valid and in force and shall apply *mutatis mutandis* to the provisions of this IRR except where otherwise specifically indicated. In case of conflict, the provisions of this IRR shall prevail over the provisions of the Regulations on Interpartes Proceedings. *(n)*

Section 2. Coverage. Invention patents, industrial design registration and utility model registration are all subject to proceedings for compulsory licensing. *(n)*

Section 3. Authority to Grant a Compulsory License. The authority to grant a compulsory license shall be vested with the Director General. *(93)*

Section 4. Period for Filing a Petition for Compulsory License. A compulsory license may not be applied for on the ground stated in Section 5(e) below before the expiration of a period of four (4) years from the date of filing of the application or three (3) years from the date of the patent whichever period expires last. A compulsory license which is applied for on

any of the grounds stated in Sections 5(b), 5(c), 5(d), 5(e) and 6 of this Rule may be applied for at any time after the grant of the patent. *(94.1)*

Section 5. Grounds for Compulsory Licensing. The Director General of the Intellectual Property Office may grant a license to exploit a patented invention, even without the agreement of the patent owner, in favor of any person who has shown his capability to exploit the invention, under any of the following circumstances:

(a) National emergency or other circumstances of extreme urgency;

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

(c) Where a judicial or administrative body has determined that the manner of exploitation by the owner of the patent or his licensee is anti-competitive; or

(d) In case of public non-commercial use of the patent by the patentee, without satisfactory reason;

(e) If the patented invention is not being worked in the Philippines on a commercial scale, although capable of being worked, without satisfactory reason: *Provided*, that the importation of the patented article shall constitute working or using the patent; and

(f) Where the demand for patented drugs and medicines is not being met to an adequate extent and on reasonable terms, as determined by the Secretary of the Department of Health. *(93)*

Section 6. Compulsory License Based on Interdependence of Patents. If the invention protected by a patent, hereafter referred to as the "second patent," within the country cannot be worked without infringing another patent, hereafter referred to as the "first patent," granted on a prior

application or benefiting from an earlier priority, a compulsory license may be granted to the owner of the second patent to the extent necessary for the working of his invention, subject to the following conditions:

(a) The invention claimed in the second patent involves an important technical advance of considerable economic significance in relation to the first patent;

(b) The owner of the first patent shall be entitled to a cross-license on reasonable terms to use the invention claimed in the second patent;

(c) The use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent; and

(d) The terms and conditions of Sections 95, 96 and 98 to 100 of the IP Code. *(97)*

Section 7. Terms and Conditions for Compulsory License. The basic terms and conditions, including the rate of royalty of the compulsory license, shall be fixed by the Director of the BLA subject to the following conditions

(a) The scope and duration of such use shall be limited to the purpose for which it was authorized; *(100.1)*

(b) Such use shall be non-exclusive; *(100.2)*

(c) The right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the grant or authorization, except that in cases where the license was granted to remedy a practice which was determined after judicial or administrative process to be anti-competitive, the need to correct the anti-competitive practice may be taken into account in fixing the amount of remuneration; *(100.6)*

(d) In case of patents involving semi-conductor technology, the license may only be granted in case of public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive; *(96)*

(e) The license shall be non-assignable, except with that part of the enterprise or business with which the invention is being exploited; *(100.3)*

(f) Use of the subject matter of the license shall be devoted predominantly for the supply of the Philippine market: *Provided*, that this limitation shall not apply where the grant of the license is based on the ground that the patentee's manner of exploiting the patent is determined by judicial or administrative process, to be anti-competitive; *(100.4)*

(g) The license may be terminated upon proper showing that the circumstances which led to its grant have ceased to exist and are unlikely to recur: *Provided*, that adequate protection shall be afforded to the legitimate interests of the licensee; *(100.5)*

(h) In case of a compulsory license based on interdependence of patents, the conditions in Section 6 above shall apply. *(97)*

Section 8. Requirement to Obtain License on Reasonable Commercial Terms. The license will only be granted after the petitioner has made efforts to obtain authorization from the patent owner on reasonable commercial terms and conditions but such efforts have not been successful within a reasonable period of time. *(95.1)*

The requirement above shall not apply in any of the following cases:

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

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

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

(d) In cases where the demand for the patented drugs and medicines in the Philippines is not being met to an adequate extent and on reasonable terms, as determined by the Secretary of the Department of Health. *(95.2)*

Section 9. Notification of Right Holder. In situations of national emergency or other circumstances of extreme urgency, the right holder shall be notified as soon as reasonably practicable. *(95.3)*

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

Section 11. Authority of DOH Secretary. Where the demand for the patented drugs and medicines in the Philippines is not being met to an adequate extent and on reasonable terms, as determined by the Secretary of the Department of Health, the right holder shall be informed promptly. *(95.5)*

Section 12. Anti-competitive Practice. The Director General has the authority to determine if a patentee's manner of exploiting the patent is anti-competitive and there is a need to correct the anti-competitive practice. *(n)*

Section 13. Procedure for Compulsory License. The procedures for Compulsory Licensing are as follows –

(i) Form and Content of Petition. The petition for compulsory licensing must be in writing, verified by the petitioner and accompanied

by payment of the required filing fee. It shall contain the name and address of the petitioner as well as those of the respondents, the number and date of issue of the patent in connection with which compulsory license is sought, the name of the patentee, the title of the invention, the statutory grounds upon which compulsory license is sought, the ultimate facts constituting the petitioner's cause of action, and the relief prayed for. The petition shall be accompanied by the affidavits of witnesses and originals of the documents which shall constitute as the evidence of the Petitioner which shall be marked consecutively beginning with Exhibit "A". *(IPP Rules)*

(ii) Notice to Answer. Within three (3) working days from receipt of the petition, the BLA shall issue a Notice to Answer for the Respondent to file an Answer together with the Affidavits of the witnesses and originals of documents, and at the same time notify all parties required to be notified in the IP Code and these Rules, provided that in case of public documents, certified true copies may be submitted in lieu thereof. *(IPP Rules)*

(iii) Filing of Answer. Within a non-extendible period of thirty (30) days from receipt of the Notice to Answer, the Respondent shall file an Answer together with the Affidavits of its witnesses and other original documents constituting its evidence to be marked consecutively beginning with Exhibit "1". *(IPP Rules)*

(iv) Filing of Reply and Rejoinder. The petitioner may file a reply within a non-extendible period of ten (10) days from receipt of the copy of the Answer. On the other hand, the Respondent may file a rejoinder also within a non-extendible period of ten (10) days from receipt of the Reply. *(IPP Rules)*

(v) Effect of Failure to File an Answer. In case the Respondent fails to file an Answer or if the Answer is filed out of time, the case shall be decided on the basis of the petition, the affidavits of

witnesses and the documentary evidence submitted by the petitioner. *(IPP Rules)*

(iv) Decision on the Pleadings. Within fifteen (15) days after the last responsive pleading has been filed, the Director of the BLA may render the decision on the case if the same does not warrant further proceedings. *(IPP Rules)*

(vii) Preliminary Conference. A preliminary conference shall be conducted within thirty (30) days from receipt of the last responsive pleading for the following purposes:

(a) Submission of the case for mediation under applicable laws, rules and regulations on mediation;
(b) Possibility of amicable settlement;
(c) Clarification of issues;

The parties themselves are required to appear during the preliminary conference. The presence of a party may be dispensed with if said party is represented by counsel provided with a duly notarized power of attorney and the corporate authorization to make admissions and/or accept and approval compromise proposals.

Immediately after the termination of the preliminary conference, the Director of the BLA shall require the parties to submit their respective position papers and, if so desired, draft decisions within a non-extendible period of ten (10) days from termination thereof. *(IPP Rules)*

(viii) Submission for Decision. After the lapse of the reglementary period provided above, the Director of the BLA shall order the case submitted for decision. *(n)*

(ix) Recommendation of the Director of BLA on the Petition for Compulsory Licensing. Within thirty (30) days after the case is submitted for decision, the Director of the BLA shall make the

recommendation to the Director General on whether or not to give due course to the petition for compulsory licensing.

The Director General shall review and approve the recommendation of the Director of BLA, and shall have the authority to uphold, in whole or in part, or deny the recommendation on the petition for compulsory license. *(100, n)*

(x) Publication of Notice to Answer. In every case, the Director of the BLA shall cause the notice to be published in a newspaper of general circulation once a week for three (3) consecutive weeks and once in the IPO Gazette at the expense of the applicant. *(IPP Rules)*

Section 14. Compulsory License Based on Sections 93.1. and 93.2. of the IP Code. The following procedures shall be observed when the petition for compulsory license is based on any of the following grounds: (a) national emergency or other circumstances of extreme urgency; or (b) where the public interest, in particular, national security, nutrition, health or the development of other vital sectors of the national economy as determined by the appropriate government agency, so requires: *(93.1, 93.2)*

(i) Form and Contents of Petition. The petition for compulsory licensing must be in writing, verified by the petitioner and accompanied by payment of the required filing fee. It shall contain the name and address of the petitioner as well as those of the respondents, the number and date of issue of the patent in connection with which compulsory license is sought, the name of the patentee, the title of the invention, the statutory grounds upon which compulsory license is sought, the ultimate facts constituting the petitioner's cause of action, and the relief prayed for. The petition shall be accompanied by the affidavits of witnesses and originals of the documents which shall constitute as the evidence of the Petitioner which shall be marked consecutively beginning with Exhibit "A". *(IPP Rules)*

(ii) Notice to Answer. Within three (3) working days from receipt of the petition, the BLA shall issue a Notice to Answer for the Respondent to file an Answer together with the Affidavits of the witnesses and originals of documents, and at the same time notify all parties required to be notified in the IP Code and these Regulations, provided that in case of public documents, certified true copies may be submitted in lieu thereof. *(n)*

(iii) Filing of Answer. Within a non-extendible period of ten (10) working days from receipt of the Notice to Answer, the Respondent shall file an Answer together with the Affidavits of its witnesses and other original documents constituting its evidence to be marked consecutively beginning with Exhibit "1". *(n)*

(iv) Effect of Failure to File an Answer. If the Respondent fails to file an Answer or if the Answer is filed out of time, the case shall be decided on the basis of the petition, the affidavits of witnesses and the documentary evidence submitted by the petitioner. *(IPP Rules)*

(v) Prohibited Pleadings and Procedures. No reply, rejoinder, motion and other pleadings shall be allowed. There shall be no preliminary conference and no requirement of publication of the Notice to Answer. *(n)*

(vi) Submission for Decision. The petition is deemed submitted for decision upon the filing of the Answer within the allowed period, or upon the lapse of the period to file the Answer. *(n)*

(vii) Recommendation and Decision on the Petition. Within fifteen (15) days after the case is deemed submitted for decision, the Director of the BLA shall make the recommendation to the Director General on whether or not to give due course to the petition for compulsory licensing. The Director General shall review and approve the recommendation of the Director of BLA, and shall have the

authority to uphold, in whole or in part, or deny the recommendation on the petition for compulsory license. *(100, n)*

Section 15. Amendment of Compulsory License. Upon the request of the patentee or the licensee, the Director General may amend the decision granting the compulsory license, upon proper showing of new facts or circumstances justifying such amendment. *(101)*

Section 16. Appeal and Review by the Competent Courts. All appeals and review of the decision of the Director General to grant a compulsory license shall be filed in accordance with the procedures under the Rules of Court. *(n)*

Rule 13. Special Compulsory Licensing.

Section 1. Coverage. Special Compulsory Licensing shall only be available for drugs and medicines. *(n)*

Section 2. Procedure. The Director General of the IPO, upon the written recommendation of the Secretary of the Department of Health, shall, upon filing of a petition, grant a special compulsory license for the importation of patented drugs and medicines. The special compulsory license for the importation contemplated under this provision shall be an additional special alternative procedure to ensure access to quality affordable medicines and shall be primarily for domestic consumption: *Provided*, that adequate remuneration shall be paid to the patent owner either by the exporting or importing country. The compulsory license shall also contain a provision directing the grantee the license to exercise reasonable measures to prevent the re-exportation of the products imported under this provision.

The grant of a special compulsory license under this provision shall be an exception to Sections 100.4 and 100.6 of the IP Code and shall be immediately executory.

No court, except the Supreme Court of the Philippines, shall issue any temporary restraining order or preliminary injunction or such other provisional

remedies that will prevent the grant of the special compulsory license. *(93-A.1)*

Section 3. Special Compulsory License for Manufacture and Export. A compulsory license shall also be available for the manufacture and export of drugs and medicines to any country having insufficient or no manufacturing capacity in the pharmaceutical sector to address public health problems: *Provided*, that, a compulsory license has been granted by such country or such country has, by notification or otherwise, allowed importation into its jurisdiction of the patented drugs and medicines from the Philippines in compliance with the TRIPS Agreement. *(93-A.2)*

Section 4. Flexibilities. The right to grant a special compulsory license under this section shall not limit or prejudice the rights, obligations and flexibilities provided under the TRIPS Agreement and under Philippine laws, particularly Section 72.1 and Section 74 of the IP Code, as amended under this Act. It is also without prejudice to the extent to which drugs and medicines produced under a compulsory license can be exported as allowed in the TRIPS Agreement and applicable laws. *(93-A.3)*

Section 5. Suppletory Application of the Procedures under the TRIPS Protocol. The following procedure outlined under the Annex to the Protocol Amending the TRIPS Agreement (ref: WT/L/641) shall be suppletory to the procedure for the granting of a Special Compulsory License under the IP Code. The Annex is also referred to in this Rule as Article 31bis. The Protocol is hereby attached to these IRR as Annex "A."

Rule 14. Rights Conferred.

Section 1. Exception to the Rights of Registered Trademark Owners. Except in the cases of importation of drugs and medicines allowed under Section 72.1 of the IP Code and of off-patent drugs and medicines, the owner of a registered mark shall have the exclusive right to prevent all third parties not having the owner's consent from using in the course of trade identical or similar signs or containers for goods or services which are

identical or similar to those in respect of which the trademark is registered where such use would result in a likelihood of confusion. In case of the use of an identical sign for identical goods or services, a likelihood of confusion shall be presumed. *(147.1)*

There shall be no infringement of trademarks or tradenames of imported or sold patented drugs and medicines allowed under Section 72.1 of the IP Code, as well as imported or sold off-patent drugs and medicines: *Provided*, that, said drugs and medicines bear the registered marks that have not been tampered, unlawfully modified, or infringed upon, under Section 155 of the IP Code. *(147.1)*

Section 2. Well-Known Marks. The exclusive right of the owner of a well-known mark defined in Subsection 123.1(e) of the IP Code which is registered in the Philippines, shall extend to goods and services which are not similar to those in respect of which the mark is registered: *Provided*, that use of that mark in relation to those goods or services would indicate a connection between those goods or services and the owner of the registered mark: *Provided, further*, that the interests of the owner of the registered mark are likely to be damaged by such use. *(147.2)*

Rule 15. Limitations to Actions for Infringement.

Section 1. Limitations. Notwithstanding any other provision of these Rules, the remedies given to the owner of a right infringed under this Rules shall be limited as follows: *(159)*

(i) Use of a Mark in Good Faith. Notwithstanding the provisions of Section 155 of the IP Code, a registered mark shall have no effect against any person who, in good faith, before the filing date or the priority date, was using the mark for the purposes of his business or enterprise: *Provided*, that his right may only be transferred or assigned together with his enterprise or business or with that part of his enterprise or business in which the mark is used. *(159.1)*

(ii) Innocent Infringer. Where an infringer who is engaged solely in the business of printing the mark or other infringing materials for others is an innocent infringer, the owner of the right infringed shall be entitled as against such infringer only to an injunction against future printing. *(159.2)*

(iii) Advertisement or other similar communication. Where the infringement complained of is contained in or is part of paid advertisement in a newspaper, magazine, or other similar periodical or in an electronic communication, the remedies of the owner of the right infringed as against the publisher or distributor of such newspaper, magazine, or other similar periodical or electronic communication shall be limited to an injunction against the presentation of such advertising matter in future issues of such newspapers, magazines, or other similar periodicals or in future transmissions of such electronic communications. The limitations of this subparagraph shall apply only to innocent infringers: *Provided*, that such injunctive relief shall not be available to the owner of the right infringed with respect to an issue of a newspaper, magazine, or other similar periodical or an electronic communication containing infringing matter where restraining the dissemination of such infringing matter in any particular issue of such periodical or in an electronic communication would delay the delivery of such issue or transmission of such electronic communication is customarily conducted in accordance with the sound business practice, and not due to any method or device adopted to evade this section or to prevent or delay the issuance of an injunction or restraining order with respect to such infringing matter. *(159.3)*

(iv) Importation of Patented and Off-Patent Drugs and Medicines. There shall be no infringement of trademarks or tradenames of imported or sold drugs and medicines allowed under Section 72.1 of the IP Code, as well as imported or sold off-patent drugs and medicines: *Provided*, that said drugs and medicines bear the

registered marks that have not been tampered, unlawfully modified, or infringed upon as defined under Section 155 of the IP Code. *(159.4)*

CHAPTER III
PARALLEL IMPORTATION

Rule 16. General Provisions.

Section 1. Centralized Importation for Government. Except for specific programs and instances allowed by DOH, for purposes of ascertaining the best and most affordable prices and quality of drugs and medicines to be imported, all government agencies must centrally procure through PPI. *(n)*

Section 2. Sourcing of Medicines from Reputable and Reliable Suppliers. Private parties may course through PPI, to avail of its facility for undertaking procurement, sourcing and marketing of quality essential and low priced medicines through drug importations and sourcing of medicines from reputable and reliable suppliers and ensuring the widest distribution of these medicines nationwide as determined with BFAD. *(n)*

Section 3. Requirements for Every Incoming Shipment of Drugs and Medicines. The BFAD in coordination with the Bureau of Customs, Bureau of Quarantine and other concerned agencies is mandated to undertake and adopt measures relating to sampling and examination in accordance with relevant existing laws and regulations of every incoming shipment of drugs and medicines. *(n)*

Rule 17. Non-Discriminatory Clause.

Section 1. General Rule. It shall be unlawful for any retail drug outlet to refuse to carry either by sale or by consignment, or offer for sale drugs and medicines brought into the country, as allowed under Section 7 of the Act, by the government or authorized third party which has been previously approved

for distribution or sale by the BFAD. For this purpose, the said products shall be displayed with equal prominence as all other products sold in the establishment. *(33)*

Section 2. Patented Drugs. This rule shall apply only to importation of patented drugs and medicines made by the government or any authorized third party. *(7)*

Section 3. Permit to Import and Distribute. All interested parties must, in addition to existing requirements, secure a license/permit to import and to distribute such drugs from the BFAD. *(n)*

Section 4. Requirements for Request for Mandatory Carry. Such parties shall submit the following information: a) volume to be procured, b) purchase prices, c) shelf life of products, d) area of distribution, and e) other specific information/conditions, as may be required by the BFAD. *(n)*

Section 5. Mandatory Carry. Imported drugs to be carried by retail outlets shall be based on the reported health needs of a community. A mechanism that will determine the carrying capacity and demands for parallel imports at the level of retailers shall be established so that demands for drugs to be covered will match their carrying capacity. After proper determination by BFAD, the concerned LGUs shall ensure that retail outlets in the area of distribution shall carry said patented drugs. *(n)*

Section 6. Refusal to Sell Drugs and Medicines. No manufacturer, importer, trader, distributor, wholesaler shall withhold from sale or refuse to sell to a wholesaler or retailer any drug or medicine without good and sufficient reasons Good and sufficient reasons may include fortuitous events or force majeure, acts of God and other analogous cases as may be determined by BFAD.*(34, n)*

CHAPTER IV
POWERS OF THE SECRETARY OF HEALTH

Rule 18. Inclusion Drugs and Medicines in the List Subject to Price Regulation. Upon application or *motu propio* when the public interest so requires and after proper determination, the Secretary of Health may order the inclusion of drugs and medicines to the list subject of price regulation under Section 23 of the Act. *(19B)*

Rule 19. Determination of Maximum Retail Prices of Drugs and Medicines. Upon application or *motu propio* when the public interest so requires, the Secretary of Health shall have the power to determine the MRP of drugs and medicines which shall be recommended to the President of the Philippines for approval. *(19A1)*

Rule 20. Implementation of Fair Price of Drugs and Medicine. The Secretary of Health shall have the power to implement the fair price of drugs and medicines for purposes of public health insurance and government procurement based on the order of the President of the Philippines imposing MRP. *(19C1)*

Rule 21. Implementation of Cost Containment Measures. The Secretary of Health shall have the power to implement any other measures that the government may avail of to effectively reduce the cost of drugs and medicines, such as, but not limited to, competitive bidding, price volume negotiations, and other appropriate mechanisms that influence supply, demand and expenditures on drugs and medicines. *(19C2)*

Rule 22. Imposition of Administrative Fines and Penalties. After due notice and hearing, the Secretary of Health shall have the power to impose administrative fines against any person, manufacturer, importer, trader, distributor, wholesaler, retailer, or any other entity, in such amount as it may deem reasonable, which in no case shall be less than Fifty thousand pesos (Php 50,000.00) nor more than Five million pesos (Php 5,000,000.00) for violations of the MRP approved by the President of the Philippines. *(19D)*

Rule 23. Deputization of Government Entities. The Secretary of Health shall have the power to call upon and deputize any official, agent, employee, agency, or instrumentality of the national and local government for any assistance that he may deem necessary to carry out the purposes of the rules on drugs and medicines price regulation. *(19 E)*

Rule 24. Inquiries, Studies, Hearings, Investigations, and Proceedings. All inquiries, studies, hearings, investigations and proceedings conducted by the Secretary of Health shall be governed by the rules adopted by him, and in the conduct thereof shall not be bound by the technical rules of evidence. *(20)*

Rule 25. Other Powers Necessary to Implement this Act. The Secretary of Health shall exercise such powers and functions as may be necessary to implement and enforce price regulation of drugs and medicines including the power to require the production and submission of records, documents, books of account, bills of lading, input documents, records of purchase and sale, financial statements, and such other documents, information and papers as may be deemed as necessary, to enable him to carry out his functions, duties, and responsibilities. *(19F)*

CHAPTER V
PRICE MONITORING AND REGULATION SYSTEM AND THE CREATION OF ADVISORY BODIES AND CONSULTATIVE COUNCILS

Rule 26. Establishment of Price Monitoring for Drug Regulation Price System. To implement the policies of this Act, the Secretary of Health shall establish and initiate an electronic price monitoring and regulation system for drugs and medicines. *(18, n)*

Rule 27. Creation of Institutional Office to Implement the Price Regulation. In implementing the price monitoring and regulation system, a policy and operational office shall be established directly under the authority of the Secretary of Health. This institutional office shall be adequately

provided with the requisite personnel complement, budgetary support, and where necessary, sufficient capital outlay. *(n)*

Section 1. Powers and Functions of the Institutional Office. The institutional office shall have the following powers, among others: *(n)*

a. Manage and implement the National Drug Policy. *(n)*
b. Undertake policy studies and make appropriate recommendations to contribute to improved access to drugs and medicines; *(n)*
c. Engage and coordinate with relevant stakeholders to build coalitions, forge agreements and for other purposes as necessary. *(n)*
d. Provide Secretariat support to any Council or body created in pursuit of the effective implementation of the Act. *(n)*
e. Shall be involved in the processing, coordinating, generating and analyzing inter-agency price monitoring reports from the DTI and local government units. *(n)*
f. Such other functions as maybe incidental to the above or as may be directed by the Secretary of Health. *(n)*

Section 2. Role of Private Sector and NGOs. In pursuit of a comprehensive and effective price monitoring and regulation system, the Secretary of Health shall seek the assistance of representatives from non-governmental organizations, civil societies, and other proponents of the private sector to help monitor, advocate, or report violations of the provisions of these implementing rules. *(n)*

Rule 28. Creation of Advisory Bodies and Consultative Councils. The Secretary of Health may create such bodies and consultative councils, from which advice may be sought in the implementation of a drug or medicine price monitoring and regulation policy. Such bodies or consultative councils shall coordinate their efforts together with other government agencies including but not limited to DTI, BIR, BFAD, PITC, and PhilHealth. *(18, n)*

Section 1. Composition of Advisory Bodies and Consultative Councils. The composition of such advisory bodies and councils shall include representatives from various stakeholders both from government and private sectors, as may be determined by the Secretary of Health. *(n)*

Rule 29. Conflict of Interest. Any person, institution, and/or organization identified by the Secretary of Health to form part of the advisory council and bodies or any part of the drugs and medicines price monitoring system shall declare any and all conflict of interests through an appropriate instrument as shall be issued by the DOH in accordance with existing laws, rules and regulations. *(n)*

CHAPTER VI
MAXIMUM RETAIL PRICE (MRP)

Rule 30. General Provisions.

Section 1. Power of the President to Impose MRP. The President of the Philippines, upon recommendation of the Secretary of Health, shall have the power to impose MRP over any or all drugs and medicines. *(17)*

Section 2. Duration on Imposing MRP. The power to impose MRP over drugs and medicines shall be exercised within such period of time as the situation may warrant as determined by the President of the Philippines. *(17)*

Section 3. Coverage of MRP. The MRP shall be construed as the imposition of maximum prices at all levels of the supply chains including but not limited to manufacturer's price, trader's price, distributor's price and wholesaler's price, and retailer's price. *(19A, 19F, 26a).*

Section 4. Senior Citizens Discounts and Discounts for People with Disabilities. For drugs and medicines with MRPs, Senior Citizen's

discounts and discounts for people with disabilities shall continue to be honored. *(n)*

Section 5. List of Drugs and Medicines that are Subject to Price Regulation. The list of drugs and medicines that are subject to price regulation shall include, inter alia:

(a) Drugs and medicines that are included in the current edition of the Philippine National Drug Formulary (PNDF) Essential Drugs List;

(b) All drugs and medicines indicated for treatment of chronic illnesses and life threatening conditions, such as, but not limited to, endocrine disorders, e.g., diabetes mellitus; gastrointestinal disorders, e.g., peptic ulcer; urologic disorders, e.g., benign prostatic hyperplasia (BPH; cardiovascular diseases, e.g., hypertension; pulmonary diseases, e.g., pulmonary tuberculosis (PTB), asthma; auto-immune diseases, e.g., systemic lupus erythematosus (SLE); skin diseases, e.g., psoriasis; neuro-psychiatric disorders; other infectious diseases, e.g., human immunodeficiency virus-acquired immune deficiency syndrome (HIV-AIDS); and other conditions such as organ transplants and neoplasm;

(c) Drugs and medicines indicated for prevention of diseases, e.g., vaccines, immunoglobulin, anti-sera;

(d) Drugs and medicines indicated for prevention of pregnancy, e.g., oral contraceptives;

(e) Anesthetic agents;

(f) Intravenous fluids; and

(g) All other drugs and medicines which, from time to time, the Secretary of Health, in accordance with the relevant provisions of these Implementing Rules and

Regulations, determines to be in need of price regulation. *(23)*

Section 6. Order of Priority. The Secretary of Health shall determine the prioritization of the drugs and medicines subject to MRP. *(n)*

Section 7. Factors to Consider in Recommending the MRP. In recommending the maximum retail price, the Secretary of Health shall consider the following factors:

(a) Retail prices of drugs and medicines that are subject to regulation in the Philippines and in other countries;
(b) Supply available in the market;
(c) Cost to the manufacturer, importer, trader, distributor, wholesaler or retailer such as but not limited to:

    (i) The exchange rate of the peso to the foreign currency with which the drug or any of its component, ingredient or raw material was paid for;
    (ii) Any change in the amortization cost of machinery brought about by any change in the exchange rate of the peso to the foreign currency with which the machinery was bought through credit facilities;
    (iii) Any change in the cost of labor brought about by a change in minimum wage; or
    (iv) Any change in the cost of transporting or distributing the medicines to the area of destination. *(19A2)*

(d) In addition to the immediately preceding section, other such factors or conditions that may aid in arriving at a just and

reasonable determination of the MRP shall include:

(i) Marketing Costs (per drug and total global costs);
(ii) Research Costs (local and global/ per drug);
(iii) Promotion Costs;
(iv) Advertising Costs;
(v) Incentives and Discounts;
(vi) Taxes and other fees, impost, duties, and other charges imposed by competent authority; and
(vii) Other analogous cases *(n)*

Section 8. Publication of MRP. In order that affordable prices of drugs and medicines from the different manufacturers, importers, traders, distributors, wholesalers, or retailers shall be made available to the public, shall have such approved MRP of drugs and medicines published in papers of general circulation and shall also be posted in the internet. *(19A1, n)*

Section 9. Prohibition Against Exceeding the MRP. Upon effectivity of the MRP, no retailer shall sell drugs and medicines at a retail price exceeding the MRP approved by the President of the Philippines. *(19A3)*

Rule 31. Labeling and Publication.

Section 1. Labeling Requirements of Drugs and Medicines Subject to Price Regulation. Within a reasonable period as may be determined by the Secretary of Health, and provided, that it conforms to existing drug product labeling requirements, every manufacturer, importer, distributor, wholesaler, trader, or retailer of a drug and medicine intended for sale shall display the retail price which shall not exceed the MRP approved by order of the President of the Philippines. The MRP shall be printed on the label of the immediate container of the drug and medicine and the minimum pack thereof

offered for retail sale with the words "**RETAIL PRICE NOT TO EXCEED**" preceding it, and "**UNDER DRUG PRICE REGULATION**" on a red strip. *(26)*

Section 2. Issuance of Price List. Within a period as may be determined by the Secretary of Health from time to time, every manufacturer, importer, or trader shall issue a price list to wholesalers, distributors, retailers and to the Secretary of Health, indicating the retail price, the MRP, and such other information as may be required by the Secretary of Health. *(26b)*

In issuing the retail price, the importers, manufacturers, and traders shall notify the wholesalers, distributors, retailers, and the Secretary of Health whenever there are changes in their prices. *(n)*

Section 3. Publication of the Order of the President on MRP. The order of the President of the Philippines imposing MRP on drugs and medicines, including the conditions implementing it, shall be published within fifteen (15) days from issuance in at least two newspapers of general circulation. All wholesalers, manufacturers, distributors, importers, or traders shall have a copy of the order of the President of the Philippines and provide the same to their clients and customers that transact with them. *(30c)*

Section 4. Posting of MRP. All drug outlets are required to post in a conspicuous area within their premises a clear copy of the MRP order. They shall always maintain a copy of the said order to be easily accessible and readable to the consuming public and shall update it regularly as the situation may warrant. *(30d)*

Rule 32. Prohibition against Injunction. No court, except the Supreme Court of the Philippines, shall issue any temporary restraining order or preliminary injunction or preliminary mandatory injunction that will prevent the immediate execution of the exercise of the power of the President of the Philippines to impose MRP. *(17)*

Rule 33. Procedure and Decision Systems on Drugs and Medicine Price Regulation Proceedings.

Section 1. Power to Conduct Inquiries, Studies, Hearings, Investigations, and Proceedings. Pursuant to Section 7 of the Act, of the Powers of the Secretary of Health and consistent with the principles of administrative due process, he may conduct inquiries, studies, hearings, investigations and proceedings as he may deem appropriate in implementing the Law. *(20)*

Section 2. Effectivity of the Decisions or Orders of the Secretary Health. All decisions or orders of the Secretary of Health pursuant to the Powers of the Secretary, particularly: (A) Power to Recommend the Maximum Retail Price of Drugs and Medicines Subject to Price Regulation, (B) Power to Include Other Drugs and Medicines in the List Subject to Price Regulation, (C) Power to Implement Cost-Containment and Other Measures, (D) Power to Impose Administrative Fines and Penalties, (E) Power to Deputize Government Entities, or (F) Other Powers Necessary to Implement Provisions of this Chapter, shall take effect immediately. *(21)*

Section 3. Review of the Decisions or Orders of the Secretary of Health. A party adversely affected by a decision, order or ruling of the Secretary of Health may, within thirty (30) days from notice of such decision, order or ruling, or in case of a denial of a motion for reconsideration thereof, within fifteen (15) days after notice of such denial, file an appeal with the Court of Appeals, which shall have jurisdiction to review such decision, order or ruling.

The filing of a petition for a writ of certiorari or other special remedies in the Supreme Court shall in no case supersede or retain any decision, order or ruling of the Secretary of Health, unless the Supreme Court shall so direct, and the petitioner may be required by the Supreme Court to give bond in such form and of such amount as may be deemed proper. *(22)*

CHAPTER VII

COST CONTAINMENT MEASURES

Rule 34. PhilHealth Actions. It is one of the objectives of the Act to reduce, if not, eliminate out-of-pocket expenses on the part of the patients who should be the primary beneficiaries of social health welfare. Henceforth, notwithstanding provisions to the contrary, the Secretary of Health shall require the Philippine Health Insurance Corporation (PHIC) to implement the following measures in support of the fair prices of drugs and medicines to ensure availability, affordability, and accessibility: (19C1)

a. Intensify and accelerate the Outpatient Drug Benefit Packages,
b. Accreditation of all health-related units such as hospital pharmacies, commercial pharmacies, and other DOH-recognized drug outlets,
c. Imposition of penalties through a penalty structure for erring accredited professionals that would not prescribe quality, generic medicine within the MRP or PhilHealth List for reimbursements,
d. Reimbursements must be based on the current edition of the PNDF and limited to drug products covered by prescriptions containing the corresponding generic names of the drug products,
e. Drug products that may be covered by the reimbursements shall be purchased only from hospital pharmacies. In case of unavailability of drug products in the hospital pharmacies, reimbursements may be made directly to the patients but shall be charged to the reimbursements earmarked for the hospital or the medical doctor for the same service provided,
f. Reimbursement of drug products and services related to rational, quality drug access including, but not limited to, setting fixed reimbursement prices/drug price reference index to selected drugs and medicines,
g. Rational reimbursement of health facilities and health

professional that principally provide health services to the poor, and

h. Any other measures as may be determined by the Secretary of Health that will benefit patients and rationalize and ensure availability, affordability, and accessibility to quality drugs and medicines. *(n)*

Rule 35. Consignment. Rules governing consignment shall follow appropriate DOH Guidelines as outlined under AO 145 series of 2005. *(n)*

Rule 36. Government Procurement. All government agencies, including local government units, shall procure drugs and medicines within the Philippine National Drug Formulary current edition in accordance with Republic Act No. 9184 and any other pertinent procurement reforms. *(n)*

Rule 37. Philippine National Drug Formulary System. In pursuit of efficiency and cost-affectivity in the procurement and reimbursement of essential medicines, and as a critical cost containment measure, the Secretary of Health shall set-up an improved Philippine National Drug Formulary System and endeavor to have this updated on a regular quarterly basis. Corollary to this, for drugs and medicines perceived to be necessary and essential for specific cases and circumstances but are not listed in the PNDF; a system shall be put in place to allow the facilitated review of specific drugs and medicines for such special cases upon request. The request should mention the reasons why a certain drug should be listed, procured, and reimbursed by PhilHealth. If such request has not been acted upon within forty five (45) calendar days, then the request is deemed approved only for that particular purpose stated and only for that specific transaction. Such approval shall be valid for a year or until decided with finality by the Secretary of Health. *(n)*

Rule 38. Power to Implement other Cost Containment Measures. The Secretary of Health shall have the power to implement any other measures that the government may avail of to effectively reduce the cost of drugs and

medicines that shall include, but not limited to, competitive bidding, price volume negotiations, consignment and other appropriate mechanisms that influence supply, demand and expenditures on drugs and medicines.
(19C2, n)

In particular, the following cost containment measures shall be adopted and followed by the government agencies:

1) All government agencies, including local government units, shall ensure transparency on the procurement of the drugs and medicines, including the prices and inventory,
2) All government agencies, including local government units, shall procure their drugs and medicines requirement from suppliers which are registered with the Department of Health,
3) A common procurement ordering facility shall be established by the DOH to ensure economies of scale, when appropriate,
4) A common essential drug list requirement of all government agencies, including local government units, based on the PNDF current edition shall be prepared by the DOH for purposes of undertaking competitive pooled procurement and price volume negotiation, and
5) Consignment procedures shall comply with DOH rules and regulations. *(n)*

Rule 39. Rationalization of Marketing Practice. Subject to existing laws on consumer protection, as a cost containment measure, the Secretary of Health may promulgate policies and directives that would rationalize promotional and marketing practices, such as scientific and product information dissemination and advocacy activities when appropriate. *(n)*

Rule 40. Prohibited Promotions by Medical and Para- or Allied Medical Practitioners. No medical practitioner or health worker shall promote, advertise or endorse any drugs and medicines in quad media, in print or visual display. *(n)*

CHAPTER VIII
ILLEGAL ACTS OF PRICE MANIPULATIONS

Rule 41. Coverage. This Rule only covers the drugs and medicines enumerated under Section 23 of the Act, of whatever brand or generic name, the sale of which to the general public has been previously approved by the BFAD for which a Certificate of Product Registration was previously issued by the BFAD. *(n)*

Rule 42. Illegal Acts of Price Manipulation.

Section 1. Illegal Acts of Price Manipulation. Without prejudice to the provisions of existing laws on goods not covered by the Act, it shall be unlawful for any manufacturer, importer, trader, distributor, wholesaler, retailer, or any person engaged in acts of price manipulation such as hoarding, profiteering, or illegal combination or forming cartel, as defined under Section 5 of Republic Act No. 7581, otherwise known as the Price Act, and all other acts committed in restraint of trade. *(24)*

Section 2. Hoarding.

(i) Definition. The following shall constitute hoarding:

a. The undue accumulation by a person or combination of persons of any drug or medicine beyond his/their normal inventory level; or
b. The unreasonable limitation or refusal to dispose, sell or distribute said drug or medicine; or
c. The unjustifiable taking out of said drug or medicine from the channels of production, trade, commerce and industry. *(n)*

(ii) Prima Facie Evidence of Hoarding. The following shall constitute *prima facie evidence* of hoarding:

a. When a person has stocks of any drug or medicine fifty percent (50%) higher than his usual inventory, and
b. Unreasonably limits, refuses or fails to sell the same to the general public at the time of discovery of the stocks.

A person's usual inventory shall be reckoned from the third month immediately preceding before the discovery of the stocks in case the person has already been engaged in the business for at least three (3) months; otherwise, it shall be reckoned from the time he started his business. *(n)*

Section 3. Profiteering.

(i) Definition. Profiteering is the sale or offering for sale of any drug or medicine at a price grossly in excess of its true worth. *(n)*

(ii) Prima Facie Evidence of Profiteering. There shall be *prima facie* evidence of profiteering whenever a drug or medicine being sold:

a. Has no price tag; or
b. Is misrepresented as to its weight or measurement; or
c. Is adulterated or diluted; or
d. Whenever a person raises the price of said drug or medicine which he sells or offers for sale to the general public by more than ten percent (10%) of its price in the immediately preceding month. *(n)*

Section 4. Cartel.

(i) Definition. Refers to any combination of, or agreement between, two or more persons engaged in the production, manufacturing, processing, storage, supply, distribution, marketing, sale or disposition of any drug or medicine designed to artificially and unreasonably increase or manipulate its price.

(ii) Prima Facie Evidence of Engaging in a Cartel. There shall be *prima facie* evidence of engaging in a cartel whenever two (2) or more persons or business enterprises competing for the same market and dealing in the same drugs or medicines that are pharmaceutical equivalents, commit any of the following:

a. Perform uniform or complementary acts among themselves which tend to bring about artificial and unreasonable increase in the price of any drug or medicine that are pharmaceutical equivalents; or
b. Simultaneously and unreasonably increase prices on their competing products that are pharmaceutical equivalents thereby lessening competition among them. *(n)*

CHAPTER IX
GENERICS LAW

Rule 43. Posting and Publication. The DOH shall publish annually in acceptable means of public dissemination such as posting in its official websites, or in at least two (2) newspapers of general circulation, the generic names and the corresponding brand names under which they are marketed, of all drugs and medicines available in the Philippines. *(37, n)*

Rule 44. Who Shall Use Generic Terminology.

a. Government – All government health agencies and their personnel as well as other government agencies, including government owned and controlled corporations shall use generic names in all transactions related to purchasing, prescribing, dispensing, reimbursing and administering of drugs and medicines. *(38a, n)*
b. Private – All private medical, dental and veterinary

practitioners shall prescribe using the generic name. The brand name may be included, if so desired**.** *(38b, n)*

c. Health workers in government and all employed by the government practicing or working in private institutions shall use generic terminology only all transactions related to purchasing, prescribing, dispensing, reimbursing and administering of drugs and medicines such as but not limited to:

    1. All those employed by government, whether full or part time, while in government facilities.
    2. Medical and other Consultants, whether for free or otherwise working in government institutions/facilities
    3. Medical Doctors having private practice in government facilities,
    4. And all other government public health workers. (n)

d. Any organization or company involved in the manufacture, importation, repacking, marketing and/or distribution of drugs and medicines shall indicate prominently the generic name of the product. In the case of branded products, the generic name shall appear prominently and immediately above the brand name in all product labels as well as in advertising and other promotional materials. *(38c)*

e. Drug outlets, including drugstores, hospital and non-hospital pharmacies and non-traditional outlets such as supermarkets, convenience stores and other retail establishments, shall inform any buyer about any and all other drug products having the same generic name, together with their corresponding prices so that the buyer may adequately be informed to exercise his option. *(38d, n)*

f. Consumer empowerment – Consumers shall have the right to demand for information on all generic equivalents available. All drug outlets are obligated to provide their clients all generic equivalents offered for sale in their establishment. *(n)*

g. The drug outlets referred to herein shall post in conspicuous places as determined by the BFAD in their establishments a list of drug products with the same generic names and their corresponding prices and shall form part of the licensing requirements for such outlets. *(38d, n)* Posting of information shall be through, but not limited to, the following: hard copies, printed materials, or through programmed computers accessible to the public. *(n)*

h. All government auditors shall disallow in audit claims/disbursements, either from regular budget, and/or trust funds, covering the procurement by any mode, of drugs and medicines which are not within the PNDF current edition or in generic names only. *(EO49)*

Rule 45. Additional Statement on the Generic Label. There shall appear prominently on the label of a generic drug the following statement: "THIS PRODUCT HAS THE SAME THERAPEUTIC EFFICACY AS ANY OTHER GENERIC PRODUCT OF THE SAME NAME. SIGNED: BFAD" or, in the alternative "THIS PRODUCT HAS THE SAME THERAPEUTIC EFFICACY AS THE INNOVATOR PRODUCT OF THE SAME GENERIC NAME." at the option of BFAD.

Rule 46. Required Production. Subject to the rules and regulations promulgated by the Secretary of Health, every drug manufacturing company operating in the Philippines shall be required to produce, distribute and make widely available to the general public an unbranded generic counterpart of their branded product. *(39)*

In the event that an essential drug becomes off-patent in the

Philippines and there are no generic versions applied for or registered with the BFAD, or sold commercially in the Philippines, the Secretary of Health shall require such manufacturing companies to manufacture or cause to manufacture generic counterparts. *(n)*

Priority shall be given to essential drugs listed in the PNDF where the unmet needs for these products have not been served. Such shall include, but shall not be limited to, drugs for priority government programs, endemic conditions and other drugs and medicines as may be determined by the DOH. Regulatory and other incentives may be given for compliant manufacturers. *(n)*

Rule 47. Education Drive. The DOH jointly with the Philippine Information Agency and the Department of Interior and Local Government and in coordination with Non-Governmental Organizations shall conduct a continuous information and education campaign for the public. The Commission on Higher Education and the Department of Education, in coordination with DOH, shall conduct training for the medical and allied medical professions on drugs with generic names as an alternative of equal efficacy to the more expensive branded drugs. *(40, n)*

Rule 48. Content of Information and Education Drive. Such educational campaign shall include information on the illnesses or symptoms which each generically named drug is supposed to cure or alleviate, as well as its contraindications. *(40, n)*

Rule 49. Curriculum Update. The DOH shall collaborate with the Commission on Higher Education and the Professional Regulations Commission, in order to update the curriculum on Pharmacy, Medical and Allied Professions Education. *(n)*

CHAPTER X
PHARMACY LAW

Rule 50. Sale of Prescription Medicines, Pharmaceuticals, Drugs and Devices. No medicine, pharmaceutical, or drug, except for those which are non-prescription or over the counter**,** of whatever nature and kind or device shall be compounded, dispensed, sold or resold, or otherwise be made available to the consuming public except through a prescription drugstore or hospital pharmacy, duly established in accordance with the provisions of this Act. *(43, n)*

Rule 51. Packaging of Over-the-Counter Drugs. Non-prescription or over-the-counter drugs may be sold in their original packages, bottles and containers to the consuming public through supermarkets, convenience stores and other retail establishments. Only solid dosage forms with individual original and primary packaging as, approved by BFAD, like blisters packs, foils packs, and other similar individual packaging, may be sold in smaller quantities. No other repackaging shall be allowed. Any new packaging shall require BFAD approval. BFAD shall issue appropriate guidelines on proper packaging of OTC drugs. *(43, n)*

Rule 52. Sale of Over-the-Counter Pharmaceutical Products in Non-traditional Outlets. Pharmaceutical, drug or biological manufacturing establishments, importers and wholesalers of drugs, medicines, or biological products shall not sell their products for re-sale except to retail drug outlets, hospital pharmacies or other drug wholesalers under the supervision of a registered pharmacist, and supermarkets, convenience stores, other retail establishments only for over-the-counter drugs, duly licensed by the BFAD. *(43)*

Rule 53. Single Drug Classification. In order to promote rational drug use, any drugs and medicines in prepared multiple dosage strength shall only be under one classification as determined by BFAD. *(n)*

Rule 54. Licensing of Non-traditional Outlets. The BFAD shall issue the appropriate implementing guidelines for the requirements in licensing non-traditional outlets and similar establishments. To ensure public safety, the requirements for License to Operate (LTO) for non traditional outlets shall include BFAD training/seminar on OTC medicines on procurement, proper storage and handling, safety and quality for outlet personnel as well as having a supervising pharmacist. *(n)*

Rule 55. Botika ng Barangay. Botika ng Barangays (BnBs) are drug outlets with special licenses to operate issued in compliance with the DOH and BFAD guidelines that serve to improve access to essential drugs and the general healthcare of the population, especially the poor. In support of this intent, BnBs shall be allowed to carry a selected list of prescription, over-the-counter, and other such drugs and medicines as deemed necessary to address the pressing health needs of an area. The DOH shall issue in a separate document the approved list of drugs and medicines that may be carried by BnBs. The list should be reviewed regularly and amended as necessary. BnBs shall be manned by DOH-BFAD trained operators and shall have a supervising pharmacist. *(n)*

CHAPTER XI
POWER TO DEPUTIZE GOVERNMENT ENTITIES

Rule 56. Power to Deputize Government Entities. The Secretary of Health shall have the power to call upon and deputize any official, agent, employee, agency, or instrumentality of the national and local government for any assistance that it may deem necessary to carry out the purposes of the rules on drugs and medicines price regulation. *(19E)*

Rule 57. Deputizing Health Attaches/Philippine Missions. The Secretary of Health may appoint or designate health attaches for detection of international drug prices for monitoring. *(n)*

In the absence of health attaches, the Secretary of Health may seek

the assistance of Philippine Missions abroad or their attached agencies, thru their respective Department or Agency heads, to accomplish the objectives of the Act. *(n)*

Rule 58. Authorizing the PPI. The PPI or its equivalent agency is hereby authorized to establish a common facility for pooled procurement in compliance with RA 9184. *(n)*

Rule 59. Deputizing the Bureau of Customs (BOC), Securities and Exchange Commission (SEC) and Bureau of Internal Revenue (BIR). The Secretary of Health shall call upon the BOC, SEC, and the BIR for assistance in determining the cost incurred and the profits earned by the industry and in order to ultimately determine the actual prices of drugs and medicines. Further, the Secretary of Health shall deputize the Bureau of Internal Revenue in obtaining and validating the documents that he may so require as described in Section 19F of the Act. *(n)*

Rule 60. Deputizing the LGUs. The Secretary of Health shall deputize the local government units (LGUs) to monitor prices of drugs and medicines in their area of jurisdiction and report all suspected violations as covered by the Act. LGUs shall also be deputized to enforce provisions of non-discriminatory clause pursuant to rules jointly put in place by the DOH and LGUs. *(n)*

Rule 61. Deputizing other Government Agencies. The Secretary of Health may deputize any other official, agent, employee, agency, or instrumentality of government as appropriate to implement drugs and medicines price regulations. *(n)*

CHAPTER XII
REPORTING AND SURVEYS

Rule 62. Reports from Local Government Units (LGUs) and the Department of Trade and Industry (DTI). All local government units and the DTI shall help ensure the implementation of pricing policies provided under

the Act and these Implementing Rules and Regulations by submitting quarterly price monitoring reports to the Secretary of Health of drugs and medicines identified by the latter, and any and all necessary information that the Secretary of Health may require. *(27)*

Rule 63. System and Standards. The system and standards for reporting shall be issued by the DOH. *(n)*

Rule 64. Scope of Price Monitoring Function of DTI. Monitoring of prices of drugs and medicines to be conducted by DTI shall be limited to drugstores operating within the territorial limits of the city or municipality where the provincial office of DTI is located. The list of drugs and medicines the prices of which are to be monitored by DTI on a quarterly basis shall be agreed upon by the Secretary of Health and the Secretary of Trade and Industry. Such list shall be subject to an annual review and revision, if necessary. *(n)*

Rule 65. Scope of Price Monitoring Function of LGUs. The monitoring of prices of drugs and medicines to be conducted by the LGUs shall be limited to drugstores operating within the territorial limits of their respective city or municipality, except the city or municipality where the provincial office of DTI is located. The list of drugs and medicines the prices of which are to be monitored by the LGUs on a quarterly basis shall be agreed upon by the Secretary of Health and the Secretary of Interior and Local Government. Such list shall be subject to an annual review and revision, if necessary. *(n)*

Rule 66. Role of the Department of Health (DOH) and the Department of Trade and Industry (DTI). The DOH and the DTI shall conduct independent periodic surveys and studies of the selling prices of all drugs and medicines all over the country as well as their share or effect on the family income of the different economic groups in the country for purposes of serving as data base for government efforts to promote access to more affordable medicines, as well as evaluating the effectivity of the measures undertaken. The DTI shall

always officially provide the Secretary of Health copies of these independent reports. *(28)*

Rule 67. Monitoring Reports. The Secretary of Health shall submit a bi-annual Monitoring Report of its performance on the implementation of the Act to the Office of the President. This report shall be published in a newspaper of general circulation within thirty (30) days upon submission. *(30a)*

Rule 68. Monitoring of Progress. The DOH with the assistance of the Department of Interior and Local Government and the Philippine Information Agency shall monitor the progress of the education drive, and shall submit regular reports to Congress. *(40)*

Rule 69. Performance Report. The Secretary of Health shall also submit an annual performance report regarding the implementation of the Act to both Houses of Congress, within fifteen (15) days from the opening of the regular session. He shall also regularly report to and immediately comply with any order of the Congressional Oversight Committee. *(30b)*

CHAPTER XIII
BFAD STRENGTHENING

Rule 70. Retention of Income. For a more effective and expeditious implementation of the Act, the Director or the Head of BFAD shall be authorized to retain, without need of a separate approval from any government agency, and subject only to existing accounting and auditing rules and regulations, all the fees, fines, royalties and other charges, collected by the BFAD under the Act and other laws that it is mandated to administer based on the immediately prior year of operations, for use in its operations, like upgrading of facilities, equipment outlay, human resource development and expansion, and the acquisition of the appropriate office space, among others, to improve the delivery the delivery of its services to the public. This amount, which shall be in addition to the annual budget of BFAD, shall be

deposited and maintained in a separate account or fund, which may be used or disbursed directly by the Director or Head. (31a)

Rule 71. Budgetary Support. After five (5) years from the coming into force of the Act, the Director or Head of the BFAD shall, subject to the approval of the Secretary of Health, determine if the fees and charges, mentioned in Section 1 hereof, are sufficient to meet its budgetary requirements. If so, it shall retain all the fees and charges it shall collect under the same conditions indicated in said Section 1 but shall forthwith, cease to receive any funds from the annual budget of the National Government; if not, the provisions of Section 1 shall continue to apply until such time when the Director or Head of the BFAD, subject to the approval of the Secretary of Health, certifies that the above stated fees and charges the BFAD shall collect are enough to fund its operations. (31b)

Rule 72. Review of Fees and Charges. In relation to the above rule, the fees and charges shall be periodically reviewed by BFAD in consultation with relevant stakeholders. *(n)*

Rule 73. Performance Report. The BFAD shall submit a yearly performance report to the Quality Affordable Medicines Oversight Committee. The report shall itemize the use of such retained funds in the past year up to the present and the budgeted use of the same in the succeeding periods. (31c)

Rule 74. Quality Assurance of Drugs. The BFAD 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 multi-source pharmaceutical products should conform to the WHO guidelines on registration requirements to establish interchangeability. (32)

CHAPTER XIV
SANCTIONS AND PENALTIES

Rule 75. General Penalties. The Secretary of Health shall have the authority to impose administrative sanctions such as, but not limited to, suspension, or revocation of license to operate; suspension or revocation of Certificate of Product Registration, product recall; or recommend suspension or revocation of license to practice profession to the Professional Regulation Commission as the case may be for the violation of the Act and these Implementing Rules and Regulations. *(41C)*

Rule 76. Administrative Sanctions. Unless otherwise provided herein, the following administrative sanctions shall be imposed upon any person, juridical or natural, found to have violated the provisions of the Act and these Implementing Rules and Regulations:

a. 1st violation – Warning

b. 2nd violation – Administrative fine of a minimum of ten Thousand (P10, 000.00) to Fifty Thousand (P 50,000.00) Pesos depending on the gravity and extent of the violation, including the recall of the offending product when applicable;

c. 3rd violation – Administrative fine of minimum of Sixty Thousand (P60, 000.00) to One Hundred Fifty Thousand (P150, 000.00) Pesos, depending on the gravity and extent of the violation, and in addition thereto, the recall of the offending product, and suspension of the Certificate of Product Registration (CPR) when applicable;

d. 4th violation – Administrative fine of a minimum of Two Hundred Thousand (P 200, 000.00) to Five Hundred Thousand (P500, 000.00) Pesos, depending on the gravity and extent of the violation, and in addition thereto, the recall of the offending product, revocation of the CPR, suspension

of the License to Operate (LTO) and or License to Import and Distribute, when applicable, for a period of one year;

e. 5th and succeeding repeated violations – Administrative fine of One Million (P1,000,000.00) Pesos, and, when applicable, the recall of the offending product, revocation of the CPR, revocation of the License to Operate (LTO) and or License to Import and Distribute of the company concerned, including the blacklisting of the company to be furnished the Government Procurement Policy Board (GPPB) and the Department of Trade and Industry (DTI);

f. An additional penalty of Two Thousand Five Hundred (P2, 500. 00) Pesos per day shall be made for every day the violation continues after having received the order from the DOH or other such appropriate body, notifying and penalizing the offending person or company for the infraction.

Rule 77. Repeated Violations. For purposes of determining whether or not there is "repeated" violation for companies, each product violation belonging or owned by a company, including those of their subsidiaries, are deemed to be violations of such concerned person or entity and shall not be based on the specific violating product alone.

Rule 78. Fees, Charges and Fines. All fees collected, charges imposed and administrative fines that have accrued as a consequence of the implementation of the Act and these Implementing Rules and Regulations shall be for the account and income of the BFAD.

Rule 79. Government Depositary Bank. All such fees and fines shall be deposited in an Authorized Government Depositary Bank (AGDB).

Rule 80. Erring Public Employees. In accordance with the Administrative Code and pertinent Civil Service laws, rules and regulations, erring

government employees found to be liable, and depending on the gravity of the said violation, shall be imposed the appropriate penalty by the disciplining authority.

Rule 81. Liability of Manufacturers/Distributors. Manufacturers and Distributors of the products covered by the Law shall be directly liable for any violation of the provisions of the Law and its IRR. Should the offense be committed by a juridical person, the Chairman of the Board of Directors, the president, general manager, or the partners and/or the persons directly responsible therefore, shall be made accountable.

Agents/Representatives of the Manufacturer or Distributor of the products within the scope of the Law, who commit any violation of the provisions of the Law and its implementing rules and regulations shall jointly and solidarily liable with the said manufacturers and distributors.

All those found responsible after the investigation shall be jointly and solidarily liable.

Rule 82. Penalty for Violations of the Maximum Retail Price. After due notice and hearing, the Secretary of Health shall have the power to impose administrative fines against any person, manufacturer, importer, trader, distributor, wholesaler, retailer, or any other entity, in such amount as it may deem reasonable, which in no case shall be less than **Fifty thousand pesos (Php50,000.00) nor more than Five million pesos (Php5,000,000.00)** for violations of the maximum retail price approved by the President of the Philippines pursuant to the provisions of this Chapter. *(19D)*

Rule 83. Penalty for Illegal Acts of Price Manipulation. Any person or entity who commits any act of illegal price manipulation of any drug and medicine subject to price regulation shall suffer the penalty of not less than five (5) years but not more than fifteen (15) years of imprisonment, or shall be imposed a fine of **not less than One hundred thousand pesos (Php100,000.00) but not more than Ten million pesos (Php10,000,000.00)**,

at the discretion of the court. The court may also order the suspension or revocation of its **license to operate (LTO), professional or business license**. Whenever any act of illegal price manipulation of any drug and medicine subject to price regulation is committed by a juridical person, its officials or employees, or in case of a foreign corporation or association, its agent or representative in the Philippines who is responsible for the violation, shall be held liable therefore. *(25)*

Rule 84. Penalties for Violations under the Non-discriminatory Clause. Any person or entity who shall refuse to carry or sell drugs and medicines pursuant to the provisions of these Rules and Regulations shall be punished with a fine of **not less than One hundred thousand pesos (Php100,000.00) but not more than Five hundred thousand pesos (Php500,000.00**), at the discretion of the court. For the succeeding offense, the penalties shall **not be less than Five hundred thousand pesos (Php500,000.00) but not more than One million pesos (Php1,000,000.00),** at the discretion of the court, and suspension or revocation of its **license to operate (LTO), business or professional license**, as the case may be. *(35)*

Rule 85. Penalties for Violation of Generics Act Amendments.

a. Any person who violate sections 2(a), 2(b), 2(c) of the Generics Law amendments as reflected in this Implementing Rules and Regulations shall suffer the penalty graduated hereunder, viz:

    1. For the first conviction, he shall suffer the penalty of reprimand which shall be officially recorded in the appropriate books of the Professional Regulation Commission.
    2. For the second conviction, the penalty of fine in the amount of not less than Ten thousand pesos (Php10,000.00) but not exceeding Twenty-five

thousand pesos (Php25,000.00), at the discretion of the court.

3. For the third conviction, the penalty of fine in the amount of not less than Twenty-five thousand pesos (Php25,000.00) but not exceeding Fifty thousand pesos (Php50,000.00) and suspension of his license to practice his profession for sixty (60) days at the discretion of the court.
4. For the fourth and subsequent convictions, the penalty of fine of not less than One hundred thousand pesos (Php100,000.00) and suspension of his license to practice his profession for one (1) year or longer at the discretion of the court. *(41)*

b. Any juridical person who violates Sections 2(d), 2(e), and 4 of the Generics Law amendments of this implementing rules and regulations as well as Section 7 of Republic Act No. 6675 otherwise known as the Generics Act of the Philippines shall suffer the penalty of a fine of not less than **One hundred thousand pesos (Php100,000.00)** and suspension or revocation of license to operate such drug establishment or drug outlet at the discretion of the court: *Provided,* That its officers directly responsible for the violation shall suffer the penalty of fine of at least **Forty thousand pesos (Php40,000.00)** and suspension or revocation of license to practice profession, if applicable, and by imprisonment of not less than six(6) months nor more than one (1) year or both fine and imprisonment at the discretion of the court: and, *Provided*, *further,* That if the guilty party is an alien, he shall be *ipso facto* deported after service of sentence without need of further proceedings. *(41 B)*

CHAPTER XV
MISCELLANEOUS PROVISIONS

Rule 86. Amendments.

Section 1. Amendments to the Implementing Rules and Regulations. The DOH, DTI, IPO, and BFAD, either collectively or individually, may initiate the amendment of the IRR. Prior to the conduct of any public hearing for the proposed amendment, the initiating party shall first inform the other parties of the same at least 30 days prior to the date of the first public consultation.

Section 2. Issuance of Appropriate Guidelines. The DOH, DTI, IPO, and BFAD may issue appropriate guidelines that may be deemed necessary to address existing and emerging situation for the purpose of effectively implementing the intentions and objectives of the Act.

Section 3. Publication of Amendments. Any amendments to these Implementing Rules and Regulation shall take effect fifteen (15) days after its publication in at least two (2) national papers of general circulation and upon filing at the UP Law Center as accorded by Law. *(n)*

Section 4. Review of IRR. After two (2) years from the effectivity of these Implementing Rules and Regulations and every 2 years thereafter, the DOH, DTI, IPO and BFAD shall jointly review these Implementing Rules and Regulations.

Rule 87. Transitory Provisions

Section 1. Submission of Prices and Inventory. Within 30 days from the effectivity of the Law, and every December 31st of every year thereafter, every manufacturer, importer, trader, distributor, wholesaler, and retailer of a drug and medicine whether included in or excluded from the list of drugs and medicines that are subject to price regulation shall furnish the Secretary of Health a list, containing on the minimum the corresponding prices and

inventory, of all drugs and medicines it manufactures, imports, trades, distributes, wholesales, or retails, data pertaining to the factors enumerated under Section 19A2 of the Law and any and all necessary information that the Secretary of Health may require. *(19F)*

Section 2. Undertake the Study to Determine the MRP. Subject to the relevant provisions of these Rules and Regulations, in order that affordable prices of drugs and medicines shall be made available to the public, the Secretary of Health shall immediately undertake a study on the prevailing prices of drugs and medicines which he/she will prioritize to be subject to price regulation and shall provide this initial list of drugs and medicines, with its recommended MRP to the President of the Philippines. *(19A3).*

Rule 88. Separability Clause. Any portion or provision of the Act or of these Rules that may be declared unconstitutional or invalid shall not have the effect of nullifying other portions and provisions hereof as long as such remaining portion or provision can still subsist and be given effect in their entirety. *(47)*

Rule 89. Repealing Clause. All administrative issuances or parts thereof inconsistent herewith are hereby repealed or modified accordingly. *(48)*

Rule 90. Effectivity Clause. This Implementing Rules and Regulation shall take effect fifteen (15) days after its publication in at least two (2) national papers of general circulation and upon filing at the UP Law Center as accorded by Law. *(n)*

ANNEX "A"

The TRIPS Protocol. Unless otherwise amended by the IP Code and these IRR, the Protocol Amending the TRIPS Agreement (ref: WT/L/641) is reproduced below:

1. For the purposes of Article 31*bis* and this Annex:

(a) "eligible importing Member" means any least-developed country Member, and any other Member that has made a notification to the Council for TRIPS Agreement of its intention to use the system set out in Article 31*bis* and this Annex ("system") as an importer, it being understood that a Member may notify at any time that it will use the system in whole or in a limited way, for example only in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. It is noted that some Members will not use the

system as importing Members and that some other Members have stated that, if they use the system, it would be in no more than situations of national emergency or other circumstances of extreme urgency;

(b) "Exporting Member" means a Member using the system to produce pharmaceutical products for, and export them to, an eligible importing Member."

2. The terms referred to in paragraph 1 above are that:

(a) The eligible importing Member(s) has made a notification to the Council for TRIPS Agreement, that:

(i) Specifies the names and expected quantities of the product(s) needed;

(ii) Confirms that the eligible importing Member in question, other than a least-developed country Member, has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question in one of the ways set out in the Appendix to this Annex; and

(iii) Confirms that, where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory license in accordance with Articles 31 and 31*bis* of this Agreement and the provisions of this Annex;

(b) The special compulsory license issued by the exporting Member under the system shall contain the following conditions:

(i) Only the amount necessary to meet the needs of the eligible importing Member(s) may be manufactured under the license and the entirety of this production shall be exported to the Member(s) which has notified its needs to the Council for TRIPS Agreement;

(ii) Products produced under the license shall be clearly identified as being produced under the system through specific labeling or marking. Suppliers should distinguish such products through special packaging and/or special colouring/shaping of the products themselves, provided that such distinction is feasible and does not have a significant impact on price; and

(iii) Before shipment begins, the licensee shall post on a website the following information:

- The quantities being supplied to each destination as referred to in indent (i) above; and

- The distinguishing features of the product(s) referred to in indent (ii) above;

(c) The exporting Member shall notify the Council for TRIPS Agreement of the grant of the license, including the conditions attached to it. The information provided shall include the name and address of the licensee, the product(s) for which the license has been granted, the quantity(ies) for which it has been granted, the country(ies) to which the product(s) is (are) to be supplied and the duration of the license. The notification shall also indicate the address of the website referred to in subparagraph (b) (iii) above.

3. In order to ensure that the products imported under the system are used for the public health purposes underlying their importation, eligible importing Members shall take reasonable measures within their means, proportionate to their administrative capacities and to the risk of trade diversion to prevent re-exportation of the products that have actually been imported into their territories under the system. In the event that an eligible importing Member that is a developing country Member or a least-developed country Member experiences difficulty in implementing this provision, developed country Members shall provide, on request

and on mutually agreed terms and conditions, technical and financial cooperation in order to facilitate its implementation.

4. Members shall ensure the availability of effective legal means to prevent the importation into, and sale in, their territories of products produced under the system and diverted to their markets inconsistently with its provisions, using the means already required to be available under this Agreement. If any Member considers that such measures are proving insufficient for this purpose, the matter may be reviewed in the Council for TRIPS Agreement at the request of that Member.

5. With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products, it is recognized that the development of systems providing for the grant of regional patents to be applicable in the Members described in paragraph 3 of Article 31*bis* should be promoted. To this end, developed country Members undertake to provide technical cooperation in accordance with Article 67 of this Agreement, including in conjunction with other relevant intergovernmental organizations.

6. Members recognize the desirability of promoting the transfer of technology and capacity building in the pharmaceutical sector in order to overcome the problem faced by Members with insufficient or no manufacturing capacities in the pharmaceutical sector. To this end, eligible importing Members and exporting Members are encouraged to use the system in a way which would promote this objective. Members undertake to cooperate in paying special attention to the transfer of technology and capacity building in the pharmaceutical sector in the work to be undertaken pursuant to Article 66.2 of this Agreement, paragraph 7 of the Declaration on the TRIPS Agreement and Public

Health and any other relevant work of the Council for TRIPS Agreement.

7. The Council for TRIPS Agreement shall review annually the functioning of the system with a view to ensuring its effective operation and shall annually report on its operation to the General Council. *(n)*

NOW THEREFORE, the parties have herein below affixed their signatures to the Joint DOH-DTI-IPO-BFAD Administrative Order No. 2008-01 this 4th day of November 2008.

FRANCISCO T. DUQUE III, MD, MSc.
Secretary
Department of Health

PETER B. FAVILA
Secretary
Department of Trade and Industry

ADRIAN S. CRISTOBAL, JR.
Director General
Intellectual Property Office

LETICIA BARBARA B. GUTIERREZ, MSc.
Director IV
Bureau of Food and Drugs