BOARD REGULATION NO. 3
Series of 2003

SUBJECT: Comprehensive Guidelines on importation, distribution, manufacture, prescription, dispensing and sale of, and other lawful acts in connection with any dangerous drugs, controlled precursors and essential chemicals and other similar or analogous substances.

Pursuant to Section 2, Section 40 of Article III, Section 81(b) and Section 81 (r) of Article IX, and Section 93 of Article XI of RA 9165, the following guidelines are hereby promulgated:

ARTICLE I
Definition of Terms

Section 1. Definitions.

In this Guidelines, unless the context indicates otherwise,

(a) “Act” refers to Republic Act No. 9165, otherwise known as the “Comprehensive Dangerous Drugs Act of 2002”;

(b) “Administer” means any act of introducing any dangerous drug into the body of any person, with or without his/her knowledge by injection, inhalation, ingestion or other means, or of committing any act of indispensable assistance to a person in administering a dangerous drug to himself/herself unless administered by a duly licensed practitioner for purposes of medication;

(c) “Analogue” means any substance whose chemical structure is substantially similar to any dangerous drug whose psychoactive effects it simulates;

(d) “Board” refers to the Dangerous Drugs Board under Section 77, Article IX of RA 9165;

(e) “Broker” refers to an agent employed to make bargains and contracts for compensation; or a middleman or negotiator between contracting parties; or a person whose business is to bring seller and purchaser together.

(f) “Controlled chemical” means a substance listed as controlled precursor and essential chemical as

defined pursuant to Section 3(h), Article I, RA 9165;

(g) “Chemical mixture” means a combination of two or more chemical substances, at least one of which is not a controlled chemical, except that such term does not include any combination of controlled chemical with another chemical that is present solely as an impurity;

(h) “Customs broker,” means a licensed agent or broker whose function is to handle the process of clearing goods through customs.

(i) “Dispense” means any act of giving away, selling or distributing medicine or any dangerous drug with or without the use of prescription;

(j) “Dangerous drugs” include those listed in the Schedules annexed to the 1961 Single Convention on Narcotic Drugs, as amended by the 1972 Protocol, and in the Schedules annexed to the 1971 Single Convention on Psychotropic Substances as enumerated in the attached annex which is an integral part of RA 9165;

(k) “End-user license” authorizes the holder to acquire controlled chemicals from a licensed importer or manufacturer or wholesaler or through import for legitimate use in analytical laboratories or in the course of commercial or industrial operation such as but not exclusive to manufacture or production processes; as solvents for paints, lacquers, gums, resins; bleaching of resins, waxes, fats, oils, straws, silk and other fibers; washing of carbon dioxide in manufacturing mineral water; tanning of leathers; purifying of water; photography; purification of petroleum; as drying agent; as component of toilet bowl cleaners, metal cleaners and antitrust compounds and automobile battery fluids; etc. The certificate holder is NOT authorized to resell such chemical in original form to others. He may sell the chemical waste resulting from the commercial or industrial operation to a licensed recycler;

(l) “Export,” means any physical departure of dangerous drugs or controlled chemicals or other goods from the customs territory of the country, which requires customs declaration;

(m) “Foreign State” means:

(i) Any country other than the Philippines; and

(ii) Every constituent part of such country, including a territory, dependency or protectorate, which administers its own laws relating to dangerous drugs, analogues, and controlled equipment and chemicals;

(n) “Import” means any physical introduction of dangerous drugs or controlled chemicals or other goods into the customs territory of the country, which requires declaration;

(o) “Institution” means a hospital, nursing home or other institution used for the accommodation, treatment and care of persons suffering from physical or mental conditions;

Drugs and Psychotropic Substances; and any other international convention to which the Philippines is a Party or may become Party after the commencement of Republic Act 9165, relating in whole or in part to the control of dangerous drugs and controlled chemicals;

(q) “Intractable pain” means a pain state in which the cause of pain cannot be removed or otherwise treated and which in the generally accepted course of medical practice no relief or cure of the cause of the pain is possible or none has been found after reasonable efforts that have been documented in the practitioner’s medical records;

(r) “Laboratory equipment” means the paraphernalia, apparatus, materials or appliances when used, intended for use or designed for use in the manufacture of any dangerous drug and/or controlled precursor and essential chemical, such as reaction vessel, preparative/purifying equipment, fermentors, separatory funnel flask, heating mantle, gas generator, or their substitute;

(s) “License” means a written permission or authorization

(t) “Manufacture” means the production, preparation, compounding or processing of any dangerous drug and/or controlled precursor and essential chemical, either directly or indirectly or by extraction from substances of natural origin, or independently by means of chemical synthesis, and shall include any packaging or repackaging of such substances, design or configuration of its form, or labeling or relabeling of its container; except that such terms do not include the preparation, compounding, packaging or labeling of a drug or other substances by a duly authorized practitioner as an incident to his/her administration or dispensation of such drug or substance in the course of his/her professional practice including research, teaching and chemical analysts of dangerous drugs of such substances that are not intended for sale or for any other purpose;

(u) “Medical practitioner” means any person who is registered and entitled under the laws of the Philippines to practice the profession of medicine;

(v) “Open individual authorization” means that a licensed operator of controlled chemicals, is allowed to import such quantities of such controlled chemicals from such countries or regions during such periods as may be specified in the authorization/permit. The open individual authorization may be valid for at least one year unless the specified threshold for the calendar year has been reached or sooner cancelled or terminated for cause by the Director General of PDEA;

(w) “Operator” means any person who carries on a business of the manufacture, acquisition or sale of:

(i) A dangerous drug for medical, scientific use or other lawful use;

(ii) A controlled chemical, intended for lawful use, or a related business, such as import, export, transit, processing or acting as a broker, but excludes person carrying on a business of customs brokerage agent, warehouse depositor or carrier when acting solely in that capacity.

(x) “Permit” means a permit of the kind referred to in Article III of this Regulation;

(y) “Person” means any entity, natural or judicial, including among others, a corporation, partnership, trust or estate, joint stock company, association, syndicate, joint venture or other unincorporated
organization or group capable of acquiring rights or entering into obligations;

(z) "Pharmacist" means any person who is registered and entitled under the laws of Philippines to practice the profession of pharmacy;

(aa) "PDEA" refers to Philippine Drug Enforcement Agency;

(bb) "Place" includes any land (whether vacant enclosed or built upon, or not), and any premises;

(cc) "Practitioner" means any person who is licensed physician, dentist, chemist, medical technologist, nurse, midwife, veterinarian or pharmacist in the Philippines;

(dd) "Prescription" means a written direction by a practitioner that a stated amount of a dangerous drug or drug containing Table I controlled chemical as the only active medicinal ingredients and drug containing controlled chemical and therapeutically insignificant quantities of another active medicinal ingredient, be dispensed for the person named therein;

(ee) "Preparation" means a solution or mixture, in whatever physical state, containing:

(i) A dangerous drug; or

(ii) A controlled chemical;

(ee) "Proceedings" means any administrative or quasi-judicial procedure conducted by the Board and includes an inquiry, investigation, or preliminary or final determination of facts;

(ff) "Recycler" means a commercial enterprise that acquires waste controlled chemicals, removes unwanted chemicals entirely or partially and then resells the processed controlled chemicals;

(gg) "Regulatory Compliance Inspector/Investigator" means any person appointed and/or designated as such by the Director General of PDEA pursuant to Article IV of this Regulation;

(hh) "Retail distributing," means the selling is limited almost exclusively for personal use, both in number of sales, either or directly to walk-in customers or in face-to-face transactions by direct sales. The person buying from the retailer is the ultimate user or consumer of the article or commodity or does not sell it again;

(ii) "Sell," means any act of giving away any dangerous drug and/or controlled precursor and essential chemical whether for money or any other consideration;

(jj) "Special prescription for dangerous drugs" means the prescription form for dangerous drugs that is made of a special kind of paper exclusively issued by and obtainable from DOH;

(kk) "Supply" includes sale, consignment, despatch, transport, delivery, distribution, dispensing, as well as offer to supply;

(ll) "Table I Controlled Chemical” means chemicals enumerated in the list of substances in Table I Bd. Reg. on Comprehensive Guidelines on Importation . . . . .
of the 1988 UN Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, which is an integral part of the Act.

(mm) “Table II Controlled Chemical” means chemicals enumerated in the list of substances in Table II of the 1988 UN Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, which is an integral part of the Act.

(nn) “Transit” means any transport of dangerous drugs or controlled chemicals between third countries through the customs territory of the Philippines and any transhipment in the Philippines;

(oo) “Therapeutic dose” means that quantity which is required to elicit the desired therapeutic response in the individual in the treatment of disease or ailment;

(pp) “Use” means any act of injecting, intravenously or intramuscularly, of consuming, either by chewing, smoking, sniffing, eating, swallowing, drinking or otherwise introducing into the physiological system of the body, any of the dangerous drugs;

(qq) “Veterinarian” means any person who is registered and entitled under the laws of the Philippine to practice the profession of veterinary medicine;

(rr) “Wholesale distributing,” means activities by any person, which stands between the manufacturer and the retail seller in purchases, consignments, or contracts for sale of dangerous drugs or controlled chemical and their preparations.

ARTICLE II
CLASSIFICATION

Section 2. Classification of dangerous drugs and controlled chemicals

(1) Each of the drugs classified as dangerous drugs appears under its international non-proprietary name or, lacking such a name, under its scientific name. Dangerous drugs and their preparations may also appear under their common trade names;

(2) Each of the chemicals classified as controlled precursor and essential chemical appears under its international non-proprietary name, or lacking such name, under its scientific name. Controlled chemicals or their preparations may also appear under their common trade names.

Section 3. Reclassification, Addition or removal of any drug from the List of Dangerous Drugs

(1) In conformity with Section 93 of Article XI of RA 9165;

(a) The Board shall have the power to reclassify, add to or remove from the list of dangerous drugs. Proceedings to reclassify, add, or remove a drug or other substance may be initiated by the PDEA, the DOH, or by petition from any interested party, including manufacturer of a drug, a medical society or association, a pharmacy association, a public interest group concerned with drug abuse, a national or local government agency, or an individual citizen. When Board received a petition, it shall immediately begin its own investigation of the drug.
The PDEA also may begin an investigation of a drug at any time based upon the information received from law enforcement laboratories, national and local law enforcement and regulatory agencies, or other sources of information.

(b) The Board after notice and hearing shall consider at its public hearing the following factors in determining whether a substance should be reclassified, added or removed from regulatory control:

(i) its actual or relative potential for abuse;

(ii) scientific evidence of its pharmacological effect if known;

(iii) the state of current scientific knowledge regarding the drug or other substance;

(iv) its history, and current pattern of abuse;

(v) the scope, duration, and significance of abuse;

(vi) risk to public health;

(vii) whether the substance is an immediate precursor of a substance already controlled under RA 9165;

(b) The Board shall also take into accord the obligations and commitments to international treaties, conventions and agreements to which the Philippines is a signatory.

(c) The Board shall give notice to the general public of the public hearing of the reclassification, addition to or removal from the list of any drug by publishing such notice in any newspaper of general circulation once a week for two (2) weeks.

(d) The effect of such reclassification, addition or removal shall be as follows:

(i) in case a dangerous drug is reclassified as precursors and essential chemicals, the penalties for the violations of the Act involving the two latter categories of drugs shall, in case of conviction, be imposed in all pending cases;

(ii) in case a precursor and essential chemicals is reclassified as dangerous drug, the penalties for violations of the Act involving precursors and essentials shall, in case of conviction, be imposed in all pending criminal prosecutions;

(iii) in case of addition of a new drug to the list of dangerous drugs and precursors and essential chemicals, no criminal liability involving the same under the Act shall arise until the lapse of fifteen (15) days from the last publication of such notice;

(iv) in case of removal of a drug from the list of dangerous drugs and precursors and essential chemicals, all persons convicted and/or detained for the use and/or possession of such drug shall be automatically released and all pending criminal
prosecution involving such a drug under the Act shall forthwith be dismissed;

(v) the Board shall, within five (5) days from the date of its promulgation submit to Congress a detailed reclassification, addition, or removal of any drug from the list of dangerous drugs.

(2) For the purpose of the Board’s public hearing, the Board may convene a Technical Working Group of the Board, which shall consist of a representative each from the Board’s Secretariat, Bureau of Food and Drug and National Drug Policy Department of Health, PDEA, NBI, PNP and UP-PGH Board of Poison Control. The Board may invite experts in the field of drugs and chemical control for consultation meeting. The representative from the Board’s Secretariat shall preside over the meeting. The Technical Working Group shall gather and collate all data relative to the drug and chemical under consideration and submit a report of its findings and recommendations to the Board.

Section 4. Preparations

(1) Unless exempted from certain measures of regulatory control, preparations shall be subject to the same measures of control under this Regulation as the dangerous drugs or controlled chemicals they contain.

(2) The Board may exempt from specific measures of regulatory control requirements any preparation containing:

(a) a dangerous drugs, when the Board is satisfied that:

(i) the preparation is compounded in such a way as to present no or negligible risk of abuse;

(ii) the preparation does not contain more than one dangerous drugs;

(iii) the dangerous drugs cannot be readily recovered from it in a quantity liable to present such a risk;

(iv) the exemption is necessary for a medical or scientific purpose and is otherwise in the public interest;

(v) the dangerous drug preparation is listed as an exempt preparation in the Schedules annexed to the 1961 Single Convention on Narcotic Drugs, as amended.

(b) a drug preparation containing a Table I controlled chemical unless:

(i) the drug preparation, in parenteral or tablet or capsule form, contains a Table I controlled chemical as the only active medicinal ingredient or contains Table I controlled chemical and therapeutically insignificant quantities of another active medicinal ingredient; or,

(ii) if it has been determined that the drug or group of drugs is being diverted to obtain the Table I controlled chemical for use in the illicit manufacture of a dangerous drug;
(c) a controlled chemical mixture, when the Table II chemical is a normal ingredient in consumer goods or finished products that were packaged for retail sale for personal use, such as epoxies, vinyl, lacquer, contact cements, plastic adhesives, waxes, cleaning agents; or

(d) liquid chemical mixture containing less than 30 per cent by weight of the Table II chemical; or

(e) solid, semisolid and highly viscous chemical mixture containing Table II chemical; or

(f) when the Board is satisfied that the mixture is formulated in such a way the controlled chemical cannot easily be used for the illicit manufacture of a dangerous drug and that the controlled chemical or chemicals contained in the mixture cannot be readily recovered.

(3) The Board shall maintain a register of the preparations exempted under this section, specifying in relation to each regulatory control measure from which it is exempted.

ARTICLE III
REGISTRATION, LICENSING AND PERMIT SYSTEM

Section 5. Requirements for registration/licensing, permit, /authorization, etc, of dangerous drugs and controlled chemical or their preparations.

(1) The applicable regulatory control measures or combination of such measures, which the PDEA shall impose, are the following:

(a) registration and/or the grant of a licence; or

(b) in the case of import and export activities, registration and/or licensing, plus;

(i) an open individual authorization issued to a controlled chemical operator by the PDEA for all such activities.

(ii) import and export permits issued to the operator by the PDEA for each of such activities;

(iii) a permit for each intended import or export transaction, or for each transit or redirection;

(iv) an export permit for each intended export transaction, conditional on the prior receipt of an import certificate issued by the competent authorities of the country of intended import;

(2) In application of this Section, the PDEA shall also take into account the following factors:

(a) the likely quantities and ultimate uses of the dangerous drugs, and controlled chemicals involved;
(b) in the case of transit or export, the countries or regions to which any such dangerous drugs or controlled chemicals are likely to be destined, particularly if they are ones in which dangerous drugs or the raw materials for making them are believed to be illicitly produced;

(c) the commercial experience and integrity of operators and their staff, including their experience in dealing with the dangerous drugs or controlled chemicals and their preparations; and

(d) any other relevant matter that the PDEA may be prescribed from time to time.

Section 6. Requirements of licences and/or permits for operators or handlers of dangerous drugs and controlled chemical and their preparations and payment of corresponding fees:

(1) No operator shall:

   (a) cultivate any cannabis plant, coca bush, opium poppy, ephedra, or any plants from which dangerous drugs may be obtained;

   (b) manufacture, acquire or supply any dangerous drug or controlled chemicals and their preparations,

   except pursuant to and in accordance with the terms and conditions of a licence granted by the PDEA.

(2) No operator shall import, export, bring into the Philippines in transit, or redirect from the Philippines while in transit, any dangerous drug or controlled chemicals and their preparations, except pursuant to and in accordance with any terms or conditions of:

   (a) a license issued by the PDEA authorizing the applicant to carry out such activities in general; and

   (b) a separate import permit, export permit, transit permit or redirection permit, or open individual authorization, as the case may be, authorizing the applicant to carry out the specific transaction the subject of the permit application.

(3) No medical or veterinary practitioner or dentist or other authorized practitioner shall prescribe a dangerous drug, or drugs preparation, in parenteral form, containing Table I controlled chemicals as the only active medicinal ingredient or containing Table I controlled chemicals and therapeutically insignificant quantities of another active medicinal ingredient without an S-2 license issued by PDEA.

(4) Transfer of dangerous drugs from one license holder to another or from one activity to another shall be made through an order form duly prescribed by PDEA. Such transaction shall have prior approval by the PDEA.

(5) Unless specified otherwise, the following groups of activities are deemed to be independent of each other and shall have separate registration and license:

   (i) retail distributing;

(ii) wholesale distributing;

(iii) importing, which includes wholesale distributing of what was imported only;

(iv) open individual authorization for controlled chemicals;

(v) exporting;

(vi) manufacturing, which includes laboratory quality control analysis of drugs and controlled chemical used in the manufacture of the drug preparation and controlled chemical, and distribution of their own manufactured drugs and/or controlled chemicals;

(vii) prescribing or dispensing of dangerous drug and/or drugs preparations, in parenteral form, containing Table I controlled chemical as the only active medicinal ingredient or containing Table I controlled chemical and therapeutically insignificant quantities of another active medicinal ingredient;

(viii) end-using of controlled chemical;

(ix) brokering of controlled chemical;

(x) recycling of controlled chemical, which includes wholesale distributing of own recycled controlled chemical;

(xi) storing or keeping in stock of dangerous drugs and/or controlled chemicals in separate address or addresses;

(xii) laboratory analysis or technical or teaching program.

(6) An operator must secure from the PDEA as many licenses as he has places of business and/or activities. Any person conducting two or more types of business at the same location shall secure from PDEA a license for each type of business. For this purpose, PDEA shall issue a consolidated license detailing the type of activities and corresponding license.

(7) An operator, after one year of operating as a license holder of good standing, may secure a license to operate for up to three years, subject to recall or cancellation at any time, if any of the conditions set in the grant of the license by PDEA or the provision of this Regulations is violated.

(8) Unless specifically exempted under this Regulation and other special laws or charters, the required fees per year for the corresponding licenses are as follow:

<table>
<thead>
<tr>
<th>Dangerous Drugs</th>
<th>Annual Fee</th>
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</thead>
<tbody>
<tr>
<td>S-1 License to sell, procure, acquire, deal in or with drugs exempted</td>
<td>P 500.00</td>
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</table>

from special prescription requirement or drug preparations, in parenteral or tablet/capsule form, containing Table I controlled chemical as the only active medicinal ingredient or contains Table I controlled chemical and therapeutically insignificant quantities of another active medicinal ingredient, that require a prescription with a doctor’s S-2 license].

<p>| (ii) | S-2 [License to prescribe (a) dangerous drugs preparation; and/or (b) drug preparations, in parenteral or tablet or capsule form containing Table I controlled chemical as the only active medicinal ingredient or containing Table I controlled chemical and therapeutically insignificant quantities of another active medicinal ingredient]. | P 500.00 or P1,500.00 for three (3) years |
| (iii) | S-3 [License to sell, procure, acquire, deal in or with specified (a) dangerous drugs preparations or (b). drug preparations, in parenteral or tablet or capsule form, containing Table I controlled chemicals as the only active medicinal ingredient or containing Table I controlled chemical and therapeutically insignificant quantities of another active medicinal ingredient. Covers activities granted to S-1 License Holders]. | P1,000.00 |
| (iv) | S-4 [License to sell, procure, acquire, deal in or with specified (a) dangerous drugs and their preparations, (b) drug preparations, in parenteral or tablet or capsule form, containing Table I controlled chemicals for wholesale distribution to license holders, and (c) Table I controlled chemicals used in the manufacture of drugs. The license holder need not obtain another license of the same nature of activity for such controlled chemicals]. | P3,000.00 |
| (v) | S-5-I [License to import specified (a) dangerous drugs and their preparations, (b) drug preparations, containing Table I controlled chemicals, (c) Table I controlled chemicals used in the manufacture of drug preparations; and (d) diagnostic test kits. The license holder need not obtain another license of the same nature of activity for such controlled chemicals. May distribute that substance or class for which license was issued; may not distribute any substance or class for which not licensed.]. | P5,000.00 |
| (vi) | S-5-C [License to manufacture specified (a) dangerous drugs and their preparations; and/or (b) drug preparations, containing Table I controlled chemical chemicals. The license holder need not obtain another license of the same nature of activity for such controlled chemicals. May distribute that substance or class for which license was issued; may not distribute any substance or class for which not licensed. May conduct chemical analysis and quality control analysis with those substances for which license as a manufacturer was issued]. | P5,000.00 |</p>
<table>
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<tr>
<th>(vii)</th>
<th>S-5-E [License to export specified (a) dangerous drugs and their preparations; and/or (b) drug preparation, containing Table I controlled chemicals; to foreign license holders. The license holder need not obtain another license of the same nature of activity for such controlled chemicals].</th>
<th>P5,000.00</th>
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<tr>
<td>(viii)</td>
<td>S-5-D [License for bulk depot/storage of specified dangerous drugs and their preparations; and/or; (b) drug preparations containing Table I controlled chemicals which require S-2 license; (c) Table I controlled chemicals used in the manufacture of drug preparations; and, stored by S-4 and S-5 license holders, when such address is separate and distinct from the office address of the license holder. The license holder need not obtain another license of the same nature of activity for such controlled chemicals].</td>
<td>P5,000.00</td>
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### b. Controlled Precursors and Essential Chemicals

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<th>Annual Fee</th>
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<tr>
<td>(i)</td>
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<tr>
<td>P-1</td>
<td>License to sell, procure, acquire, dealing in or with specified controlled chemical or their mixtures or preparations, except drugs containing controlled chemicals, for retail sale.</td>
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<tr>
<td>(ii)</td>
<td>End-user certificate of specified controlled chemicals. NOT authorize to resell the controlled chemical. Authorized to purchase from local sources only.</td>
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<tr>
<td>(iii)</td>
<td>License to sell, procure, acquire, dealing in or with specified controlled chemical except drugs containing controlled chemicals for wholesale distribution to license holders.</td>
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<td>(iv)</td>
<td>License to import specified controlled chemicals. May distribute that substance for which license was issued; may not distribute any substance for which not licensed.</td>
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<td></td>
<td>-[Additional fee of P500.00 shall be paid when granted an open individual authorization (P-5-OIA)].</td>
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<tr>
<td>(v)</td>
<td>License to act as broker/middleman in an authorized importation of specified controlled chemical.</td>
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<td>(vi)</td>
<td>License to manufacture or recycle specified controlled chemicals or chemical mixtures excluding drugs containing controlled chemicals. May distribute that substance or class for which license was issued; may not distribute any substance or class for which not licensed. May conduct chemical analysis and quality control analysis with those substances for which license as a manufacturer was issued.</td>
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<tr>
<td>(vii)</td>
<td>License to export specified controlled chemicals excluding drug preparations containing controlled chemicals.</td>
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(viii) P-5-D [License for bulk depot/storage for P-4 and P-5 license holders. The address is separate and distinct from the office address of the license holder].

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<th>Fee</th>
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<tr>
<td>P3,000.00</td>
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(ix) P-5-IM [License to import specified controlled chemicals, as End-user. Acquisition of controlled chemical shall be made through importation. The license holder is authorized also to acquire controlled chemical from local sources. Not authorized to resell the chemicals acquired.].

- Additional fee of P500.00 shall be paid when granted an open individual authorization (P-5-OIA)].

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<th>Fee</th>
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<tr>
<td>P5,000.00</td>
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c. Others

(i) S/P-6 [License to conduct laboratory analysis or technical research or instructional program, using dangerous drugs or controlled chemicals or drugs containing controlled chemicals as the only active medicinal ingredient or containing controlled chemical and therapeutically insignificant quantities of another active medicinal ingredient].

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<th>Fee</th>
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<td>P500.00 per year</td>
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(ii) S/P-7 [For importer, manufacturer of dangerous drugs or controlled chemicals in any form, their salts, isomers, any material, compound, mixture or preparation which contains any quantity of dangerous drugs, drugs preparations containing controlled chemicals, and diagnostic test kits or controlled chemicals imported into the Philippines and sold or removed for consumption or sale, which fee shall be in addition to any import duty on such dangerous drugs preparation, drug preparations containing controlled chemicals or diagnostic test kits or controlled chemicals and shall be paid immediately before removal from or before the release of such drugs or controlled chemicals and their reparations or diagnostic from the customs house].

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<tr>
<th>Fee</th>
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<tr>
<td>a. Raw materials – P0.01 per one thousand grams of drugs or controlled chemicals used in the manufacture of medicinal drug preparations, such as, but not exclusive to ephedrine, pseudo-ephedrine or norephedrine or ergonovine or ergotamine or any fractional part thereof.</td>
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<tr>
<td>b. Drug Ampoules –</td>
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<td>(i) P0.20 per ampoule of from 1 ml to 5 ml</td>
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<td>(ii) P0.40 per vial of 10 ml.</td>
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<tr>
<td>c. Drug Tablets – P 15.00 per two hundred fifty grams or a fraction thereof.</td>
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<tr>
<td>d. Drug Capsules – 15.00 per two hundred fifty grams or a fraction thereof.</td>
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<td>e. Drug Vials –</td>
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<tr>
<td>(i) P 0.40 per vial of from 0.001 gram to 1.0 gram</td>
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<tr>
<td>(ii) P 0.60 per vial of 1.5 grams</td>
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<tr>
<td>(iii) P 0.80 per vial of more than 2.5 grams</td>
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<tr>
<td>f. Drugs in Patches –</td>
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<tr>
<td>(i) P 0.10 per patch per 25 mcg</td>
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</table>
(9) License holders shall obtain from the PDEA, prescribed PDEA forms for such activities as local purchase order, open import authorization, importation or exportation of dangerous drugs or controlled chemicals or their respective preparations, at a price prescribed by PDEA.

(10) At the end of a year when re-application for a new license is needed, a holder of an import license or open individual authorization intending to import/export dangerous drugs or controlled precursors and essential chemicals towards the end of the year or start of the year, may apply for renewal of license from October of the year, provided that the applicant is able to supply a copy of business license from the City/Municipal Government, valid for the forthcoming year.

(11) The DDB may, upon legitimate request in writing by the concerned operator or party, issue certification that a substance is included or not in the list of dangerous drugs or controlled chemicals. Such certification shall be valid for one (1) year unless revoked due to inclusion of such substance in the list of dangerous drugs or controlled chemicals. A fee of P 150.00 shall be charged per certification regardless of number of substances. Exempted from payment of fees are national government agencies and government controlled or owned corporations and foreign counterpart regulatory or enforcement agencies.

Section 7. Application for operators licence

(1) An operator shall apply in writing to PDEA for the grant of a licence and specify:

(a) the full name, private and business address of the applicant;

(b) each activity to which the application relates;

(c) if the applicant is a company, the full name and residential address of each director and the company secretary;

(d) if the applicant proposes to engage in the activity under a business name, that name;

(e) the specific dangerous drug or controlled chemical or their preparations to which the application relates;

(i) the address of each:

(ii) place where the proposed activity would be carried out;

(f) premises where the dangerous drug or controlled chemical or their preparations be stored;

(g) the security arrangements that would be implemented at each address (storage, access, type of
building construction, alarm systems, adequacy of supervision over employees having access, procedure for handling guests and maintenance personnel, adequacy of system for monitoring receipt, distribution and disposition of dangerous drugs or controlled chemicals or their preparations;

(h) the name, residential address and qualifications of each person under whose supervision the activity would be carried out;

(i) whether the person (and, if a company, any director or the company secretary) has ever been convicted in the Philippines or elsewhere for a serious offence or any offence however described relating to trafficking in dangerous drugs or controlled chemicals or their respective preparations;

(j) volume estimate in the forthcoming year, plus volume statistics for the past year of dangerous drugs or controlled chemicals needed; in the case of manufacture, the extraction, manufacturing and denaturing procedure to be used, name and quantities of the substances and raw materials to be used, estimates relating to each dangerous drug or controlled chemical or their respective preparations produced; etc.

(k) others as the PDEA may prescribe from time to time.

(2) An application for licence shall be accompanied by:

(a) a plan of each of the relevant premises, indicating where the dangerous drug, controlled chemical or their respective preparations would be stored, and the location and nature of any security devices;

(b) Bureau of Food and Drug’s license to operate related to drugs and drug registration;

(c) Registration from the Philippine Export Zone Authority or Board of Investments, as applicable;

(d) Business permit issued by the Local Government Unit, and Department of Trade and Industry or Securities and Exchange Commission;

(e) National Bureau of Investigation clearance;

(f) others as PDEA may prescribe from time to time; and

(g) the prescribed fee.

Section 8. Grant of license

Where an appropriate application has been made accordingly, PDEA may grant a licence if satisfied that:

(a) the applicant and, if a company, each director and the company secretary:
(i) has never been convicted in the Philippines or elsewhere for any serious offence, or any offence however described relating to a dangerous drug or controlled chemical; and

(ii) is otherwise a fit and proper person to hold a licence;

(b) all places and premises at or in which the activity is to be undertaken are in fit condition and appropriate;

(c) the security arrangements and devices proposed at each relevant place and premises are appropriate and sufficient;

(d) the activity will at all times be carried out under the supervision of a person who is a fit and proper person to carry out that supervision; and

(e) where the activity relates to a dangerous drug, the activity will be carried out exclusively for medical or scientific purposes.

(f) the outcome of physical security inspection by PDEA representatives is satisfactory. Prescribed inspection fee is P500.00 per inspection, subject to issuance of an official receipt.

Section 9. Contents and conditions of licences

(1) A licence issued by the PDEA shall specify:

(a) the full name and address of the licensee;

(b) each activity to which the licence relates;

(c) the dangerous drug or controlled chemical and their preparations to which the licence relates;

(d) the address of each place and premises at which:

   (i) the licensed activity is to be carried out; and

   (ii) the dangerous drug or controlled chemical and their preparations is to be stored;

(e) such terms and conditions as are necessary and reasonable for ensuring the proper:

   (i) carrying out and supervision of the licensed activity;

   (ii) establishment, maintenance and preservation of record relating to that activity;

   (iii) reporting to the PDEA in relation to the carrying out of that activity;

   (iv) maintenance and security of all places and premises at or in which the licensed activity will be carried out;
(f) in the case of any licence to import, export or bring to the Philippines in transit a dangerous drug or controlled chemical or their preparations, the condition that a separate import, export or transit permit be first obtained in relation to any such transaction before it takes place; and

(g) official receipt number of prescribed fee.

Section 10. Applications for import, export or transit permits

(1) An application for an import, export or transit permit shall be made in writing by a licensed operator to the PDEA at least fifteen (15) working days in advance before the transaction is to take place and specify:

(a) the full name and address of the importer, exporter, carrier, consignee and, if known, of any ultimate consignee;

(b) in the case of a proposed import, export or transit of a dangerous drug or its preparation:

(i) its international non-proprietary name or failing this, its name as listed in the attached annex of the Act, together with its trade name, if it has one; and

(ii) its pharmaceutical form;

(c) in the case of a proposed import, export or transit of a controlled chemical or its preparation, the name as specified in attached annex of the Act and trade name, if it has one;

(d) in the case of a proposed export of a dangerous drug or controlled chemical or their preparations, the intended point of entry in the foreign State of intended import;

(e) the quantity, mass, and volume or percent in mixture of any dangerous drug or controlled chemical or their respective preparation that is the subject of the proposed operation;

(f) the date, or period within which, the planned import, export or transit is to take place; and

(g) the planned transport route, if known, including the planned point of entry or exit from the Philippines; and

(h) in the case of a proposed import of a dangerous drug or controlled chemical or their preparations to a bonded warehouse, the identity and address of the warehouse.

(2) In the case of a proposed export of a dangerous drug, the import permit (by whatever name described) issued by the Government of the foreign State of intended import shall be attached to the application for export permit.

Section 11. Grant of import, export or transit permits

(1) The PDEA may, on written application made by a registered or licensed importer or licensed exporter, grant an import permit, export permit, or transit permit in relation to a specified import or export transaction.
involving a dangerous drug or controlled chemical or their preparations within a period of fifteen (15) working days from the date on which the PDEA considers the file to be complete. This period shall be extended if, PDEA is obliged to make further inquiries in order to satisfy itself that the importation or exportation or transit shipment is proper.

(2) An approved import permit, export permit or transit permit may allow import, export or transit in more than one consignment, provided however that the total amount duly approved is not exceeded.

(3) The PDEA shall not grant an export permit in relation to any consignment of a dangerous drug or controlled chemical and their preparations to a bonded warehouse in a foreign State, unless the competent authority of that State has certified on the import permit that it has approved the import to a bonded warehouse.

(4) An import permit, export permit or transit permit shall specify:

(a) the full name and address of the registered or licensed operator granted it;

(b) the name (including any international non-proprietary name and trade name), quantity and form of any dangerous drug or controlled chemical or their respective preparation for which it is granted;

(c) in the case of an import permit:

(i) the name and address of the exporter; and

(ii) whether the import is to be effected in a single consignment or more than one consignment.

(iii) intended international point of entry in the Philippines

(d) in the case of an export permit:

(i) the name and address of the immediate consignee, and if known, of the ultimate consignee;

(ii) the number and date of any required import permit, affirming that the import of the dangerous drug or controlled chemical or their respective preparations, as the case may be, has been authorized;

(iii) the intended point of entry in the foreign State of import;

(iv) if the export consignment is intended for a bonded warehouse and is not prohibited, that the consignment is to be so exported; and

(e) the period during which import or export is to be effected;

(f) in all cases of imports or exports of controlled chemicals the Material Safety Data Sheet of the

controlled chemical should be submitted to PDEA and the Bureau of Customs.

(g) the case of an intended import to a bonded warehouse, a term that:

(i) any subsequent withdrawal from the bonded warehouse shall require a permit from the PDEA; and

(ii) if the withdrawal is intended for a foreign destination, a separate export permit shall be first obtained prior to export;

(h) such other particulars, terms and conditions as the PDEA may consider operationally necessary and reasonable;

(3) Copies of approved import, export, transit or redirection permits shall be distributed as follows:

(a) one duly designated copy for the operator;

(b) two duly designated copies intended for the Commissioner of Customs or the Collector of Customs of the designated port of entry, one of which copies is to retained by the operator for customs clearing purpose and other copy to serve as advance copy of the Bureau of Customs;

(c) one duly designated copy for the foreign counterpart competent authority of the country where the dangerous drug or controlled chemical is being imported or exported;

(d) one duly designated copy for the Philippine Embassy in the country where the import or export or transit or redirection will be made;

(e) one duly designated copy for the PDEA’s file.

Section 12. Redirection permits

(1) The PDEA may, on production by a licensed operator of a valid import authorization issued by an authority in the foreign State to which it is proposed to redirect a dangerous drug or controlled chemical or their respective preparations, issue a redirection permit in respect of the drug or chemical in transit. The licensed operator shall make an application in writing not later than fifteen (15) working days in advance before the transaction is to take place.

(2) A redirection permit shall specify:

(a) the full name and address of the registered or licensed operator granted it;

(b) the name (including any international non-proprietary name and trade name), quantity and form of any dangerous drug or controlled chemical or their respective preparations for which it is granted;

(c) the name and address of the immediate consignee, and if known, of the ultimate consignee;
(d) the number and date of any required import permit affirming that the import of the dangerous drug or controlled chemical or their respective preparations has been authorized;

(e) the intended point of entry in the foreign State of import;

(f) if the export consignment is intended for a bonded warehouse and is not prohibited, that the consignment is to be so exported;

(g) the period during which import or export is to be effected;

(h) in the case of an intended import to a bonded warehouse, a term that:

(i) any subsequent withdrawal from the bonded warehouse shall require a permit from the PDEA and the Commissioner for Customs or Collector of Customs of the designated port of entry of the consignment; and

(ii) if the withdrawal is intended for a foreign destination, a separate export permit shall be first obtained prior to export;

(i) such terms and conditions as the PDEA may consider necessary and reasonable.

(3) The PDEA shall not issue a redirection permit unless the PDEA is satisfied that the dangerous drug or controlled chemical or their respective preparations is to be sent to the new country of destination in a lawful manner and for a proper purpose.

Section 13. Permits in relation to first-aid kits and medical missions

(1) The PDEA may, on written application made in the prescribed form by an applicant, grant a permit:

(a) to include a dangerous drug or drugs preparations in parenteral or tablet or capsule form containing Table I controlled chemicals as the only active medicinal ingredient or containing Table I controlled chemicals and therapeutically insignificant quantities of another active medicinal ingredient in a first-aid kit for medical use during domestic or international flights or voyages; or

(b) for a foreign medical mission sponsored by the Department of Health or other government agencies or other civic organizations to import reasonable quantities of dangerous drug or drugs preparations in parenteral or tablet or capsule form containing Table I controlled chemicals as the only active medicinal ingredient or containing Table I controlled chemicals and therapeutically insignificant quantities of another active medicinal ingredient, needed during the mission, subject to prior export authorization to be granted by the competent authority of the foreign country where the medical mission or medicine originated.

(2) A permit to include a dangerous drug and/or drugs drug preparations, in parenteral or tablet or capsule form, containing Table I controlled chemical as the only active medicinal ingredient or contains Table I controlled chemical and therapeutically insignificant quantities of another active medicinal ingredient shall specify:

(a) the full name and address of the authorized person;

(b) the name and maximum quantity of the dangerous drug and/or drugs containing controlled chemicals that may be kept in the first aid kit at any one time;

(c) such terms and conditions as are necessary and reasonable to ensure the proper use and safe keeping of the dangerous drug and/or drugs containing controlled chemicals; and

(d) such other particulars as may be prescribed.

Section 14. Permits in relation to laboratory use and/or programmes for medical, scientific or instructional purposes

(1) The PDEA may, on written application made in the prescribed form by a person, grant a permit to conduct laboratory analysis or a programme for scientific or instructional or strictly limited medical purposes that would require the import, possession or use of:

(a) a dangerous drug;

(b) a controlled chemical;

(2) An application to conduct such a programme/activity shall specify:

(a) the full name, address, academic, professional or other relevant qualifications of the applicant;

(b) the dangerous drug or controlled chemical in relation and their preparations to which the permit is sought;

(c) the strength and form in which the dangerous drug or controlled chemical to be used;

(d) the maximum quantity of the dangerous drug or controlled chemical and their preparations be possessed at any one time, and the total quantity to be possessed during the laboratory analysis or period of the programme;

(e) details of the manner in which the dangerous drug or controlled chemical and their preparations to be used;

(f) the name and address of the place where the laboratory analysis or programme is to be conducted;

(g) the name and academic, professional or other relevant qualifications of any person other than the applicant, under whose supervision the laboratory analysis or programme would be conducted; and

(h) the security arrangements that would be undertaken while the dangerous drug or controlled chemical and their preparations are possessed, used or disposed of.
(3) An application to conduct such a laboratory analysis or programme shall be accompanied by:

(a) a written description of the laboratory analysis or programme, including its estimated duration;

(b) in the case of a programme of research, a research protocol;

(c) in the case of a clinical trial, a clinical trial protocol;

(d) in the case of instructional purpose, a program of instruction;

(e) a written statement approving the conduct of laboratory analysis or programme, signed by the person in charge of the institution;

(f) a National Bureau of Investigation clearance of the applicant(s) or in the case of a government employee, a certificate of no pending criminal and administrative case from his agency; and,

(g) prescribed fee, except for government agencies or exempted officials.

(4) The PDEA may authorize the conduct of such laboratory analysis or programme if satisfied that:

(a) the conduct of laboratory analysis or programme cannot be carried out satisfactorily without the use of the specified dangerous drug or controlled chemical;

(b) the programme is scientifically viable having regard to any relevant protocol;

(c) the applicant is a fit and proper person to conduct the laboratory analysis or programme;

(d) the programme will be adequately supervised; and

(e) the programme is to be conducted at, or under the auspices of, a recognized institution or government institution.

(5) A permit shall specify:

(a) the full name and address of the authorized person;

(b) the dangerous drug or controlled chemical and their preparations to which the permit relates;

(c) the strength and form in which the dangerous drug or controlled chemical or their preparations may be used;

(d) the maximum quantity of the dangerous drug or controlled chemical and their preparations that may be possessed at any one time, and the total quantity that may be possessed during the period of the programme;

(e) the purpose for which the permit is granted;
(f) the institution in relation to which the permit is granted;

(g) such conditions as are necessary and reasonable for ensuring:

(i) the proper use and safe-keeping of the dangerous drug or controlled chemical and their preparations; and

(ii) that proper records are kept concerning its receipt, use and disposal;

(h) the condition that such reports as the PDEA may specify are sent to it on the use of the dangerous drug or controlled chemicals and their preparations in the programme, including particulars of the quantities acquired, used, disposed of and still held;

(i) such other particulars as may be prescribed from time to time by the PDEA; and

(j) official receipt number of payment of prescribed fee (S-6).

Section 15. Permit in relation to international transfer of samples of seized dangerous drugs or controlled chemicals

(1) The PDEA may, upon written request, grant an export permit for the authorized transfer of samples of seized drugs or controlled chemicals and their preparations to the requesting government agency in foreign country for the purpose of drug profiling and international investigation.

(2) The request shall contain the following information:

(a) the full name and address of the immediate consignee and ultimate consignee;

(b) purpose of the transfer;

(c) the name (including any international non-proprietary name and trade name), quantity and form of any dangerous drug and/or controlled substances;

(d) the number and date of any required import permit duly issued by the PDEA’s counterpart competent authority in the country of destination, affirming that the import of the dangerous drug or controlled chemicals and their preparations has been authorized;

(e) the intended point of entry in the foreign State of import, specific mode of transport and the intended point of exit in the Philippines;

(f) the period during which export is to be effected;

(g) if the source of the sample of dangerous drug or controlled chemical and their preparations is from evidence in a pending or on-going criminal case, copy of court order from the relevant Regional Trial Court, authorizing the taking of such samples;
(h) location of the seized dangerous drug or controlled chemical and their preparations from which the sample would be taken.

(i) brief particulars of the criminal case.

Section 16. Open individual authorization for certain imports of controlled chemicals

(1) Where a licensed operator intends to hold open individual authorization the operator shall, notify the PDEA in writing of:

(a) the full name, private and business address of the operator;

(b) the activity for which authorization is sought;

(c) if the operator is a company, the full name and residential address of each director and of the company secretary;

(d) if the operator will engage in the activity under a business name, that name;

(e) each controlled chemical which authorization is sought;

(f) details of the operator’s commercial experience relevant to the controlled chemicals, and of each person under whose supervision the activity will be carried out;

(g) details in summary form of import or export transactions in the relevant chemicals during the preceding **twenty-four (24) months**, specifying by country of import or export in relation to each chemical imported, the total quantities and total number of transactions involved;

(h) details of the precautions he has taken to prevent the diversion of controlled chemicals to the illicit manufacture of dangerous drugs;

(i) registration from PEZA or BOI, as the case maybe; and

(i) such other particulars as may be prescribed by PDEA due to operational necessity.

(2) On receipt of an application made, the PDEA may:

(a) grant an open individual authorization; and

(b) subject the authorization to such terms and conditions as it thinks fit.

(3) The **PDEA** may refuse to grant the open individual authorization, if the operator (and, if a company, any director or the company secretary) has:

(a) failed to comply with a provision of the Act or any other law in the **Philippines** relating to any dangerous drug or controlled chemical; or

(b) not provided sufficient safeguard against the risk of diversion;

(c) been convicted in **the Philippines** or elsewhere for any serious offence or any offence however described relating to trafficking in drugs, or controlled chemicals.

(4) A license holder granted an open individual authorization may import such controlled chemicals as specified in the authorization for a period of one calendar year without having to secure an import permit from the PDEA for each importation made. The license holder shall notify the PDEA in writing every time an importation is made.

(5) The threshold amounts of controlled chemicals that may imported per calendar year under the open individual authorization shall be as follows:

(a) Single component chemical:

<table>
<thead>
<tr>
<th>Controlled Chemicals</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetone</td>
<td>1,500 kg</td>
</tr>
<tr>
<td>Ethyl ether</td>
<td>1,300 kg</td>
</tr>
<tr>
<td>Hydrochloric acid</td>
<td>1,500 kg</td>
</tr>
<tr>
<td>Methyl ethyl ketone (2-Butanone)</td>
<td>1,500 kg</td>
</tr>
<tr>
<td>Sulphuric acid</td>
<td>1,500 kg</td>
</tr>
<tr>
<td>Toluene</td>
<td>1,600 kg</td>
</tr>
<tr>
<td>Potassium Permanganate</td>
<td>500 kg</td>
</tr>
</tbody>
</table>

(b) As listed below, the threshold weight of each of the controlled chemical is the weight percentage of that controlled chemical calculated on the absolute (total) weight of the chemical mixture.

<table>
<thead>
<tr>
<th>Controlled Chemicals in Mixture/solution</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetone</td>
<td>1,500 kg</td>
</tr>
<tr>
<td>Ethyl ether</td>
<td>1,300 kg</td>
</tr>
<tr>
<td>Hydrochloric acid</td>
<td>1,500 kg</td>
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<tr>
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<td>1,500 kg</td>
</tr>
<tr>
<td>Toluene</td>
<td>1,600 kg</td>
</tr>
<tr>
<td>Potassium Permanganate</td>
<td>500 kg</td>
</tr>
</tbody>
</table>

(8) Where the importation met the established threshold amount of a listed controlled chemical within the calendar year, the licensed holder shall subsequently immediately apply with the PDEA for an import permit for every import of the chemical concerned.

(9) The holder of the open individual authorization shall comply with the following additional obligations:

(a) provide Material Safety Data Sheet for each chemical imported, to PDEA and Bureau of Customs on all importations;

(b) enter the assigned control number of the authorization in any relevant customs declaration;

(c) carry out the entry into the records when the consignment arrives at the premises of the importer;

(d) ensure that the consignment is accompanied at any time during the transport by a copy of the authorization;

(e) furnish PDEA, by the end of each quarter, summary information on the import operations carried out. The information shall contain, as a minimum, information on the number of operations, the substances, actual quantities and source countries.

Section 17. Extended permit or authorization for related activities.

Where a person is registered and licensed, or holds a permit or authorization in relation to any activity, the person shall, subject to the Act and this Regulation and to any terms or conditions of the licence, permit or authorization, be deemed to be entitled to possess the relevant dangerous drug or controlled chemical and their preparations for the purpose of that activity.

Section 18. Duration of licences, permits and authorizations

(1) A licence shall remain in force for one year for new licence holder and three (3) years for old licence holders, unless earlier surrendered, suspended or revoked, and may be successively renewed for a period of three (3) years by application in writing, signed by the applicant and accompanied by the prescribed fee.

(2) A permit shall only remain in force for such period as may be specified in it, which in the case of an import permit for dangerous drugs or controlled chemicals and their preparations shall not exceed six (6) months, and in the case of export permit or transit permit for dangerous drugs or controlled chemicals and their preparations shall not exceed three (3) months.

Section 19. Duty of authorized persons to notify material changes, etc

(1) Where, in relation to any licence or permit granted to any person, a material change occurs in the:

(a) name or address of the person, or in the case of a company, of any director or the company secretary;

(b) address of the place or premises where:

(i) the licensed or permitted activity is carried out; or

(ii) any dangerous drug or controlled chemical and their preparations are stored;

(c) raw materials, or manufacturing or denaturing processes used in the licensed manufacture of any dangerous drug or drugs containing controlled chemicals;

(d) security arrangements implemented at any relevant address;
(e) identity of persons under whose supervision the licensed activity is carried out; or

(f) planned transport route, including the planned date and point of entry or exit from the Philippines of any import, export or transit consignment which a permit has been granted;

(g) quantities of dangerous drugs or controlled chemical and their preparations arriving in relation to the import permit;

(h) status of the planned importation of dangerous drugs or controlled chemicals and their preparations.

the person shall, within five (5) working days of its occurrence or prior to the arrival of the consignment being imported, furnish the PDEA with a written notice containing full particulars of the change, and shall return to the PDEA any licence or permit.

Section 20. Variation, suspension or revocation of licences, permits or authorizations

(1) If, at any time after the grant of a licence, permit, registration or individual authorization, it appears to the PDEA that:

(a) it was granted on the basis of information that was false or misleading;

(b) a material change of circumstance has occurred since it was granted, whether notified or not;

(c) a condition to which it was subject has not been complied with; or

(d) the person has been charged or convicted of a drug offence, or of other serious criminal offence,

the PDEA may, as it deems necessary and reasonable in all the circumstances to prevent the risk of unlawful diversion:

(i) impose conditions, or vary any existing conditions specified in the license, permit or authorization, with effect from five (5) working days following the date of issue of a notice of variation;

(ii) suspend the licence, permit or authorization for such period as PDEA deems necessary; or

(iii) revoke the licence, permit or authorization.

(2) Any person whose licence, permit or authorization is suspended or revoked under subsection (1) shall return it, including the unused PDEA forms for import or export or distribution to the PDEA no later than five (5) working days after the PDEA notify the person in writing of the revocation or suspension.

Section 21. Duty of operators to check and notify suspicious orders and transactions
Whenever an operator:

(a) is registered and licensed, permitted or authorized;

(b) receives an order or becomes party to a transaction involving a dangerous drug or controlled chemical and their preparations; and,

(c) has reasonable grounds to suspect that the information that it has concerning the order or transaction, may be relevant to an offence or a possible offence against the Act,

the operator shall, immediately communicate to the PDEA, after establishing that suspicion, particulars of the suspicion, the basis for it, and such other information, if requested, as the person has in relation to the order or transaction.

Section 22. Licensed operators NOT to deal with unlicensed operators

(1) No licensed-operator shall sell to or acquire from another operator in the Philippines any dangerous drug or controlled chemical and their preparations unless the second operator is also licensed.

(2) A licensed retail seller/handler of controlled chemical may sell a Table II controlled chemical in a quantity not exceeding the prescribed total weight/volume in a single transaction or multiple transactions in one month to a regular or known customer without the latter presenting a license, as follows:

<table>
<thead>
<tr>
<th>Single Component Chemical</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetone</td>
<td>1 liter</td>
</tr>
<tr>
<td>Hydrochloric Acid</td>
<td>25 liters</td>
</tr>
<tr>
<td>Sulphuric Acid</td>
<td>25 liters</td>
</tr>
<tr>
<td>Ethyl ether</td>
<td>1 liter</td>
</tr>
<tr>
<td>Toluene</td>
<td>1 liter</td>
</tr>
<tr>
<td>Methyl ethyl ketone</td>
<td>1 liter</td>
</tr>
<tr>
<td>Potassium permanganate</td>
<td>1 kg</td>
</tr>
</tbody>
</table>

(3) A licensed retail seller/handler of controlled chemical may sell chemical mixture, containing Table II controlled chemical in a quantity not exceeding the prescribed aggregate weight/volume of the mixture in a single transaction or multiple transactions in one month to a regular or known customer without the latter presenting a license. In case of mixtures containing more than one Table II controlled chemicals, the threshold limit shall be based on the Table II controlled chemical, which represents the major proportion of the mixture. The prescribed aggregate weight/volume is as follows:

<table>
<thead>
<tr>
<th>Chemical Mixture/Solution</th>
<th>Aggregate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Containing Acetone</td>
<td>5 liters</td>
</tr>
<tr>
<td>Containing Hydrochloric Acid</td>
<td>50 liters</td>
</tr>
<tr>
<td>Containing Sulphuric Acid</td>
<td>50 liters</td>
</tr>
<tr>
<td>Description</td>
<td>Quantity</td>
</tr>
<tr>
<td>--------------------------------------------------</td>
<td>----------</td>
</tr>
<tr>
<td>Containing Ethyl ether</td>
<td>5 liters</td>
</tr>
<tr>
<td>Containing 30% Toluene</td>
<td>20 liters</td>
</tr>
<tr>
<td>Containing 30% Methyl ethyl ketone</td>
<td>5 liters</td>
</tr>
<tr>
<td>Containing potassium permanganate</td>
<td>5 liters</td>
</tr>
</tbody>
</table>

(4) The licensed seller shall ask the customer for any identifying document such as driver’s license, office or voter’s identification card and signature of the individual.

(5) Purchases made under Sections 22(2) and 22(3), shall not be resold by the purchaser.

(6) In relation to Sections 22 (2) and 22(3), the licensed seller shall not sell controlled chemical in whatever form to a customer who is less than eighteen (18) years old without the written consent of his/her parents or guardian, or knowing that the buyer will sell or give it to a person who is less than eighteen (18) years old for the purpose of abuse.

(7) A transaction made under Sub-Section (2) shall:

(a) be recorded by the licensed seller in a record book, and subject to inspection at any reasonable time by a PDEA Regulatory Compliance officer;

(b) be for legitimate use by the purchaser and not for resale.

Section 23. Dangerous drug or controlled chemical in lawful transit

(1) No person shall cause a dangerous drug or controlled chemical and their preparations lawfully in transit to be subjected to any process which could alter its nature; or otherwise than in accordance with instructions issued by the PDEA, wilfully open or break any package or container containing any dangerous drug or controlled chemical in transit.

(2) No licensed operator shall, except under the authority of a duly redirection permit, cause or procure any dangerous drug or controlled chemical and their preparations, in transit to be redirected to any destination other than that shown on the export permit or redirection permit accompanying the drug or chemical.

Section 24. Commercial documents

Any commercial document, such as an invoice, cargo manifest or a customs, transport and other shipping document, relating to any transaction by an operator involving a dangerous drug or controlled chemical and their preparations shall include:

(a) the name and quantity of the dangerous drug or controlled chemical and their preparations as listed in the relevant Schedule of the Act;

(b) in the case of any import or export, the name and address of the exporter, the importer the consignee, origin of the substance, port of embarkation, port of debarkation, registered name of the conveyor, date of departure from origin, date of arrival at port of entry.

Section 25. Forwarding of import permit in advance to proposed foreign exporter
Where the PDEA issues an import permit to an operator, the operator shall as soon as possible but no later than twenty-one (21) working days after its receipt forward the permit to the exporter named in the permit.

Section 26. Export permits to be attached to consignments

Where the PDEA issues an export permit to an operator, the operator shall attach an authenticated copy of the permit to each consignment on export.

Section 27. Notification, endorsement and return of export permits following import

(1) After an imported consignment of dangerous drugs or controlled chemical and their preparations has entered Philippines or when the period stipulated in the import permit expires:

   (a) the licensed operator granted the permit should immediately report to the PDEA the arrival of the subject consignment at the designated port of entry; pay the corresponding S-7 fee with the PDEA for presentation to the Bureau of Customs for clearance of the consignment;

   (b) the PDEA shall cause the export permit issued by the competent authority of the exporting country or territory to be returned to that authority, with an endorsement specifying the quantity of each dangerous drug or controlled chemical and their preparations, actually imported and date of arrival or that no import has taken place;

   (c) the Commissioner of Customs or his duly authorized representative at the duly designated port of entry shall endorse the Customs copy of the import permit, confirming the date and mode of arrival of the consignment, within the first ten days of the month following its arrival;

   (d) In case the consignment is less than the amount to be imported under the import permit, the balance amount will remain available to the importer: provided, that the importer informs the PDEA prior to the arrival of the consignment, and provided, further that the balance amount of the importation is confirmed by PDEA;

   (e) In case the consignment is more than the amount to be imported under the import permit, and the import permit does not specifically provide for such occurrence, the consignment shall be subject to seizure proceedings by the Bureau of Customs under applicable laws, rules and regulations.

(2) After the consignment is cleared from Customs, the importer must also report immediately the date of arrival of the consignment at the operator’s licensed depot or storage facility for inspection or verification by the PDEA;

(3) Importation of dangerous drugs and Table I controlled chemicals or Table II controlled chemicals in bulk released from the Bureau of Customs shall be provided with security escort assigned by PDEA, accompanied by a mission order.

(4) If the consignment did not arrive within the period specified in an import permit, the Commissioner of Customs or the Collector of Customs of the designated port of entry shall endorse the expired import permit and notify the PDEA.
permit to the PDEA, with notation that the consignment did not arrive. Likewise, the importer must also notify the PDEA.

Section 28. Forwarding of redirection permits, etc

(1) Where a redirection permit is duly issued:

(a) one copy shall accompany the dangerous drug or controlled chemical and their preparations when it is exported from the Philippines;

(b) the PDEA shall cause another copy of the redirection permit to be sent forthwith, upon issue to the authority in the foreign country to which the consignment has been redirected;

(c) one copy shall be retained by the operator;

(d) one copy shall be provided to the Collector of Customs of the port of entry/exit; and

(e) one copy to be retained by the PDEA for file.

(2) Upon the issue of a redirection permit, any person holding the export permit or redirection permit accompanying the drug or chemical on its arrival in the Philippines shall remit it to the PDEA who shall return it to the competent authority issuing it, together with:

(a) notice of the name of the foreign country to which the consignment has been redirected; and

(b) an endorsement specifying the quantity of each dangerous drug or controlled chemical, actually imported.

Section 29. Liability to forfeiture of improperly or undocumented consignments

(1) A consignment of a dangerous drug or controlled chemical and their preparations is liable to forfeiture if:

(a) even though it is accompanied by an export permit or redirection permit, there are reasonable grounds to believe that the permit is false, or has been obtained by fraud or wilful misrepresentation of a material particular; or

(b) there are reasonable grounds to believe that any import permit relating to it is false; or

(c) in the case of a consignment of a dangerous drug, it is not accompanied by any export or redirection permit;

(d) in case of a consignment of a controlled chemical, no import permit from the PDEA; or

(e) in case of a consignment of dangerous drugs or controlled chemical, the condition of the permit is violated.
(2) Where the Collector of Customs of the designated port of entry of the consignment, is satisfied that any consignment referred to in subsection (1) is legitimate, the consignment shall be released forthwith to the person lawfully entitled to it.

Section 30. Limitation of licensee's stocks

(1) On or before 31 December each year, the DDB shall, in the light of the prevailing market conditions, and the estimates submitted to and approved by the International Narcotics Control Board, determine the maximum quantities (if any), of each dangerous drug or controlled chemical that may be manufactured or held in stock for the normal conduct of business during the following year.

(2) When the need arises, the DDB may, at any time amend, any such determined quota, and shall promptly notify PDEA in writing of the amended quota.

Section 31. Persons authorized to engage in professional supply of dangerous drugs or drugs containing controlled chemicals

(1) No person shall engage in conduct that constitutes professional supply of any dangerous drug or drug preparations, in parenteral form or tablet or capsule, containing Table I controlled chemical as the only active medicinal ingredient or contains controlled chemical and therapeutically insignificant quantities of another active medicinal ingredient, except:

   (a) a pharmacist, acting in accordance with the norms and standards of the pharmacy profession, who supplies to another person on prescription or on requisition, in the ordinary course of a pharmacy business;

   (b) a licensed person, provided that such supply at all times takes place under the immediate supervision of a pharmacist;

   (c) a practitioner who, in accordance with the norms and standards of his or her profession:

      (i) administers the drug directly to a patient or animal in the ordinary course of treatment; or

      (ii) supplies the drug to a patient or for an animal in the ordinary course of treatment from a place more than five (5) kilometres-radius from the place of business of a pharmacy.

Section 32. Prescriptions

(1) No person shall prescribe a dangerous drug or drug preparations, in parenteral or tablet or capsule form, containing Table I controlled chemical as the only active medicinal ingredient or contains controlled chemical and therapeutically insignificant quantities of another active medicinal ingredient, unless that person is:

   (a) a medical practitioner, who prescribes the drug in the ordinary course of treatment of another person's physical or mental condition; or
(b) a dentist, who prescribes the drug in the ordinary course of treatment of another person's dental condition; or

c) a veterinary surgeon, who prescribes the drug in the ordinary course of treatment of an animal; and

d) granted an S-2 license to prescribe such drugs by the PDEA.

(2) A prescription for a dangerous drug shall

(a) be on a form as prescribed by the Department of Health;

(b) if the prescription is issued by a veterinary surgeon:

(i) be endorsed as being for the treatment of an animal;

(ii) specify the name and address of the owner or caretaker of the animal;

(iii) specify the species of animal;

(iv) if possible, specify a means of identifying the animal; and

(c) be signed and dated by the prescribing practitioner;

(d) contain only one dangerous drug

(3) The prescription required for drug preparation, in parenteral or tablet or capsule containing Table I controlled chemical as the only active medicinal ingredient or containing Table I controlled chemical and therapeutically insignificant quantities of another active medicinal ingredient, shall be in an ordinary form and shall contain the name, address, telephone number, S-2 License number and Privilege Tax Receipt of the prescribing physician, name and address of the patient, date of the prescription, the preparation to be supplied, its strength and the total number of units to be supplied in words, direction of use and the word “non-repetition” and signature of the doctor.

(4) No prescription once served by the drugstore or pharmacy shall be reused nor any prescription once fully issued be refilled, provided however, that when a prescription is partially filled, the balance may be fully filled by the drugstore or pharmacy;

(5) No person shall supply any dangerous drug or drug preparation in parenteral or tablet or capsule, containing Table I controlled chemical as the only active medicinal ingredient or containing Table I controlled chemical and therapeutically insignificant quantities of another active medicinal ingredient, on presentation of a prescription, if the person knows or has reason to believe that the prescription is:

(a) forged, unlawfully altered, or cancelled; or

(b) issued more than one (1) month before presentation.
(6) The quantities of dangerous drugs, that may be prescribe in a single applicable prescription by a licensed practitioner should not exceed the specified quantities as follow:

(a) For cancer patients:
   (i) Morphine Sulfate (tablets [oral]) 3,000 mg
       Morphine Sulfate (ampoules/vials) 448 mg
   (ii) Fentanyl patch 25 ug/hour 30 patches
        Fentanyl patch 50 ug/hour 15 patches
        Fentanyl ampoules 50 ug/ml 10 ampoules (1 ml)
        3 ampoules (2 ml)
        50 ampoules (2 ml) for use in Patient Controlled Analgesic (PCA) machine
   (iii) Oxycontin 1,200 mg
        Oxycontin 10 mg 120 tablets
        Oxycontin 20 mg 60 tablets
        Oxycontin 40 mg 30 tablets
        Oxycontin 80 mg 15 tablet
   (iv) Demerol 14 vials
   (v) Dangerous Drugs (ampoules or hypodermic tablets) 20 pieces
       Dangerous Drugs (tablets) 40 pieces
       Dangerous Drugs (capsules) 40 pieces

(b) Ordinary circumstances:
   (i) Benzodiazepines (anxiolytic or hypnotic or both) 30 tablets or capsules
       Benzodiazepines (anxiolytic or hypnotic or both) 10 ampoules X 1 ml
       3 ampoules X 2 ml
       2 ampoules X 3 ml
       2 ampoules X 5 ml
       1 ampoule X 10 ml
       Benzodiazepines (muscle spasm/dystonia/tetanus) 90 tablets (5 mg)
   (ii) Phenobarbital preparations 2 weeks supply
       2 bottles (100 tablets each) for Epilepsy patients
   (iii) Sodium Pentothal 3 vials (in case of hospital use)
   (iv) Demerol 3 ampoules
   (v) Other Dangerous Drugs (in vials) 1 vial (in case of hospital use)

(7) The quantities of drug preparations in parenteral or tablet or capsule form, containing Table I controlled chemical as the only active medicinal ingredient or containing Table I controlled chemical and therapeutically insignificant quantities of another active medicinal ingredient that may be prescribe in a single applicable prescription by a licensed practitioner should not exceed the specified quantities as follow:

(a) Ordinary circumstances
   (i) Ephedrine (parenteral form) 1 vial (in case of hospital use)
   (ii) Ephedrine, pseudo-ephedrine, norephedrine (tablet/capsule) 1.6 grams of base
(8) A prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients.

(9) A practitioner may prescribe, administer, or dispense dangerous drugs or drug preparations in parenteral or tablet or capsule containing controlled chemicals as the only active medicinal ingredient or containing Table I controlled chemical and therapeutically insignificant quantities of another active medicinal ingredient, for a therapeutic purpose to a person diagnosed and treated by a practitioner for a condition resulting in intractable pain, if this diagnosis and treatment has been documented in practitioner’s medical record. A prescription cannot be written nor dispensed for more than 100 dosage units or a 31-day supply whatever is the greater at one time.

(10) A prescription may not be issued for the dispensing of dangerous drugs or drug preparations in parenteral or tablet or capsule form containing Table I controlled chemicals as the only active medicinal ingredient or containing Table I controlled chemical and therapeutically insignificant quantities of another active medicinal ingredient, to a drug dependent person for the purpose of continuing his dependence upon such drugs.

(11) A doctor with an S-2 license, whose area of residence/clinic/office is within a 5-kilometer radius from a drugstore which is not dispensing dangerous drug preparations or drug preparations, in parenteral or tablet or capsule form containing Table I controlled chemical as the only active medicinal ingredient or containing Table I controlled chemical and therapeutically insignificant quantities of another active medicinal ingredient for emergency use, may store or carry in his medical carry bag a reasonable quantity of such drugs, including, paraphernalia for administering the drug. He/She shall maintain record of receipts and disposal in a record book.

Section 33. Requisitions in an institution for purpose of treatment

(1) No person shall issue a requisition for a dangerous drug or drug preparations, in parenteral or tablet or capsule form, containing Table I controlled chemical as the only active medicinal ingredient or containing Table I controlled chemical and therapeutically insignificant quantities of another active medicinal ingredient, unless the person is:

   (a) a licensed pharmacist in a dispensary in an institution; or

   (b) any attending licensed practitioner in an institution.

(2) A person shall not supply a drug against a requisition except to a person referred to in subsections (1) (a) or (b) at an institution for the treatment of a person therein.

(3) A requisition for such drug shall:

   (a) be legible;

   (b) specify the name of the person issuing it and the capacity in which he or she issues it;

   (c) specify the name, quantity, form and strength of the drug;
(d) specify the ward or dispensary where the drug is required;

(e) be signed and dated by the person issuing it; and

(f) be countersigned by either the pharmacist who is to supply the dangerous drug or drug preparation, in parenteral or tablet or capsule form, containing Table I controlled chemical as the only active medicinal ingredient or containing Table I controlled chemical and therapeutically insignificant quantities of another active medicinal ingredient, or a medical practitioner.

Section 34. Prescribing and filing of an order in emergency situation

(1) Where the need for treatment is urgent in an emergency case, an ordinary prescription not in DOH prescribed official form may be given, and shall be acted upon by the licensed seller. The prescribing physician, dentist, veterinarian or practitioner shall inform the DOH, copy to PDEA unit responsible for the area where the emergency occurred, in writing within three days (3) after issuing such ordinary prescription. Such prescription should contain at the back of it statement of date and nature of emergency condition. The prescription should clearly state the name and address of the patient, and the name and signature of the prescribing person.

(2) In cases of emergency where life or health is endangered, an order for dangerous drugs made not in the prescribed form and duly signed by the purchaser should be recognized by the license seller and forthwith supply the dangerous drugs so ordered. The purchase order should be signed by the City/Municipal Health Officer or attending physician or senior medical officer or police medical officer or military doctor or any available doctor supervising the medical team or unit rendering medical service in the area where the emergency situation arose. The seller shall notify immediately the PDEA unit responsible for the area where the emergency occurred. The purchaser shall submit to the PDEA a written statement of the circumstances leading to the purchase and how the medicine was dispensed or administered and to whom, within 7 days after the particular emergency situation ended.

Section 35. Emergency situation related to filing of emergency order and prescribing dangerous drugs

The following are specified as falling within the category of emergency situation:

(a) as a result of man-made, natural and other disasters such as war in any form, terrorist attack, rebellion, insurrection, typhoons, earthquakes, volcanic eruptions, fire, deluge, grave accidents, epidemic, etc, as to preclude prompt access to the official prescription form or order form for dangerous drugs;

(b) where, in the opinion of the prescribing physician, the immediate availability and administration of the dangerous drugs would save the life and/or alleviate the pain of the patient.

Section 36. Carrying of dangerous drugs by international travellers

Any person undergoing treatment of a medical condition, who is entering, leaving or passing through the Bd. Reg. on Comprehensive Guidelines on Importation . . . . .
Philippines may possess such quantities of a dangerous drug or drugs preparations, in tablet or capsule or parenteral form containing Table I controlled chemical as the only active medicinal ingredient or containing controlled chemical and therapeutically insignificant quantities of another active medicinal ingredient, wherever prescribed by a licensed medical doctor, as are reasonable for the purposes of such treatment.

Section 37. Exempt Officials or persons

Government run-hospitals or similar institutions, universities and laboratories as well as responsible officials and employees in the active service of the national government agency and local government units, and government-owned or controlled corporations, who in the exercise of their official functions or duties engage in activities dealing with dangerous drugs or controlled chemicals and their preparations, and persons that have expressed exemption under special laws or charter shall register with the PDEA for the appropriate license. However, they shall be exempted from paying the corresponding fee for the license.

Section 38. Dangerous Drugs registers

(1) The following persons shall keep or maintain an appropriate dangerous drug register in accordance with the prescribed format:

(a) any registered person granted a licence or a permit under Article III of this Regulation in relation to any dangerous drug;

(b) any person authorized under Article III of this Regulation to issue a prescription or requisition for a dangerous drug, or to supply such a drug;

(c) any pharmacist, including a pharmacist responsible for the supervision of all other pharmacists employed in a hospital or other institution for medical treatment or care.

(2) Every pharmacist dealing in dangerous drugs or controlled chemicals shall maintain and keep an original record of sales, purchases, acquisitions and deliveries of dangerous drugs, indicating therein:

(a) license number and address of the pharmacist;

(b) name, address and license of the manufacturer, importer or wholesaler from whom the dangerous drugs have been purchased;

(c) quantity and name of the dangerous drugs purchased or acquired;

(d) date of acquisition or purchase;

(e) name, address and community tax certificate number of the buyer;

(f) serial number of the prescription and the name of the physician, dentist, veterinarian or practitioner issuing same;

(g) quantity and name of dangerous drugs soled or delivered;

(h) date of sale or delivery;

(i) in the case of supply on requisition in an institution, details of the dispensary, ward or other place to which the drug was supplied;

(j) in the case of return, the name of the person to whom the drug was returned.

(3) A certified true copy or computer print out of such record covering a period of six months, duly signed by the pharmacist or the owner of the drugstore, pharmacy shall be forwarded to the Board through the PDEA, within fifteen days (15) days following the last day of June and December of each year, with a copy thereof furnished the city or municipal health officer concerned.

(4) A person who makes entry in a drug register shall sign and date the entry.

(5) A person may, in the presence of a witness, correct, by notation, a mistake in an entry in drugs register, providing the person making the correction makes, signs and dates the notation, and the witness countersigns the notation.

(6) Any person who:

(a) delivers a dangerous drugs to a ward or other area of an institution; or

(b) in the ordinary course of duties in a medical, dental or veterinary practice, or in a ward or other area of an institution, witnesses the administration of the drug

shall countersign the relevant entry in the register.

(7) Any person required by this section to keep a dangerous drugs register shall, subject to any written Direction to the person by the PDEA, retain possession of the register and all prescriptions, requisitions and commercial documents relating to entries therein for two (2) years after the date of the last entry in the register. Such records shall be subject anytime to review by the Board through the PDEA.

(8) Any person required under subsection (1) to keep and maintain a register in relation to any dangerous drug shall within twenty four (hours) of any import, export, manufacture, supply, acquisition or disposal by that person of any such chemical or item, enter or cause to be entered in such register:

(a) the date of the import, export, manufacture, supply, acquisition or disposal;

(b) the name of the chemical equipment or material, and the quantity involved;

(c) in the case of a controlled chemical, its form and purity;

(d) in the case of disposal, the method of disposal; and

(e) in the case of import, export, acquisition or supply, the name, licenses and occupational or business address of the person to or from whom the chemical was imported, exported,
Section 39 Controlled chemical registers

(1) Any person granted registration, license or permit under article III of this Regulation, in relation to any controlled chemical shall keep, or cause to be kept, at a place where any such chemical or item is kept by that person, a register in accordance with the prescribed format.

(2) Any person required under subsection (1) to keep and maintain a register in relation to any controlled chemical shall within twenty four (hours) of any import, export, manufacture, supply, acquisition or disposal by that person of any such chemical or item, enter or cause to be entered in such register:

   a) the date of the import, export, manufacture, supply, acquisition or disposal;
   b) the name of the chemical equipment or material, and the quantity involved;
   c) in the case of a controlled chemical, its form and purity;
   d) in the case of disposal, the method of disposal; and
   e) in the case of import, export, acquisition or supply, the name, licenses and occupational or business address of the person to or from whom the chemical was imported, exported, acquired or supplied, and where known, the name of any ultimate consignee;

(3) Any register required to be kept under subsection (1), and all commercial documents relating to entries therein such as orders, invoices, despatch notes, cargo manifests or customs or other shipping documents shall be kept for at least 2 years after the end of the calendar year of the last entry in the register. Such registers may be subject anytime for review by the Board through the PDEA.

Section 40. Drug preparations containing controlled chemicals

(1) A pharmacist dealing in drugs containing Table I controlled chemical, which requires ordinary prescription containing an S-2 license of prescribing doctor shall maintain and keep an original record of sales, purchases, acquisitions and deliveries of such drug preparations, indicating therein:

   a) license number and address of the pharmacist;
   b) name, address and license of the manufacturer, importer or wholesaler from whom the drugs have been purchased;
   c) quantity and name of the drugs purchased or acquired;
   d) date of acquisition or purchase;
   e) name, address and community tax certificate number of the buyer;
   f) the name of the physician, dentist, veterinarian or practitioner issuing same, and telephone...
number;

(g) quantity and name of drugs soled or delivered;

(h) date of sale or delivery;

(i) in the case of supply on requisition in an institution, details of the dispensary, ward or other place to which the drug was supplied;

(j) in the case of return, the name of the person to whom the drug was returned.

(2) A certified true copy or computer print out of such record covering a period of six months, duly signed by the pharmacist or the owner of the drugstore, pharmacy shall be forwarded to the Board through the PDEA, within fifteen days (15) days following the last day of June and December of each year, with a copy thereof furnished the city or municipal health officer concerned.

Section 41. False or misleading entries in registers and records

Any person required to keep a register or other record under the Act and this Regulation shall not:

(a) make, or cause or permit to be made, an entry in or on it that is, to the knowledge of that person, false or misleading; or

(b) cancel, obliterate or alter any entry, except to correct an error.

Section 42. Duty to notify loss, destruction or discrepancies in registers

Any person required to keep a register shall upon discovery, submit a written report immediately to PDEA:

(a) the loss or destruction of the register, or of the whole or any part of the contents of the register; or

(b) any discrepancy in the register, other than a mistaken entry.

Section 43. Safe keeping of dangerous drugs and controlled chemicals

(1) Any person authorized:

(a) to import, export, manufacture, administer, supply or acquire a dangerous drug or controlled chemical or their respective preparations;

(b) to engage in professional supply of dangerous drugs or drug preparations, in parenteral or tablet or capsule form, containing Table I controlled chemical as the only active medicinal ingredient or contains controlled chemical and therapeutically insignificant quantities of another active medicinal ingredient containing controlled chemicals,

shall, while the drug or chemical is in the person's custody or control, keep it or cause it to be kept in a vault, Bd. Reg. on Comprehensive Guidelines on Importation . . . .
safe or other prescribed secure storage or depot;

(2) A person referred to in subsection (1) shall take such measures as the PDEA may direct in writing to ensure that no unauthorized person has:

(a) access to the combination, key or other means of access to any secure storage facilities or depot containing a dangerous drug or controlled chemical; or

(b) the drug or chemical contained therein.

(3) The licensed operator shall ensure that the safekeeping and handling of the chemicals is in accordance with the requirements defined in the Material Safety Data Sheet of the chemical concerned.

Section 44. Duties where there is loss or theft of a dangerous drug or controlled chemical or their preparations

Any person authorized:

(a) to import, export, manufacture, administer, supply or acquire a dangerous drug or controlled chemical; or

(b) to engage in professional supply of dangerous drugs or drug preparations, in parenteral or tablet/capsule form, containing Table I controlled chemical as the only active medicinal ingredient or contains controlled chemical and therapeutically insignificant quantities of another active medicinal ingredient

shall immediately report to PDEA, in writing, the loss or theft of any quantity of the dangerous or chemical in the person's custody or control and record relevant particulars of the loss or theft in the appropriate register.

Section 45. Chemical Containers and Labeling and Relabeling Requirements

Suppliers of controlled chemicals, whether manufacturers, importers or distributors, shall ensure that:

(a) Controlled chemicals shall be kept in appropriate containers as indicated in the Material Safety Data Sheet of the particular controlled chemicals. The containers should have labels indicating the following:

(i) Trade name and chemical;

(ii) Identity and concentration;

(iii) Danger markings; safety precautions;

(iv) Manner of destroying the container;

(v) Risks associated with the use of the chemical;

(vi) Name of manufacturer or importer and address
(b) the container in which any controlled chemical is kept or stored shall be clearly marked and labelled on the outside thereof, including the English names of the substance;

(c) the container shall not contain any substance other than the substance so marked thereon;

(d) all repackaged chemicals, including commercial products that are mixtures of chemicals should have labels containing the hazard labels and first aid steps, as well as the full name of the materials in the container, including the chemical name, the concentration of a solution or mixture and disclosing the toxic/regulated component, name of manufacturer or importer and address.

ARTICLE IV
ADMINISTRATION, COMPLIANCE AND ENFORCEMENT

Section 46. Appointment/designation of regulatory compliance officers

(1) The Director General of PDEA shall appoint, designate and/or assign qualified PDEA personnel, as regulatory compliance officers for the purposes of the Act and this Regulation.

(2) The Director General of PDEA shall cause to be issued to the regulatory compliance officers an identity card which states the name and appointment of regulatory compliance officer and on which appears a recent photograph of the officer.

Section 47. Inspection of authorized premises and operations

A license holder shall, when required to do by a visiting regulatory compliance officer open the registry for dangerous drugs, and/or controlled chemicals, including drug preparations, in parenteral or tablet or capsule form containing Table I controlled chemical as the only active medicinal ingredient or containing Table I controlled chemical and therapeutically insignificant quantities of another active medicinal ingredient for inspection. Such person shall, when required to do in writing, provide the PDEA officer with a statement in writing, signed and dated by the person, accounting for each dangerous drug, or controlled chemical in possession of the authorized person at any time since the grant of the registration/licence, or permit.

Section 48. Duties of PDEA regulatory compliance officers

(1) A person duly designated or assigned as PDEA Regulatory Compliance officer by the Director General of PDEA and armed with a mission order may, at any time during ordinary business or professional hours, with such assistance and by such force as is necessary and reasonable, enter any premises or place at which any activity is carried out by any person in accordance with the license provided by PDEA.

(2) A Regulatory Compliance officer who enters any premises or place pursuant to subsection (1) shall:

(a) require the occupant of the premises to supply his or her name and address;

(b) inspect the premises or place in order to ascertain whether or not the Act, or a term or
condition of any licence or permit granted pursuant to this Regulation has been or is being complied with;

(c) examine any label, advertising material, register, record, book, electronic data or other document therein relating to any dangerous drug or controlled chemical or their preparations;

(d) make an extract of the record or take a copy thereof, and require from any person an explanation of an entry in any such register, record or document;

(e) open and examine any receptacle or package found in that place in which a dangerous drug, or controlled chemical or their preparations may be found;

(f) examine any thing found in that place that is used or may be capable of being used for the manufacture, packaging or storage of a dangerous drug or controlled chemical or their preparations;

(g) examine any substance found in that place and take, for the purpose of analysis, such samples thereof as are reasonably required. The officer shall issue a receipt for such samples taken.

(3) The PDEA Regulatory Compliance officer may ask for a signed certificate from the occupant of the premises that the conduct of inspection was reasonable and properly done.

(4) Where in the ordinary course of duty, a Regulatory Compliance officer becomes aware of any possible violation of the provisions of the Act and this Regulation, he or she shall immediately report that fact to the Director General or Director of Compliance Service or Regional Director of PDEA and proceed with the reasonable or necessary investigation or proceeding relating to that possible offence.

Section 49. Inspection of approved treatment centres

(1) A PDEA Regulatory Compliance officer may, at any reasonable hour of the day enter the premises of an approved treatment centre.

(2) An inspector who enters an approved treatment centre may:

(a) inspect the premises and any facilities provided at, or equipment used at the premises for, or in connection with, the provision of treatment or accommodation at the centre;

(b) inspect any drug register, prescribed book, record or document kept on the premises relating to such treatment or accommodation, or otherwise relating to the conduct of the centre in relation to patients;

(c) require the occupant of the premises to produce any drug register, prescribed book, record or document or to give to the inspector any prescribed information in his or her possession relating to such treatment or accommodation or otherwise relating to the conduct of the centre in relation to such patients.

Section 50. Presentation of authority to make inspection/compliance investigation

(1) A PDEA Regulatory Compliance officer shall present his or her duly issued identity card and letter
order to the person in charge of any place entered pursuant to this Regulation for the purposes of inspection.

(2) Any person who claims to have regulatory powers and who enters a licensed establishment in accordance with this regulation, is not authorized to remain on the premises if the person does not present the duly PDEA issued identification card and letter order, and the licensed holder or any person in or on the premises is not obliged to comply with the requirement of that person claiming such authority.

Section 51. Coordinating System

The concerned agencies shall endeavor to establish a coordination system to enhance dangerous drugs and controlled chemical interdiction capability.

Section 52. Obstruction of regulatory compliance officer

No person shall, without reasonable excuse, by act or omission:

(a) obstruct or hinder a PDEA Regulatory Compliance officer in the performance of his duties under this regulations; or

(b) refuse or fail to comply with a reasonable request of a PDEA Regulatory Compliance officer who has entered any premises in accordance with the Act and this Regulation.

Section 53. Liability for Violation of Regulation.

Any person found violating Sections 6, 13, 20, 22, 23, 29, 32, 33, 40, 41, 43, 44, 45, 50(2), and 51 of this Regulation is liable under Section 32 of Article II of RA 9165.

Section 54. Repealing Clause

Board Regulations No. 7 s-1972, No. 1 s-1980, No. 4 s-1989, No. 6-A s-1989, No. 4 s-1991, No. 5 s-1991, No. 3 s-1996, No. 2 s 2001 and all other resolutions, orders and other rules and regulations or parts thereof, which were issued pursuant to RA 6425, as amended and are inconsistent with RA 9165 and its Implementing Rules and Regulations or with this Regulation are hereby repealed, amended or modified accordingly.

ARTICLE V
EFFECTIVITY

Section 55. Effectivity. This regulation shall take effect fifteen (15) days after its publication in a newspaper of general circulation and fifteen (15) days after registration with the Office of National Administrative Regulations, UP Law Center, Quezon City.

Done in Quezon City this 4th day of July 2003.
ROLANDR. DIZON  
(Chairperson, Commission on Higher Education)  
Ex-Officio Member  

ANSELMO S. AVENIDO, JR.  
(Director-General, Philippine Drug  
Enforcement Agency)  
Ex-Officio Member  

PAOLO BENIGNO A. AQUINO IV  
(Chairperson, National Youth Commission)  
Ex-Officio Member  

LUCITA S. LAZO  
(Undersecretary, Representing the  
Secretary of Labor and Employment)  
Ex-Officio Member  

BERNARDO T. LASTIMOSO  
(Undersecretary, Permanent Member,  
Dangerous Drugs Board)  

EDGAR C. GALVANTE  
(Undersecretary, Permanent Member,  
Dangerous Drugs Board)  

JOSE D. LINA, JR.  
Secretary, Department of Interior and Local Government and  
OIC Chairman, Dangerous Drugs Board  

Attested:  

EFREN Q. FERNANDEZ  
Undersecretary  
Executive Director, Dangerous Drugs Board  