S. No. 1284 H. No. 5666 / 92 OG No. 43, 7040 (Oct. 21, 1996) ; Standard 10/11/96 ; 6 VLD 2d 119

[REPUBLIC ACT NO. 8203, September 04, 1996]

AN ACT PROHIBITING COUNTERFEIT DRUGS, PROVIDING PENALTIES FOR VIOLATIONS AND APPROPRIATING FUNDS THEREFOR

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

SECTION 1. *Title.* – This Act shall be known as the "Special Law on Counterfeit Drugs."

SEC. 2. *Declaration of Policy.* – It is hereby the policy of the State to protect and promote the right to health of the people and instill health consciousness among them as provided in Section 15, Article II of the Constitution.

It is also further declared the policy of the State that in order to safeguard the health of the people, the State shall provide for their protection against counterfeit drugs.

SEC. 3. *Definition of Terms.* – For purposes of this Act, the terms:

a. *Drugs* shall refer to any chemical compound or biological substance, other than food, intended for use in the treatment, prevention or diagnosis of disease in man or animals, including but not limited to:

    1. any article recognized in the official United States Pharmacopoeia-National Formulary (USP-NF), official Homeopathic Pharmacopoeia of the United States, Philippine National Drug Formulary, British Pharmacopoeia, any National Compendium or any supplement to any of them;

    2. any article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals;

    3. any article other than food intended to affect the structure or any function of the body of man or animals;

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

    5. herbal and/or traditional drugs which are articles of plant or animal origin used in folk medicine which are: (a)recognized in the Philippine National Drug Formulary; (b) intended for use in the treatment or cure or mitigation of disease symptoms, injury or bodily defect in man; (c) other

than food, intended to affect the structure or any function of the body of man; (d) in finished or ready-to-use dosage form; and (e) intended for use as a component of any of the articles specified in clauses (a), (b), (c) and (d).

b. *Counterfeit drug/medicine* refers to medicinal products with the correct ingredients but not in the amounts as provided hereunder, wrong ingredients, without active ingredients, with insufficient quantity of active ingredient, which results in the reduction of the drug's safety, efficacy, quality, strength or purity. It is a drug which is deliberately and fraudulently mislabeled with respect to identity and/or source or with fake packaging, and can apply to both branded and generic products. It shall also refer to:

    1. the drug itself, or the container or labeling thereof or any part of such drug, container or labeling bearing without authorization the trademark, trade name or other identification mark or imprint or any likeness to that which is owned or registered in the Bureau of Patent, Trademark and Technology Transfer (BPTTT) in the name of another natural or juridical person;

    2. a drug product refilled in containers by unauthorized persons if the legitimate labels or marks are used;

    3. an unregistered imported drug product, except drugs brought in the country for personal use as confirmed and justified by accompanying medical records; and

    4. a drug which contains no amount of, or a different active ingredient; or less than eighty percent (80%) of the active ingredient it purports to possess, as distinguished from an adulterated drug including reduction or loss of efficacy due to expiration.

c. *Brokering* shall refer to any act of facilitating the disposal or sale of counterfeit drugs, including acts of agency.

d. *Bureau* shall refer to the Bureau of Food and Drugs (BFAD) of the Department of Health (DOH).

e. *Department* shall refer to the Department of Health.

f. *Business establishment* shall refer to any entity, whether a single proprietorship, partnership or corporation engaged in, or doing business in the Philippines.

g. *Owner* shall refer to a person or group of persons who is the registered owner of a license to operate a business or business undertaking in the Philippines or the branch manager or operator, licensee, franchisee, or any person acting on behalf of the corporate entity.

h. *Residence* shall refer to a private dwelling or abode where a person lives, either as owner or lessee, or usufructuary including, for purposes of this Act, its yard, garage, storage rooms or premises.

SEC. 4. *Prohibited Acts.* – The following acts are declared unlawful and therefore prohibited:

a) The manufacture, sale, offering for sale, donation, distribution, trafficking, brokering, exportation, or importation or possession of counterfeit drugs as defined in Section 3 hereof not otherwise covered by Republic Act No. 3720, as amended. The presence or availability of such counterfeit drugs within the premises of any entity engaged in the sale, manufacture or distribution of drugs and/or pharmaceutical products or in a private residence, or in public or private vehicle, or in the premises not covered by a valid license to operate from the Bureau, shall constitute a *prima facie* evidence of violation of this Act: *Provided, however,* That this presumption shall not apply to the legitimate owners of trademarks, trade names or other identifying marks, or the legitimate or authorized representatives or agents of such owners, who have in their possession counterfeit drugs which bear the trademarks, trade names or marks if they can show the sales invoices or official receipts evidencing their purchase from a drugstore, manufacturer or distributor suspected by them of dealing in counterfeit drugs involving the trademarks, trade names and other similar identifying marks registered in their names: *Provided, further,* That such counterfeit products shall be reported and immediately turned over to the Bureau: *Provided, finally,* That compliance with the preceding *proviso* shall be made within a reasonable period from the date of purchase of such counterfeit drugs as indicated in the sales invoice, official receipt, or other similar documents abovementioned to the time the counterfeit drugs are reported and turned over to the Bureau;

b) Possession of any such counterfeit drugs. However, any person found in possession of counterfeit drugs, in violation of this subsection, shall be excepted from liability under the provisions of this Act after:

1. presentation of sales invoices, official receipts, or other legally acceptable documents evidencing his purchase thereof from a drugstore, distributor, manufacturer, hospital pharmacy or dispensary, or any other person or place duly licensed to sell and/ or dispense drugs or medicines, and indicating therein the batch and lot numbers, as well as the expiry dates of such drugs; or

2. presentation of certificates and other documents evidencing the importation or exportation of the counterfeit drugs found in his possession as required by existing laws, including those documents required in the preceding paragraph covering the commercial transactions involving counterfeit drugs.

In both cases, the subject counterfeit drugs must not on their face, appear to be as such, or do not bear any marking or any patently unusual characteristic sufficient to arouse the suspicion of a reasonable and prudent person that such drugs are counterfeit. Furthermore, the amount or volume of counterfeit drugs held is such that it does not negate or is inconsistent with the averment that the same are for personal use, notwithstanding the presentation by the possessor of medical records and other similar documents accompanying and justifying the use of such drugs;

c) Forging, counterfeiting, simulating or falsely representing, or without proper authority, using any mark, stamp, tag, label or other identification mark or device authorized or required by Republic Act No. 3720, as amended, and/or the