



Republic of the Philippines
Office of the President
DANGEROUS DRUGS BOARD

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BOARD REGULATION NO. 8
Series of 2019

SUBJECT: REQUIREMENTS FOR THE ISSUANCE OF A LICENSE TO ACQUIRE, POSSESS, AND USE UNREGISTERED DRUG PRODUCTS CONTAINING DANGEROUS DRUGS FOR PERSONAL USE

WHEREAS, Section 77 of Republic Act No. 9165 or the Comprehensive Dangerous Drugs Act of 2002, as amended (the "Act"), provides that the Dangerous Drugs Board (the "Board") is the policy-making and strategy-formulating body in the planning and formulation of policies and programs on drug prevention and control;

WHEREAS, Section 2 of the Act provides that it is a declared policy of the State to "achieve a balance in the national drug control program so that people with legitimate medical needs are not prevented from being treated with adequate amounts of appropriate medications, which includes the use of dangerous drugs";

WHEREAS, Section 81(r) of the Act states that the Board shall formulate guidelines, in coordination with other government agencies, for the importation, distribution, production, manufacture, compounding, prescription, dispensing and sale of, and other lawful acts in connection with any dangerous drug, controlled precursors and essential chemicals and other similar or analogous substances of such kind and in such quantity as it may deem necessary according to the medical and research needs or requirements of the country;

WHEREAS, Food and Drug Authority counterparts in reference countries have registered medications which are currently restricted, regulated and still unregistered in the Philippines which may be beneficial to Filipinos but only obtainable in respective countries of origin;

WHEREAS, the Department of Health issued Administrative Order No. 4, Series of 1992 which provides for the requirements leading to the issuance of a Compassionate Special Permit for Restricted Use of Unregistered Drug and Device Product/Preparation by the Food and Drug Administration (the "FDA");

WHEREAS, there is an immediate need to provide for a set of guidelines covering the restricted acquisition and possession of medicines containing dangerous drugs which are currently unregistered with the FDA but are registered in other countries for personal use;

NOW, THEREFORE, be it **RESOLVED**, as it is hereby **RESOLVED**, to promulgate this Regulation governing the access to such medicines through the issuance of a license to acquire, possess, and use unregistered drug products containing dangerous drugs for personal use;

SECTION 1: Objective

The Board recognizes that access to drug products classified as medicines is an essential right of any individual.

For purposes of this Regulation, a *drug* is defined as an article recognized in official pharmacopeias and formularies, including official homeopathic pharmacopeias, or any documentary supplement to any of them, which are recognized and adopted by the FDA; (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; (3) articles (other than food) intended to affect the structure of any function of the body of humans or animals; or (4) articles intended for use as a component of any article specified in clauses (1), (2), or (3) but do not include devices or their components, parts or accessories. A *drug product* means an article in finished dosage form that contains a drug substance that may or may not be in association with other active or inactive ingredients.

This Regulation provides for a License to Acquire, Possess, and Use Unregistered Drug Products Containing Dangerous Drugs for Personal Use (the "License") to be acquired prior to actual acquisition, possession, and use, and shall pertain to drug products containing dangerous drugs which are currently unregistered or in the process of being registered with the FDA but are already registered in FDA reference countries.

SECTION 2: Who May Apply for a License

The License may be applied with the PDEA by the patient himself/herself, his/her parent, spouse, guardian, or relative within the fourth degree of consanguinity or affinity.

The License shall only be used to acquire drug products for patients with the following medical conditions;

- a. Diseases covered by RA 10747 or the "Rare Disease Act of the Philippines";
- b. Life-threatening and debilitating diseases;
- c. Cancer and other terminal diseases;
- d. Rare forms of neurological conditions; and
- e. Other diseases with limited therapeutic options identified by the Department of Health.

SECTION 3: Requirements for the Issuance of the License

The applicant shall file an application to the PDEA indicating the intention to acquire and possess unregistered drug products containing dangerous drugs for personal use. Attached to said letter shall be the following:

- a. Copy of the medical certificate of the patient with diagnosis;
- b. Copy of the prescription signed by the prescribing medical practitioner which shall clearly indicate the prescription quantity or volume not exceeding one-year supply of the medicine, the clinical practice address, and the contact information of the prescribing medical practitioner;
- c. Copy of the proof of registration of the medicine in reference country of origin;
- d. A Clinical Study Report to be submitted by the attending physician which shall provide for the quantity of medicine administered, dosage and frequency of use, therapeutic effect desired and any adverse reactions observed, if present;
- e. Payment of License Fee in the amount of Five Hundred Pesos (Php 500.00).

staggered/installment basis, the same should be indicated in the prescription issued by the prescribing medical practitioner.

Provided finally, that the application shall include the manner of transporting the unregistered drug products from the foreign country, which may be through courier/parcel service or personal transport by patient or authorized family members. The PDEA shall issue a form indicating the required information to be filled up by the applicant. The form, which shall form part of the procedural guidelines stated in Section 5 hereof, shall authorize the patient or his/her authorized representative to claim the medicines, in case of delivery of the same through courier/parcel service, or possess the medicine in case of personal transport.

SECTION 4: Effect of the License

Issuance of the License allows the patient or his/her authorized representative to acquire, possess, and use specific volume/quantity of restricted, regulated and unregistered medications containing dangerous drugs for a specific period of time as indicated in the prescription. The License also authorizes PDEA to conduct random inspection of records pertaining to Section 3 [e] of this Regulation.

SECTION 5. Procedural Guidelines

The Board, thru the Secretariat, the PDEA, and the Department of Health, shall formulate the procedural guidelines within sixty (60) days from the approval of this Regulation.

SECTION 6: Penalty Clause

Failure to comply with the above-mentioned requirements shall subject the patient and/or his/her authorized representative to criminal prosecution under RA 9165.

SECTION 7: Effectivity

This Regulation shall take effect fifteen (15) days after its publication in two (2) newspapers of general circulation and after its registration with the Office of the National Administrative Register (ONAR), UP Law Center, Quezon City.

APPROVED and ADOPTED this 17th day of December, in the year of Our Lord, 2019 in Quezon City.


Secretary CATALINO S. CUY, CEO VI
Chairman, Dangerous Drugs Board

Attested:


Undersecretary EARL P. SAAVEDRA, MPA
Secretary of the Board