UNITED NATIONS

E/NL. 1990/26-28
17 August 1990
ENGLISH ONLY

LAWS AND REGULATIONS

PROMULGATED TO GIVE EFFECT TO THE PROVISIONS OF THE INTERNATIONAL TREATIES ON NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES

In accordance with the relevant articles of the international treaties on narcotic drugs and psychotropic substances, the Secretary-General has the honour to communicate the following legislative texts.

PHILIPPINES

Communicated by the Government of the Philippines

NOTE BY THE SECRETARIAT

(a) Some editing of texts may be done by the Secretariat in the interest of clarity. In this connection, words in square brackets [ ] have been added or changed by the Secretariat.

(b) Only passages directly relevant to the control of narcotic drugs or psychotropic substances have been reproduced in this document. Non-relevant parts of laws and regulations have been deleted by the Secretariat; such deletions are indicated by [...].

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BOARD REGULATION No. 5 s. 1989, 17 August 1989

INCLUSION OF BUPRENORPHINE AND PEMOLINE; THEIR SALTS, ISOMERS, AND SALTS OF ISOMERS; AND COMPOUNDS, MIXTURES, AND PREPARATIONS CONTAINING SUCH SUBSTANCES IN THE LIST OF DANGEROUS DRUGS

Section 1

Pursuant to its powers under section 36 (a) of Republic Act No. 6425, as amended, 1/ the Dangerous Drugs Board, finding after evaluation that the following substances:

International Non-proprietary name (INN)	Chemical name 2/	Other name
BUPRENORPHINE		Temgesic Buprenex
PEMOLINE		Phenoxazole Phenylisohydantoin Phenylpseudohydantoin

have the capacity to produce dependence and are likely to be so abused as to constitute a public health and social problem, which finding is in agreement with the decisions of the United Nations Commission on Narcotic Drugs identified as 1(XXXIII) and 2(XXXIII), hereby classified as Dangerous Drugs and further categorized as Regulated Drugs, the said substances as well as their salts, isomers (whether optical, position, or geometric) which (a) exist within the specific chemical designations by whatever official name, common name or usual name, chemical name or brand name and (b) have the same or similar psychologic and/or physiologic effects as the parent drugs mentioned above.

Section 2

All compounds, mixtures, or preparations containing these substances and their salts, isomers, and salts of isomers qualified in section 1 hereof are classified as Dangerous Drugs and further categorized as Regulated Drugs.

Section 3

In view of this classification, these dangerous drugs shall be subject to all control measures in article III, "Regulated Drugs" and article IV, "Provisions of Common Application to Offenses Penalized under articles II and III" of Republic Act 6425, as amended, 1/ and pertinent regulations issued by the Dangerous Drugs Board.

Section 4

Any violation hereof shall be a ground for administrative action, without prejudice to the filing of a criminal case, if warranted in the premises.

Section 5

This regulation supplements Board Regulation No. 6, Series of 1972 3/ and shall take effect fifteen (15) days after its publication in the Official Gazette and in a newspaper of general circulation once a week for two (2) consecutive weeks, whichever is earlier.

TOMAS P. MARAMBA, JR., M.D., M.H.A.
Vice-Chairman
(Undersecretary of Health for
Standards and Regulation)

(Signed)

E/NL.1990/27

BOARD REGULATION No. 7 s. 1989, 19 October 1989

PROVIDING GUIDELINES FOR THE IMPLEMENTATION OF BOARD REGULATIONS WHEREIN CERTAIN PROVISIONS OF THE GENERICS ACT OF 1988 (R.A. 6675) ARE APPLICABLE

Pursuant to the powers of the Board under section 36 (a) of R.A. 6425, as amended, 1/ in relation to section 9 and section 6 (a) and (b) of The Generics Act of 1988, the following guidelines are hereby prescribed:

Section 1

For Practitioners:

In issuing a prescription, a duly authorized practitioner shall indicate therein the generic name of the dangerous drug or exempt dangerous drug preparation prescribed. He shall also comply with the conditions set forth in section 3 of Administrative Order No. 62, Series of 1989 of the Department of Health.

Section 2

For manufacturers, compounders, exporters and importers:

They shall indicate the generic name on the label of the dangerous drugs or exempt dangerous drug preparations which they deal on. They shall also comply with Administrative Order No. 55, Series of 1989 of the Department of Health.

Section 3

For drug outlets:

Drug outlets dispensing dangerous drugs and exempt dangerous drug preparations shall practice generic dispensing and shall comply with the conditions set forth in section 3 of Administrative Order No. 63, S. 1989 of the Department of Health, except the provision of section 3, paragraph 3.1.1.2, which is, posting in a conspicuous place in their establishment a list of drug products using generic names with their brand names.

They shall also comply with the provisions of Board Regulation No. 11, Series of 1973 governing the partial filing of dangerous drugs. 4/

Section 4

Prohibition against advertising:

Dangerous drugs and exempt dangerous drug preparations shall not be advertised to the general public. They may, however, be advertised in scientific journals.

Section 5

Prohibition against distribution of samples:

Dangerous drugs and exempt dangerous drug preparations shall not be distributed as samples.

Section 6

Report of violations:

Violations of this regulation shall be reported to the Department of Health for appropriate action.

Section 7

Repealing clause:

All rules and regulations inconsistent herewith shall be deemed repealed or modified accordingly.

Section 8

Effectivity:

This regulation shall take effect after its publication in the Official Gazette and in a newspaper of general circulation once a week for two (2) consecutive weeks, whichever is earlier.

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E/NL.1990/28

BOARD REGULATION No. 9 s. 1989, 19 October 1989

EXEMPT REGULATED PREPARATIONS

Pursuant to the powers of the Dangerous Drugs Board under section 36 (a), article VIII of R.A. 6424, as amended, 1/ the following regulation is hereby prescribed:

Section 1

Definition of terms:

(a) "Dangerous Drug Preparation" refers to any solution or mixture, in whatever physical state, containing:

(1) one or more dangerous drugs; or

(2) one or more dangerous drugs in dosage form.

As herein construed, a dangerous drug preparation is in dosage form when it consists of a measured, small quantity of dangerous drugs or a combination of dangerous drugs in whatever form (tablet or pill, ampoule or powder) ready for consumption by, or administration to, a patient or animal, whether orally or parenterally or through other routes.

(b) "Exempt Dangerous Drug Preparation" is any dangerous drug preparation which is compounded in such a way that it presents no, or a negligible, risk of abuse and the dangerous drug it contains cannot be recovered by readily applicable means in a quantity liable to abuse, so that the preparation does not give rise to a public health and social problem; and has high therapeutic value, a wide use for legitimate purposes and is a much needed medicine required to be easily available to the public in medical need thereof. The word "compounded" as herein used means the process of combining a controlled drug with a non-controlled ingredient counteractive of the abuse liability of the controlled drug present.

(1) "Exempt Regulated Drug Preparation" is any dangerous drug preparation which:

(i) contains only one regulated drug internationally controlled under Schedules III or IV of the 1971 Convention on Psychotropic Substances and not exceeding the quantitative limits for such as determined by the Board;

(ii) is not a combination of a regulated drug with a prohibited drug;

(iii) is not a combination of a psychotropic drug under international control with an uncontrolled drug having similar psychotropic properties;

(iv) does not contain any psychotropic substance listed in Schedule II annexed to the 1971 Convention on Psychotropic Substances;

(v) includes one or more non-narcotic or non-psychotropic active medicinal ingredients in proportion sufficient to confer upon the preparation valuable medicinal properties other than those possessed by the regulated drug alone and to prevent enhancement, potentiation or synergism of the abuse liability of the regulated drug (or any of its salts) that it contains; or if it consists of a single psychotropic substance in dosage form, is compounded with a counteracting non-psychotropic or non-narcotic material;

(vi) is devoid of any prohibited drug under Schedule IV of the 1961 Convention on Narcotic Drugs or another psychotropic drug not under domestic or international control but with known abuse potential; and

(vii) is not in injectable form.

This last criterion does not apply when the preparation has high therapeutic usefulness. As herein construed, a preparation in injectable form is deemed to have high therapeutic usefulness if it is very effective for the indicated use, is safely administered by skilled professionals and is widely used in medicine.

Section 2

Jurisdiction:

The dangerous Drugs Board has jurisdiction and control over all exempt dangerous drug preparations except where registration of the product and determination of its efficacy, purity and safety are concerned which are within the functions of the Bureau of Food and Drugs under R.A. 3720, as amended.

Section 3

Control measures not required for Exempt Regulated Preparations:

Exempt regulated preparations are not subject to the following control measures:

(a) Compulsory use of DDB Form 1-72 or Yellow Prescription.

The preparation shall, however, be prescribed through an Ordinary Prescription wherein the S-2 licence of the practitioner shall be indicated.

(b) Recording in the Dangerous Drugs Record Book.

The preparation should, however, be recorded in the Additional Dangerous Drugs Record Book.

Section 4

Effect of the presence of a prohibited drug:

When the exempt regulated preparation is compounded with a prohibited drug, the preparation shall be deemed to be a prohibited drug.

Section 5

Prohibition against sample distribution:

Exempt regulated drug preparation shall not be distributed as samples to the practitioners or to the general public.

Section 6

Advertising:

Exempt dangerous drug preparations may be advertised in scientific journals. In no case, however, shall such preparations be advertised to the general public.

Section 7

Sanctions:

Any individual or entity found, after notice and hearing, guilty of violating this regulation shall be penalized with the sanctions embodied in section 36 (1), article VIII of Republic Act No. 6425, as amended, 1/ without prejudice to the institution of criminal proceedings if circumstances so warrant.

Section 8

Repealing clause:

All regulations inconsistent herewith are hereby repealed or modified accordingly.

Section 9

Effectivity:

This regulation shall take effect after the completion of its publication in the Official Gazette and in a newspaper of general circulation once a week for two (2) consecutive weeks, whichever is earlier.

TOMAS P. MARAMBA, JR., M.D., M.H.A.
Vice-Chairman
(Undersecretary of Health for
Standards and Regulation)

(Signed)

Notes by the Secretariat

1/ E/NL.1982/43.

2/ Chemical names given in the text were identical to those which appear in the international drug control treaties and are accordingly not reproduced.

3/ E/NL.1976/55.

4/ E/NL.1976/67.