



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 Gouvernement 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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E/NL.1985/25

BOARD REGULATION No. 3 s.1984, 15 August 1984
INCLUSION OF PENTAZOCINE IN THE LIST OF DANGEROUS DRUGS

SECTION 1. Unless specifically excepted, any material, compound, mixture or preparation which contains any quantity of 1, 2, 3, 4, 5, 6-hexahydro-6, 11-dimethyl-3 (3-methyl-2-butenyl)-2, 6-methano-3-benzazocin-8-ol, the international non-proprietary name of which is pentazocine, or by whatever trivial or brand name designated, is hereby classified as Dangerous Drugs and further categorized as Regulated Drug.

SECTION 2. This regulation shall take effect upon completion of its publication in a newspaper of general circulation once a week for two consecutive weeks.

(Signed) J. C. Azurin
Minister of Health
Chairman

E/NL.1985/26

BOARD REGULATION No. 3-A s.1984, 15 August 1984
INCLUSION OF ALFENTANIL IN THE LIST OF DANGEROUS DRUGS

SECTION 1. In accordance with the decision 3(S-VIII) of the Commission on Narcotic Drugs and pursuant to Section 40, Article X of Republic Act No. 6425, as amended, any material, compound, mixture or preparation which contains any quantity of N-[1-[2-(4-ethyl-4, 5-dihydro-5-oxo-1H-tetrazol-1-yl)ethyl]-4-(methoxymethyl)-4-piperidinyl]-N-phenylpropanamide monohydrochloride, the international non-proprietary name of which is alfentanil, or by whatever trivial or brand name designated, is classified as Dangerous Drug and further categorized as Prohibited Drug.

SECTION 2. This regulation shall take effect upon completion of its publication in a newspaper of general circulation once a week for two weeks.

(Signed) J. C. Azurin
Minister of Health
Chairman

E/NL.1985/27

BOARD REGULATION No. 4 s.1984, 14 November 1984
TEMPORARY EXCLUSION OF PENTAZOCINE FROM THE LIST OF
REGULATED DRUGS SUBJECT TO CERTAIN CONDITIONS

Pursuant to the powers vested in it under Section 36 (a) of RA 6425, ^{1/} as amended, and following its decision arrived at in a meeting on this date, the Dangerous Drugs Board hereby temporarily excludes from the list of Regulated Drugs, the drug Pentazocine (1, 2, 3, 4, 5, 6-hexahydro-6, 11-dimethyl-3-(3-methyl-2-butenyl)-2, 6-methano-3-benzazocin-8-ol).

As so excluded, the designated drug shall be subject to the following requirements:

(a) It shall be prescribed through the ordinary prescription form wherein shall be stated the name, address, S-2 licence number and privilege tax receipt number of the prescribing physician as well as the name and address of the patient.

(b) Its sale by the retail drug establishment shall be recorded in the additional opium book.

(c) It shall continue to be governed by the provisions under article 12 concerning Control of the International Trade, and article 13 concerning the Prohibition of and Restriction on Export and Import under the Convention on Psychotropic Substances 1971.

1/ Note by the Secretariat: E/NL.1976/50.

(d) That the importers, manufacturers, compounders, producers and distributors (wholesaler) thereof shall:

1. Render semi-annual and annual reports to the Dangerous Drugs Board specifying therein the quantities of the drugs to be exported, imported or distributed locally as well as of the drugs used for manufacture;
2. Record such sales in the dangerous drugs book;
3. Monitor all distributions closely and submit to the Board periodic report thereof. All cases of reported drug abuse obtained during such monitor shall be fully documented and submitted to the Board.
4. Submit properly filled DDB Form No. 8-72 (Local Purchase) in every case where purchase of the drug is to be made locally, DDB Form No. 11-72 (Export Authorization) if exportation of the drug is intended, or Form No. 10-72 (Import Permit) if importation is contemplated.

(e) That the drug product will be distributed by the manufacturers, importers, compounders, producers and distributors (wholesaler) only to hospitals (including medical clinics) and reputable outlets.

This temporary exclusion shall cover a period of one year from the date this regulation takes effect, upon expiration of which, the drug shall automatically revert to the category of a regulated drug unless the applicability of the regulation is extended by the Board.

This regulation shall take effect fifteen (15) days following the completion of its publication in a newspaper of general circulation once a week for two consecutive weeks.

(Signed) J. C. Azurin
Minister of Health
Chairman

E/NL.1985/28

BOARD REGULATION No. 1 s.1985, 19 June 1985
INCLUSION OF DOB IN THE LIST OF DANGEROUS DRUGS

SECTION 1. Any material, compound, mixture or preparation which contains any quantity of 2, 5-dimethoxy-4-bromoamphetamine, the international non-proprietary name of which is DOB, or by whatever trivial or brand name designated, is hereby classified as Dangerous Drugs and further categorized as Prohibited Drug.

SECTION 2. This regulation shall take effect upon completion of its publication in a newspaper of general circulation once a week for two consecutive weeks.

(Signed) J. C. Azurin
Minister of Health
Chairman

E/NL.1985/29

BOARD REGULATION No. 1-A s.1985, 19 June 1985
INCLUSION OF MDA IN THE LIST OF DANGEROUS DRUGS

SECTION 1. Any material, compound, mixture or preparation which contains any quantity of 3, 4-methylenedioxamphetamine, the international non-proprietary name of which is MDA, or by whatever trivial or brand name designated, is hereby classified as Dangerous Drugs and further categorized as Prohibited Drug.

SECTION 2. This regulation shall take effect upon completion of its publication in a newspaper of general circulation once a week for two consecutive weeks.

(Signed) J. C. Azurin
Minister of Health
Chairman

E/NL.1985/30

BOARD REGULATION No. 2 s.1985, 17 July 1985
INCLUSION OF FLUNITRAZEPAM IN THE LIST OF DANGEROUS DRUGS

SECTION 1. Any material, compound, mixture or preparation which contains any quantity of 5-(o-fluorophenyl)-1, 3-dihydro-1-methyl-7-nitro-2H-1, 4-benzodiazepin-2-one, the international non-proprietary name of which is flunitrazepam, or by whatever trivial or brand name designated, is hereby classified as Dangerous Drug and further categorized as Regulated Drug.

SECTION 2. This regulation shall take effect after the lapse of fifteen (15) days from its second publication in a newspaper of general circulation.

(Signed) J. C. Azurin
Minister of Health
Chairman

E/NL.1985/31

BOARD REGULATION No. 2-A s.1985, 17 July 1985
EXEMPTING DRUG PREPARATIONS CONTAINING CERTAIN BENZODIAZEPINES
FROM CERTAIN REQUIREMENTS OF RA 6425, AS AMENDED

Pursuant to the powers vested in the Dangerous Drugs Board under Section 36 (a), Article VIII of RA 6425, as amended, and in accordance with the decision in its meeting of 17 July 1985, the Dangerous Drugs Board hereby prescribes the following relating to benzodiazepine substances and preparations thereof:

Section 1. For the purpose of this Board Regulation, the following benzodiazepine substances are hereby categorized as Category A and Category B, as follows:

Category A:

International Nonproprietary Names (INN) 2/

- (a) Clonazepam
- (b) Diazepam
- (c) Flurazepam
- (d) Lorazepam
- (e) Triazolam

Category B:

- (a) Alprazolam
- (b) Bromazepam
- (c) Camazepam
- (d) Chlordiazepoxide
- (e) Clobazam
- (f) Clorazepate
- (g) Clotiazepam
- (h) Cloxazolam

2/ Note by the Secretariat: Chemical names were given in the text for the substances listed. These names were identical to those which appear in the international drug control treaties and are accordingly not reproduced.

- (i) Delorazepam
- (j) Estazolam
- (k) Ethyl Loflazepate
- (l) Fludiazepam
- (m) Halazepam
- (n) Haloxazolam
- (o) Ketazolam
- (p) Loprazolam
- (q) Lormetazepam
- (r) Medazepam
- (s) Nimetazepam
- (t) Nordazepam
- (u) Oxazepam
- (v) Oxazolam
- (w) Pinazepam
- (x) Prazepam
- (y) Temazepam
- (z) Tetrazepam

Section 2. All pharmaceutical preparations containing quantities of benzodiazepine substances listed under Category A are hereby exempted from the requirements of the Dangerous Drugs Act of 1972, as amended, and shall be subject to the following requirements:

(a) Registration: (With whom to register)

- (a) Dangerous Drugs Board. Applications for registration and issuance of licenses to qualified persons or entities which handle or intend to deal in dangerous drugs and exempt preparations shall be filed with the Dangerous Drugs Board, or with the Board's authorized representatives if situated outside Metro Manila area.
- (b) Bureau of Food and Drugs. Drug preparations containing quantities of benzodiazepine substances shall be duly registered with the Bureau of Food and Drugs.

(b) Record-keeping:

(a) Records as it applies to exempt preparations:

Manufacturers of exempt preparations shall keep records as to the quantity of each benzodiazepine substance used in the manufacture of exempt preparations:

- (a) as to the dosage form
 - (b) total quantity produced
 - (c) disposal of exempt preparations manufactured
- (b) Retail establishments shall record all transactions of said preparations in the additional Opium Record Book which is duly registered with the Dangerous Drugs Board.

(c) Reporting:

- (a) Semi-Annual and Annual reports of transactions in said preparations shall be submitted to the Board by importers, manufacturers and distributors thereof.

(d) Prescription:

That the said drug preparations shall be dispensed through ordinary prescription wherein the name, address and S-2 (Narcotic Licence) number and Privilege Tax Receipt number 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 (tablets, ampules, etc.) direction for use, signature of doctor.

(e) Inspection:

That all products thereof are subject to inspection by authorized Officers of the Dangerous Drugs Board

- (a) Inspection of licences, as it applies to importation of exempt preparations containing benzodiazepine substances.
- (b) Inspection of licences, as it applies to manufacture of exempt preparations containing benzodiazepine substances.
- (c) Inspection of licences, as it applies to disposal of exempt preparations containing benzodiazepine substances whether in wholesale or retail.

(f) Restriction on export and import:

All bulk importations of any or all of the aforementioned benzodiazepine substances whether in bulk or in dosage form shall be subject to Special Permit for the importation of exempt preparations and Import Permit for the importation of raw materials intended for the manufacture of exempt preparations.

Section 3. All drug preparations containing benzodiazepine substances listed under Category B shall remain as Ordinary Prescription Drugs which shall be subject to the provisions of Administrative Order No. 92, s.1968.

Section 4. All bulk importations of raw materials of any or all of the aforementioned benzodiazepine substances listed under categories A and B shall be considered as Dangerous Drugs and further categorized as Regulated Drugs, and shall be subject to the following requirements:

- (a) Registration. Handlers of Dangerous Drugs are required to register with the Dangerous Drugs Board.
- (b) Record-keeping. Records of transactions of Dangerous Drugs shall be kept in the Dangerous Drugs Record Book (Opium Book) by handlers.
- (c) Reporting requirements. The required statistical reports by importers, manufacturers, producers, exporters and wholesalers of Dangerous Drugs shall be filed with the Dangerous Drugs Board semi-annually and annually.
- (d) Inspection. Bulk importations of dangerous drugs and/or exempt preparations whether of raw materials or in dosage form shall be subject to the requirements of the Dangerous Drugs Board under Board Regulation No. 3-A, s.1983.

Section 5. This regulation shall take effect upon its publication once a week for two consecutive weeks in a newspaper of general circulation.

(Signed) J. C. Azurin
Minister of Health
Chairman