

AMENDMENT OF BOARD REGULATION NO. 2-A, SERIES 1985, PRESCRIBING UNIFORM CONDITIONS/REQUIREMENTS FOR EXEMPTED PHARMACEUTICAL PREPARATIONS CONTAINING ANY OF THE BENZODIAZEPINE SUB...

DDB BOARD REGULATION NO. 1, s. 1987, February 19, 1987

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Pursuant to the powers vested in the Dangerous Drugs Board under Section 36 (a), Article VIII of Republic Act 6425, as amended, Board Regulation No. 2-A, Series of 1985 is hereby amended as follows:

SECTION 1. Definition

Preparation means (i) Any solution or mixture, in whatever physical state, containing benzodiazepine substances; (ii) Any benzodiazepine substances in dosage form.

SECTION 2. Unless specifically classified by regulations as Regulated Drugs, pharmaceutical preparations in whatever form containing a quantity of the following benzodiazepine substances are hereby classified as exempt preparations:

International Non-proprietary
Names (INN)

Chemical Name

a. Alprazolam

8-chloro-1-methyl-6 phenyl-4H-s
triazolo [4,3-a] benzodiazepine

b. Bromazepam

7-bromo-1, 3-dihydro-5-
(pyridil-2H-1, 4-benzo
diazepin-2-one

c. Camazepam

7-chloro-1, 3-dihydro-3
hydroxy-1 methyl-5 phenyl-2H-1,
4-benzodiazepin-2-one
dimethylcarbamate (ester)

d. Chlordiazepoxide

7-chloro-2 (methylamine) 5-phenyl-3H
1, 4-benzodiazepin-4-oxide

e. Clobazam

7-chloro-1-methyl-5- phenyl-1H-1,
5-benzodiazepine-2,4 (3H, 5H)- dione

f. Clonazepam

5-(o- chlorophenyl)-1. 3-dihydro-7
nitro-2H-1 ,4-benzodiazepin-2-one

g. Clorazepate

7-chloro-2, 3-dihydro-2-oxo-
5-phenyl-1-1H 1 ,4-benzodiazepine-
3-carboxylic acid

h. Clotiazepam

5-(chlorophenyl)-7-ethyl-1,
3-dihydro-1- methyl-2H-thieno [2,
3-e]-1, 4-diazepin-2-one

i. Clonazolam

10-chloro-11b-(o- chlorophenyl)-
2, 3, 7, 11b-tetrahydrooxazolo-[3,
2-d] [1, 4] benzodiazepin-6 (5H)-one

j. Delorazepam

7-chloro-5-(o-chlorophenyl)-1,
3-dihydro-2H 1, 4- benzodiazepine-
2-one

k. Diazepam

7-chloro-1, 3-dihydro-1-methyl-
5-phenyl-2H-1, 4-benzodia-
zepin-2-one

l. Estazolam

8-chloro-6-phenyl-4H-s-
triazolo [4, 3-a] [1, 4] benzodiazopine

m. Ethyl Loflazepate

Ethyl-7-chloro-5-(o-fluorophenyl)-
2, 3-dihydro-2-oxo-1H, 4-benzodia-
zepine-3-carboxylate

n. Fludiazepam

7-chloro-5-(o- fluorophenyl)-1, 3-
dihydro-1-methyl-2H-1, 4-benzodiazepine-

2-one

o. Flurazepam

7-chloro-1-[2-diethylamine) ethyl]-5-(ofluorophenyl)-1, 3-dihydro-2H-1, 4-benzodiazepin-2-one

p. Helazepam

7-chloro-1, 3-dihydro-5-phenyl-1-(2, 2, 2-trifluoroethyl)-2H-1, 4-benzodiazepin-2-one

q. Haloxazolam

10-bromo-11b-tetrahydrooxazolo[3,2-d]-benzodiazepine-6 [5H]-one

r. Ketazolam

11-chloro-8, 12b dihydro-2, 8-dimethyl-12b-phenyl-4H [1, 3]-oxazine-[3, 2-d] [1, 4] benzodiazepine-4, 7 (6H)-dione

s. Loprazolam

6-(chlorophenyl)-2, 4-dihydro-2-[4-methyl-1-piperidinyl) methylene]-8-nitro-1H-imidazo [1, 2-a] [1,4] benzodiazepin-1-one

t. Lorazepam

7-chloro-5-(o-chlorophenyl)-1, 3-dihydro-3-hydroxy-2H-1, 4-benzodiazepine-2-one

u. Lormetazepam

7-chloro-5-(o-chlorophenyl)-1,3-dihydro-3-hydroxy-1-methyl-2H-1, 4-benzodiazepin-2-one

v. Medazepam

7-chloro-2, 3-dihydro-1-methyl-5-phenyl-1H-1, 4-benzodiazepine

w. Nimetazepam

1,3-dihydro-1-methyl-7-nitro-5-phenyl-2H-2, 4-benzodiazepin-2-one

x. Nordazepam

7-chloro-1,3-dihydro 5-phenyl-2H-1, 4-benzodiazepin-2-one

y. Oxazepam

7-chloro-1, 3-dihydro-3-hydroxy-
5-phenyl-2H-1, 4-benzodiazepin-2-one

z. Oxazolam

10-chloro-2, 3, 7, 11b-tetrahydro-
2-methyl-11b-phenylloxazolo [3, 2-d] [1, 4]
benzodiazepin-6 (5H)-one

aa. Pinazepam

7-chloro-1, 3-dihydro-5-phenyl-1(2-
propynyl)-2H-1, 4-benzodiazepin-2-one.

ab. Prazepam

7-chloro-1, (cyclopropyl-methyl)-1,3-
dihydro-5-phenyl-1 (2-propynyl)-
2H-1, 4-benzodiazepin-2-one

ac. Temazepam

7-chloro-1, 3-dihydro 3-hydroxy-1-
methyl-5-phenyl-2H 1, 4-benzodiazepin-2-
one

ad. Triazolam

8-chloro-6-(o-chlorophenyl)-1-
methyl-4H-S- triazolo [4,3-a] [1,4] Benzodiazepine

ae. Tetrazepam

7-chloro-5-(cyclohexen-1-yl)-1, 3-
dihydro-1-methyl-2H 1, 4-benzodiazepin
-2 one

Provided, however, that the benzodiazepine substance is not in association with (a) another benzodiazepine substance, (b) a regulated drug, (c) a prohibited drug, (d) a psychoactive drug not under international control with known abuse potential.

SECTION 3. All exempted benzodiazepine preparations shall be subjected to the following requirements:**a. Registration (With whom to register and file application): — .**

1. Dangerous Drugs Board — all applications for registration and for the issuance of a license 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 of the Metro Manila Area.

2. Bureau of Food and Drugs — Benzodiazepine drug preparations shall be duly registered with the Bureau of Food and Drugs.

b. Records to be maintained

Every person or any establishment registered with the DDB and BFD as Importer, Manufacturer, Producer, Compounder, Distributor at wholesale or retail, shall maintain a true and accurate record for any benzodiazepine drug preparations, as defined herein, received by him and its disposal, in a record book designed for the purpose to be kept for at least two (2) years after the last entry has been made, and is subject to inspection and verification at any time of the day at reasonable hours by authorized officers of the DDB. Each entry of D.D. /or drug benzodiazepine preparations received shall be made on the date of receipt of the drugs or preparation. The following data shall appear in the record book:

1. Manufacturer, Compounder, Producer

- a. Date raw materials received.
- b. Name and quantity of raw materials on hand.
- c. Name and total quantity and description of finished product.
- d. Name and address of drug establishment and registry number of the registrant to whom the drug was delivered.
- e. Name and quantity of finished products disposed or sold.
- f. Balance of stock on hand.

2. Importer, Producer

- a. Date of receipt of the raw materials or preparation imported.
- b. Name and quantity of raw material finished drug product imported.
- c. Number of import permit and the date issued by DDB.
- d. Name and quantity of drug disposed or sold.
- e. Name and address of person or establishment to whom it was delivered.
- f. Date of delivery.
- g Balance of Stock on hand.

3. Retailer

- a. Date of receipt of benzodiazepine drug preparations.
- b. Name and quantity of drug received or purchased.
- c. Name and address of supplier.
- d. Date and quantity when drug was disposed or sold under prescription.
- i. Date of prescription
- ii. Name and address of prescriber
- iii. Preparation and quantity prescribed
- iv. Name and address of patient.
- v. Privilege Tax Receipt No. of the prescribing physician.

vi. S-2 (Narcotic license) No. of the prescribing physician.

e. Balance of stock on hand.

Provided, however, that in the case of records of benzodiazepine drug preparations dispensed for in-patients in hospitals and/or similar institution, the following shall be observed:

1. Each entry of benzodiazepine drug preparations disposed of shall be recorded in a prescribed format containing the following information:

Record of Benzodiazepine Drug Preparation In-Patient in Hospital and Similar Institutions

Name of Benzodiazepine Dispensing

Drug of preparation _____ Pharmacist _____ Date _____

Date

Time

Full Name of Patient

Bed No.

Room No.

Quantity:Dispensed

Name of Physician

and thereafter transferred to the additional opium book at the end of the period.

2. At the end of each prescribed period, an ending balance for the day of stocks on hand shall be indicated in the record book in red ink, the quantities of which shall be carried forward to the account for the following day.

3. Recording or dispensing of benzodiazepine drug preparations in the additional opium book shall cover a period of twenty four (24) hours, i.e., from 8:00 a.m. of the preceding day to 8:00 a.m. of the following day.

c. Reporting

Importers, manufacturers, compounders, producers and distributors (wholesalers) thereof shall render semi-annual and annual reports of transactions of benzodiazepine drug preparations on or before the tenth day of the month following the period on which report is rendered to the DDB, which shall show:

1. Name of benzodiazepine drug preparation
2. Size of package
3. Dosage form and dangerous drug content
4. Stocks on hand at the beginning of the period
5. Amount imported
6. Amount locally purchased
7. Total of 4, 5 and 6 — amount available

8. Amount sold to wholesalers
9. Amount sold to retailers
10. Amount used in the preparation of benzodiazepine drug preparations
11. Amount disposed of — totals of 8, 9, 10
12. Balance on hand at the end of the period

d. Prescription/Dispensing

1. In prescribing the exempted benzodiazepine drug preparations, only one drug per prescription should be made. The quantity of tablets and/or capsules of exempted benzodiazepines prescribed should be based on the physician's judgment but should not exceed a week's supply. For ampules, the number should not exceed 3 ampules x 2 ml or 1 ampule x 10 ml per prescription except for hospital use.

Said preparations shall be dispensed through Ordinary Prescription wherein the following should be indicated:

- a) Date of prescription
- b) Name and address of the prescribing physician
- c) Privilege Tax Receipt No. of the prescribing physician
- d) S-2 (narcotic license) No. of the prescribing physician
- e) Name and address of patient
- f) Benzodiazepine transactions to be supplied, the number of drugs prescribed in words and enclosed in parenthesis under the roman numeral to depict the quantity of the drug to be prescribed, its strength and the total no. of units to be supplied.
- g) Direction for use and the word "non-repetition".
- h) Signature of the doctor

e. Inspection. To ensure that Section 25, Article IV, in relation to Section 36 (1), Article VIII, RA 6425, as amended, is being complied with, the Executive Director, the Chief, CRID, DRO's deputized by the Chairman of the Board, may at all times:

- a. enter and inspect any place or premises occupied by a person authorized to deal in benzodiazepine substances/preparations.
- b. require the production of any register, record book, prescription, or other documents relating to dealings/transactions in benzodiazepine substances/ preparations.
- c. Inspect any stocks of benzodiazepine substances/preparations in possession of such person or drug establishment.

f. Export/Import/Special Permit

All bulk importations or exportations of any benzodiazepine drug preparations whether in bulk or in dosage form shall be subject to Special Permit for the importation of exempt preparations and requirements of the DDB under Board Regulation No. 3-A, s. 1983 (Procedures to be followed by Importers of Dangerous Drug and Exempt Preparations in the Philippines).

g. Samples. The giving away of physician samples of benzodiazepine drug preparations is not allowed in

conformity with the provisions of Article 10 of the 1971 Convention on Psychotropic Substances.

h. Advertising. The advertisement of benzodiazepine drug preparations in any form is not allowed.

Warnings or Caution. Packaging or labeling of benzodiazepine drug preparations should conspicuously bear the following information/statements:

1. Direction for use.
2. A frank statement of the principal hazard or hazards involved such as: "Warning — may be habit forming", for the safety of the user.
3. Precautionary measures describing the action to be followed or avoided.
4. Instructions, when necessary or appropriate, for first-aid-treatment.
5. Instructions for handling or storage and the statement "Keep out of reach of Children" or its practical equivalent.

SECTION 4. Benzodiazepine substances other than in preparation form are classified as dangerous drugs and further categorized as Regulated Drugs.

SECTION 5. This Regulation supersedes Board Regulation No. 2-A, Series of 1985.

SECTION 6. Non-compliance or violation of any provision of this Regulation shall be subject to the appropriate provision of RA 3720, as amended, [Sec. 11 (b), Sec. 20b (1) and RA 6425, as amended.

SECTION 7. This Regulation shall take effect upon its publication once a week for two (2) consecutive weeks in a newspaper of general circulation.

Adopted: 19 Feb. 1987

(SGD.) ALFREDO R.A. BENGZON, M.D.

(Secretary of Health)

Chairman

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