

EXEMPTING PHARMACEUTICAL PREPARATIONS CONTAINING PHENOBARBITAL SUBSTANCES FROM CERTAIN REQUIREMENTS OF RA 6425, AS AMENDED

DDB BOARD REGULATION NO. 3, s. 1987, March 19, 1987

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SECTION 1. Definition

- Preparation means (i) Any solution or mixture, in whatever physical state, contain phenobarbital substances;
- (ii) Any phenobarbital substance in dosage form.

SECTION 2. Unless specifically classified by Regulations as Regulated Drugs, all pharmaceutical preparations in whatever form containing a quantity of phenobarbital substances are hereby classified as exempt preparations. Provided, however, that the phenobarbital substance is not in association with: (a) regulated drug; (b) a prohibited drug; (c) a psychoactive drug not under international control with known abuse potential.

SECTION 3. Exempted phenobarbital 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 representative if situated outside of the Metro Manila area.
2. Bureau of Food and Drugs — phenobarbital 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 BFAD as Importer, Manufacturer, Producer, Compounder, Distributor at wholesale or retail, shall maintain a true and accurate record for any phenobarbital drug preparation, 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 dangerous drugs or phenobarbital drug preparations received shall be made on the date of receipt of the drugs or preparations. 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 preparations imported.

(b) Name and quantity of raw materials/finished drug product imported.

(c) Number of import permit and the date issued by the 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 phenobarbital 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 Number of the prescribing physician

vi. S-2 (narcotic license) number of the prescribing physician

Provided, however, that when a phenobarbital preparation contains not more than 8 mg for oral or injectable use and 16 mg for suppositories, S-2 license of the doctor is not required and the recording will be done in the ordinary prescription book.

(e) Balance of stock on hand.

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

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

Record of Phenobarbital Drug Preparation In-patient in Hospitals and Similar Institutions

Name of Phenobarbital

Drug Preparation _____ Dispensing

Pharmacist _____ Date _____

Date Time Full Name of Patient Bed No. Room No. Quantity

Dispensed Name

Physician

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

ii. 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.

iii. Recording or dispensing of phenobarbital 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 phenobarbital 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 phenobarbital 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 phenobarbital drug preparations
11. Amount disposed of — total of 8, 9, 10
12. Balance on hand at the end of the period.

d. Prescription/Dispensing

In general, the quantity of phenobarbital preparations prescribed/dispensed should be based on the physician's judgment but should not exceed a week's supply; provided, however, that when the patient is an epileptic case, a supply of not more than sixty (60) days may be prescribed by the attending physician.

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

1. Date of prescription
2. Name and address of the prescribing physician

3. Privilege Tax Receipt Number of the prescribing physician
4. S-2 (narcotic license) number of the prescribing physician
5. Name and address of patient
6. Phenobarbital 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 number of units to be supplied.
7. Direction for use and the word non-repetition
8. Signature of the doctor

Provided, however, that when a phenobarbital preparation contains not more than 8 mg for oral or injectable use and 16 mg for suppositories, S-2 license of the doctor is not required.

A physician with an S-2 license, whose area of residence/clinic/office is within a 5-kilometer radius and beyond of a drugstore which is not dispensing phenobarbital preparation may store phenobarbital preparations for use in treating convulsions/epilepsy, provided, however, that he/she shall maintain record of receipts and disposal in additional opium book.

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, Drug Regulation Officers, and such other officers deputized as Drug Regulation Officers by the Chairman of the Board, may at all times:

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

f. Export/Import/ Special Permit

All bulk importations or exportations of any phenobarbital drug preparation 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 (See p. 188).

g. Samples

The giving away of physician samples of phenobarbital 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 phenobarbital drug preparations in any form to the general public is not allowed.

i. Warnings or Caution:

Packaging or labelling of phenobarbital 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. Phenobarbital substances other than in preparation form remain classified as dangerous drugs and further categorized as regulated drugs.

SECTION 5. 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 6. This Regulation shall take effect upon its publication once a week for two (2) consecutive weeks in a newspaper of general circulation.

Adopted: 19 March 1987

(SGD.) ALFREDO R.A. BENGZON, M.D.
(Secretary of Health)
Chairman

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