GOVERNMENT OF ZAMBIA

STATUTORY INSTRUMENT No. 47 OF 1993

The Pharmacy and Poisons Act
(Laws, Volume XI, Cap. 536)

The Pharmacy and Poisons (Medicines) (Importation, Manufacture and Sale) Order, 1993

IN EXERCISE of the powers contained in section *twenty-five* and *twenty-six* of the Pharmacy and Poisons Act and upon the recommendation of the Board, the following Order is hereby issued:

Title

1. This Order may be cited as the Proprietary Medicines (Importation and Manufacture) Order, 1993.

Interpretation

2. In this Order, unless the context otherwise requires—

" medicines " means all medicines including any secret, patent, proprietary, generic or homoeopathic medicine or preparation;

" Board " means the Pharmacy and Poisons Board.

Import or manufacture of medicine

3. (1) No person shall import or manufacture any medicine without an appropriate licence, and a product licence from the Board.

(2) An application for an importation, a manufacturing or licence under this paragraph shall contain the following information:

(a) the name and address of the application;
(b) the name of the medicine;
(c) the dosage form of the medicine,
(d) the active constituents of the medicine;
(e) the indications and method of use;
(f) the contra-indications, warnings, precautions;
(g) the composition;
(h) the shelf life;
(i) the containers and packaging;
(j) the labelling

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(k) the method of sale, that is to say, whether it is to be by—

(i) prescription sale only;

(ii) pharmacy sale only; or

(iii) general sale;

(l) the manufacturer's name and address;

(m) the distributors name and address;

(n) the World Health Organisation (WHO) pharmaceutical certificate of quality and free sale certificate;

(o) the name and designation of the person signing the application; and

(p) any other information which may be requested by the Board.

(3) Where the medicine to be imported or manufactured is to be marketed in Zambia for the first time, the application shall, in addition to the information submitted under sub-paragraph (2), contain the following:

(a) the chemistry of the medicine;

(b) the pharmacological data;

(c) the toxological data;

(d) the teratology;

(e) the clinical studies; and

(f) the countries in which the sale of the medicine has been authorised.

(4) This regulation shall not apply to—

(a) a person importing medicine for his own use or use by members of his family where the quantity imported is not more than a year's supply;

(b) a person importing medicine to the order of a physician, dentist or veterinary surgeon for administration to an individually named person or animal;

(c) an authorised seller who manufactures medicine for sale in his own pharmacy;

(d) medicine manufactured in a hospital; and

(e) medicine donated charitably for which no charge is made to the patient.

Advertising

4. (1) No person shall advertise medicine unless the advertisement conforms with the information submitted to obtain a licence.

(2) Medicine which is sold by prescription only shall not be advertised to the general public without prior written authority of the Board.

Labelling

5. (1) Every package or container of medicine shall be labelled to show—

(a) the name of the medicine;

(b) the pharmacological properties;

(c) the names and quantities of active ingredients;

(d) the quality of the medicine;

(e) the directions for use;

(f) the contra-indications, warnings and precautions;

(g) the storage instructions, when necessary;

(h) the expiry date;

(i) the batch number;

(j) the date of manufacture;

(k) the licence number;

(l) the name and address of the manufacturer;

(m) the method of sale, that is to say, if it is to be by—

(i) prescription only;

(ii) pharmacy sale only; or

(iii) general sale.

(2) When the space on the container of medicine is not adequate to accommodate the information specified in sub-paragraph (1), the container shall be labelled to indicate the particulars specified under paragraphs *(a)*, *(c)*, *(d)*, *(h)* and *(n)* of sub-paragraph (1):

Provided that the particulars specified under paragraph *(b)*, *(e)*, *(f)*, *(g)*, *(i)*, *(j)*, *(k)* and *(l)* of sub-paragraph (1) shall be set out on the package.

(3) Where the container of medicine is in the form of a blister or strip packet, the container shall be labelled to indicate the particulars specified in paragraphs *(a)* and *(m)* of sub-paragraph (1) and the other particulars specified in that sub-paragraph shall be set out on the package.

(4) The provisions of this paragraph shall not apply to dispensed medicine:

Dispensed medicine

6. (1) Every package or container of dispensed medicine shall be labelled to indicate—

(a) the name of the person to whom the medicine is to be administered;

(b) the dosage or where the medicine is to be used;

(c) the date on which the medicine is dispensed; and

(d) any other information necessary to ensure the correct use of the medicine.

(2) A package or container of dispensed medicine may indicate the name and address of suppliers of the medicine.

(3) Where a package or container of dispensed medicine is to be administered to an animal, the package or container shall be labelled to indicate—

(a) the name and address of the person in control of the animal;

(b) name and address of the suppliers of medicine;

(c) the date on which the medicine is dispensed; and

(d) any other information necessary to ensure the correct use of the medicine.

Sale of medicine

7. (1) No person shall sell by retail or otherwise supply medicine in a place other than a pharmacy except with the written authority of the Board.

(2) Where the medicine is to be sold, under sub-paragraph (1) in a place other than a pharmacy—

(a) it shall be sold in the original package labelled with—

(i) full instructions for use;

(ii) contra-indications, warnings and precautions; and

(b) the package shall be marked in a conspicuous way with the letters "G S" that is, for general sale.

(3) No physician, dentist or veterinary surgeon shall sell medicine unless it is in a package for an individual patient's use only.

(4) No wholesaler, manufacturer, or importer shall sell medicine to any person other than a pharmacist unless the medicine is for general use.

(5) Except for herbal or traditional medicine containing poison, this paragraph shall not apply to herbal or traditional medicine.

Parenteral injection of medicine

8. (1) No person shall supply medicine which is administered by parenteral injection to the general public without prescription except—

(a) in cases of diabetic conditions; or

(b) where specified written authority has been obtained from the Board.

(2) In this regulation " parenteral injection " means injection by breach of skin or mucous membrane.

Revocation of S.I. No. 52 of 1989

9. The Proprietary Medicine (Importation and Manufacture) Order, 1989, is hereby revoked.

DR B. M. KAWIMBE,
Minister of Health

LUSAKA
19th March, 1993
[MH.101/4/20]