

CHAPTER 310

THE THERAPEUTIC SUBSTANCES ACT (Repealed by Act No. 14 of 2004)

ARRANGEMENT OF SECTIONS

PART I

PRELIMINARY

Section

1. Short title
2. Interpretation

PART II

CONTROL OF IMPORTATION, EXPORTATION, POSSESSION, SALE, DISTRIBUTION AND USE OF CERTAIN THERAPEUTIC SUBSTANCES

3. Substances to which Part II applies
4. Restriction of importation and exportation of substances to which Part II applies
5. Control of sale and supply of substances to which Part II applies
6. Control of administration of substances to which Part II applies
6. Control of administration of substances to which Part II applies
7. Control of dispensing of substances to which Part II applies
8. (*Repealed by No. 22 of 1972*)
9. Regulations

PART III

MISCELLANEOUS PROVISIONS

10. Powers of search and inspection
11. Penalty and forfeiture
12. Offences by companies
13. Licences and authorities

SCHEDULE-Substances to which Part II applies.

CHAPTER 310

THERAPEUTIC SUBSTANCES

37 of 1968
22 of 1972
86 of 1986
13 of 1994

An Act to control the importation, exportation, possession, sale, distribution and use of certain therapeutic substances; and to provide for matters incidental thereto.

[*1st April, 1972*]

PART I

PRELIMINARY

- | | | |
|----|--|----------------|
| 1. | This Act may be cited as the Therapeutic Substances Act. | Short title |
| 2. | In this Act, unless the context otherwise requires- | Interpretation |
| | "authorised seller of poisons" has the meaning assigned to it by the Pharmacy and Poisons Act; | Cap. 299 |
| | "dental surgeon" means a person registered as a dental surgeon under the Medical and Allied Professions Act; | Cap. 297 |
| | "medical practitioner" means a person registered as a medical practitioner under the Medical and Allied Professions Act; | Cap. 297 |

"Pharmacy and Poisons Board" means the Board established under the provisions of section *three* of the Pharmacy and Poisons Act; Cap. 299

"preparation" includes compound, mixture and salt;

"veterinary surgeon" means a person registered as a veterinary surgeon under the Veterinary Surgeons Act; Cap. 243

"wholesale dealer" means any person holding a licence under the provisions of subsection (2) of section *sixteen* of the Pharmacy and Poisons Act. Cap. 299

PART II

CONTROL OF IMPORTATION, EXPORTATION, POSSESSION, SALE, DISTRIBUTION AND USE OF CERTAIN THERAPEUTIC SUBSTANCES

3. The substances to which this Part applies are the substances specified in the Schedule and any other therapeutic substances which may from time to time be added to that Schedule by regulations made under this Part. Substances to which Part II applies
4. It shall not, except under a licence granted by the Minister, be lawful for a person to import into or to export from Zambia a substance to which this Part applies. Restriction of importation and exportation of substances to which Part II applies
5. (1) Subject to the provisions of subsection (2), no person shall sell or otherwise supply a substance to which this Part applies or any preparation of which any such substance is an ingredient or part unless- Control of sale and supply of substances to which Part II applies

(a) he is a medical practitioner, a dental surgeon or a person acting in accordance with the directions of any such practitioner or surgeon, and the substance or preparation is sold or supplied for the purposes of treatment by or in accordance with the directions of that practitioner or surgeon; or

(b) he is an authorised seller of poisons, and the substance or preparation is sold or supplied under the authority of a prescription signed and dated by a medical practitioner, dental surgeon or veterinary surgeon.

(2) The provisions of subsection (1) shall not apply to the sale or supply of any substance to which this Part applies or any preparation of which any such substance is an ingredient or part-

(a) for the purpose of being exported;

(b) to any person conducting a hospital, clinic, nursing home or other institution which is approved by the Minister and which provides medical, surgical, dental or veterinary treatment;

(c) to any person conducting an institution or business which has among its recognised activities the conduct of scientific education or research for use by persons engaged in that education or research;

(d) to a person authorised under section *ten*;

(e) to a Government analyst;

(f) to any person or institution authorised in writing by the Minister; or

(g) by way of wholesale dealing if that sale or supply is made-

(i) to a medical practitioner, dental surgeon or veterinary surgeon;

(ii) to an authorised seller of poisons; or

(iii) to a wholesale dealer.

6. (1) No person shall administer to any human being by way of treatment a substance to which this Part applies or a preparation of which any such substance is an ingredient or part unless he is a medical substances to Control of administration of

practitioner, a dental surgeon or a person acting in accordance with the directions of such a practitioner or surgeon. which Part II applies

(2) The provisions of subsection (1) shall not apply to insulin.

7. (1) A prescription signed by a medical practitioner, a dental surgeon or a veterinary surgeon authorising the sale or supply of a substance to which this Part applies or a preparation of which any such substance is an ingredient or part shall not, subject as hereinafter provided, be dispensed on more than one occasion or more than three months after the date on which it was signed: Control of dispensing of substances to which Part II applies

Provided that, if the prescription expressly directs that it may be dispensed on a specified number of occasions or at specified intervals in a specific period, it may be dispensed in accordance with that direction.

(2) Notwithstanding the provisions of subsection (1), insulin may be sold or supplied any number of times under a prescription of a medical practitioner.

8. *(Repealed by No. 22 of 1972)*

9. For the purpose of preventing the improper use of the substances to which this Part applies, the Minister may by regulations provide for controlling the importation, exportation, sale, possession, distribution, use and labelling of those substances, and in particular, but without prejudice to the generality of the foregoing powers, for- Regulations

(a) adding to the Schedule any therapeutic substance which, in the opinion of the Minister, is capable of causing danger to the health of the community if used without proper safeguards:

(b) excluding any therapeutic substance or preparation thereof from the operation of this Part of of any of the provisions thereof;

(c) prohibiting, regulating or restricting the manufacture of the substances to which this Part applies;

(d) controlling the importation, exportation, transport, labelling, possession, storage or safe custody of the substances to which this Part applies;

- (e) regulating the issue by any medical practitioner, dental surgeon or veterinary surgeon of prescriptions containing a substance to which this Part applies and the dispensing of any such prescriptions;
- (f) prescribing the fees for licence;
- (g) prescribing the form of licences under this Part and of applications therefor; and
- (h) prescribing any other matter which under this Part is to be prescribed.

PART III

MISCELLANEOUS PROVISIONS

10. (1) Any Government Medical Officer, any police officer or any other person duly authorised in writing in that behalf by the Pharmacy and Poisons Board, in this Part referred to as an authorised officer, may, for the purpose of securing compliance with this Act, at all reasonable times enter any business premises in which he has good cause to suspect that a breach of law in relation to the substances to which Part II applies has been committed, and may make such examination and inquiry and do such other things, including the taking of samples on payment, as may be necessary for ascertaining whether the provisions of this Act are being complied with. Powers of search and inspection

(2) Any person who wilfully delays or obstructs an authorised officer in the lawful exercise of his powers under this section or fails to produce or conceals or attempts to conceal any substance to which Part II applies or any books, stocks or documents relating to such substance or refuses to allow any sample to be taken, or to give information which he is duly required to give under this section, is guilty of an offence.

(3) An authorised officer specially authorised by the Pharmacy and Poisons Board and exercising his powers under this section shall produce his authorisation on demand.

11. (1) Any person who contravenes any provision of this Act is guilty of an offence and is liable on conviction to a fine not exceeding three thousand penalty units or, in the case of a second or subsequent Penalty and forfeiture

conviction under this Act, to such a fine or to imprisonment for a period not exceeding six months, or to both

(2) (2) A person convicted of an offence under this Act shall forfeit to the Republic all substances in respect of which the offence was committed, and the court before which he is convicted may order those substances to be destroyed or otherwise disposed of as the court thinks fit.

(As amended by Act No. 13 of 1994)

12. Where a person convicted of an offence against this Act is a company, the chairman and every director and every officer concerned in the management of the company shall be guilty of the like offence unless he proves that the act constituting the offence took place without his knowledge or consent. Offences by companies

13. (1) A licence or authority issued or granted for the purposes of this Act by the Minister may be issued or granted on such terms and subject to such conditions (including, in the case of a licence, the payment of a fee) as the Minister thinks proper. Licences and authorities

(2) Whenever the Minister is empowered under the provisions of this Act to issue any licence or authority, he may delegate to the Director of Medical Services such power, subject to the right of any person to whom the issue of such licence or authority has been refused to appeal in writing to the Minister against such refusal.

SCHEDULE

(Section 3)

SUBSTANCES TO WHICH PART II APPLIES

1. Antibiotics, any antimicrobial or antifungal substances synthesised by bacteria, fungi or protozoa, and any substances the chemical properties of which are identical with or similar to any such antimicrobial or antifungal substances but which are not produced from living organisms, being substances which are used in the specific treatment of infections; the following substances, their salts or derivatives and the salts of their derivatives:

Actinomycin D	Gentamicin
Amikacin	Gramicidin
Amphotericins	Griseofulvin
Amphotericin B	Kanamycin
Antitoxin	Kefoconazole
Asphernamic	Lincomycin
Bacitracin	Miconazole
Bleomycin	Mitomycin
Capreomycin	Moxalacturn
Carbomycin	Neomycin
Cefactor	Novobiocin
Cefadroxil	Nyastatin
Cefamandole	Nystantin
Cefazolin	Oleandomycin
Cefoperazone	Oxytetracycline
Cefotaxime	Penicillin
Cefoxitin	Plicamycin
Cephalexin	Polymixins
Cephalothin	Puromycin
Cephaprin	Rifampicin
Cephradine	Ristocetins
Chloramphenicoln	Spectinomycin
Chlortetracycline	Spiramycin
Clindamycin	Streptomycin
Cycloserine	Tetracycline
Daunorubicin	Tobramycin
Demethylchlortetracycline	Toxin
Erythromycin	Vaccine
Flucytosine	Vancomycin
Framycetin	Viomycin
Fumagillin	Virus

2. Corticotrophin.
3. Insulin.
4. Preparations of the posterior lobe of the pituitary body for use by injection.
5. Cortisone, hydrocortisone, prednisone and prednisolone; their esters; derivatives of these substances with hydroxyl or alkyl groups of hologens as substituents and esters and salts of esters of such derivatives.
6. Isoniazid; its salts.
7. Blood: its components and derivatives.
8. Therapeutic serum.
9. Allergic product or analogous product.

(As amended by SIs Nos. 86 of 1986 and 54 of 1990)

SUBSIDIARY LEGISLATION

THERAPEUTIC SUBSTANCES

SECTIONS 5 AND 9-THE THERAPEUTIC SUBSTANCES REGULATIONS Regulations by the Minister

*Statutory
Instrument
32 of 1972
Act No.
13 of 1994*

- | | | |
|----|--|---|
| 1. | These Regulations may be cited as the Therapeutic Substances Regulations. | Title |
| 2. | In these Regulations, unless the context otherwise requires- | Interpretation |
| | "pharmacist" means a person registered as a pharmacist under the Medical and Allied Professions Act; | Cap. 297 |
| | "prescription" means any writing or document signed by a registered medical practitioner, dentist or a veterinary surgeon whereunder medicine is prescribed for the use of the person named therein; | |
| | "recognised name" means a name recognised and contained in the British Pharmacopoeia, British Pharmaceutical Codex, British Veterinary Codex or British National Formulary; | |
| | "substance" means any substance mentioned in the Schedule to the Act or any preparation containing such substance. | |
| 3. | (1) Every person who is granted a licence under section <i>four</i> of the Act shall- | Conditions relating to an import and export licence |
| | (a) produce all such documents, as he may be required to do by the Minister, or by any other authorised officer, relating to the manufacture and testing of any batch of any substance exported from or imported | |

into Zambia;

(b) retain records of all transactions in respect of imports, exports or sales of all such substances for a period of at least one calendar year from the respective dates of expiry printed on the respective labels of each batch of such substances.

(2) A licence granted under section *four* of the Act shall specify the period for which, and the premises in respect of which, it is issued, and shall be in the form prescribed in the First Schedule.

(3) The fee payable for such licence shall be thirty fee units per annum.

(As amended by Act No. 13 of 1994)

4. No person shall-

(a) manufacture on any premises any substance unless an approval in writing for such manufacture is granted to him by the Minister;

(b) carry on any business in which a substance is either manufactured or compounded for the treatment of human ailments unless such manufacture or compounding is done under the care and direct supervision of a pharmacist.

Conditions as to
manufacture and
compounding of
substances

5. A prescription must be-

(a) signed and dated by, and bear the name and address of, the prescriber, and also the name and address of the person for whom it is intended, but in the case of a prescription for veterinary purposes, the name and address of the person to whom it is to be delivered;

(b) retained for a period of at least two years after the date of dispensing thereof.

Prescriptions

6. (1) No substance shall be sold, or offered for sale, unless it is contained in a sealed container labelled with the following particulars:

Labelling

(a) the name and address of the maker;

(b) the recognised name of the substance, in letters no less conspicuous than those in which the proprietary name, if any, is stated,

which should appear immediately after or under such proprietary name;

(c) a distinctive batch number, being the number by reference to which the details of manufacture and tests carried out by the manufacturer on the substance contained in such container are recorded;

(d) a statement showing potency which shall relate-

(i) in the case of tablets, capsules, single dose injections or similar articles, to each article;

(ii) in the case of a mixture, elixir or similar preparation, to a stated dose volume of the mixture, elixir or similar preparation; and

(iii) in the case of a powder, solution or ointment, to the percentage of substance contained in the powder, solution or ointment;

(e) where the substance is a solid, liquid or in the form of tablets, capsules or similar articles-

(i) in the case of a solid, the total weight of the contents of the container;

(ii) in the case of a liquid, the total volume of liquid in the container; and

(iii) in the case of tablets, capsules or similar articles, the total number of such articles in the container;

(f) the expiry date, that is to say, the date up to which a preparation may be expected to retain its potency if stored in accordance with any special instructions shown on the label;

(g) special storage instructions if any.

(2) When a preparation is contained in an ampoule, cachet or similar article, it shall not be necessary to label the article itself if the box or other covering in which such article is enclosed is duly labelled.

(3) Subject to regulation 5, the provisions of sub-regulation (1) shall not apply to a substance dispensed by an authorised seller of poisons in accordance with the prescription of a medical practitioner, dental surgeon or veterinary surgeon.

7. No person shall, except with the written authority of a medical practitioner, dental surgeon or veterinary surgeon, sell or offer for sale any substance after the expiry date shown on the label. Sale after expiry date

8. The provisions contained in Part II of the Act shall not apply to the substances or preparations contained in the Second Schedule. Exemptions

9. The provisions of subsection (1) of section five of the Act shall not apply to the institutions named in the Third Schedule. Approved institutions

FIRST SCHEDULE

(Regulation 3)

THE THERAPEUTIC SUBSTANCES ACT

*IMPORT/EXPORT LICENCE

(Section 4)

File Ref. No.

Licence No.

Date .

Messrs

of

carrying on business in

at

are hereby authorised to *import/export the following Therapeutic Substances *into/from Zambia during the calendar year(s) 19.....: 19.....:

<i>Therapeutic Substance</i>	<i>Quality</i>	<i>Form of Preparation</i>
-----	-----	-----
-----	-----	-----
-----	-----	-----
-----	-----	-----

subject to the conditions that

This Licence is valid until the , 19

Director of
Medical Services,
Ministry of
Health

*Delete where necessary

SECOND SCHEDULE

(Regulation 8)

EXEMPTIONS

1. Feedstuff intended solely for feeding pigs or poultry and containing not more than one part by weight of an antibiotic or mixture of antibiotics in ten thousand parts by weight of feeding stuff:

Provided that the following labelling requirements are complied with:

- (a) the quantity by weight of antibiotic added per tonne of feedstuff is stated;
- (b) the purpose for which the feedstuff is intended to be used;
- (c) particulars relating to storage and expiry date are stated.

2. Supplements for feedstuff intended solely for feeding pigs or poultry which contain not more than one part of an antibiotic or mixture of antibiotics in ninety parts by weight of such supplement:

Provided that the container in which any such supplement is contained is suitable for preserving the potency of the antibiotic, and the label on the container states-

- (a) the name of the supplement;
- (b) the purpose for which it is intended to be used;
- (c) the nature of the diluent;
- (d) the weight of the contents;
- (e) the quantity by weight of antibiotic in a stated weight of supplement; and

(f) the date up to which the container may be expected to contain the amount of antibiotic specified if stored in accordance with the conditions stated on the label.

3. Preparations for use in horticulture containing an antibiotic or mixture of antibiotics:

Provided that the antibiotic is mixed with materials which will render the preparation unfit for use in medical, surgical, dental or veterinary treatment and also unfit for human consumption.

THIRD SCHEDULE

(Regulation 9)

APPROVED INSTITUTIONS

1. All Government hospitals, clinics or similar institutions having a medical practitioner on their staff or whose orders have been countersigned by a Provincial Medical Officer.

2. All mission hospitals, clinics or similar institutions in respect of orders countersigned by a Provincial Medical Officer.

3. All the hospitals, clinics or similar institutions in which the Republic has or retains more than fifty per centum interest, having a medical practitioner on their staff or whose orders have been countersigned by a Chief Medical Officer.

4. Institutions of the Department of Veterinary and Tsetse Control Services of the Ministry of Rural Development whose orders for substances are countersigned by a Veterinary Surgeon.