Zambia

Therapeutic Substances Act, 1968

Chapter 310

Legislation as at 31 December 1996

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Chapter 310

Commenced on 1 April 1972

[This is the version of this document at 31 December 1996.]

[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.

Part I – Preliminary

1. Short title

This Act may be cited as the Therapeutic Substances Act.

2. Interpretation

In this Act, unless the context otherwise requires—

"**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. Substances to which Part II applies

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.

4. Restriction of importation and exportation of substances to which Part II applies

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.

5. Control of sale and supply of substances to which Part II applies

(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—

(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. Control of administration of substances to which Part II applies

(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 practitioner, a dental surgeon or a person acting in accordance with the directions of such a practitioner or surgeon.

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

7. Control of dispensing of substances to which Part II applies

(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:

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. Regulations

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—

(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. Powers of search and inspection

(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.

(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. Penalty and forfeiture

(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 thounsand penalty units or, in the case of a second or subsequent conviction under this Act, to such a fine or to imprisonment for a period not exceeding six months, or to both

(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. Offences by companies

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.

13. Licences and authorities

(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.

(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]