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SCHEDULE**THE LAWS OF BARBADOS**

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CHAPTER 330

THERAPEUTIC SUBSTANCES

An Act to regulate the manufacture, importation, storage, sale and supply of penicillin and other antibiotics, and of sulphonamide drugs and other therapeutic substances.

1949-40.
L.N. 159/
1957.
L.N. 168/
1967.

[1st December, 1950] Commence-
ment.

1. This Act may be cited as the Therapeutic Substances Act. Short title.

2. For the purposes of this Act, the expression "Minister" means the Minister responsible for Health. Inter-
pretation.

3. This Act shall apply to the drugs and therapeutic substances specified in the Schedule and to any other drugs or therapeutic substances which may from time to time be added to the Schedule by regulations. Drugs to
which Act
applies.

Schedule.

4. (1) No person shall manufacture for sale or supply any drug or therapeutic substance to which this Act applies unless he is the holder of a licence granted for this purpose by the Licensing Authority. No manu-
facture or
sale of drugs
without a
licence.

(2) For the purposes of this Act the Licensing Authority shall be the Chief Medical Officer.

5. (1) Subject to this section, no person shall sell or supply any drug or therapeutic substance specified in the Schedule or any preparation of which any such drug or substance is an ingredient or part, unless— Restrictions
on sale or
supply of
drugs, etc.
 - (a) he is a duly qualified medical practitioner or a registered dental practitioner or a registered veterinary surgeon or a person acting in accordance with the directions of any such practitioner or surgeon, and the drug, substance or preparation is sold or supplied for the purposes

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of treating by and in accordance with the directions of the practitioner or surgeon; or

- (b) he is a registered druggist and the drug, substance or preparation is sold or supplied under the authority of a prescription signed and dated by any such practitioner or surgeon:

Provided that this subsection shall not apply to the sale or supply of any such drug, substance or preparation—

- (a) by way of wholesale dealing; or
 (b) for the purpose of being exported; or
 (c) to any such practitioner or surgeon; or
 (d) to any authority or person carrying on a hospital, clinic, nursing home or other institution providing medical, surgical, dental or veterinary treatment; or
 (e) to any government department.

(2) A prescription signed by any such practitioner or surgeon, authorising the sale or supply of any such drug, substance or preparation shall not, unless it expressly so directs, 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 within a specified period it shall on the last time of dispensing be retained for a period of one year by the person last dispensing it and be made available for inspection by the Licensing Authority or by any person duly authorised by him to make inspections under this Act.

No drugs to be imported without a licence.

6. It shall not be lawful to import into this Island any drug or therapeutic substance to which this Act applies unless—

- (a) the person is the holder of a licence granted by the the Licensing Authority to import such drug or substance; and
 (b) the drug or substance has been manufactured by a pharmaceutical firm approved by the Minister; and
 (c) the drug or substance complies with such standard of strength, quality and purity as may be prescribed by regulations.

7. No person shall store any drug or therapeutic substance to which this Act applies for the purpose of sale unless he is the holder of a licence granted by the Licensing Authority to store such drugs; and no such licence shall be granted except on proof to the satisfaction of the Licensing Authority that the storage facilities of the applicant are adequate.

Licence to store drugs.

8. Licences issued under this Act shall be in such form as may be prescribed in regulations.

Form of licence.

9. The Licensing Authority may, subject to the approval of the Minister, cancel or suspend for such period as he thinks fit any licence issued under this Act if the holder thereof fails to comply with any of the provisions of this Act or of any regulations or of any of the conditions contained in such licence.

Cancellation of licence.

10. No importer of any drug or therapeutic substance to which this Act applies shall sell or transfer any such drug or substance to any person other than a person registered under the Medical Registration Act (in this Act referred to as a medical practitioner), or as a dentist under the Dental Registration Act, or as a veterinary surgeon under the Veterinary Surgeons Act, unless such person is the holder of a licence to store such drug or substance granted under this Act.

Sale of drugs to medical practitioners, dentists & veterinary surgeons. Cap. 371. Cap. 367. Cap. 374.

11. (1) Any person authorised in writing by or on behalf of the Licensing Authority may at any time between the hours of 6 a.m. and 6 p.m. enter any premises in which he has reason to believe that any drug or therapeutic substance to which this Act applies is being kept which has been acquired or is being kept in contravention of this Act or of any regulations and may carry out such inspection of the premises as he may consider necessary, or may require the occupier or person in charge of the premises to furnish him with such information in connection with such drug or substance as he may consider necessary.

Right to enter and inspect premises.

(2) Any drug or substance in respect of which there has been a breach of any of the provisions of this Act or of any regulations may be seized by such authorised person and on conviction of the offender shall be forfeited to the Licensing Authority.

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Authority to
take samples
of drugs.

12. (1) Any person authorised in writing by or on behalf of the Licensing Authority may require the holder of a licence to store drugs or therapeutic substances granted under this Act to produce samples of any drug or therapeutic substance to which this Act applies which may be in his possession and, on payment of the current market value of any sample may require that it be delivered to him for purposes of assay.

(2) Where any such sample is found on assay to have deteriorated to an extent or to contain toxic substances in amounts which, in the opinion of the Licensing Authority, render it ineffective or unfit for use as a drug or therapeutic substance or to be of a lesser degree of potency than it purports to be, the Licensing Authority may, subject to the approval of the Minister, require to be destroyed the entire stock of the drug or therapeutic substance in the possession of the licensee which bears the same batch identification number as the sample.

Identification
numbers and
date of
manufacture
on con-
tainers.

13. (1) Every container of a drug or therapeutic substance to which this Act applies shall carry a batch identification number and the date of manufacture of such drug or substance; and the contents of any such container supplied by any person and bearing the same identification marks shall be deemed to have been manufactured at the same time and under identical conditions until the contrary is proved.

(2) No person shall sell, transfer or dispense any drug or therapeutic substance to which this Act applies after the date of expiry endorsed on the container thereof, except to a medical practitioner, dentist or veterinary surgeon, who has been informed in writing of such date by the person selling, transferring or dispensing such drug or substance.

Licence
holder to
keep records

14. Every holder of a licence under this Act shall keep records showing—

- (a) the quantities of drugs and therapeutic substances to which this Act applies, which he has imported into the Island and the identification marks or numbers of the consignments;
- (b) the date of the importation into the Island of any drug or therapeutic substance to which this Act applies which he has imported;

- (c) the names of the manufacturers of any such drug or therapeutic substance;
- (d) the names and addresses of the persons to whom any such drug or therapeutic substance has been issued, sold or otherwise disposed of by him and the quantity and date of every such issue, sale or disposal.

15. The Licensing Authority shall submit to the Minister lists of pharmaceutical firms for approval as manufacturing firms from whom any drug or therapeutic substance may be imported into the Island and the names of the firms approved shall be published in the *Official Gazette*.

List of approved pharmaceutical firms.

16. The Minister may, on the recommendation of the Licensing Authority add to or delete from the list of approved firms, and every such addition or deletion shall be published in the *Official Gazette*.

Variation of list of approved pharmaceutical firms.

17. Any person authorised in writing by or on behalf of the Licensing Authority may at any time during business hours enter the premises of any holder of a licence under this Act and call for and examine any records required to be kept by such holder.

Authority to enter and examine records.

18. (1) The Minister shall from time to time as may be necessary make regulations for the following purposes, that is to say—

Regulations.

- (a) for prescribing the standard of strength, quality and purity of any drug or therapeutic substance to which this Act applies;
- (b) for prescribing the test to be used for determining whether such prescribed standard has been maintained;
- (c) for adding to the Schedule any drug or therapeutic substance;
- (d) for prescribing the form of licences and of application therefor and of notices to be given in connection therewith;
- (e) for prescribing the conditions subject to which licences may be issued;

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- (f) for excluding from the operation of this Act or of any of the provisions thereof, any drug or therapeutic substance intended to be used solely for veterinary purposes;
 - (g) for listing pharmaceutical firms for approval as manufacturing firms from whom drugs or therapeutic substances may be imported into the Island;
 - (h) for adding to or deleting from the list of approved firms;
 - (i) for regulating the storage and transport of any drug or therapeutic substance;
 - (j) for controlling or prohibiting any process which may affect the potency, sterility or toxicity of any drug or therapeutic substance.
- (2) All regulations shall be subject to negative resolution.

Offences.

19. Any person obstructing any person authorised in writing by or on behalf of the Licensing Authority in the performance of any duty imposed under this Act or refusing to give any information lawfully demanded by any such authorised person or otherwise contravening or failing to comply with any of the provisions of this Act shall be guilty of an offence.

Offence by
body
corporate.

20. Where an offence under this Act has been committed by a body corporate, every person who at the time of the commission of the offence was director, general manager, secretary or other similar officer of the body corporate, or was purporting to act in any such capacity, shall be guilty of that offence, unless he proves that the offence was committed without his consent or connivance and that he exercised all such diligence to prevent the commission of the offence as he ought to have exercised having regard to the nature of his functions in that capacity and to all the circumstances.

Penalty.

21. Any person guilty of an offence under this Act shall be liable on summary conviction to a fine of four hundred and eighty dollars, or in default of payment to imprisonment for three months, or in the case of a second or subsequent conviction to such fine or to imprisonment for three months or to both such fine and imprisonment and in either case to forfeit any goods in connection with which the offence was committed and without prejudice, if the offender is the holder of a licence, to the power of the Licensing Authority to cancel or suspend the licence.

SCHEDULE

s. 2(2).

1. Para-aminobenzene sulphonamide**Its Salts**

Derivatives of para-aminobenzene sulphonamide having one or both of the hydrogen atoms of the para-amino group or of the sulphonamide group, substituted by other radicals;

Their Salts

The derivatives shall include—

Sulphonamidochrysoidin

Azosulphonamide

Benzyl sulphanilamide

Sulphanyldimethylsulphanilamide

Sulphapyridine

Sulphathiazole

Sulphacetamide

Sulphadiazine

Sulphaguanidine

Sulphamezathine

Succinyl Sulphathiazole

Sulphamerazine

2. Penicillin

Such other anti-microbial organic substances as may be prescribed by regulations.

3. Streptomycin.**4. Oleandomycin.**L.N. 159/
1957.**5. All other anti-biotic substances whether produced synthetically or by living micro-organisms.****THE LAWS OF BARBADOS**