

CHAPTER 17

THE ANTIBIOTICS AND THERAPEUTIC SUBSTANCES ACT

Arrangement of Sections

Section

1. Short title.
 2. Drugs to which Act applies.
 3. Licence for manufacture or sale.
 4. Restriction on sale or supply of drugs, etc.
 5. No drugs to be imported without a licence.
 6. Licence to store drugs.
 7. Form of licence.
 8. Cancellation of licence.
 9. Sale of drugs to medical practitioners, dentists and veterinary surgeons.
 10. Right to enter and inspect premises.
 11. Authority to take samples of drugs.
 12. Identification numbers and date of manufacture on containers.
 13. Licence holder to keep records,
 14. Authority to enter and examine records.
 15. Regulations.
 16. Offences.
 17. Offence by body corporate.
 18. Penalty.
- SCHEDULE.
-

ANTIBIOTICS AND THERAPEUTIC SUBSTANCES

(1st June, 1951.)

911950.
S.R.O. 2511953.
S.R.O. 2211956.
18/1989.

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

2. This Act shall apply to the antibiotics and therapeutic substances specified in the Schedule and to any antibiotic or therapeutic substances which may from time to time be added to the Schedule by regulations made under this Act. Drugs to which Act applies. Schedule.

3. (1) No person shall manufacture for sale or supply any antibiotic or therapeutic substance to which this Act applies unless he is the holder of a licence granted for this purpose by the Licensing Authority. Licence for manufacture or sale.

(2) For the purposes of this Act and the administration thereof the Licensing Authority shall be such person as is appointed in that behalf by the Governor-General.

4. (1) Subject to the provisions of this section, no person shall sell or supply any antibiotic or therapeutic substance specified in the Schedule or any preparation of which any antibiotic or therapeutic substance is an ingredient or part unless— Restriction on sale or supply of drugs, etc. Schedule.

(a) he is a registered medical practitioner or a registered dentist or a veterinary surgeon or a person acting in accordance with the directions of any such practitioner, dentist or surgeon, and the antibiotic, therapeutic substance or preparation is sold or supplied for the purposes of treating by and in accordance with the directions of the practitioner, dentist or surgeon, or

(b) he is a registered chemist and druggist and the antibiotic, therapeutic substance or preparation is sold or supplied under the authority of a prescription signed and dated by any such practitioner, dentist or surgeon, as aforesaid:

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

(a) by way of wholesale dealing; or

(b) for the purpose of being exported; or

(c) to any such practitioner, dentist or surgeon as aforesaid; 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 the head of which is in possession of a permit issued by the Licensing Authority authorizing him to obtain and use for the purposes specified in such permit any such antibiotic, therapeutic substance or preparation.

(2) A prescription signed by any such practitioner, dentist or surgeon, authorizing the sale or supply of any such antibiotic, therapeutic 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 authorized by him to make inspections under this Act.

No drugs to be imported without a licence.

5. It shall not be lawful to import into Antigua and Barbuda any antibiotic or therapeutic substance to which this Act applies unless—

(a) the person is the holder of a licence granted by the Licensing Authority to import such antibiotic or therapeutic substance; and

(b) the antibiotic or therapeutic substance has been manufactured by a pharmaceutical firm approved by the Licensing Authority; and

(c) the antibiotic or therapeutic substance complies with such standard of strength, quality and purity as may be prescribed by regulations made under this Act.

6. No person shall store any antibiotic 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 antibiotic or therapeutic substance 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.

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

Form of licence.

8. The Licensing Authority may 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 made thereunder or of any of the conditions contained in such licence:

Cancellation of licence.

Provided that on such cancellation or suspension the licensee may appeal to the Cabinet whose decision shall be final.

9. No importer of any antibiotic or therapeutic substance to which this Act applies shall sell or transfer any such antibiotic or therapeutic substance to any person other than a registered medical practitioner or to a registered dentist or to a veterinary surgeon unless such person is the holder of a licence to store such antibiotic or therapeutic substance granted under the provisions of this Act.

Sale of drugs to medical practitioners, dentists, and veterinary surgeons.

10. Any person authorized 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 antibiotic or therapeutic substance to which this Act applies is being kept which has been acquired or is being kept in contravention of the provisions of this Act or of any regulations made thereunder, 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 antibiotic or therapeutic substance

Right to enter and inspect premises.

as he may consider necessary. Any antibiotic or therapeutic substance in respect of which there has been a breach of any of the provisions of this Act or of any regulations made thereunder may be seized by such person authorized as aforesaid and on conviction of the offender shall be forfeited to Her Majesty and shall be dealt with as the Governor-General may direct.

Authority to take samples of drugs.

11. Any person authorized in writing by or on behalf of the Licensing Authority may require the holder of a licence to store antibiotic or therapeutic substances granted under the provisions of this Act to produce samples of any antibiotic 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. If any such sample is found on assay to have deteriorated to such an extent, or to contain toxic substances in such amounts, as in the opinion of the Licensing Authority to render it ineffective or unfit for use as an antibiotic or therapeutic substance, or to be of a lesser degree of potency than it purports to be, the Licensing Authority may require to be destroyed the entire stock of the antibiotic or therapeutic substance in the possession of the licensee which bears the same batch identification number as the sample:

Provided that any licensee whose entire stock of antibiotics or therapeutic substances is so required by the Licensing Authority to be destroyed, may appeal against such requirement to the Cabinet whose decision shall be final.

Identification numbers and date of manufacture on containers.

12. (1) Every container of an antibiotic or therapeutic substance to which this Act applies shall carry a batch identification number and the date of manufacture of such antibiotic or therapeutic 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 antibiotic or therapeutic substance to which this Act applies after the date of expiry endorsed on the container thereof, except to a registered medical practitioner, registered dentist

or veterinary surgeon, who has been informed in writing of such date by the person selling, transferring or dispensing such antibiotic or therapeutic substance.

13. Every holder of a licence under this Act shall keep records showing— **Licence holder to keep records.**

(a) the quantities of antibiotic and therapeutic substances to which this Act applies, which he has imported into Antigua and Barbuda and the identification marks or numbers of the consignments;

(b) the date of the importation into Antigua and Barbuda of any antibiotic or therapeutic substance to which this Act applies which he has imported;

(c) the names of the manufacturers of any such antibiotic or therapeutic substance;

(d) the names and addresses of the persons to whom any such antibiotic 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.

14. Any person authorized 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.**

15. The Cabinet may make regulations for the following purposes— **Regulations.**

(a) for prescribing the standard of strength, quality and purity of any antibiotic or therapeutic substance to which this Act applies;

(b) for prescribing the test to be used for determining whether the standard prescribed as aforesaid has been maintained;

(c) for adding to the Schedule any antibiotic or therapeutic substance; **Schedule.**

(d) for prescribing the form of licences under this Act and of applications therefor, and of notices to be given in connection therewith;

(e) for prescribing the conditions subject to which licences may be issued;

(f) for excluding from the operation of this Act or of any of the provisions thereof, any antibiotic or therapeutic substance intended to be used solely for veterinary purposes;

(g) for regulating the storage and transport of any antibiotic or therapeutic substance;

(h) for controlling or prohibiting any process which may affect the potency, sterility or toxicity of any antibiotic or therapeutic substance.

Offences.

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

Offence by body corporate.

17. 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 a** 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.

18. Any person guilty of an offence under this Act shall be liable on summary conviction to a fine not exceeding five thousand dollars or to imprisonment for six months or to both such fine and imprisonment.

SCHEDULE

Ss. 2, 4, 15.

1. "Penicillin" —
which term shall include any anti-infective acid produced by penicillin notatum whether obtained from penicillin notatum or not, and any salt or derivative obtained from any such acid, and any solution containing such salt or acid or derivative.
2. "Streptomycin" —
which term shall include all compounds of streptomycin and all medicinal preparations containing streptomycin.
3. "Aureomycin" —
which term shall include all compounds of aureomycin and all medicinal preparations containing aureomycin.
4. "Chloromycetin" —
which term shall include the antibiotic and the synthetic product of that name.
5. Para-aminobenzenesulphonamide.

ITS SALTS

Derivatives of **para-aminobenzenesulphonamide** 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 derivations shall include—
 Sulphonamidochrysoidin
 Azosulphamide
 Benzylsulphanilamide
 Sulphanilyldimethylsulphanilamide
 Sulphapyridine
 Sulphathiazole
 Sulphacetamide
 Sulphadiazine
 Sulphaguanidine
 Sulphamezathine
 Succinylsulphathiazole
 Sulphamerazine
 Phthalylsulphathiazole.

6. Terramycin
7. Bacitracin.

LAWS OF ANTIGUA AND BARBUDA

10

CAP. 17) Antibiotics and Therapeutic Substances

8. Aureotracin.
 9. Neomycin.
 10. Tyrothricin.
 11. Gramicidin
 12. Niomycin
 13. Iso-Nicotinic Acid Derivatives
 14. Deoxycortoni Acetas and all other Adrenal Cortical Hormones.
 15. Amino-salicylic acid and its derivatives.
 16. Cycloserine, which term shall include all compounds of cycloserine and all medicinal preparations containing cycloserine.
-