ST. CHRISTOPHER AND NEVIS

CHAPTER 9.04

ANTIBIOTICS AND THERAPEUTIC SUBSTANCES ACT
and Subsidiary Legislation

Revised Edition
showing the law as at 31 December 2002

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ANTIBIOTICS AND THERAPEUTIC SUBSTANCES ACT 3

Act 9 of 1950 … in force 1st June 1951
Amended by: Act 6 of 1976
Act 7 of 1976

ANTIBIOTIC AND THERAPEUTIC SUBSTANCES REGULATIONS – Section 15
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CHAPTER 9.04

ANTIBIOTICS AND THERAPEUTIC SUBSTANCES ACT

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CHAPTER 9.04

ANTIBIOTICS AND THERAPEUTIC SUBSTANCES ACT

AN ACT TO REGULATE THE IMPORTATION AND SALE OF ANTIBIOTICS AND THERAPEUTIC SUBSTANCES; AND TO PROVIDE FOR RELATED OR INCIDENTAL MATTERS.

Short title and Construction.

1. (1) This Act may be cited as the Antibiotics and Therapeutic Substances Act.

(2) In this Act, "Minister" means the Minister responsible for Health.

Drugs to which Act applies.

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

Licence for manufacture or sale.

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

(2) For the purposes of this Act and the administration thereof in the State the Licensing Authority shall be the Chief Medical Officer.

(Amended by Act 6 of 1976)

Restriction on sale or supply of drugs etc. Schedule.

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

(a) he or she 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 or she 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.

(2) Subsection (1) shall not apply to the sale or supply of any such antibiotic, therapeutic substance or preparation—

(a) by way of wholesale dealing;

(b) for the purpose of being exported;

(c) to any such practitioner, dentist or surgeon as aforesaid;

(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 authorising him or her to obtain and use for the purposes specified in such permit any such antibiotic, therapeutic substance or preparation.

(3) A prescription signed by any such practitioner, dentist or surgeon, authorising 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 authorised by him or her to make inspections under this Act.

No drugs to be imported without a licence.

5. It shall not be lawful to import into the State 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;

(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.

Licence to store drugs.

6. No person shall store any antibiotic or therapeutic substance to which this Act applies for the purpose of sale unless he or she 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.

Form of licence.

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

Cancellation of licence.

8. The Licensing Authority may cancel or suspend for such period as he or she 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:

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

(Amended by Act 6 of 1976)

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

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.

Right to enter and inspect premises.

10. (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 or she 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 or she may consider necessary, or may require the occupier or person in charge of the premises to furnish him or her with such information in connection with such antibiotic or therapeutic substance as he or she may consider necessary.

(2) 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 authorised as aforesaid and on conviction of the offender shall be forfeited to the Crown and shall be dealt with as the Minister may direct.

(Amended by Act 7 of 1976)

Authority to take samples of drugs.

11. (1) Any person authorised in writing by or on behalf of the Licensing Authority may require the holder of a licence to store antibiotics 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 or her possession and, on payment of the current market value of any sample, may require that it be delivered to him or her for purposes of assay.

(2) 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.

Licence holder to keep records.

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

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

(b) the date of the importation into the State of any antibiotic or therapeutic substance to which this Act applies which he or she 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 or her and the quantity and date of every such issue, sale or disposal.

Authority to enter and examine records.

14. 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.

Regulations.

15. The Minister may make regulations for the following purposes—

(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 First Schedule any antibiotic or therapeutic substance;

(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 granting exemption 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.

(Amended by Act 6 of 1976)

Offences.

16. Any person who obstructs any person authorised in writing by or on behalf of the Licensing Authority in the performance of any duty imposed by or under this Act, or refuses to give any information lawfully demanded by such authorised person or

otherwise contravenes or fails to comply with any of the provisions of this Act commits 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 director, general manager, secretary or other similar officer of the body corporate, or was purporting to act in any such capacity, commits that offence, unless he or she proves that the offence was committed without his or her consent or connivance and that he or she exercised all such diligence to prevent the commission of the offence as he or she ought to have exercised having regard to the nature of his or her functions in that capacity and to all the circumstances.

Penalty.

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

(Amended by Acts 7 of 1976 and 9 of 1986)

FIRST SCHEDULE

(Sections 2, 4 and 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

Sulphanilyldimethysulphanilamide

Sulphapyridine

Sulphathiazole

Sulphacetamide

Sulphadiazine

Sulphaguanidine

Sulphamezathine

Succinylsulphathiazole

Sulphamerazine

Phthalylsulphathiazole.

6. Terramycin.

7. Bacitracin.

8. Aureotracin.

9. Neomycin.

10. Tyrothricin.
11. Gramicidin.
12. Niomycin.
13. Iso-Nicotinic Acid Derivatives.
14. Deoxycortoni Acetas and all other Adrenal Cortical Hormones.

SECOND SCHEDULE

(Section 15)

ANTIBIOTICS AND THERAPEUTIC SUBSTANCES REGULATIONS

Short Title.

1. These Regulations may be cited as the Antibiotics and Therapeutic Substances Regulations.

Licence to Manufacture.

2. Every application for a licence to manufacture for sale or supply any antibiotic or therapeutic substance to which the Antibiotics and Therapeutic Substances Act (hereinafter referred to as "the Act"), applies shall be made to a Licensing Authority and shall set out—

(a) the name of the applicant;

(b) the exact description of the antibiotic or therapeutic substance to be manufactured, or supplied;

(c) the estimated quantities of the antibiotic or therapeutic substance, proposed to be manufactured or supplied in each year;

(d) the address at which it is proposed to manufacture the antibiotic or therapeutic substance.

Licence to Import.

3. Every application for a licence to import any antibiotic or therapeutic substance to which the Act applies shall be made in writing to a Licensing Authority and shall set out—

(a) the name and address of the importer;

(b) the exact description of the antibiotic or therapeutic substance to be imported;

(c) the quantity of antibiotic or therapeutic substance to be imported; and

(d) the name and address of the firm in the exporting country from which the antibiotic or therapeutic substance is to be obtained.

Licence to Store.

4. Every application for a licence to store for the purpose of sale of any antibiotic or therapeutic substance to which the Act applies shall be made in writing to a Licensing Authority and shall set out—

(a) the name and address of the applicant;

(b) an exact description of the antibiotic or therapeutic substance to be stored;

(c) the quantity of antibiotic or therapeutic substance to be stored;

(d) the address at which it is proposed to store the antibiotic or therapeutic substance.

Additional Information.

5. A Licensing Authority may require an applicant for a licence to manufacture for sale or supply, or to import, or to store for the purpose of sale, any antibiotic or therapeutic substance to which the Act applies, to furnish to the Licensing Authority such additional information as the Licensing Authority may consider necessary to enable him or her to decide whether or not the application should be granted.

Grant of Licences Discretionary.

6. The grant of a licence to manufacture for sale or supply, or to import, or to store for the purpose of sale, any antibiotic or therapeutic substance to which the Act applies, shall be in the absolute discretion of the Licensing Authority who may, with or without assigning any reason, grant or withhold such a licence as he or she may think most conducive to the public good.

Form of Licences.

7. A Licence to manufacture for sale or supply, or to import, or to store for the purpose of sale, any antibiotic or therapeutic substance to which the Act applies, shall, respectively, be in one of the Forms "A," "B" or "C" in the Schedule to these Regulations.

Storage.

8. Antibiotics or therapeutic substances stored for the purpose of sale shall be stored in accordance with the conditions for storage in respect of temperature or otherwise prescribed or indicated by the manufacturers thereof.

Control of Potency, etc.

9. No person other than a registered medical practitioner, or a registered dentist, or a veterinary surgeon or a person acting under the direction of any such practitioner, dentist or surgeon, shall—

(a) adulterate;

(b) mix with any other substance; or

(c) transfer from one container to another,

any antibiotic or therapeutic substance in such a manner as to be likely to cause its potency, sterility or toxicity to be affected.

Transport.

10. No person shall transmit any antibiotic or therapeutic substance by post without registering the packet in which it is contained.

SCHEDULE TO THE REGULATIONS

FORM A

The Antibiotics and Therapeutic Substances Act

LICENCE TO MANUFACTURE AND SUPPLY

(a) ……	(a) Name of Manufacturer.
of (b) ……	(b) Address of Manufacturer.
(hereinafter called "the Licensee") is hereby licensed, subject to the provisions of the Antibiotics and Therapeutic Substances Act, and to the subjoined conditions, to manufacture for sale and to supply at premises situate at (c) …….. …….... the following antibiotic and therapeutic substances:	(c) Address at which antibiotics etc. to be manufactured.
(d) ……...……. ……..	(d) Exact description of antibiotics etc. to be manufactured.

CONDITIONS

1. This Licence shall expire on the …… day of …… , 20……...

2. The Licensee shall permit any person authorised in writing by or on behalf of the Licensing Authority to enter the aforementioned premises at all reasonable times for the purpose of inspecting, and to inspect the said premises.

3. The Licensing Authority may at any time revoke this Licence upon the failure of the Licensee to comply with Condition 2 contained herein.

Dated at ……. This ……day of……, 20……..

Licensing Authority

FORM B

The Antibiotics and Therapeutic Substances Act

LICENCE TO IMPORT

(a) ……. (a) Name of Importer.

of (b) ……. (b) Address of Importer.

(hereinafter called "the Licensee") is hereby licensed, subject to the provisions of the Antibiotics and Therapeutic Substances Act, and to the subjoined conditions, to

import into the State the antibiotics and therapeutic substances set out hereunder in the respective quantities, and from the respective manufacturers set opposite thereto:

Antibiotic *Quantity* *Name and Address of Manufacturer*

CONDITIONS

1. The abovementioned antibiotics and therapeutic substances shall be imported on or before the …… day of ……., 20……...

2. Nothing in this Licence shall be deemed to authorise the Licensee to store any antibiotic and therapeutic substance for the purpose of sale.

3. This Licence must be produced to the proper officer of Customs or of the Post Office for endorsement upon the importation of the antibiotics and therapeutic substances, or any of them.

4. As soon as the aforesaid antibiotics and therapeutic substances shall have been imported into the State, the Licensee shall return this Licence to the Licensing Authority, together with copies of the respective invoices relating to such importation.

5. The Licensing Authority may at any time revoke this Licence upon the failure of the Licensee to comply with all or any of the conditions contained herein.

6. This Licence is not transferable.

Dated at ……. This …….day of ……., 20……...

Licensing Authority

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FORM C

The Antibiotics and Therapeutic Substances Act

LICENCE TO STORE

(a)…….	(a) Name of Importer.
of (b)……	(b) Address of Importer.
(hereinafter called "the Licensee") having proved to the satisfaction of the Licensing Authority that the storage facilities of the hereinafter mentioned premises are adequate, is hereby licensed, subject to the provisions of the Antibiotics and Therapeutic Substances Act, and to the subjoined conditions to store on premises situate at (c) ……for the purpose of sale the undermentioned antibiotics and therapeutic substances:	(c) Premises on which antibiotics etc. to be stored.
(d) ……. ……	(d) Exact description of antibiotics etc. to be stored.

CONDITIONS

1. This Licence shall expire on the …… day of …….., 20……...

2. The aforesaid antibiotics and therapeutic substances shall be stored in accordance with such conditions for storage in respect of temperature or otherwise as may be prescribed or indicated by the manufacturers thereof.

*or**

The aforesaid antibiotics and therapeutic (e) Here insert conditions of storage.

substances shall be stored in accordance with the

following conditions (e)

…….

…….

…….

3. The antibiotics and therapeutic substances shall be kept in locked receptacles which shall be opened only by the Licensee or by a person directed by him or her, such person being a registered druggist or chemist.

4. At the expiration of three months from the date of the grant of the Licence and thereafter at the expiration of each succeeding period of three months the Licensee shall make a return to the Licensing Authority showing the quantities of antibiotics and therapeutic substances in his or her possession at the commencement of such period, the quantities received during such period, the quantities disposed of during such period and the quantities on hand at the end of such period.

5. The Licensing Authority may at any time revoke this Licence upon the failure of the Licensee to comply with all or any of the conditions contained herein.

Dated at …… this ……. day of …….., 20……...

Licensing Authority

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*The alternative clause should be used only when the Licensing Authority is satisfied that the manufacturers of the relevant antibiotics and therapeutic substances have not prescribed or indicated any conditions for storage.