

LAWS OF DOMINICA

ANTIBIOTICS ACT

CHAPTER 40:06

**Act
8 of 1958**

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CHAPTER 40:06**ANTIBIOTICS ACT****ARRANGEMENT OF SECTIONS**

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CHAPTER 40:06

ANTIBIOTICS ACT

1961 Ed.
Cap. 143.
8 of 1958.

AN ACT to regulate the importation, storage, distribution, sale and use of antibiotics.

Commencement.

[31st July 1958]

Short title.

1. This Act may be cited as the –

ANTIBIOTICS ACT.

Interpretation.

2. In this Act –

“antibiotic” means penicillin, streptomycin, all compounds of streptomycin, aureomycin, all compounds of aureomycin, chloromycetin, all compounds of chloromycetin, and any other anti-microbial organic substance produced by living organisms or synthetically with the same structural formula as the natural product of the organism which the Minister may from time to time by Order published in the *Gazette* declare to be an antibiotic to which this Act applies;

Ch. 39:02.

“board” means the medical board established under the provisions of the Medical Act;

“dentist” means a person registered as a dentist under the Medical Act;

“medical practitioner” means a person registered as a medical practitioner under the Medical Act;

“veterinary surgeon” means a person holding such qualifications as approved by the Minister.

Restriction on manufacture of antibiotics.

3. No person shall manufacture any antibiotic in the State unless he is the holder of a licence granted by the board to manufacture such antibiotic.

Restriction on importation of antibiotics.

4. No person shall import into the State any antibiotic other than an antibiotic manufactured by a pharmaceutical firm approved by the Minister.

Licences to import antibiotics.

5. No person shall import any antibiotic into the State unless he is the holder of a licence granted by the board to import such antibiotic.

6. No person shall store any antibiotic for the purpose of sale unless he is the holder of a licence granted by the board to store such antibiotic.

Licences to store antibiotics.

7. The board may appoint a fit and proper person to be licensing officer under this Act.

Appointment of licensing officer.

8. Licences issued under this Act shall be in such form as the board may from time to time approve.

Form of licences.

9. The board may cancel 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 under this Act.

Cancellation of licences.

10. No importer of antibiotics shall sell or transfer any antibiotic to any person other than a medical practitioner, dentist or veterinary surgeon, unless that person is the holder of a licence to store antibiotics granted under this Act.

Restriction of sale or transfer of antibiotics.

11. Any person authorised in writing by or on behalf of the board may at any time between the hours of 6:00 a.m. and 6:00 p.m. enter any premises in which he has reason to believe that any antibiotic is being kept which has been acquired or is being kept in contravention of this Act or any Regulations hereunder, and may carry out such inspection of the premises as he considers necessary, and may require the occupier or person in charge of the premises to furnish him with such information in connection with the antibiotic as he considers necessary. Any antibiotic in respect of which there has been a breach of any of the provisions of this Act or of any Regulations hereunder may be seized by the persons authorised as aforesaid and on conviction of the offender shall be forfeited to the board if the Court so orders.

Right of entry on premises to ensure compliance with Act.

12. Any person authorised in writing by or on behalf of the board may require the holder of a licence to store antibiotics granted under this Act to produce samples of any antibiotic which may be in his possession and, on payment of the current market value any sample which is found on assay to have deteriorated to an extent or to contain toxic substances in amounts which, in the opinion of the board, render it ineffective or unfit for use as a therapeutic substance, or not to contain the antibiotic or to contain the antibiotic in a lesser degree of potency than it purports to possess, the board may require to be destroyed the entire stock of the

Taking samples of antibiotics.

antibiotic in the possession of the licensee which bears the same batch identification number of the sample.

Further
restriction on
issue of
antibiotics.

13. (1) Subject to section 6, no antibiotic shall be issued to any person except on the prescription of a medical practitioner, dentist or veterinary surgeon.

(2) Every prescription as is referred to in subsection (1) shall –

- (a) be in indelible writing or typescript and be signed by the person giving it with his usual signature in indelible writing and dated by him;
- (b) specify the address of the person giving it;
- (c) specify the name and address of the person for whose treatment it is given or, if it is given by a veterinary surgeon, of the person to whom the medicine is to be delivered.

(3) Every person dispensing any such prescription shall comply with the following requirements:

- (a) the prescription shall not be dispensed otherwise than in accordance with the prescription or more than once unless the prescription contains a direction in accordance with the provisions of paragraph (b);
- (b) if the prescription contains a direction that it may be dispensed a stated number of times or at stated intervals it shall not be dispensed otherwise than in accordance with such direction;
- (c) there must be noted on the prescription at the time of dispensing, immediately above the signature of the person giving the prescription the name and address of the person supplying the antibiotic and the date on which the prescription is dispensed;
- (d) if the prescription may be again dispensed it shall on the last time of dispensing be retained for a period of two years by the person last dispensing it on the premises on which it was last dispensed and be made available for inspection by any person authorised by or on behalf of the board.

14. An antibiotic shall not be administered to any person except by or under the direction of a medical practitioner or dentist; but where a case of emergency arises in any area of the State and the services of a medical practitioner are not available, any registered dispenser or registered nurse stationed in that area, who possesses a certificate issued by the board that he is competent to administer penicillin, a compound of penicillin, or any medical preparation containing penicillin, may administer penicillin, a compound of penicillin, or any medical preparation containing penicillin.

Administering of antibiotics.

15. (1) Every container of an antibiotic shall carry a batch identification mark or number and the date of manufacture of such antibiotic, and the contents of any such containers supplied by any person bearing the same identification marks or numbers shall be deemed to have been manufactured at the same time and under identical conditions until the contrary is proved.

Identification marks or numbers on containers.

(2) No person shall sell, transfer or dispense any antibiotic 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 the antibiotic.

16. Every holder of a licence to import antibiotics under this Act shall keep records showing –

Licence holder to keep records.

- (a) the quantities of antibiotics which he has imported into the State and the identification marks or numbers of the consignments;
- (b) the date of importation into the State of any antibiotic which he has imported or has in stock;
- (c) the names of the manufacturers of any such antibiotics;
- (d) the names and addresses of the persons to whom any such antibiotics have been issued by him and the quantity and date of every such issue.

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

Examination of records.

Lists of approved pharmaceutical firms.

18. The board shall submit to the Minister lists of pharmaceutical firms for approval as manufacturing firms from which antibiotics may be imported into the State. The names of the firms so approved shall be published in the *Gazette*.

Variation of lists of approved pharmaceutical firms.

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

Regulations.

20. The Minister may make Regulations –

- (a) defining the powers and duties of the board;
- (b) providing for regulating the storage and transport of any antibiotic;
- (c) controlling or prohibiting any process which may affect the potency, sterility or toxicity of any antibiotic;
- (d) providing the punishment for any breach of any regulation made under this section.

Offences.

21. Any person obstructing any person authorised in writing by or on behalf of the board in the performance of any duty imposed by or under this Act or refusing to give any information lawfully demanded by any such authorised person or otherwise contravening any of the provisions of this Act is guilty of an offence against this Act.

Penalty.

22. Any person found guilty of an offence against this Act is liable on summary conviction to a fine of five thousand dollars and to imprisonment for six months.

SUBSIDIARY LEGISLATION

ANTIBIOTICS REGULATIONS

25/1958.

made under section 20

[18th December 1958]

Commencement.

1. These Regulations may be cited as the –

Short title.

ANTIBIOTICS REGULATIONS.

2. In these Regulations “pharmaceutical firm” means a firm, company or person who possess a valid licence to manufacture any antibiotic issued by the appropriate authority either in this State or elsewhere.

Interpretation.

3. (1) An antibiotic shall not be imported into the State unless it conforms with the requirements in respect of its standard of strength, purity and quality as if it were intended for the consumption of the inhabitants of the country in which it may be manufactured and such standards have been approved by the board.

Standard of strength, purity and quality of antibiotics.

(2) The board may at its discretion require proof to its satisfaction either in respect of importation generally, or in respect of any particular importation, that the antibiotics imported or proposed to be imported into the State, conform to the standards of strength, purity and quality as set out in subregulation (1) and that they have been manufactured by a pharmaceutical firm which has been approved in accordance with the Act.

4. (1) Before submitting to the Minister the name of any pharmaceutical firm in accordance with section 18 of the Act the board shall require proof to its satisfaction –

Listing pharmaceutical firms.

- (a) that the pharmaceutical firm has been licensed in the country in which it carried or carries on its manufacturing process for the proper authorities there, to manufacture antibiotics;
- (b) whether the firm manufactures any antibiotics for export which according to the terms of any enactments or licences under which it carried or carries on its manufacturing processes may be of a different standard,

strength and purity from antibiotics of a same or similar name manufactured by the firm for the consumption of the inhabitants of the country in which the antibiotic may be manufactured.

(2) If it is proved to the satisfaction of the Minister that any pharmaceutical firm which has been approved under section 18 of the Act has not complied with or has infringed the conditions under which its inclusion in the approved list was allowed or has by any action by itself or persons acting on its behalf caused or permitted such non-compliance or infringement then the Minister may by Order remove the name of the offending pharmaceutical firm from the approved list and the fact of the removal shall be published in the *Gazette*.

Storage and transport.

5. (1) No person other than a medical practitioner, a dentist or a veterinary surgeon shall store any antibiotic unless he holds a valid licence issued by the licensing officer to store antibiotics.

(2) The licensing officer either before or after granting the licence shall take such steps as he considers necessary to satisfy himself that the premises to be used or in use for storing the antibiotics are in every way suitable especially with regard to keeping the antibiotics at the correct temperature.

(3) The licensing officer may at his discretion give such instructions either verbally or in writing so as to permit, regulate and safeguard the transportation of any antibiotic from the place where it is stored to the person authorised to receive it.

Board may issue instructions.

6. The board may at any time at its discretion issue such instructions or directions as it considers necessary to control or prohibit any process or action with regard to any antibiotic which in its opinion may affect the potency, sterility or toxicity of such antibiotic.
