LAWS OF GUYANA

ANTIBIOTICS ACT

CHAPTER 34:02

Act
40 of 1951
Amended by

5 of 1955
36 of 1958
18 of 1973

Current Authorised Pages

Pages (inclusive)				*Authorised by L.R.O.*
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of

Subsidiary Legislation

CHAPTER 34:02

ANTIBIOTICS ACT

ARRANGEMENT OF SECTIONS

CHAPTER 34:02

ANTIBIOTICS ACT

1953 Ed.
c. 143
40 of 1951

An Act to regulate the importation, storage, distribution, sale and use of antibiotics.

[1ST MARCH, 1952]

Short title.

1. This Act may be cited as the Antibiotics Act.

Interpretation.

2. In this Act—

"antibiotic" means penicillin, all compounds of penicillin, and all medicinal preparations containing 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;

c. 134
1953 Ed.

"the Board" means the Pharmacy and Poisons Board established by section 3 of the Pharmacy and Poisons Ordinance;

"captain" means the person who is the commanding officer or master of any ocean-going vessel;

c. 32:03

"dentist" means a person registered as a dentist under the Dental Registration Act;

"health officer" means any officer appointed under section 3(2) of the Quarantine Ordinance;

c. 32:02

"medical practitioner" means a person registered as a medical practitioner under the Medical Practitioners Act;

"ocean-going vessel" means every description of ocean-going ship registered in Guyana or foreign, plying between Guyana and any other country;

"veterinarian" means a duly registered practitioner of veterinary medicine.

Restriction on manufacture of antibiotics.

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

Licences to store antibiotics.

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.

Authority for captains of ocean-going vessels to be supplied with antibiotics.
[5 of 1955]

7. Notwithstanding anything contained in this Act, it shall be lawful for any person who is licensed to import or store any antibiotics to supply such antibiotic as may be required by any captain of any ocean-going vessel subject to the following conditions –

(a) no antibiotic shall be supplied to any captain of any ocean-going vessel

except on a written order signed by him and counter-signed by a health officer;

(b) any person who supplies an antibiotic in accordance with this Act shall retain the written order referred to in paragraph (a), and shall mark it with the date on which the antibiotic was supplied, and shall keep it on his premises available at all times for inspection within a period of two years from the date of supply;

(c) where an antibiotic is supplied by any captain for the treatment of a member of the crew of an ocean-going vessel, an entry of the medical treatment in the official logbook shall be sufficient record of the supply, and such entry shall specify the antibiotic supplied.

Appointment of Licensing Officer.

8. The Board may appoint a fit and proper person to be Licensing Officer under this Act.

Form of licences.

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

Cancellation of licences.

10. The Board may cancel any licence issued under this Act if the holder thereof fails to comply with this Act or of any regulations made under this Act.

Restriction of sale or transfer of antibiotics.

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

Right of entry on premises to ensure compliance with Act.

12. Any person authorised in writing by or on behalf of the Board 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 is being kept which has been acquired or is being kept in contravention of this Act or of any regulations hereunder, and may carry out such inspection of the premises as he may consider necessary, and may require the occupier or person in charge of the premises to furnish him with such information in connection with such antibiotic as he may consider necessary. Any antibiotic in respect of which there has been a breach of this Act or of any regulations hereunder may be seized by such person authorised as aforesaid and on conviction of the offender shall be forfeited to the Board if the court so orders.

Taking samples of antibiotics.

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

Further restriction on use of antibiotics.

14.(1) Subject to section 6, no antibiotic shall be issued to any person except on the prescription of a medical practitioner, dentist or veterinarian except that the Minister may on the recommendation of the Board exempt any antibiotic or any medical preparation containing an antibiotic from this subsection. The name of the antibiotic or preparation so exempted shall be published in the *Gazette*.

(2) Every such prescription as is referred to in subsection (l) shall—

(a) be in indelible writing or typescript and be signed by the person giving it with his usual signature in indelible writing and be 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 veterinarian, 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 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.

Administering of antibiotics. [18 of 1973]

15. An antibiotic shall not be administered to any person except by or under the direction of a registered medical practitioner or dentist except that where a case of emergency arises in any area of Guyana 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 Chief Medical Officer 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.

Identification marks or numbers on containers.

16.(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 and 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.

(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 veterinarian who has been informed in writing of such date by the person selling, transferring or dispensing such antibiotic.

Licence holder to keep records.

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

(a) the quantities of antibiotics which he has imported into Guyana and the identification marks or numbers of the consignments;

(b) the date of importation into Guyana 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.

Examination of records.

18. 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.

Lists of approved pharmaceutical firms.

19. It shall be the function of the Board to submit to the Minister lists of pharmaceutical firms for approval as manufacturing firms from whom antibiotics may be imported into Guyana. The names of the firms so approved shall be published in the *Gazette*.

Variation of lists of approved pharmaceutical firms.

20. 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.

21. 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.

22. 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 shall be guilty of an offence against this Act.

Penalty.
[6 of 1997]

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

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SUBSIDIARY LEGISLATION

O. in C. 7/1952.

ANTIBOTIC REGULATIONS

made under section 20

Citation.

1. These Regulations may be cited as the Antibiotics Regulations.

Interpretation.

2. In these Regulations "pharmaceutical firm" means a firm, company or person who possesses a valid licence to manufacture any antibiotic issued by the appropriate Authority either in Guyana or elsewhere.

Standards of strength, purity and quality of antibiotics.

3. (1) An antibiotic shall not be imported into Guyana 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.

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

Listing pharmaceutical firms.

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 –

(a) that the pharmaceutical firm has been licensed in the country in which such firm carried or carries on its manufacturing process for the proper authorities there, to manufacture anti-biotics;

(b) whether such firm manufactures any antibiotics for export which according to the terms of any enactments or licences under which such firm 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 such firm for the consumption of the inhabitants of that country in which such 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 such offending pharmaceutical firm from the approved list and the fact of such removal shall be published in the *Gazette.*

Storage and transport.

5. (1) No person other than a medical practitioner, a dentist or a veterinaian 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 such licence shall take such steps as he may deem necessary to satisfy himself that the premises to be used or in use for storing such antibiotics are in every way suitable especially with regard to keeping such 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 is stored to the person authorised to receive it.

Instructions regarding antibiotics.

6. The Board may at any time at its discretion issue such instructions or directions as may be deemed 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.

O. in C. 33/1952 84/1953 92/1953 5/1954 73/1956 34/1957 49/1958 72/1960

DECLARATION OF ANTIBIOTICS ORDER

made under section 2

Citation.

1. This Order may be cited as the Declaration of Antibiotics Order.

Antibiotics.

2. The following substances, all compounds of such substances and all medicinal preparations containing such substances are hereby declared to be antibiotics to which the Act applies –

[O. in C. 33/1952]

Tryrothricin, all compounds of tryrothricin and all medicinal preparations containing tryrothricin;

Bacitracin, all compounds of bacitracin and all medicinal preparation containing bacitracin;

[O. in C. 84/1953]

Terramycin, all compounds of terramycin and all medicinal preparation containing terramycin;

Neomycin, all compounds of neomycin and all medicinal preparation containing neomycin;

Erythomcyin, all compounds of erythomycin and all medicinal preparation containing erythomcyin;

[O. in C. 92/1953]

Ilotycin, all compounds of ilotycin and all medicinal preparation containing ilotycin;

[O. in C. 5/1954]

Kemicetine, all compounds of kemicetine and all medicinal preparations containing kemicetine;

[O. in C. 73/1956]

Albamycin, all compounds of albamycin and all medicinal preparations containing albamycin;

[O. in C. 34/1957]

Novophenicol, all compounds of novophenicol and all medicinal preparations containing novophenicol;

Biophtal, all compounds of biophtal and all medicinal preparations containing biophtal;

Novocillin, all compounds of novocillin and all medicinal

preparations containing novocillin;

[O. in C. 49/1958] Distavone, all compounds of distavone and all medicinal preparations containing distavone;

Chloramphenical, all compounds of chloramphenical and all medicinal preparations containing chloramphenical;

Bicomycin, all compounds of bicomycin and all medicinal preparations containing bicomycin;

[O. in C. 72/1960] Ambramycin, all compounds of ambramycin and all medicinal preparations containing ambramycin;

Synthomycetine, all compounds of synthomycetine and all medicinal preparations containing synthomycetine.

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