

20/12/60

CHAPTER 12. No. 8.

ANTIBIOTICS.

AN ORDINANCE TO REGULATE THE IMPORTATION, STORAGE, DISTRIBUTION, SALE AND USE OF ANTIBIOTICS.

Commencement.

[1st April, 1949.]

Short title.

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

Interpretation.

2. In this Ordinance, "antibiotic" * means ^{means any of the substances specified in the Schedule to this Ordinance and includes all compounds of and all} penicillin, all compounds of streptomycin and all medicinal preparations containing streptomycin, and any other anti-microbial organic substance produced by living organisms which may be declared by the Governor in Council by Order published in the Royal Gazette to be an antibiotic to which this Ordinance shall apply.

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"Minister" means the member of the Cabinet for the time being charged with the administration of the subject of health.

Establishment of Antibiotics Control Committee.

3. (1) For the purposes of this Ordinance, a Committee shall be established to be called the Antibiotics Control Committee (hereinafter referred to as "the Committee") consisting of the Director of Medical Services, who shall be Chairman of the Committee, one member to be appointed by the Council of the Medical Board of Trinidad, two registered members of the said Board and one other person

* G.N. 190-1950. The following substances have been declared to be antibiotics— (a) Aureomycin, all compounds of Aureomycin and all medicinal preparations containing Aureomycin. (b) Chloromycetin, all compounds of Chloromycetin and all medicinal preparations containing Chloromycetin, and (c) Cytamen (Vitamin B 12 Concentrate) produced by deep fermentation methods from the mould Streptomyces.

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"antibiotic" means any of the substances specified in the Schedule to this Ordinance and includes all compounds of, and all medicinal preparations containing, any of such substances;

"Minister" means the member of the Cabinet for the time being charged with the administration of the subject of Health."

3. The Principal Ordinance is hereby amended by inserting immediately after section 20 thereof the following new section, to be numbered 20A:—

Minist may amend Schedule.

20A. The Minister may, on the recommendation of the Committee, by Order amend the Schedule to this Ordinance by adding thereto or deleting therefrom any antimicrobial organic substance produced by living organisms."

4. The Principal Ordinance is hereby amended by substituting the word "Minister" for the word "Governor" and for the words "Governor in Council" wherever such word or words appear in the Principal Ordinance.

and appoint any other person to act in the place of such member.

4. No person shall manufacture any antibiotic in the Colony unless he is the holder of a licence granted by the Committee to manufacture such antibiotic.

Restriction on manufacture of antibiotics.

5. No person shall import into the Colony any antibiotic other than an antibiotic manufactured by a pharmaceutical firm approved by the ~~Governor in Council~~ *Minister.

Restriction on importation of antibiotics.

6. No person shall import any antibiotic into the Colony unless he is the holder of a licence granted by the Committee to import such antibiotic.

Licences to import antibiotics.

7. No person shall store any antibiotic for the purpose of sale unless he is the holder of a licence granted by the Committee to store such antibiotic; and no such licence shall be granted except on proof to the satisfaction of the Committee that the storage facilities of the applicant are adequate.

Licences to store antibiotics.

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

Appointment of Licensing Officer.

* For List of Approved pharmaceutical firms, see G.N. 167-1950, and G.N. 273-1950.

- Form of licence. **9.** Licences issued under this Ordinance shall be in such form as the Committee may from time to time approve.
- Cancellation of licences. **10.** The Committee may cancel any licence issued under this Ordinance if the holder thereof fails to comply with any of the provisions of this Ordinance or of any regulations made under this Ordinance.
- Restriction of sale or transfer of antibiotics. **11.** No importer of antibiotics shall sell or transfer any antibiotic to any person other than a person registered as a member of the Medical Board of Trinidad (hereinafter referred to as a "medical practitioner") or as a dentist under the Medical Board Ordinance (hereinafter referred to as a "dentist") or as a veterinary surgeon under the Veterinary Surgeons (Registration) Ordinance (hereinafter referred to as a "veterinary surgeon") unless such person is the holder of a licence to store antibiotics granted under the provisions of this Ordinance.
- Right of entry on premises to ensure compliance with provisions of Ordinance. **12.** Any person authorised in writing by or on behalf of the Committee 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 any of the provisions of this Ordinance 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 any of the provisions of this Ordinance 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 Committee.
- Taking samples of antibiotics. **13.** Any person authorised in writing by or on behalf of the Committee may require the holder of a licence to store antibiotics granted under the provisions of this Ordinance 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 Committee, 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 Committee may require to be destroyed the entire stock of the antibiotic in the possession of the licensee which bears the same batch identification number as the sample.

14. (1) Subject to the provisions of section 7 of this Ordinance, no antibiotic shall be issued to any person except on the prescription of a medical practitioner, dentist or veterinary surgeon. Further restriction on issue of antibiotics.

(2) Every such prescription as is referred to in the last preceding subsection 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 veterinary surgeon, of the person to whom the medicine is to be delivered;

(d) have written or typed thereon, if given by a dentist, the words "for dental treatment only", and, if given by a veterinary surgeon, the words "for animal treatment only";

(e) indicate the total quantity of the antibiotic to be supplied and instructions for its use.

(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) of this subsection;

(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 Committee;

(e) if the prescription may not be dispensed more than once it shall be retained for a period of two years by the person dispensing it on the premises on which it was dispensed and be made available for inspection by any person authorised by or on behalf of the Committee.

Administer-
ing of
antibiotics.

15. An antibiotic shall not be administered to any person except by or under the direction of a medical practitioner or dentist: Provided that in any case of emergency it may be administered by a nurse who is a state registered nurse in the Colony or has passed the final examination for nurses at one of the Colonial Hospitals.

Identifica-
tion marks
or numbers
on con-
tainers.

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

17. Every holder of a licence under this Ordinance shall keep records showing—
- Licence holder to keep records.
- (a) the quantities of antibiotics which he has imported into the Colony and the identification marks or numbers of the consignments;
- (b) the date of importation into the Colony of any antibiotic which he has imported or has in stock;
- (c) the names of the manufacturers of any such antibiotic;
- (d) the names and addresses of the persons to whom any such antibiotic has been issued by him and the quantity and date of every such issue.
18. Any person authorised in writing by or on behalf of the Committee may, at any time during business hours enter the premises of any holder of a licence under this Ordinance and call for and examine any records required to be kept by such holder.
- Examination of records.
19. It shall be the function of the Committee to submit to the ~~Governor in Council~~ ^{Minister} lists of pharmaceutical firms for approval as manufacturing firms from whom antibiotics may be imported into the Colony; and the names of the firms so approved shall be published in the *Royal Gazette*.
- Lists of approved pharmaceutical firms.
20. The ~~Governor in Council~~ ^{Minister} may, on the recommendation of the Committee, add to or delete from the list of approved firms, and every such addition or deletion shall be published in the *Royal Gazette*.
- Variation of lists of approved pharmaceutical firms.
21. The ~~Governor in Council~~ ^{Minister} may make regulations—
- Regulations.
- (a) defining the powers and duties of the Committee;
- (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.
22. Any person obstructing any person authorised in writing by or on behalf of the Committee in the performance of any duty imposed by or under this Ordinance or refusing
- Offences.

to give any information lawfully demanded by any such authorised person or otherwise contravening any of the provisions of this Ordinance shall be guilty of an offence against this Ordinance.

Penalty

23. Any person found guilty of an offence against this Ordinance shall be liable on summary conviction to a fine of four hundred and eighty dollars or to imprisonment for six months, or to both such fine and imprisonment.

5. The following Schedule is hereby inserted as the Schedule to the Principal Ordinance immediately after section 23 thereof:—

(Sections 2 and 20A)

"SCHEDULE

Amphotericin B.
Bacitracin
Chloramphenicol
Cycloserine
Erythromycin
Eramycetin
Fumagillin
Griseofulvin
Oleandomycin

Neomycin
Novobiocin
Nystatin
Penicillins
Polymixins
Spiramycin
Streptomycins
Tetracyclines
Tyrothricin
Viomycin."

Amphotericin B. et c.

Passed in Council this twenty-fourth day of June, in the year of Our Lord one thousand nine hundred and sixty.

G. R. LATOUR

Clerk to the Council.