Therapeutic Substances

Cap. 330.

THERAPEUTIC SUBSTANCES REGULATIONS, 1950

Made by the Minister under section 18 of the Therapeutic Substances Act. Cap. 330.

1. These Regulations may be cited as the Therapeutic Substances Regulations, 1950. Short title.

2. (1) In these regulations, unless the context otherwise requires— Definitions.

" the Licensing Authority " means the Director of Medical Services or person acting as such for the time being;

" therapeutic substance " or "substance" means any one of the drugs or substances specified in the Schedule to the Act, and includes any drug or substance which may be added to that Schedule by these regulations;

" registered druggist " means a person who is registered under the Druggists Act and in addition is a person keeping open shop for the retail of poisons or is employed as a druggist in such open shop; Cap. 368.

" pharmaceutical firm " means a firm, company or person who possesses a valid licence to manufacture any therapeutic substance issued by the appropriate authority, either in this Island or elsewhere;

" importer " means a firm, company or person possessing a valid licence issued under the provisions of the Act and these regulations to import any therapeutic substance:

Provided that in case any importer proposes to store any such substance, he shall require in addition a licence for storing such substance.

3. (1) A substance shall not be imported into this Island unless it conforms with the requirements in respect of its standard of strength, purity and quality as if it were intended Standard of strength, purity and quality of therapeutic substances.

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for the consumption of the inhabitants of the country in which it may be manufactured and such standards have been approved by the Licensing Authority.

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

Forms.

4. The forms of licences to be used in connection with the Act or these regulations shall be substantially in the forms as set out in the First Schedule to these regulations.

Exclusions for veterinary purposes.

5. (1) Any preparation which is to be used solely for veterinary purposes and which contains any proportion of a therapeutic substance shall be exempted from the operation of the Act, provided always that where necessary the onus of proof of such sole use shall be on the person using or proposing to use such preparation.

(2) Any person using, for purposes other than veterinary, any preparation exempted under this regulation shall be deemed to have committed a breach of the Act.

Listing pharmaceutical firms.

6. (1) Before submitting to the Minister of Health the name of any pharmaceutical firm in accordance with the provisions of section 15 of the Act, the Licensing Authority shall require proof to his satisfaction—

(*a*) that the pharmaceutical firm has been licensed in the country in which such firm carried or carries on its manufacturing process by the proper authorities there, to manufacture therapeutic substances;

(*b*) whether such firm manufactures any substances 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 substances of the

same or a similar name manufactured by such firm for the consumption of the inhabitants of that country in which such substance may be manufactured.

(2) If it be proved to the satisfaction of the Minister of Health that any pharmaceutical firm which has been approved under section 15 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 *Official Gazette*.

Storage and transport.

7. (1) No person other than a medical practitioner, a registered dental practitioner or a registered veterinary surgeon shall store any therapeutic substance unless he holds a valid licence issued by the Licensing Authority to store such substances.

(2) The Licensing Authority, 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 substances are in every way suitable, especially with regard to keeping such substances at the correct temperature.

(3) In circumstances where any substance is stored legally but a licence to store it is not necessary, the Licensing Authority shall nevertheless have such power to take the necessary action to satisfy himself with regard to its proper and efficient storage as if such substance were stored under a licence issued under the authority of the Act.

(4) The Licensing Authority may at his discretion give, either verbally or in writing, such instructions as he shall think proper so as to permit, regulate and safeguard the transportation of any substance from the place where it is stored to the person authorised to receive it.

Process which may affect any substance.

8. The Licensing Authority may at any time at his discretion issue such instructions or directions as he may deem necessary

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to control or prohibit any process or action with regard to any such substances as in his opinion may affect the potency, sterility or toxicity of any therapeutic substance.

SCHEDULE

Reg. 4

FORM 1

BARBADOS

Cap. 330. *Therapeutic Substances Act, Cap. 330*

LICENCE TO MANUFACTURE

Pursuant to the powers conferred on me by section 4 of the Therapeutic Substances Act, a licence is hereby granted to.....
..... of .....
to manufacture at.....
the undermentioned drugs, preparations and therapeutic substances for sale—

.....
.....
.....
.....
.....
.....

This licence is granted subject to the conditions appertaining to the manufacture of the abovementioned substances which are prescribed for the manufacture of like substances in England and Wales and may be suspended or revoked if the licensee contravenes or fails to comply with any of the said conditions, or any other conditions contained in the Licence.

This Licence will, unless previously suspended or revoked, continue in force until the.....
day of.....

GIVEN at Bridgetown, Barbados this.....
day of.....

Licensing Authority.

FORM 2

BARBADOS

Therapeutic Substances Act, Cap.330 Reg. 4

LICENCE TO IMPORT AND STORE Cap. 330.

.....
(*Address*)

.....19....

To the Licensing Authority,

Application is hereby made for a licence to import.....
..... store
..... (quantity)
of.....(substance).....to be obtained from
.....
.....
Name, address, etc. of pharmaceutical firm.....
.....

Storage for the above substance is provided at.....
and business hours are.....
Applicant.

To.....Please report on storage facilities for the above in connection with the issue of a licence under sections 5 and 6 of the Act.

Licensing Authority.

.....
Date

LICENCE

This Licence showing my approval of the above application is issued on the special condition that the Applicant notifies the Licensing Authority of the dates on which the above permitted substance (i) arrives in Barbados; (ii) is received by him; (iii) is stored in accordance with the terms herein approved, and may be suspended or revoked if the licensee contravenes or fails to comply with any of the said conditions or any other conditions contained in the Licence.

GIVEN at Bridgetown, Barbados this.....
day of.....19....

Licensing Authority.

THE LAWS OF BARBADOS

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