CHAPTER 189
MEDICAL PRODUCTS (REGULATIONS) ACT

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ACT

Act No. 10 of 1995

ARRANGEMENT OF SECTIONS

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CHAPTER 189
MEDICAL PRODUCTS (REGULATIONS) ACT

An Act to regulate medicinal products.

[Act No. 10 of 1995.]

[5*th April*, 1995.]

PART I

Preliminary

1. Short title

This Act may be cited as the Medical Products (Regulations) Act.

2. Interpretation

In this Act—

"appointed date" means the date specified in the order made by the Registrar under section 6 of the Act;

"authorised officer" means an officer authorised under section 4 of the Act;

"inventory" refers to the listing of provisionally registered medicinal products under section 6(2) of the Act;

"medicinal product" means any medicine intended for human use or veterinary product administered to food-producing animals, presented in its finished dosage form or as a starting material for use in such dosage form;

"Minister" means the Minister responsible for health;

"person" includes a natural person as well as a body corporate, partnership or association of persons, and establishment such as hospital pharmacies, clinics, and health centers storing or distributing medicinal products;

"Pharmacy Council" means the Pharmacy Council established under section 3 of the Pharmacy Act, Chapter 241;

"provisionally registered" is used in relation to a medicinal product which has been listed in the inventory under section 6 of the Act and which has not been screened for purposes of a product licence under section 7 of the Act;

"register" means the register of medicinal products for which a product licence has been issued in terms of section 6 of the Law;

"Registrar" means the Chief Pharmacist in the Ministry of Health appointed by the Public Service Commission;

"sell" means to sell for cash or on credit or by way of exchange and whether by wholesale or retail and "sale" shall have a corresponding meaning.

3. Functions of Registrar

The functions of the Registrar shall, *inter alia*, be—

(*a*) to require that all medicinal products manufactured in, imported into or exported from Grenada conform to prescribed standards of quality, safety and efficacy, and that the personnel, premises and practices employed to manufacture, promote, procure, store, distribute and sell such products comply with defined codes of practice and other requirements;

(*b*) to require continued conformity of medicinal products with such standards until their delivery to the end user;

(*c*) to require that medicinal products are imported, manufactured, exported, stocked, sold, distributed or otherwise deal with by duly authorised persons;

(*d*) to grant, after due assessment, licences for medicinal products, whether locally manufactured or imported, and whether destined for the national market or export;

(*e*) to inspect and licence all manufacturing premises, importing agents, wholesalers, distributors, hospital dispensaries, pharmacies and retail outlets;

(*f*) to provide for sampling and analytical and other testing of finished medicinal products released into the distribution chain to assure their compliance with labelled specifications; and

(*g*) to monitor and review the implementation of this Act.

4. Appointment of authorised officers

The Public Service Commission shall appoint such public officers as may be necessary to assist the Registrar to perform duties and to exercise powers under this Act. Such officers shall be known as "authorised officers".

5. Pharmacy Council to advise Registrar

The Pharmacy Council shall advise the Registrar on any general matter concerning the implementation of the Act or with regard to any specific medicinal product.

PART II

Provisional Registration and Inventory

6. Registrar to publish order requiring manufacturing, etc., to give particulars specified in order

(1) The Registrar shall, by order published in the *Gazette*, require manufactures, importers and exporters of medicinal products to notify the Registrar of such particulars as are specified in the order concerning the medicinal products which such manufacturers, importers, or exporters wish to continue to manufacture, import, export or sell after such date as is specified in the order.

(2) Medicinal products in respect of which a notification has been received by the Registrar on or before the appointed date shall be listed in the provisionally registered medicinal products inventory and until granted a product licence or ordered by the Registrar not to be manufactured, imported, exported or sold such products shall have the status of provisionally registered medicinal products.

(3) After the appointed date no person shall import, manufacture, export or sell a medicinal product not listed in the inventory without the prior written permission of the Registrar unless a product licence has been granted in respect of such product under section 6 of this Law.

(4) The inventory, the format of which may be laid down in regulations, shall be made available for inspection at such place and at such times as specified by the Registrar in an order published in the *Gazette* or one or more newspapers as may be specified in the regulations.

(5) The inventory shall be revised accordingly as and when provisionally registered products listed therein have been granted a product licence under section 6(3) that any

such provisionally registered medicinal product should not be manufactured, imported, exported or sold from such date as is specified in the order.

7. Registrar to make order in respect of licences

(1) In accordance with the national drug policy and Grenada's health-care needs, and in relation to considerations of product quality, safety and efficacy, the Registrar shall make an order as to whether a provisionally registered product or a product which is not listed in the inventory but in respect of which an application for its manufacture, import, export or sale has been filed after the appointed date, should be granted a product licence.

(2) The Registrar may be at any time call upon any manufacturer, importers or exporters to furnish such information as is required in order to enable a provisionally registered product or a product sought to be manufactured, imported, or exported after the appointed date, to be evaluated and assessed.

(3) The Registrar may at anytime, in the interest of public health, determine that a provisionally registered product should not be eligible for a product licence and that such product should not be manufactured, imported, or sold or exported either with immediate effect or from such date as specified in an order made by the Registrar.

(4) Upon an order made under subsection (1) or (3) taking effect, the inventory shall be accordingly revised with respect to the entry in relation to the relevant product.

8. Manufacturer defaulting not entitled to manufacture, sell or export

Any manufacturer, importer or exporter who fails, without valid reason, to furnish such particulars within the stipulated time-limit, or within an extended time-limit as may have been granted by the Registrar, shall not be entitled to manufacture, import, sell or export such medicinal product from such date as is specified by the Registrar in a communication addressed to such manufacturer, importer or exporter.

9. Registrar may consult Pharmacy Council

In determining whether a product licence should be granted or not, the Registrar may consult the Pharmacy Council, relevant authorities and health professionals and take into account regulatory information from other countries and relevant international organisations.

10. Registrar to maintain register

The Registrar shall maintain a register of medicinal products for which product licences have been issued and shall make the register, or extracts from it, available at such place and at such times as specified by the Registrar in an order published in the *Gazette* or one or more newspapers as may be specified in the regulations.

11. Regulations to specify validity of product licences

Regulations made under this Act shall specify the terms, conditions, and validity of product licences, the format of the register, and the particulars to be furnished to obtain a product licence for provisionally registered products or for products not listed in the inventory, and other requirements, including the payment of fees, for applications for a product licence.

12. Registrar may by order withdraw product licences

(1) Notwithstanding that a product licence has been granted, where it appears to the Registrar that in the interest of public health a licensed product should not be

manufactured, imported, sold or exported the Registrar may make an order to take effect immediately on publication or on such other day as is mentioned therein.

(2) The order of the Registrar may specify how the order is to take effect, particularly with regard to recalling the product from the market, and the procedures, if any, for notifying health professionals and the public.

13. Aggrieved party may appeal order of Regulations

(1) Any manufacturer, importer or exporter who is aggrieved by an order made by the Registrar under this Part may appeal to the Minister, in writing, within two weeks from the date of the order.

(2) On receipt of an appeal the Minister may decide whether or not the Registrar should be directed to rescind, suspend, vary, modify, reconfirm or reconsider the order in respect of which the appeal has been lodged.

PART III

Licensed Personnel

14. No person may manufacture, import, etc., medical product unless licensed

(1) On or after such date as is specified by the Registrar in a notice published in the *Gazette* or one of the newspaper as may be specified in the regulations, no person shall manufacture, import, export, compound, store, dispense, sell or distribute a medicinal product unless such person has a valid licence granted by the Registrar or is otherwise legally entitled to engage in any such activity.

(2) The particulars to be furnished by applicants for a licence, their qualifications and suitability, and the terms requirements and conditions subject to which such licences may be granted shall be specified by the Minister in regulations made under the Act.

(3) Any persons aggrieved by a decision of the Registrar may appeal, within two weeks of the notification of the decision of the Registrar, to the Minister.

15. Offence to manufacture, etc., a product neither provisionally registered or covered by a product licence

It shall be an offence under this Act for any person to manufacture, import, sell or export a product after the appointed date unless such product at the time of manufacture, import, distribution or export has the status of a provisionally registered product under section 6(2) or has received a product licence under section 7.

16. Offence for person to engage in activity mentioned in section 14(1) without a licence

After such date as is specified under section 14(1) of the Act, it shall be an offence for any person to engage in any of the activities mentioned in that section, unless such person holds a valid licence granted by the Registrar or is otherwise legally entitled to engage in any such activity.

17. No person may manufacture, etc., medical products unless acceptable standards are maintained

No person shall manufacture, import, export, compound, store, sell, promote or distribute a medicinal product—

(*a*) that is unfit for human consumption or for use in food-producing animals;

(*b*) that is adulterated;

(*c*) that has upon it any natural deleterious substance which renders it injurious to health;

(*d*) that has been manufactured, prepared, preserved, packaged or stored for sale under insanitary conditions; or

(*e*) that has been labelled, packaged or promoted in a manner that is false, misleading, deceptive or likely to create an erroneous impression regarding its source, character, value, quality, composition, potency, merit or safety.

18. Inspection of premises

(1) The Registrar or any authorised officer designated by him or her in writing (hereinafter referred to as a designated authorised officer) shall have the power to visit and inspect any manufacturing plant, processing unit, business establishment, warehouse, office or any premises used for or in connection with the manufacture, import, export, distribution, sale or use of any medicinal product, to take samples of any medicinal product of any substance, and to examine records or other documents relating to any medicinal product.

(2) Any person who without valid reason refuses to permit the Registrar or any authorised officer to enter and inspect or take samples or documents is guilty of an offence.

19. Label, package, etc., to conform to prescribed standards

Where any standard is prescribed for any medicinal product, no person shall label, package, sell, offer for sale, distribute or promote any such medicinal product which does not conform to such standard in such manner as is likely to be mistaken for the medicinal product for which the standard has been prescribed.

20. Penalty

Any person who commits an offence against this Act or any regulation made thereunder shall on summary conviction be liable to a fine not exceeding five thousand dollars or to imprisonment for a term not exceeding six months, or to both.

21. Act extends to the State

The provisions of this Act shall extend to all persons, including the State and the public sector, engaged in manufacturing, importing, exporting, compounding, storing, distributing, selling or in any other way dealing with medicinal products.

22. Regulations

The Minister may make regulations for all or any of the matters for which the Act provides for regulations to be made and, in particular, for the following purposes—

(*a*) prohibiting, limiting, restricting, or imposing conditions on, either generally or in relation to a particular medicinal product, manufacture, importation, exportation, compounding, packing, labelling, promoting, dispensing, administration, sale or supply of medicinal products;

(*b*) withdrawing medicinal products from sale or distribution;

(*c*) prescribing the standards to be followed in the manufacture, storage, sale and distribution of medicinal products;

(*d*) classifying medicinal products for purposes of regulating importation, manufacture, compounding, prescribing, dispensing, selling, storage and distribution;

(*e*) regulating persons entitled to import, manufacture, compound, export, store, prescribe, dispense or sell medicinal products;

(*f*) prescribing the terms, conditions, procedures and time-limit for the issuance of licences under Part II and III of the Law and the forms, fees, particulars and records necessary in connection with applications for licensing and grounds for suspension, cancellation or withdrawal of licences;

(*g*) granting exemptions from the requirement of a product licence for imports of medicinal products required for a named patient or to meet a public health emergency; and

(*h*) designating laboratories and analysts for the purpose of conducting analyses and submitting reports.

CHAPTER 189
MEDICAL PRODUCTS (REGULATIONS) ACT

SUBSIDIARY LEGISLATION

No Subsidiary Legislation