CAYMAN ISLANDS

PHARMACY LAW, 1991

(Law 15 of 1991)

Supplement No. 2 Published with Extraordinary Gazette Dated Thursday, 15th August, 1991.

PUBLISHING DETAILS

NOT IN FORCE

CAYMAN ISLANDS

PHARMACY LAW, 1991

(Law 15 of 1991)

Arrangement of Sections

Section Page

PART 1 – PRELIMINARY

PART II - ESTABLISHMENT, CONSTITUTION, ETC., OF PHARMACY BOARD

PART III – PHARMACY

PART IV - MEDICINAL PRODUCTS

PART V - DEALINGS IN MEDICINAL PRODUCTS

PART VI - CONTAINERS, PACKAGES AND IDENTIFICATION OF MEDICINAL PRODUCTS

PART VII - PROMOTION OF SALES OF MEDICINAL PRODUCTS

PART VIII - POISONS

PART IX - PROVISIONS FOR NON-MEDICINAL PRODUCTS

PART X – INSPECTION

PART XI - MISCELLANEOUS AND SUPPLEMENTARY

CAYMAN ISLANDS

PHARMACY LAW, 1991

(Law 15 of 1991)

A LAW TO CONTROL DEALINGS IN MEDICINAL PRODUCTS AND POISONS HAVING POTENTIAL DANGER TO HEALTH IF MISAPPLIED, AND FOR MATTERS CONNECTED THEREWITH AND INCIDENTAL THERETO

ENACTED by the Legislature of the Cayman Islands.

PART 1 – PRELIMINARY

Short title and commencement

1. This Law may be cited as the *Pharmacy Law, 1991*, and shall come into operation on such date as the Governor shall, by Notice published in the Gazette, appoint.

Interpretation

2. In this Law, unless the context otherwise requires —

"**administer**" with its cognate expressions means administer to a human being or an animal, whether orally, by injection, or by introduction into the body in any other way, or by external application, whether by direct contact with the body or not, and any reference in this Law to administering a substance or article is a reference to administering either in its existing state or after it has been dissolved or dispensed in, or diluted or mixed with, some other substance used as a vehicle for such administration;

"**animal**" includes any bird, fish, or reptile;

"**assemble**", in relation to a medicinal product means —

(a) enclosing the product (with or without other medicinal products of the same description) in a container which is labelled before the product is sold or supplied; or

(b) where the product (with or without other medicinal products of the same description) is already enclosed in the container in which it is to be sold or supplied, labelling the container before it is sold or supplied,

and "assembly" has a corresponding meaning;

"**authorised seller of poisons**" means a person, other than a person lawfully conducting a retail pharmacy business, who may sell substances on the Part II Poisons List pursuant to section 42;

"**Authority**" means the Cayman Islands Health Services Authority established under section 3 of the *Health Services Law, 1991*;

"**Board**" means the Pharmacy Board established under section 3.

"**Chairman**" means the Chairman of the Board;

"**Chief Pharmacist**" means the person employed by the Authority in that capacity;

"**clinical trial**" means an investigation or series of investigations consisting of administration of one or more medicinal products of a particular description by, or under the direction of, a medical practitioner or dentist to his patient where there is evidence that medicinal products of that description have effects which may be beneficial to the patient in question and the administration of that medicinal product is for the purpose of ascertaining whether or to what extent the product has those or any other effects whether beneficial or harmful;

"**container**" in relation to a medicinal product means bottle, jar, box, packet or other receptacle which contains or is to contain it, not being a capsule, cachet, or other article in which the product is or is to be administered, and, where any such receptacle is or is contained in another receptacle, includes the former but does not include the latter receptacle;

"**dentist**" means a person licensed under the *Health Practitioners' Law, 1974 [Law 19 of 1974]*, to practise the profession of dentistry;

"**Governor**" means the Governor in Council;

"**hospital**" includes a clinic, nursing home, or other similar institution;

"**inspector**" means a person appointed by the Governor under section 45;

"**labelling**" in relation to a container or package of a medicinal product means affixing to, or otherwise displaying on, the container or package, a notice describing or otherwise relating to the contents thereof, and "**label**" has a corresponding meaning;

"**leaflet**" includes any written information;

"**licensing authority**" has the meaning assigned to it under section 9;

"**manufacture**" in relation to a medicinal product includes any process carried out in the course of making the medicinal product but does not include dissolving or dispensing the medicinal product in, or diluting or mixing it with, some other substance used as a vehicle for the purpose of administering it or the incorporation of the product in any animal feed;

"**medical practitioner**" means a person licensed under the *Health Practitioners' Law, 1974 [Law 19 of 1974]*, to practise the profession of medicine;

"**medicinal product**" means any substance or article (not being an instrument, apparatus, or appliance) which is manufactured, sold, supplied, imported or exported for use wholly or mainly in either or both of the following ways, that is to say —

(a) use by being administered to one or more human beings or animals for a medicinal purpose;

(b) use as an ingredient in the preparation of a substance or article which is to be administered to one or more human beings or animal for a medicinal purpose;

"**medicinal purposes**" means any one or more of the following purposes, that is to say —

(a) treating or preventing disease;

(b) diagnosing disease or ascertaining the existence, degree, or extent of a physiological condition;

(c) contraception;

(d) anesthesia;

(e) otherwise preventing or interfering with the normal operation of a physiological function, whether temporarily or permanently and whether by way of terminating, reducing or postponing, increasing or accelerating, the operation of that function or in any other way;

"**nurse**" means a person licensed under the *Health Practitioners' Law, 1974 [Law 19 of 1974]*, to practise the profession of nursing;

"**package**" in relation to a medicinal product means any box, packet or other article in which one or more containers of medicinal products are, or are to be, enclosed, and, where any such box, packet or other article is or is to be enclosed in one or more other boxes, packets or articles in question, the collective number thereof;

"**pharmacist**" means a person licensed under the *Health Practitioners Law, 1974 [Law 19 of 1974]*, to practise the profession of pharmacy;

"**poison**" means a substance listed in regulations made under section 53;

"**prescription**" means an order complying with regulations made under section 53, issued by a medical practitioner, dentist, or veterinary surgeon;

"**retail pharmacy business**" means a business (not being a professional practice) which consists of or includes the retail sale or supply of medicinal products which are on the Pharmacy Only List or on the Prescription Only List;

"**Registrar**" means the person performing the duties of Registrar to the Board;

"**registered pharmacy**" has the meaning assigned to it under section 13;

"**veterinary surgeon**" means a person registered as such under the *Veterinary Law, 1978 [Law 5 of 1978]*;

"**wholesale dealing**" means the sale or supply of a medicinal product to a person for the purpose of —

(a) selling or supplying it; or

(b) administering it or causing it to be administered to one or more human beings or to one or more animals.

PART II - ESTABLISHMENT, CONSTITUTION, ETC., OF PHARMACY BOARD

Establishment of Pharmacy Board

3. (1) There is hereby established a Board to be called the Pharmacy Board which shall, subject to the provisions of this law, exercise the powers conferred, and discharge the duties imposed upon it by this Law.

(2) The Board shall consist of the Chief Pharmacist, *ex officio*, as Chairman and Registrar, and three other members appointed by the Governor.

(3) The appointment of every member of the Board, other than the Chairman, shall be by instrument in writing and shall, subject to subsections (5) and (6), be limited to three years.

(4) Every appointed member shall be eligible for re-appointment.

(5) Notwithstanding subsection (3) the Governor may, at any time, revoke the appointment of a member appointed by him.

(6) An appointed member may, at any time, resign his office by instrument in writing addressed to the Governor and transmitted through the Chairman, and from the date of receipt of such instrument by the Governor such member shall cease to be a member of the Board.

(7) If an appointed member is unable to perform his duties as a member, whether by reason of ill health or other sufficient cause, the Governor may appoint another person to act in his place during his inability to perform his duties.

Meetings and procedure of Board

4. (1) The Board shall meet at such times and places as the Chairman shall decide.

(2) A quorum of the Board shall be three.

(3) The Chairman shall preside at all meetings of the Board at which he is present, but in the event of his absence or inability to act, the members present and constituting a quorum shall elect one of their number to preside at that meeting.

(4) The Chairman, or person elected to preside at a meeting in place of the Chairman, shall not have an original vote but in the case of an equality of votes he shall have a casting vote.

(5) A member who has a pecuniary interest, whether direct or indirect, in any contract or other matter under consideration at any meeting of the Board at which he is present, shall, as soon as practicable after the commencement of the meeting, disclose the fact, and his disclosure shall be recorded in the minutes of the meeting, and such member may then take part in the deliberations by the meeting of such contract or other matter, but he shall not vote or otherwise take part in the decision of the Board thereon.

(6) Subject to the other provisions of this section the Board shall regulate its own procedure.

(7) The validity of any proceedings of the Board shall not be affected by any vacancy amongst its members or by any defect in the appointment of a member thereof.

Protection of members of the Board

5. No action, suit, prosecution or other proceedings shall be brought or instituted against the Board or any of its members (including an acting member) in respect of any act done *bona fide* in pursuance or execution or intended execution of anything under this Law.

Registrar of the Board

6. The Chief Pharmacist shall be the Registrar to the Board and shall maintain a register of all licence authorisations issued under this Law.

Funds of the Board

7. (1) The funds in the possession of the Board shall be the property of the Authority and shall consist of —

(a) all fees payable under this Law;

(b) such other monies that may come into the possession of the Board in the course of its functions.

(2) The accounts of the Board shall be examined and audited annually by auditors appointed by the Board and approved by the Governor.

Payment of allowances

8. A member, not being a public officer, may be paid and receive from public funds such allowances for travelling and subsistence as may from time to time be payable to persons serving on public bodies.

Licensing authority

9. (1) The Board shall be the licensing authority under this Law and shall be responsible for granting, renewing, varying, suspending, or revoking licences and certificates issued under Part IV, and otherwise as may be necessary for the purposes of this Law.

(2) Any person aggrieved or dissatisfied with any decision of the Board to refuse a licence pursuant to section 14 or section 20(3), or to revoke a licence pursuant to section 14 or section 21 (1) may within 21 days of the communication of the decision to him (or such longer period as the Governor may, for good cause shown, allow) appeal therefrom to the Governor whose decision shall be final and binding upon the appellant.

(3) Appeals under subsection (2) shall be by notice in writing addressed to the Clerk of the Executive Council and shall set forth the decision against which appeal is made and the grounds of the appeal, and shall be accompanied by any statement or other documents upon which the appellant seeks to rely in support of his appeal.

(4) The Governor shall decide an appeal under subsection (2) upon the written grounds of appeal and any supporting documents supplied under subsection (3), together with the response of the Board thereto.

PART III – PHARMACY

Only pharmacist may conduct retail pharmacy business, etc.

10. (1) Except as provided in this Law, no person other than a person registered as a pharmacist under the *Health Practitioners Law, 1974*, shall —

(a) conduct a retail pharmacy business;

(b) in the course of any trade or business prepare, mix, compound or dispense any medicinal product or poison except under the supervision of a pharmacist;

(c) assume, take, exhibit, or in any way make use of, any title, emblem, description or addition which may suggest that he is registered as a pharmacist.

(2) Paragraph (b) of subsection (1) shall not apply to medicinal products administered by —

(a) a medical practitioner or a dentist, to his patient when acting in the ordinary course of his practice;

(b) a veterinary surgeon in the ordinary course of his practice with animals under his care.

(3) For the purpose of subsection (1)(c) the use of the word "pharmacist" or "chemist" or "druggist" or any similar word or combination of words shall be deemed to suggest that the owner of the business or the person having control of the business on those premises is or purports to be, a registered pharmacist.

Company may conduct pharmacy business

11. (1) Notwithstanding anything contained in section 10, but subject to the provisions of this section, a company may lawfully conduct a retail pharmacy business.

(2) A company may be licensed to conduct a retail pharmacy business if —

(a) the business under the personal management and control of a superintendent pharmacist;

(b) a copy of the certificate of incorporation of the company is lodged with the Board; and

(c) the other provisions of this Law are complied with.

(3) A company licensed to conduct a retail pharmacy business in accordance with this section, may use the description "chemist" or "dispensing chemist" and may use the description "pharmacy" in connection with premises on which the business is conducted.

Death of pharmacist

12. Notwithstanding anything contained in sections 10 and 11 —

(a) if a pharmacist dies, or becomes of unsound mind, or is adjudged bankrupt or enters into an arrangement with his creditors, his representatives may, with the permission of the Board and subject to such directions and conditions as the Board may in its discretion impose, carry on the business, and it shall be necessary for such representatives to be licensed and the business continued only under the personal management and control of a pharmacist, and for such period not exceeding five years, as the Board may decide;

(b) the representatives of a pharmacist carrying on a retail pharmacy business in accordance with paragraph (a) of this section shall be a person lawfully conducting a retail pharmacy business within the meaning of this Law and may use any title, emblem, or description which might have been lawfully used by the pharmacist whose representatives they are.

Licensing of premises

13. (1) Every pharmacist or company conducting a retail pharmacy business in accordance with this Law shall cause each set of premises where such business is being carried on to be licensed. Each set of premises so licensed is a "registered pharmacy" for the purposes of this section.

(2) An application for a licence for premises under this section shall be made to the Board in the prescribed form and such application shall be accompanied by the prescribed fee.

(3) The licensing of any premises under this section shall become void upon the expiry of thirty days from the date of any change in ownership of the business carried on therein.

(4) When an application is made for a licence under this section the Board shall, before issuing the licence to which the application relates, consider the following —

(a) the suitability of the premises on which medicinal products will be sold, supplied, dispensed, or stored;

(b) the equipment which is or will be available for storing, dispensing or distributing medicinal products;

(c) the arrangements made or to be made for securing the safekeeping and the maintenance of adequate records in respect of medicinal products sold, supplied, dispensed or stored.

Refusal or revocation of licence

14. The Board may, for good and sufficient reason to be stated in writing, refuse to licence, or may revoke a licence for, any premises which in its opinion are, or have become unsuitable for the purpose of carrying on a retail pharmacy business

Penalty for contravention of s.10

15. Any person who contravenes section 10 of this Law shall be guilty of an offence and liable on summary conviction to a fine not exceeding $5,000.00 or to imprisonment for a term not exceeding 12 months.

Application of Part

16. Nothing in this Part shall apply to —

(a) any transaction mentioned under section 17(2) and (3).

(b) the sale of poisons under Part II of the Poisons List by a licensed seller of poisons in accordance with section 42.

PART IV - MEDICINAL PRODUCTS

Limitations on sale, etc., of medicinal products

17. (1) Subject to the provisions of this Law no person shall in the course of a business carried on by him —

(a) sell, supply or export any medicinal product;

(b) produce for sale, supply or exportation, any medicinal product;

(c) procure the manufacture or assembly of any medicinal product for sale, supply or exportation;

unless the medicinal product concerned is subject to a marketing authorisation (hereinafter referred to as a "product licence') granted by the licensing authority in the Islands or in a State listed in regulations made under section 53.

(2) No person shall import a medicinal product except in accordance with a product licence which has to be declared to Customs on such importation.

(3) No person shall, in the course of a business carried on by him, manufacture or assemble any medicinal product except in accordance with a licence granted for that purpose (hereinafter referred to as a "manufacturer's licence").

(4) No person shall, in the course of a business carried on by him, sell or supply any medicinal product by way of wholesale dealing, except in accordance with a licence granted for that purpose (hereinafter referred to as a "wholesale dealer's licence").

(5) No person other than a person lawfully conducting a retail pharmacy business shall sell or supply any medicinal product by way of dispensing except in accordance with a licence granted for that purpose (hereinafter referred to as a "dispensing licence").

Application for licence

18. (1) An application for a licence under this Part shall be made to the licensing authority in the prescribed form and accompanied by the prescribed fee.

(2) The application referred to in subsection (1) shall contain a description of the medicinal products to which the licence will relate.

Matters to be considered by licensing authority.

19. Where an application is made for a licence under this Part, the licensing authority shall, before issuing the licence to which the application refers, consider the following —

(a) in the case of an application for a product licence —

(i) the safety of medicinal products of each description to which the application relates;

(ii) the efficacy of medicinal products of each description for the purposes for which they are proposed to be administered;

(iii) the quality of medicinal products of each such description, according to the specification and the method or proposed method of manufacture of the medicinal products, and the provisions proposed for securing that the medicinal products when sold or supplied will be of that quality;

(b) in the case of an application for a manufacturer's licence —

(i) the operations proposed to be carried out pursuant to the licence;

(ii) the premises in which those operations are to be carried out;

(iii) the equipment which is or will be available on those premises for carrying out those operations;

(iv) the qualifications of the person under whose supervision the operations will be carried out; and

(v) the arrangements made or to be made for securing the safekeeping and the maintainence of adequate records in respect of medicinal products manufactured or assembled in pursuance of the licence;

(c) in the case of an application for a wholesale dealer's licence —

(i) the premises on which the medicinal products of the description to which the application applies will be stored;

(ii) the equipment which is or will be available for storing medicinal products on those premises;

(iii) the equipment and facilities which are or will be available for distributing medicinal products from those premises;

(iv) the qualifications of the persons under whose supervision those operations will be carried out; and

(v) the arrangements made or to be made for securing the safekeeping of, and the maintainence of adequate records in respect of medicinal products stored on or distributed from those premises;

(d) in the case of an application for a dispensing licence —

(i) the premises on which the medicinal products of the description to which the application relates will be dispensed;

(ii) the equipment which is or will be available for storing medicinal products on those premises;

(iii) the equipment which is or will be available for the dispensing of medicinal products;

(iv) the qualifications of the persons under whose supervision the dispensing of medicinal products will take place; and

(v) the arrangements made or to be made for securing the safekeeping of, and the maintainence of adequate records in respect of medicinal products stored and dispensed on the premises.

Grant of licences

20. (1) If the licensing authority is satisfied that the applicant is a fit and proper person to carry on any business set out in section 17, it may issue to the applicant the licence appropriate to such business subject to such general or special conditions as the licensing authority may consider appropriate.

(2) A licence issued under subsection (1) shall be in the form, and shall be for such duration, as the licensing authority may decide.

(3) Where the licensing authority considers that the applicant is not a fit and proper person to whom a licence should be issued for the carrying out of any business specified in section 17, it shall refuse to issue the licence.

Suspension of licence

21. (1) Subject to the provisions of this Part, the licensing authority may suspend a licence for such period as it may determine, or may revoke, or vary the provisions of such licence.

(2) The suspension or revocation of a licence under this section may be limited to medicinal products of one or more descriptions, or to any particular premises or to a particular part of any premises.

Variation of licence

22. Subject to section 19, the licensing authority may, on the application of the licensee under this part, vary the provisions of the licence in accordance with any proposals contained in the application, if the licensing authority is satisfied that the variation will not adversely affect the safety, quality, and efficacy of medicinal products.

Application of S. 17

23. (1) Section 17 shall not apply —

(a) to anything done in a registered pharmacy if it is done by or under the supervision of a pharmacist and consists of —

(i) preparing, dispensing, assembling, or procuring a medicinal product in accordance with a prescription given by a medical practitioner or a dentist;

(ii) preparing or dispensing a medicinal product for administration to a person where the pharmacist is requested by or on behalf of that person to do so in accordance with the pharmacist's own judgement as to the treatment required and that person is present in the pharmacy

at the time of the request in pursuance of which that medicinal product is prepared or dispensed;

(iii) preparing a stock of medicinal products with a view to dispensing them as provided under sub-paragraphs (i)and (ii)

(iv) preparing, dispensing, assembling, or procuring a medicinal product in accordance with a prescription given by a veterinary surgeon;

(v) preparing a stock of medicinal products with a view to dispensing them as provided under sub-paragraph (iv);

(b) to anything done by a medical practitioner or a dentist which —

(i) relates to the sale or supply of a medical product specially prepared, or specially imported by him or to his order, for administration to his patients; or

(ii) relates to the sale or supply of a medical product specially prepared by a medical practitioner or a dentist for administration to a particular patient at the request of another medical practitioner or dentist;

(c) to anything done by a veterinary surgeon which —

(i) relates to a medicinal product specially prepared or specially imported by him or to his order for administration to or sale or supply for administration to a particular animal or herd under his care;

(ii) .relates to a medicinal product specially prepared by one veterinary surgeon at the request of another for administration to or sale or supply for a particular animal or herd under the care of that other veterinary surgeon;

(d) to the assembly of any medicinal products by a person in the course of that person's profession as a nurse;

(e) to the importation of a medicinal product by any person for administration to himself or to any member of his household, or to the importation of a medicinal product specially imported by or to the order of a medical practitioner or dentist for administration to his patient provided that in other case the quantity so imported shall not be greater than is reasonably necessary for that purpose and is not of commercial value;

(f) to the importation of a medicinal product in such circumstances as may be specified by the Governor in a notice published in the *Gazette*.

Regulations

24. (1) The Governor may, by regulations, provide that section 17 shall have effect subject to such exemptions and modifications (other than those for the time being having effect by virtue of section 17 as may be specified in the regulations).

(2) Any exemption or modification granted or conferred by regulations under subsection (1) may be granted or conferred subject to such conditions or limitations as may be specified.

(3) Regulations made under this section may provide that any of the provisions of section 23 shall cease to have effect, or shall have effect subject to such exemptions or modifications as may be specified.

Conditions for sale, supply, etc., of medicinal products for clinical trial

25. (1) Subject to the provisions of this Part, no person shall, in the course of a business carried on by him —

(a) sell, supply or import any medicinal product for the purpose of a clinical trial; or

(b) procure the sale or supply of any medicinal product for the purpose of a clinical trial; or

(c) procure the manufacture or assembly of any medicinal product for sale or supply for the purpose of a clinical trial,

unless the following conditions have been fulfilled by that person —

(i) that he is the holder of a product licence which authorises the clinical trial in question, or he does it to the order of the holder of such a licence and, in either case, he does it in accordance with that licence; and

(ii) that a certificate for the purposes of this section (referred to as a "clinical trial certificate") has been issued certifying that, subject to the provisions of the certificate, the licensing authority has authorised the clinical trial in question and that a certificate is for the time being in force and the trial is carried out in accordance with that certificate.

(2) This section shall not apply to anything which is done in a registered pharmacy or hospital by or under the supervision of a pharmacist in accordance with a prescription given by a medical practitioner or dentist.

Medical test on animals

26. (1) Subject to this Part a person shall not in the course of a business carried on by him —

(a) sell, supply or import any medicinal product for the purposes of a medicinal test on animals; or

(b) procure the sale, supply or import of any medicinal product for the purposes of a medicinal test on animals; or

(c) procure the manufacture or assembly or for the manufacture or assembly of any medicinal product for the purposes of any medicinal test on animals, unless the following conditions have been fulfilled by that person —

(i) that he is the holder of a product licence which authorises the test in question, or he does it to the order of the holder of such a licence and, in either case, he does it in accordance with that licence;

(ii) that a certificate for the purpose of this section (referred to as an "animal test certificate") has been issued to him certifying that, subject to the provisions of the certificate, the licensing authority has authorised the test in question and that a certificate is for the time being in force and the test is carried out in accordance with that certificate.

Duration or clinical trial or animal test certificate

27. (1) Subject to the provisions of this ·section every clinical trial certificate or animal test certificate shall expire at the end of the period of one year from the date on which it was issued or renewed.

(2) Any certificate, if it has not been revoked, may, on the application of the holder of the certificate be renewed by the licensing authority for a further period of one year from the date on which it would have otherwise expired.

(3) The licensing authority may suspend, for such period as it may determine, a clinical trial certificate or animal test certificate, or it may revoke or vary the provisions of any such certificate.

Offences

28. (1) Any person who contravenes any of the provisions of section 17, 26 or 27 of this Law shall be guilty of an offence.

(2) Where a medicinal product is imported in contravention of section 17, 26, or 27 of this Law any person who is in possession of the product knowing or having reasonable cause to suspect that it was so imported shall be guilty of an offence.

(3) Any person guilty of an offence under any of the provisions of this section shall be liable on summary conviction therefor to a fine not exceeding $5000.00 or to imprisonment for a term not exceeding 12 months or both.

PART V - DEALINGS IN MEDICINAL PRODUCTS

Restrictions on retail sale of medicinal products

29. Subject to any exemption conferred by or under this Part a person shall not, unless he is a person lawfully conducting a retail pharmacy business or a person holding a dispensing licence, sell or supply by retail any medicinal product unless —

(a) such sale is made from premises capable of being closed so as to exclude the public; and

(b) the medicinal product has been made up for sale or supply in a container or package elsewhere than at the place at which it is sold or supplied and the container has not been opened since the product was made up for sale or supply.

Restrictions on sale or supply of pharmacy medicines

30. (1) Subject to any exemptions conferred by or under this Part a person shall not sell or supply by retail, or offer or expose for sale or supply by retail, any medicinal product of a description or a class specified in regulations made under section 53 (hereinafter referred to as "pharmacy medicines") unless the medicinal product is sold or supplied —

(a) by a person lawfully conducting a retail pharmacy business; and

(b) on premises which are a registered pharmacy; and

(c) personally by a pharmacist, or under the direct supervision of a pharmacist

(2) The restrictions imposed by subsection (1) shall not apply to the sale or supply of a medicinal product —

(a) by a medical practitioner, dentist or nurse, any of whom holds a dispensing licence, to a patient of his;

(b) by a veterinary surgeon, who holds a dispensing licence, for administration by him or under his personal direction, to an animal or herd which is under his care;

(c) in the course of the business of a hospital, where the medicinal product is sold or supplied under the supervision of a pharmacist for the purpose of being administered (whether in the hospital or elsewhere) in accordance with the written directions of a medical practitioner or dentist;

(d) of a description or class specified in regulations made under section 53 provided such medicinal product is administered by a nurse who is acting under the written directions of a medical practitioner.

Possession or sale of prescription only medicines

31. (1) Subject to any exemption conferred by or under this Part a person shall not —

(a) possess or, sell or supply by retail, a medicinal product of a description or class specified in regulations made under this Part (hereinafter referred to as "prescription only medicines") except in accordance with a prescription given by a medical practitioner, dentist, or veterinary surgeon;

(b) administer (otherwise than to himself) any such medicinal product for human use unless he is a medical practitioner or a dentist or a person acting in accordance with the written directions of a medical practitioner or dentist.

(2) Subsection (1) (a) of this section shall not apply —

(a) to the sale or supply of such a medicinal product by a medical practitioner, dentist or nurse who holds a dispensing licence, to a patient of his;

(b) to the sale or supply of such a medicinal product by a veterinary surgeon, who holds a dispensing licence, for administration to an animal or herd under his care;

(c) to the possession of such medicinal products by —

(i) a person lawfully conducting a retail pharmacy business;

(ii) a medical practitioner, dentist nurse or veterinary surgeon who holds a dispensing licence;

(iii) a person acting under the written directions of a medical practitioner, dentist, or veterinary surgeon.

Regulations

32. (1) The Governor may, by regulations —

(a) provide that section 29, 30, or 31 shall have effect subject to such exceptions (other than those having effect by virtue of sections 30(2) and 31 (2)), conditions, or limitations as may be specified;

(b) provide for restrictions on the sale or supply of medicinal products by way of wholesale dealing;

(c) where it appears to him necessary to do so in the interest of safety, prohibit the sale, supply, or importation of medicinal products of any description or falling within any specified class, or designate (in such manner as may appear to him to be sufficient to identify the products) particular medicinal products.

(2) Before making any regulations under this section the Governor shall consult the Board, unless he considers it essential to make the regulations with immediate effect to avoid danger to health.

Alteration of medicinal product prohibited

33. (1) A person shall not —

(a) with the intention of selling or supplying the product in the changed state add any substance to, or abstract any substance from, a medicinal product so as to adversely affect the composition thereof; or

(b) sell or supply, or offer or expose for sale or supply, or have in his possession for the purpose of sale or supply, any medicinal product the composition of which has been adversely affected by the addition thereto or abstraction therefrom of any substance; or

(c) sell or supply any medicinal product which is not of the nature or quality specified by the purchaser.

(2) Subsection (1) shall not be taken to have been contravened by reason only that a medicinal product contains some extraneous matter if it is proved that the presence of that matter was an inevitable consequence of the process of manufacture of the product.

(3) Where a medicinal product is sold or supplied pursuant to a prescription given by a medical practitioner or dentist, subsections (1) and (2) shall have effect as if —

(a) any reference to the "purchaser" includes a reference to the person for whom the medicinal product was prescribed by a medical practitioner or dentist; and

(b) for the words "demanded by the purchaser there were substituted the words "specified in the prescription".

Penalty for contravention of S. 29, 30, 31 or 33

34. Any person who contravenes section 29, 30, 31, or 33 or any regulations made under section 32 shall be guilty of an offence, and liable on summary conviction to a fine of $5,000.00 or to imprisonment for a term not exceeding 12 months or to both.

PART VI - CONTAINERS, PACKAGES AND IDENTIFICATION OF MEDICINAL PRODUCTS

Packaged product to be correctly labelled

35. (1) A person shall not, in the course of a business carried on by him, sell or supply or have in his possession for the purpose of selling or supplying any medicinal product in a container or package which is not labelled in accordance with regulations made under section 53.

(2) Without prejudice to subsection (1) a person shall not, in the course of a business carried on by him, sell or supply, a medicinal product of any description in a container or package which is labelled or marked in such a way that the container or package —

(a) falsely describes the product; or

(b) is likely to be misleading as to the nature, efficacy or quality of the product or as to the uses or effects of medicinal products of that description.

Leaflet relating to medicinal products

36. (1) A person shall not, in the course of a business carried on by him, supply or have in his possession for the purpose of supplying together with medicinal products, a leaflet relating to such medicinal products which does not comply with regulations made under section 53.

(2) Without prejudice to subsection (1) a person shall not, in the course of a business carried on by him, supply together with a medicinal product or have in his possession for the purpose of so supplying, a leaflet which —

(a) falsely describes the medicinal product to which it relates; or

(b) is likely to be misleading as to the nature, efficacy or quality of such medicinal product.

Penalty for contravention of S.35 or 36.

37. Any person who contravenes the provisions of section 35 or 36 shall be guilty of an offence and liable on summary conviction to a fine not exceeding $1000.00 to imprisonment for a term not exceeding three months or both.

PART VII - PROMOTION OF SALES OF MEDICINAL PRODUCTS

Interpretation of Part

38. (1) In this Part "advertisement" includes every form of advertising, whether in a publication, or by the display of any notice, or by means of any catalogue, price list, letter (whether circular or addressed to a particular person) or other document, or by words inscribed on any article, or by the exhibition of a photograph or a cinematograph film, or by way of sound recording, sound broadcasting or television, or in any other way, and any reference to the issue of an advertisement shall be construed accordingly.

(2) Except as regulations made under section 39 may otherwise provide, for the purpose of this Part the following shall not constitute an advertisement —

(a) the sale or supply, or offer or exposure for sale or supply, of a medicinal product in a labelled container or package;

(b) the supply together with a medicinal product, of a leaflet relating solely to the use of the medicinal product supplied.

Regulations

39. The Governor may make regulations which may prohibit any issue of advertisements —

(a) relating to medicinal products of a description, or falling into a class, specified in the regulations;

(b) likely to lead to the use of any medicinal product, or any other substance or article, for the purpose of treating or preventing a specified disease or for the purpose of diagnosis of a disease so specified, or of ascertaining the existence, degree or extent of a physiological condition so specified, or of permanently or temporarily preventing or otherwise interfering with

the normal operation of a physiological function so specified, or for the purpose of artificially inducing a condition of body or mind so specified;

(c) likely to lead to the use of medicinal products of a particular description or falling within a class specified in the regulations, or the use of any other substance or article of a description or class so specified for any such purpose as is mentioned in paragraph (b) of this section.

(d) relating to medicinal products and containing a word or phrase specified in the regulations, as being a word or phrase which, in the opinion of the Governor, is likely to mislead the public as to the nature or effects of the product or as to any condition of the body or mind in connection with which the medicinal product might be used.

Contravention of regulations

40. Any person who contravenes the provisions of any regulations made under this Part of the Law shall be guilty of an offence and shall be liable on summary conviction to a fine not exceeding $3,000.00 or to imprisonment for a term not exceeding six months or both.

PART VIII - POISONS

The Poisons List

41. (1) The Governor shall, after consultation with the Board, prescribe by way of regulations under section 53, a list of non-medicinal poisons (hereinafter referred to as the "Poisons List").

(2) The Poisons List shall be divided into two parts as follows —

(a) Part I shall consist of those substances which, subject to the provisions of this Law, are prohibited from being sold except by a person lawfully conducting a retail pharmacy business; and

(b) Part II shall consist of those substances which, subject to the provisions of this Law, are prohibited from being sold except by a person lawfully conducting a retail pharmacy business or an authorised seller of poisons listed with the Board.

Conditions of sale of substance on the Poisons List

42. (1) Subject to the provisions of this Law, a person shall not —

(a) sell or supply any poison which is a substance included in Part I of the Poisons List, unless —

(i) he is a person lawfully conducting a retail pharmacy business; and

(ii) the sale or supply is effected on premises which are a registered pharmacy; and

(iii) the sale or supply is effected personally by a pharmacist or under the supervision of a pharmacist;

(b) sell or supply any poison which is a substance included in Part II of the Poisons List, unless —

(i) he is a person lawfully conducting a retail pharmacy business and the sale or supply is effected on premises which are a registered pharmacy; or

(ii) he is a person who is an authorised seller of Part II poisons;

(c) sell or supply any poison, whether it is a substance included in Part I or Part II of the Poisons List, unless the container of the poison is labelled —

(i) with the name of the poison;

(ii) in the case of a preparation which contains a poison as one of its ingredients, with the prescribed particulars as to the proportion which the poison contained in the preparation bears to the total ingredients;

(iii) with the word "poison";

(iv) with the name and address of the seller and the address of the premises on which it is sold; and

(v) any indication of a general or specific risk together with any safety precautions to be taken in its use as provided for in regulations made under section 53.

(2) Subject to the provisions of this Law a person shall not sell or supply any poison which is a substance included in Part I of the Poisons List to any other person unless that other person is either —

(a) known by the seller or a pharmacist in the employment of the seller at the premises at which the sale is effected to be a person to whom the poison may properly be sold; or

(b) certified in writing by a person authorised in that behalf by the Governor.

(3) Subject to the provisions of this Law a person shall not sell or supply or deliver any poison included in Part I of the Poisons List until he has made or caused to be made an entry in a bound book to be kept for that purpose stating the date of the sale, the name and address of the purchaser and of the person giving a certificate (if any), the name and the quantity of the article sold and the purpose for which it is stated by the purchaser to be required.

(4) A person shall not by means of an automatic machine, expose or offer a poison for sale.

Penalty for contravention of S. 42

43. Any person who contravenes the provisions of section 42 shall be guilty of an offence and liable on summary conviction to a fine not exceeding $5,000.00 or a term of imprisonment not exceeding twelve months or both.

PART IX - PROVISIONS FOR NON-MEDICINAL PRODUCTS

Regulations

44. The Governor may, by regulations, specify any description or class of articles or substances which —

(a) are manufactured, sold, supplied, imported or exported in a manner similar to medicinal products;

(b) are used as ingredients in the manufacture of medicinal products;

(c) if used without proper safeguards are likely to be a risk to public health or to be dangerous or injurious to animals; and he may direct that, subject to such exceptions and modifications as may be specified, the provisions of this Law, including those relating to offences and penalties, shall have effect to such descriptions or classes of articles or substances as those provisions apply to medicinal products.

PART X – INSPECTION

Appointment of inspectors

45. (1) The Governor shall, for the purposes of enforcing the provisions of this Law, appoint such number of inspectors as he considers appropriate and shall issue to them in writing or in such form as may be prescribed, certificates of authority to act as inspectors.

(2) A person shall not be qualified for appointment as an inspector unless he is a pharmacist.

(3) A person appointed by the Governor as an inspector under this section shall hold office subject to such conditions at the Governor may determine.

Right of entry on premises by inspectors

46. (1) Subject to the provisions of this section, an inspector shall, at any reasonable time and on production of his certificate of authority, have a right to enter any premises —

(a) for the purpose of ascertaining whether there is or has been, on or in connection with those premises, any contravention of this Law;

(b) generally for the purpose of discharging his functions under this Law.

(2) An inspector shall, at any reasonable time and on production of his certificate of authority, have a right to —

(a) enter any ship, aircraft or any vehicle for the purpose of ascertaining whether there is in the ship, aircraft or vehicle any substance or article imported in contravention of this Law;

(b) enter any ship, aircraft or any vehicle for any purpose for which the inspector is authorised to enter any premises under subsection (1) of this section.

(3) Without prejudice to subsection (1) an inspector shall, at any reasonable time and on production of his certificate of authority, have a right to enter any premises occupied by an applicant for a licence or certificate under Part III, Part IV, or Part VIII of this Law for the purpose of verifying any statement in the application for a licence or certificate.

Powers of inspector

47. (1) For the purpose of ascertaining whether there is or has been a contravention of this Law an inspector may inspect and examine —

(a) any substance or article appearing to him to be a medicinal product or poison;

(b) any article appearing to him to be a container or package used or intended to be used to contain any medicinal product or poison or to be a label or leaflet used or intended to be used in connection with a medicinal product or poison;

(c) any plant or equipment appearing to him to be used or intended to be used in connection with the manufacture or assembly of medicinal products, and any process of manufacture or assembly of any medicinal products and the means employed, at any stage in the processes of manufacture or assembly, for testing the materials after they have been subjected to those processes.

(2) Where an inspector requires a sample of any substance of article appearing to him to be —

(a) a medicinal product or poison sold or supplied or intended to be sold or supplied; or

(b) a substance or article used or intended to be used as an ingredient in the manufacture of a medicinal product or poison;

he shall (if he does not obtain the sample by purchase) have a right to take a sample of that substance or article.

(3) For the purposes of this section, an inspector may —

(a) require any person carrying on a business which consists of the manufacture, assembly, sale or supply of medicinal products or poisons, and any person employed in connection with such a business, to produce any books or documents relating to the business which are in his possession or under his control;

(b) take copies of, or of any entry in any book or document produced in pursuance of paragraph (a) of this subsection.

(4) An inspector may seize and detain any substance or article which he has reasonable cause to believe to be a substance or article in relation to which, or by means of which, an offence under this Law is being or has been committed, and any document which he has reasonable cause to believe to be a document which may be required in evidence in proceedings under this Law.

(5) In exercising the powers under this section, an inspector may, in order to secure that the provisions of this Law are observed, require any person who owns the substance or article or has authority over the substance or article which is contained in a container or package to break open the container or package or permit the inspector to do so.

(6) Where an inspector seizes any substance or article, including any document pursuant to subsection (4), he shall inform the person from whom it is seized of the fact of its seizure.

(7) An inspector entering any premises, ship, aircraft or vehicle pursuant to section 46 may take with him such other persons and such equipment as may appear to him to be necessary, and on leaving any such premises, ship, aircraft or vehicle he shall, if the premises are unoccupied or if the occupier, or in the case of a ship, aircraft, or vehicle the master, commander or other person in charge of it is temporarily absent, leave it as effectively secured against trespass as he found it.

(8) Any person who —

(a) wilfully obstructs an inspector in the discharge of his duties; or

(b) wilfully fails to comply with any requirement properly made to him by an inspector; or

(c) without reasonable cause fails to give to the inspector any assistance or information which the inspector may reasonably require of him for the purpose of the performance of his duties under this Law,

shall be guilty of an offence and shall be liable on summary conviction to a fine not exceeding $1,500.00

(9) If any person, in giving any such information as is mentioned in subsection (8)(c) of this section makes any statement which he knows to be false or which he does not believe to be true, he shall be guilty of an offence and liable on summary conviction to a fine not exceeding $1,500.00.

(10) Nothing in this section shall be construed as requiring a person to answer any question or give any information if to do so might incriminate him.

Disclosure of information an offence

48. If any person discloses to any other person —

(a) any information with respect to any manufacturing process or trade secret obtained by him in premises which he has entered pursuant to this Law; or

(b) any information obtained by or furnished to him pursuant to this Law;

he shall, unless the disclosure was made in the performance of his duty, be guilty of an offence and shall be liable on summary conviction to a fine not exceeding $1,500.00 or a term of imprisonment not exceeding six months or both.

Inspector not personally liable

49. An inspector shall not be personally liable in respect of any act done by him in the course of his employment and in the execution or purported execution of any duty under this Law.

Offences by body corporate

50. Where under this law an offence which is committed by a body corporate is proved to have been committed with the consent and connivance of, or to be attributable to any neglect on the part of any director, manager, secretary or other similar officer of the body corporate or any person who was purporting to act in any such capacity, such persons and the body corporate shall jointly and severally be guilty of an offence and shall be liable to be proceeded against and punished accordingly.

Punishment where no specific penalty provided

51. Any person who is guilty of an offence under this Law for which a specific penalty has not been provided shall be liable on summary conviction to a fine not exceeding $3,000.00 or to a term of imprisonment not exceeding 6 months or both.

Forfeiture of substance or article

52. Upon conviction of any person for an offence under this Law the court may, in addition to any other penalty imposed, declare any substance or article seized and detained by an inspector and found to have been used in, or in connection with the commission of that offence to be forfeited, and may order it to be destroyed or otherwise disposed of without compensation.

PART XI - MISCELLANEOUS AND SUPPLEMENTARY

Regulations

53. The Governor may, with the advice of the Board, make regulations for carrying out or giving effect of the provisions of this Law and, without prejudice to the generality of the foregoing, such regulations may —

(a) specify such States whose authorisations for marketing medicinal products are accepted within the Islands;

(b) specify descriptions or classes of medicinal products or poisons or any articles or substances required to be specified under this Law;

(c) control, regulate, or prohibit the sale or supply, possession export or import of any medicinal products or poisons or any article or substance of any specified description or class;

(d) provide for the manner in which containers and packages of medicinal products may be labelled;

(e) provide for the manner in which medicinal products may be advertised and the manner in which leaflets relating to the advertising of medicinal products or poisons may be made;

(f) prescribe such requirements as may be necessary with respect to —

(i) the manner in which, or persons under whose supervision, medicinal products or poisons may be prepared or dispensed;

(ii) the amount of space to be provided in any premises for persons preparing or dispensing medicinal products, the separation of any such space from the reminder of the premises, and the facilities to be provided in any premises tor such persons;

(iii) the accommodation to be provided in any premises for the sale or supply of medicinal products or poisons;

(iv) the accommodation to be provided in any premises for members of the public to whom medicinal products or poisons are sold or supplied or for whom medicinal products are prepared, dispensed or assembled;

(v) the amount of space to be provided for, and the conditions under which, medicinal products are stored;

(vi) the safekeeping of medicinal products and poisons;

(vii) the disposal of medicinal products or poisons;

(viii) precautions to be observed before medicinal products or poisons are sold or supplied;

(ix) the keeping of records relating to the sale or supply of medicinal products or poisons;

(x) the supply of medicinal products or poisons distributed as samples;

(xi) sanitation, cleanliness, temperature, humidity or other factors relating to the conditions pertaining in any premises where medicinal products or poisons are manufactured, assembled, prepared, dispensed or stored and in any premises from which medicinal products or poisons are sold or supplied;

(g) prescribe forms of any applications, notices, licences, certificates and any other documents required to be prescribed under this Law;

(h) prescribe forms of any register, book or record to be kept for the purposes of this Law;

(i) prescribe the fees payable upon application for any licence or certificate or for renewal of any licence or certificate required under this Law;

(j) prescribe anything to be prescribed under this Law.

Repeal and saving

54. (1) The *Pharmacy Law, 1979*, is repealed.

(2) Any subsidiary legislation made under the *Pharmacy Law, 1979*, in force immediately before the commencement of this Law shall be deemed to be made under this Law and shall continue in force until amended or replaced by subsidiary legislation made under this Law.

Passed by the Legislative Assembly on the 5th day of July, 1991.

SYBIL McLAUGHLIN
Speaker.

GEORGETTE MYRIE
Clerk of the Legislative Assembly.