SAINT LUCIA

CHAPTER 11.21

PHARMACY ACT

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PHARMACY ACT

Act 8 of 2003 in force 1 April 2003 (S.I.32/2003)

FORMS AND FEES REGULATIONS – Section 68

Statutory Instrument 43/2006 in force 22 May 2006

PHARMACY REGULATIONS – Section 68

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CHAPTER 11.21

PHARMACY ACT

ARRANGEMENT OF SECTIONS

Section

CHAPTER 11.21

PHARMACY ACT

(Act 8 of 2003)

AN ACT to establish the Pharmacy Council, to provide for the registration of pharmacists, pharmacies and authorised sellers of poisons, to regulate the supply of drugs and poisons to the public, and for related matters.

Commencement [1 April 2003]

PART 1
PRELIMINARY

DIVISION 1
Short Title

1. SHORT TITLE

This Act may be cited as the Pharmacy Act.

2. INTERPRETATION

(1) In this Act—

"**authorised seller of poisons**" means a person registered as such under Part 2;

"**Code of Ethics**" means the Code of Ethics contained in Schedule 1;

"**certificate of inspection**" means a certificate issued by a Pharmacy Inspector under section 54;

"**certificate of registration**" means a certificate issued by the Registrar under section 38;

"**Chairperson**" means the Chairperson of the Pharmacy Council elected under section 5;

"**dispensing**" when used in relation to drugs or poisons means supplying a medicine or a poison in accordance with a prescription;

"**drug**" includes any substance or mixture of substances, manufactured, sold or represented for use in—

(a) the diagnosis, treatment, mitigation or prevention of any disease, disorder, abnormal physical or mental state, or their symptoms, in human beings or animals;

(b) the restoration, correction or modification of organic functions in human beings or animals;

(c) disinfection of premises in which food is manufactured, prepared or kept;

"**drug procurement and distribution agency**" means any person, other than the Pharmaceutical Procurement Service, purchasing drugs in bulk for the purpose of wholesale distribution;

"**health care aids and devices**" means the items listed in Schedule 2;

"**List of Poisons**" means the list published under section 14(1);

"**member**" means a member of the Pharmacy Council appointed under section 5;

"**Minister**" means the Minster responsible for health;

"**misconduct**" means conduct that, in the opinion of the Pharmacy Council, undermines the honour and dignity of the pharmacy profession, and includes behaviour that falls short of the standards contained in the Code of Ethics;

"**pesticides**" means any drug used for the control of pests which is therefore regulated by the Pesticides and Toxic Chemicals Control Act;

"**pests**" has the same meaning given to it in the Pesticides and Toxic Chemicals Control Act;

"**Pharmaceutical Procurement Service**" means the Organisation of Eastern Caribbean States Eastern Caribbean Drug Service established by Agreement Establishing the Eastern Caribbean Drug Service of 2 June 1989;

"**pharmacist**" means a person registered as such under Part 2;

"**pharmacy**" means premises or that part of it that is registered for use for the practice of pharmacy under Part 2;

"**Pharmacy Council**" means the Pharmacy Council established under section 5;

"**Pharmacy Inspector**" means a person appointed as such under section 46;

"**poison**" means a substance, that is dangerous to human or animal health or life, and that is contained in the List of Poisons;

"**practice of pharmacy**" includes—

(a) the supply of drugs or poisons in accordance with a prescription given by a duly registered doctor, dentist, veterinarian or other authorised person;

(b) the compounding, packaging, labelling, storage and dispensing of drugs;

(c) the provision of non-prescription drugs;

(d) the provision of health care aids and devices; and

(e) the provision of information related to drug use;

"**prescribed**" means prescribed by regulations;

"**Registers**" means the Register of Pharmacists, the Register of Authorised Sellers of Poisons and the Register of Pharmacies kept by the Registrar undersection 37;

"**Registrar**" means the Registrar of the High Court;

"**regulations**" means regulations made under section 68.

"**Vice Chairperson**" means the Vice Chairperson of the Pharmacy Council elected under section 5;

3. APPLICATION

(1) This Act does not apply to pesticides.

(2) This Act shall not be construed as authorising the manufacture, compounding, supply or possession of controlled drugs contrary to the Drugs (Prevention of Misuse) Act or its replacement.

(3) This Act shall not be construed as giving the Pharmacy Council responsibility over any activity over which the Pharmaceutical Procurement Service has responsibility.

4. ADMINISTRATION

The Pharmacy Council is responsible for the administration of this Act.

5. ESTABLISHMENT

(1) There is hereby established a council to be called the Pharmacy Council.

(2) The Pharmacy Council shall comprise 7 persons appointed by the Minister as follows—

(a) the Chief Pharmacist of the Public Service who shall be the Secretary;

(b) two registered pharmacists from the private sector who, subject to subsection (3), shall be nominated by the Pharmaceutical Association of Saint Lucia Incorporated;

(c) two professionals, who subject to subsection (3), shall be nominated in accordance with the selection procedure contained in guidelines issued by the Pharmaceutical Association of Saint Lucia Incorporated;

(d) two persons representing the public interest appointed by the Minister.

(3) In the event that the Pharmaceutical Association of Saint Lucia Incorporated ceases to exist, the Minister shall appoint the persons referred to in subparagraphs (b) and (c).

(4) The Pharmacy Council shall elect a Chairperson and a Vice-Chairperson from among its members.

(5) The Chairperson is the chief executive officer of the Pharmacy Council and shall supervise and direct its work and preside over its meetings.

(6) The Vice-Chairperson shall act if the Chairperson is absent, incapacitated or ineligible to perform his or her duties.

(7) The names of the initial members, their titles, if any, and every change in membership, in the Pharmacy Council shall be published in the Gazette.

6. TENURE AND REMOVAL

A member shall hold office for 3 years during good behaviour but may be removed by the Minister for cause.

7. REAPPOINTMENT

A member may be reappointed as member in the same or another capacity.

8. ALTERNATE MEMBERS

(1) The Pharmacy Council may appoint a person to be an alternate member for any member, other than the Chairperson.

(2) The alternate member may act as a member if that member is temporarily absent or incapacitated or ineligible to perform the duties of a member.

9. VACANCY

If a vacancy occurs in its membership, the Pharmacy Council shall appoint a person to fill the vacancy in a manner that is consistent with the requirements in section 5(2) for the composition of the Pharmacy Council.

10. HEAD OFFICE

The Pharmacy Council shall have a head office in Saint Lucia and may establish other offices within Saint Lucia as it considers desirable.

11. QUORUM

Four members of the Pharmacy Council constitute a quorum.

12. REMUNERATION

A member of the Pharmacy Council shall not be paid remuneration or fees for his or her services as a member, but a member is entitled, within the limits that the Council may establish, to be paid for reasonable travel and other expenses that he or she may incur in connection with the work of the Pharmacy Council.

DIVISION 2

Functions, Duties etc.

13. FUNCTIONS

The Pharmacy Council has the following functions—

(a) to ensure the maintenance of high standards in the practice of pharmacy, in the interest of public health and safety;

(b) to foster ethical behaviour among pharmacists in order to uphold the dignity and honour of the profession;

(c) to manage and control the registration of pharmacists, pharmacies and authorised sellers of poisons;

(d) to discipline pharmacists and authorised sellers of poisons under this Act;

(e) to advise the Minister on—

(i) matters relating to the inspection of premises by Pharmacy Inspectors,

(ii) the management and control of the pharmaceutical industry in general, including importation of drugs and poisons and their wholesale to private pharmacies,

(iii) matters referred to it by the Minister.

14. LIST OF POISONS

(1) Within 90 days after the commencement of this Act, the Pharmacy Council shall publish a notice in the Gazette, containing a list of all drugs that it deems poisons.

(2) The List of Poisons shall not include any pesticide.

(3) The Pharmacy Council may amend the List of Poisons, by adding to or deleting from it, by notice published in the Gazette.

15. DIRECTIONS FROM MINISTER

The Minister may give to the Pharmacy Council general directions with regard to its functions under this Act that the Minister considers necessary in the public interest, and the Pharmacy Council shall give effect to these directions.

16. REPORT TO MINISTER

The Pharmacy Council shall give the Minister any information that the Minister may require regarding its operations.

17. REPORT OF PROCEEDINGS

The Pharmacy Council shall submit to the Minister an annual report of its proceedings during the 12 months ending on 31 December, in the year preceding that in which the report is submitted.

18. FEES

The Pharmacy Council may impose reasonable fees for processing applications for registration and any other service that it provides under this Act.

19. COMMITTEE

(1) The Pharmacy Council may appoint a committee to examine and report to it on any matter relating to any of its functions under this Act.

(2) A committee shall include not less than 2 members of the Pharmacy Council, and may include persons who are not members.

(3) The Pharmacy Council shall determine the composition and functions of a committee.

20. DELEGATION

(1) The Pharmacy Council may delegate, in writing, to a committee or to a member, the exercise of any power or the performance of any duty vested in it by this Act, except the power to delegate under this section.

(2) A delegation under subsection (1) may be revoked or varied in like manner.

21. EXEMPTION FROM LIABILITY

Civil liability or criminal liability shall not attach to any member of the Pharmacy Council in respect of anything done, or omitted, in good faith under the provisions of this Act.

DIVISION 3

Disciplinary and Remedial Measures

22. DECISION TO HOLD INQUIRY

(1) In sections 22 to 29 " **judge**" means a judge or a retired judge, of the High Court or Court of Appeal of any Commonwealth jurisdiction.

(2) A pharmacist may recommend to the Minister, or the Minister may decide, that an inquiry be held to determine whether any member of the Pharmacy Council be subject to disciplinary or remedial measures on any of the following grounds—

(a) the member has become incapacitated, mentally or physically, from the due execution of his or her duties;

(b) the member is guilty of misconduct;

(c) the member has failed in the due execution of his or her duties; or

(d) the member has been placed, by conduct or otherwise, in a position that is incompatible with the due execution of his or her office.

(3) If the Minister considers it appropriate that any inquiry be held, a judge shall conduct the inquiry.

23. POWERS OF INQUIRY

A judge conducting the inquiry has all the powers, rights and privileges that are vested in the High Court.

24. HEARING PUBLIC

(1) Subject to subsections (2) and (3), an inquiry shall be conducted in public.

(2) On application, a judge conducting an inquiry may take any measures or make any order that the judge considers necessary to ensure the confidentiality of the inquiry if the judge is satisfied that financial or personal or other matters may be disclosed and are of such a nature that the desirability of avoiding public disclosure of those matters in the interest of any person affected, or in the public interest, outweighs the desirability of adhering to the principle that the inquiry be conducted in public.

(3) If the judge considers it appropriate to do so, the judge may take any measures or make any order that the judge considers necessary to ensure the confidentiality of any hearing held in respect of an application referred to in subsection (2).

25. RULES OF EVIDENCE

A judge conducting an inquiry is not bound by any legal or technical rules of evidence and, in any proceedings of the inquiry, the judge may receive and base a decision on evidence adduced in the proceedings and considered credible or trustworthy in the circumstances of the case.

26. NOTICE OF INQUIRY

A member of the Pharmacy Council shall be given reasonable notice of the subject-matter of the inquiry and of the time and place of any hearing and shall be given an opportunity, in person or by counsel, to be heard at the hearing, to cross-examine witnesses and to adduce evidence.

27. REPORT OF INQUIRY

(1) When an inquiry is completed, the judge who conducted the inquiry shall submit a report of the conclusions of the inquiry to the Minister and a copy of the report and the reasons for the direction shall be sent to the member of the Pharmacy Council.

(2) If the judge finds that any of the grounds in subsection 22(2) has been established, the judge may direct in the report that—

(a) the member of the Pharmacy Council be suspended without remuneration;

(b) the member of the Pharmacy Council be removed from office;

(c) remedial measures that the judge considers necessary be taken.

28. APPEAL TO THE HIGH COURT

(1) A member of the Pharmacy Council in respect of whom a direction has been made under section 27(2) may appeal against it to the High Court.

(2) The appeal shall be lodged before the expiration of 28 days after the day on which notice of the direction is sent to the member.

(3) The appeal shall be by way of rehearing.

(4) The High Court may—

(a) confirm the direction;

(b) vary the direction; or

(c) replace the direction with any other direction that the judge conducting the inquiry has the power to make under section 27(2).

29. ACTION BY MINISTER

The Minister shall suspend without remuneration or remove the member, or take any remedial measure directed to be taken by the judge—

(a) if no appeal is lodged, after the expiration of 28 days after the report is sent to the Minister; or

(b) if an appeal is lodged, upon receipt of the direction of the High Court.

PART 2
REGISTRATION

DIVISION 1
Requirement for Registration

30. PHARMACIST

Unless a person is a pharmacist or is exempt under section 33, he or she shall not engage in the practice of pharmacy or represent himself or herself to be entitled to engage in the practice of pharmacy, whether or not by the use of the following titles—

(a) pharmacist;

(b) druggist;

(c) pharmaceutical chemist;

(d) dispenser; or

(e) chemist.

31. AUTHORISED SELLER OF POISONS

A person shall not sell poisons or represent himself or herself as a person entitled to sell poisons, whether as a wholesaler or retailer unless that person is an authorised seller of poisons or is exempt under this Act.

32. PREMISES OF PHARMACY

A person in possession of premises shall not—

(a) permit their premises to be represented as a pharmacy by any means, such as the use of emblems, signs or titles unless that person is the holder of a certificate of registration in respect of those premises;

(b) permit the premises, or any part of it, to be used as a pharmacy, unless the premises, or the part so used, is registered as a pharmacy;

(c) operate a pharmacy unless—

(i) compounding, dispensing and sale of poisons is under the direct supervision of an authorised seller of poisons,

(ii) the practice of pharmacy is under the direct supervision of a registered pharmacist,

(iii) there is conspicuously displayed in the pharmacy a valid certificate of registration relating to the premises, a certificate of regisration relating to the pharmacist under whose supervision the practice of pharmacy is carried on and a certificate of registration relating to the authorised seller of poisons under whose supervision the compounding dispensing and sale of poisons is carried on.

33. EXEMPTIONS

(1) Medical doctors and veterinarians may be allowed to stock an emergency supply of medicines, provided that, the dispensation is only for 48 hours supply of medicines to a patient at any time.

(2) Subsection (1) may be amended by an order made by the Minister and published in the Gazette.

(3) A person licensed as a Family Nurse Practitioner under the Registration of Nurses and Midwives Act may prescribe only those drugs specified in Schedule 3 to that Act.

DIVISION 2

Registration of Pharmacists, Pharmacies and Authorised Sellers of Poisons

34. APPLICATION

(1) A person who wishes to engage in the practice of a pharmacist may apply in the prescribed form to the Pharmacy Council to be registered as a pharmacist.

(2) A person who wishes to sell poisons may apply in the prescribed form to the Pharmacy Council to be registered as an authorised seller of poisons.

(3) A person in possession of premises who wishes to operate a pharmacy on these premises may apply in the prescribed form

to the Pharmacy Council for registration of the premises as a pharmacy.

(4) An application made under subsection (1), (2) or (3) shall be accompanied by the prescribed application fee.

35. APPROVAL

(1) The Pharmacy Council shall approve an application for registration as a pharmacist if the applicant—

(a) has a degree, certificate or diploma in Pharmacy from an institution recognised by the Pharmacy Council; and

(b) is of good character.

(2) The Pharmacy Council shall approve an application for registration as an authorised seller of poisons if the Pharmacy Council considers that the applicant is fit to sell the poisons in respect of which the application is made.

(3) The Pharmacy Council shall approve an application for registration of premises as a pharmacy if it is satisfied that the premises complies with the prescribed standards for a pharmacy and is fit for operation as a pharmacy.

36. GRANT OF REGISTRATION

Where an application made under section 34 is approved under section 35, the Pharmacy Council shall—

(a) inform the applicant in writing;

(b) direct the Registrar, by letter accompanied by applicaition documents, to issue a certificate of registration and to register the applicant or the premises.

37. RECORD OF REGISTRATION

The Registrar shall keep in the prescribed form—

(a) a Register of Pharmacists;

(b) a Register of Authorised Sellers of Poisons; and

(c) a Register of Pharmacies.

38. CERTIFICATE OF REGISTRATION

(1) Where the Registrar has been given a direction under section 36 the Registrar shall, on payment by the applicant of the prescribed registration fee, register the name of the applicant or the premises in the appropriate register.

(2) The certificate of registration shall include—

(a) the registration number of the applicant;

(b) the name of the applicant and, in the case of an application for the registration of a pharmacy, the address and description of the premises in respect of which a Pharmacy Certificate of Registration was issued;

(c) the date of issue;

(d) the date of the expiration of registration; and

(e) the address of the Pharmacy Council where complaints can be lodged.

39. VALIDITY OF REGISTRATION

A certificate of registration—

(a) is valid for one year; and

(b) may be renewable for further periods of one year upon the prescribed application being made and payment of the prescribed annual fee if, the applicant or the premises continues to meet the requirements of section 35.

40. REJECTION

(1) The Pharmacy Council may reject an application made under section 34, if the criteria for approval in section 35 are not satisfied.

(2) Where an application is rejected under subsection (1) the Pharmacy Council shall inform the applicant in writing, indicating the reasons for the rejection of the application.

41. APPEAL AGAINST DECISION OF COUNCIL

The applicant may appeal a rejection by the Pharmacy Council under section 40, to a judge of the High Court in Chambers within 28 days of receipt by the applicant of the reasons for the rejection.

42. OBLIGATION CONSEQUENT ON REGISTRATION

(1) A pharmacist shall duly execute his or her duties as pharmacist, complying with prescribed requirements for the practice of pharmacy and with the prescribed requirements relating to the packaging, labelling, storage and dispensing of poisons.

(2) The conduct of a pharmacist shall accord with the principles set out in the Code of Ethics specified in Schedule 1.

(3) An authorised seller of poisons shall comply with the prescribed requirements relating to the packaging, labelling, storage and dispensing of poisons.

(4) A holder of a certificate of registration in respect of premises shall ensure that the premises complies with the prescribed standards for pharmacies.

43. INSPECTION BY PUBLIC

(1) The Registers shall be open to inspection by members of the public at all reasonable times.

(2) The Registrar shall cause a copy of each Register to be published in the Gazette at the times prescribed.

44. AMENDMENT OF REGISTER

(1) A person may apply in the prescribed form to the Pharmacy Council for a Register to be amended—

(a) to correct an inaccuracy; or

(b) to restore an entry wrongfully removed,

and the Pharmacy Council if satisfied that the application is justified, may direct the Registrar to amend that Register and the Registrar shall amend the Register accordingly.

(2) The Registrar shall remove from the—

(a) Register of Pharmacists and the Register of Authorised Sellers of Poisons, entries relating to—

(i) persons who have died,

(ii) persons whom the Pharmacy Council directs to be removed under sections 66 and 67;

(b) Register of Pharmacies, premises that the Pharmacy Council—

(i) deems to be no longer used as a pharmacy, or

(ii) considers to be unfit for the operation of a pharmacy having regard to this Act and the regulations.

(3) If an entry in a register is removed under subsection (2), a certificate of registration relating to that entry is invalid and the holder of the certificate of registration shall return it to the Registrar.

(4) The Registrar shall publish in the Gazette a notice of the suspension, removal or restoration of a pharmacist, an authorised seller of poisons or premises as a pharmacy within 60 days after the suspension, removal or restoration.

PART 3
ENFORCEMENT

DIVISION 1
Appointment, Functions and Powers of Inspectors

45. INSPECTORS

There shall be as many Pharmacy Inspectors as the Minister considers necessary.

46. APPOINTMENT

(1) A Pharmacy Inspector shall be appointed by the Public Service Commission after consultation with the Pharmacy Council from among the persons who are pharmacists under this Act.

(2) Notice of every appointment made under subsection (1) shall be published in the Gazette.

47. CERTIFICATE OF APPOINTMENT

(1) The Minister shall cause a card to be issued to every pharmacist appointed to be a Pharmacy Inspector to serve as proof of the appointment.

(2) A Pharmacy Inspector shall produce the card issued under subsection (1) on entering any premises under this Act.

48. TENURE AND REVOCATION OF APPOINTMENT

A Pharmacy Inspector shall hold office for 2 years during good behaviour, and his or her appointment may be revoked at any time by the Minister for reasonable cause.

49. REAPPOINTMENT

A Pharmacy Inspector is eligible for reappointment.

50. FUNCTIONS

A Pharmacy Inspector is responsible for—

(a) the inspection of premises for the purpose of monitoring compliance with this Act and the regulations;

(b) the investigation of complaints directed to him or her by the Pharmacy Council under section 55(1)(a); and

(c) any other function, related to the purposes of this Act, assigned to the Pharmacy Inspector by the Pharmacy Council or the Minister.

51. POWER OF ENTRY AND INSPECTION

(1) For the purpose of monitoring compliance with this Act and the regulations, a Pharmacy Inspector may enter and inspect—

(a) any premises in respect of which an application for registration under this Act has been made;

(b) any premises that is a registered pharmacy;

(c) any premises in which the Pharmacy Inspector believes on reasonable grounds that any aspect of the practice of pharmacy is being carried out in contravention of this Act or the regulations; or

(d) over the counter products sold in supermarkets or other shops.

(2) In carrying out the inspection the Pharmacy Inspector may—

(a) open and examine any receptacle or package which he or she believes on reasonable grounds contains an article to which this Act or the regulations apply;

(b) take samples free of charge;

(c) require any person to produce for inspection or copying, in whole or in part, any record or document that the Pharmacy Inspector believes on reasonable grounds contains any information relevant to the administration or enforcement of this Act or the regulations.

(3) The owner or person in charge of premises referred to in subsection (1) and every person found in that place shall give the Pharmacy Inspector all reasonable assistance in the discharge of his or her duties, and shall furnish the Pharmacy Inspector with any information that the Pharmacy Inspector may reasonably require.

52. REQUIREMENT FOR CONSENT OR WARRANT

(1) A Pharmacy Inspector may not enter a dwelling-place except with the consent of the occupant of the dwelling-place or under the authority of a warrant issued under subsection (2).

(2) A magistrate or judge may issue a warrant authorising a Pharmacy Inspector named in the warrant to enter a dwelling-place, if, on an *ex parte* application, the magistrate or judge is satisfied by information on oath that—

(a) the circumstances described in section 51(1), entitling the Pharmacy Inspector to enter and inspect, obtains in relation to the dwelling-place;

(b) entry to the dwelling-place is necessary for any purpose relating to the administration of this Act or the regulations; and

(c) entry to the dwelling-place has been refused or that there are reasonable grounds for believing that entry will be refused.

(3) The authorisation to enter may be made subject to conditions specified in the warrant.

(4) A Pharmacy Inspector who executes a warrant issued under this section shall not use force unless the Pharmacy Inspector is accompanied by a police officer and the use of force has been specifically authorised in the warrant.

(5) A police officer shall provide any assistance that the Pharmacy Inspector requests for the purposes of enforcing this Act or the regulations.

53. POWER TO SEIZE

A Pharmacy Inspector may seize and detain any sample of a drug or other thing—

(a) by means of or in relation to which the Pharmacy Inspector believes on reasonable grounds that the Act or regulations or both are contravened; or

(b) that the Pharmacy Inspector believes on reasonable grounds will afford evidence in respect of the contravention.

54. ANALYSIS AND CERTIFICATE OF INSPECTION

(1) A Pharmacy Inspector may submit, any sample, or part of it, that he or she seizes, to an analyst for analysis or examination.

(2) An analyst who has made an analysis or exmination shall issue a report to the Pharmacy Inspector setting out the results.

(3) Subject to subsection (4), the Pharmacy Inspector shall issue a certificate of inspection in the prescribed form in respect of any sample seized by him or her under section 53.

(4) A report issued under subsection (5) shall be annexed to the certificate of inspection and shall form part of the certificate of inspection.

(5) A certificate of inspection is not admissible in evidence unless it is proved that the Pharmacy Inspector—

(a) divided the sample into 2 parts at the time of seizure, or caused it to be so divided, and, in the presence of a witness, gave one part of it to the person from whom it was taken; and

(b) not less than 2 weeks before the certificate of inspection was introduced into evidence—

(i) gave notice in writing to the person from whom the sample was taken of the intention to produce the certificate of inspection in evidence, and

(ii) served on that person a copy of the certificate of inspection.

(6) A certificate of inspection issued under this section is admissible in evidence in a prosecution for a contravention of this Act or the regulations and in the absence of any evidence to the contrary is proof of the statements contained in it without proof of the signature or the official character of the person appearing to have signed the certificate of inspection.

DIVISION 2

Enforcement

55. INVESTIGATION OF BREACHES

(1) If a person makes a complaint in writing to the Pharmacy Council, or if the Pharmacy Inspector or a member of the Pharmacy Council believes on reasonable grounds, that a person is in breach of the Act or the regulations, the Pharmacy Council may—

(a) direct a Pharmacy Inspector to determine whether a breach has occurred, and report his or her findings, conclusions and reasons for the conclusions to the Pharmacy Council; or

(b) subject to sections 57 and 58 conduct an inquiry to determine whether a breach has occurred.

(2) If a person makes a complaint to the Pharmacy Council, or if the Pharmacy Council believes on reasonable grounds that a pharmacist or authorised seller of poisons has become incapacitated, physically or mentally, to properly discharge his or her duties, the Pharmacy Council shall conduct an inquiry to

determine whether the pharmacist or authorised seller of poisons should be subject to disciplinary measures.

56. SEARCH UNDER WARRANT

(1) Any search required for the purpose of an investigation shall be conducted by the Pharmacy Inspector under a warrant issued under this section.

(2) A magistrate or a judge may issue a warrant authorising a Pharmacy Inspector named in the warrant to enter and search specified premises, if, on an *ex-parte* application, the magistrate or judge is satisfied by information on oath, that any aspect of the practice of pharmacy is being carried out in contravention of this Act or the regulations on the premises.

(3) A Pharmacy Inspector who executes a warrant issued under this section, may exercise the powers described in section 51(2) and may seize, in addition to anything mentioned in the warrant—

(a) anything by means of or in relation to which the Pharmacy Inspector believes on reasonable grounds that this Act or the regulations have been contravened; or

(b) anything that the Pharmacy Inspector believes on reasonable grounds will afford evidence in respect of a contravention of this Act or the regulations.

57. POWERS OF INQUIRY

(1) For the purposes of an inquiry under section 55, the Pharmacy Council has the power—

(a) to summon any witnesses, and to require them to—

(i) give evidence orally or in writing, and on oath or, if they are persons entitled to affirm in civil matters on solemn affirmation, and

(ii) produce any documents and things that it considers necessary for the full inquiry into matters before it;

(b) to make rules governing its procedure;

(c) to receive any evidence that it considers relevant and trustworthy; and

(d) to enforce the attendance of witnesses and to compel them to give evidence in the same manner as the High Court in civil cases.

58. INVESTIGATION IN PRIVATE

An inquiry under section 55 shall be conducted in private.

59. EVIDENCE IN OTHER PROCEEDINGS

Statements made by a person in an inquiry, and evidence of the existence of the inquiry, are inadmissible against the person in a court, or in any other proceeding, other than in a prosecution under the Criminal Code for perjury for a statement made to the Pharmacy Council.

60. OPPORTUNITY TO PUT CASE

Before finding that a person has breached the Act or the regulations the Pharmacy Inspector or the Pharmacy Council shall give the person reasonable opportunity to put his or her case at a hearing.

61. SECURITY REQUIREMENTS

(1) Subject to this Act, the Pharmacy Inspector, the Pharmacy Council or any person acting on their behalf or under their direction shall not disclose any information that comes to their knowledge in the performance of their duties and functions under the Act.

(2) The Pharmacy Council may disclose or may authorise any person acting on its behalf or under its direction to—

(a) disclose information that, in the opinion of the Pharmacy Council is necessary to—

(i) carry out an investigation under this Act, or

(ii) establish the grounds for findings and recommendations contained in any report under this Act; or

(b) disclose information in the course of a prosecution for an offence under this Act, a prosecution for an offence under the Criminal Code for perjury for a statement made under

this Act, a review before the Court under this Act or an appeal from the review.

(3) The Pharmacy Council may disclose to the Attorney General information relating to the commission of an offence against any law in force in Saint Lucia by any person if in the opinion of the Pharmacy Council there is evidence of the offence.

62. NO SUMMONS

(1) A member of the Pharmacy Council, or the agent of a member, is neither a competent nor a compellable witness, in respect of any matter coming to the knowledge of the member, or the agent, as a result of performing their duties during an investigation under this Act.

(2) This section does not apply to any proceeding for a statement made under this Act, a review before the Court under this Act or an appeal from the review.

63. APPEAL

(1) A person who is dissatisfied with a decision made by the Pharmacy Inspector under section 55(1)(a) may appeal the decision to the Pharmacy Council.

(2) A person who is dissatisfied with a decision made by the Pharmacy Council under subsection (1) or to section 55(1)(b) may appeal to a judge in chambers whose decision is final.

(3) An appeal shall be lodged within 90 days after the decision against which the appeal is brought.

64. OFFENCES

(1) A person shall not—

(a) falsely procure the entry of his or her name in any of the Registers;

(b) allow a certificate of registration that has been issued to him or her to be used by another person;

(c) assault or obstruct a Pharmacy Inspector or fail to give him or her any assistance or information that he or she may require in the performance of his or her duties;

(d) knowingly give false information to a Pharmacy Inspector or give information that is likely to mislead the Pharmacy Inspector;

(e) by the offer of any inducement, prevent the Pharmacy Inspector from performing his or her functions;

(f) open or cause to be opened for operations, the dispensing area of premises registered as a pharmacy unless there is a pharmacist present in the premises.

(2) A person who contravenes subsection (1) commits an offence and is liable on conviction to a fine of $5,000 or to imprisonment for a term not exceeding one year or both.

65. GENERAL PENALTY

A person who contravenes a provision of this Act for which no penalty is specified commits an offence and is liable upon conviction to a fine not exceeding $5,000 or to imprisonment for a term not exceeding one year or to both.

66. EXERCISE OF DISCRETION

(1) Despite section 64, if the Pharmacy Inspector or the Pharmacy Council finds, under section 55, that a pharmacist or an authorised seller of poisons is in breach of this Act or the regulations, and the decision is not appealed, or is confirmed on appeal, the Pharmacy Council may—

(a) censure the pharmacist or authorised seller of poisons;

(b) suspend the registration of the pharmacist or authorised seller of poisons for a specified period;

(c) cause the registration of the pharmacist or authorised seller of poisons to be cancelled by directing the Registrar to remove the pharmacist or the authorised seller of poisons from the relevant register.

(2) In exercising its discretion under this section the Pharmacy Council shall take into consideration the nature of the breach and the circumstances surrounding it.

67. REMOVAL MANDATORY

The Pharmacy Council shall direct the Registrar to remove from the Register of Pharmacists, any pharmacist, or from the Register of Authorised Sellers of Poisons, any seller of poisons—

(a) who is incapacitated, whether physically or mentally, from properly discharging the duties of a pharmacist or a seller of poisons respectively; or

(b) who, despite having received a reminder in the precribed form fails to pay the prescribed annual fee under section 39.

PART 4
MISCELLANEOUS

68. REGULATIONS

(1) The Minister may, after consultation with the Pharmacy Council, make regulations to give effect to this Act.

(2) Despite the generality of subsection (1), the Minister may, after consultation with the Pharmacy Council, make regulations—

(a) relating to the practice of pharmacy which includes standards and requirements for the packaging, labelling, storage and dispensing of drugs and poisons, and may include exemptions of classes of persons from the restrictions on the practice of pharmacy contained in sections 30 to 33;

(b) prescribing standards for premises used as pharmacies;

(c) prescribing the content of the Registers and setting out the details of the procedure for registration of pharmacists, authorised sellers of poisons and pharmacies, including the forms to be used;

(d) prescribing fees for the certification of premises, registration of pharmacists, authorised sellers of poisons and pharmacies and any service provided by it;

(e) amending the Code of Ethics;

(f) relating to the writing of prescriptions;

(g) relating to the importation and wholesale of drugs and poisons, retail pharmacy businesses and any other aspect of the pharmaceutical industry;

(h) relating to record keeping by authorised sellers of poisons;

(i) relating to the procedure for inquiries and appeals under this Act;

(j) relating to inspections.

69. EXPENSES

(1) All expenses incurred in the administration of this Act are to be defrayed out of monies voted by Parliament for the purpose.

(2) All monies received by the Pharmacy Council under this Act shall be paid into and shall form part of the Consolidated Fund.

70. TRANSITIONAL

A person registered as a druggist under section 4 of the Druggists and Poisons Act 1960 shall, without application, be entered by the Registrar on the Register of Pharmacists kept under this Act.

SCHEDULE 1

(Sections 2, 42, 68(e))

CODE OF ETHICS

1. A pharmacist's prime concern shall be for the welfare of both patients and public.

2. A pharmacist shall uphold the honour and dignity of the profession and not engage in any activity which may bring the profession into disrepute.

3. A pharmacist shall at all times have regard to the laws and regulations applicable to pharmaceutical practice and maintain a high standard of professional conduct. A pharmacist shall avoid any act or omission which would impair confidence in the pharmaceutical profession. When a pharmaceutical service is provided, a pharmacist shall ensure that it is efficient.

4. A pharmacist shall respect the confidentiality of information relating to patients and their families. Such information shall not be disclosed to anyone without the patient's or appropriate guardian's consent except where it is in the best interest of the patient so to do.

5. A pharmacist shall keep abreast of the progress of pharmaceutical knowledge in order to maintain a high standard of professional competence relative to his or her sphere of activity.

6. A pharmacist shall neither agree to practise under any conditions of service which prevent his or her professional independence nor impose such conditions on other pharmacists.

7. Publicity for professional services is permitted provided that such publicity does not create an invidious distinction between pharmacists or pharmacies, is dignified and does not bring the profession into disrepute.

8. A pharmacist offering services directly to the public shall do so in premises which reflect the professional character of pharmacy.

9. A pharmacist shall at all times endeavour to cooperate with professional colleagues and members of other health professions so that patients and the public may benefit.

SCHEDULE 2

(Sections 2 (1) and (2))

AIDS AND DEVICES SOLD IN A PHARMACY

Air Purifiers
Diabetes – Lancets
Meters
Test Strips
Thermometers
Blood Pressure Monitors
Humidifiers
Spacers for Asthma
HIV Test
Cholesterol Test
Pregnancy Test & Ovulation
Colostomy bags
Breast Pumps
Cervical Collars
Elastic Stockings & Supports
Bandages, Dressing & Tapes
Hot & Cold Packs
Ankle, Knee Support, etc.
Wheel chair
Canes
Crutches
Walkers
Cushions
Bed Pans
Syringes
Surgical Blades
Surgical Gloves
Heating Pads
Catheters
Urine Bags
Eye Patches
Gauze
Lint
Surgical Tape
Nebulisers

FORMS AND FEES REGULATIONS – SECTION 68

(Statutory Instrument 43/2006)

Commencement [22 May 2006]

1. CITATION

These Regulations may be cited as the Pharmacy (Forms and Fees) Regulations.

2. INTERPRETATION

In these Regulations —

"**Act**" means the Pharmacy Act;

"**Minister**" means Minister responsible for health;

"**Pharmacy Council**" means the Pharmacy Council established under section 5 of the Act.

3. FEES

The fees prescribed in Schedule 1 shall be the fees payable under sections 34, 38 and 39 of the Act.

4. APPLICATION FOR REGISTRATION OR RENEWAL OF REGISTRATION AS A PHARMACIST

An application for registration of a person as a pharmacist under section 34(1) of the Act or renewal of registration of a person as a pharmacist under section 39 of the Act shall be in the form prescribed in Form 1 of Schedule 2 and shall be accompanied by—

(a) the application fee prescribed in Schedule 1;

(b) an official transcript, certificate or other relevant document from the place of study stating that the applicant has graduated;

(c) two passport size photographs;

(d) one official form of identification, for example, a passport, identification card or driver's licence;

(e) evidence of the applicant's good character;

(f) evidence that the applicant has not been convicted of an offence in Saint Lucia or elsewhere relating to the control of dangerous substances, drugs or narcotics;

(g) evidence that the applicant has not been convicted of an offence in Saint Lucia or elsewhere relating to the practice of pharmacy;

(h) evidence that the applicant has not had a certificate of registration for a pharmacy, practice as a pharmacist or practice as an authorised seller of poisons suspended or revoked in the last 5 years under this Act or any other law in force relating to the practice of pharmacy in Saint Lucia or elsewhere; and

(i) any other information as the Pharmacy Council deems necessary.

5. APPLICATION FOR REGISTRATION OR RENEWAL OF REGISTRATION OF PREMISES AS PHARMACY

An application for registration of premises as a pharmacy under section 34(3) of the Act or renewal of registration of premises as a pharmacy under section 39 shall be in the form prescribed in Form 2 of Schedule 2 and shall be accompanied by—

(a) the application fee prescribed in Schedule 1;

(b) two passport size photographs;

(c) one official form of identification, for example, a passport, identification card or driver's licence;

(d) evidence of the applicant's good character;

(e) evidence that the applicant has not been convicted of an offence in Saint Lucia or elsewhere relating to the control of dangerous substances, drugs or narcotics;

(f) evidence that the applicant has not been convicted of an offence in Saint Lucia or elsewhere relating to the practice of pharmacy;

(g) evidence that the applicant has not had a certificate of registration for a pharmacy, practice as a pharmacist or practice as an authorised seller of poisons suspended or revoked in the last 5 years under this Act or any other law

in force relating to the practice of pharmacy in Saint Lucia or elsewhere; and

(h) any other information as the Pharmacy Council deems necessary.

6. APPLICATION FOR REGISTRATION OR RENEWAL OF REGISTRATION AS AN AUTHORISED SELLER OF POISONS

An application for registration of a person as an authorised seller of poisons under section 34(2) of the Act or renewal of registration as an authorised seller of poison under section 39 of the Act shall be in the form prescribed in Form 3 of Schedule 2 and shall be accompanied by—

(a) the application fee prescribed in Schedule 1;

(b) two passport size photographs;

(c) one official form of identification, for example, a passport, identification card or driver's licence;

(d) evidence of the applicant's good character;

(e) evidence that the applicant has not been convicted of an offence in Saint Lucia or elsewhere relating to the control of dangerous substances, drugs or narcotics;

(f) evidence that the applicant has not been convicted of an offence in Saint Lucia or elsewhere relating to the practice of pharmacy;

(g) evidence that the applicant has not had a certificate of registration for a pharmacy, practice as a pharmacist or practice as an authorised seller of poisons suspended or revoked in the last 5 years under this Act or any other law in force relating to the practice of pharmacy in Saint Lucia or elsewhere; and

(h) any other information as the Pharmacy Council deems necessary.

7. CERTIFICATE OF REGISTRATION AS PHARMACIST

A certificate of registration for registration of a person as a pharmacist issued under sections 36 and 38 of the Act or renewed under section 39—

(a) shall be in the form prescribed in Form 4 of Schedule 2; and

(b) shall be issued on payment of the registration fee or the annual fee prescribed in Schedule 1, as the case may be.

8. CERTIFICATE OF REGISTRATION AS PHARMACY

A certificate of registration for registration of premises as a pharmacy issued under sections 36 and 38 of the Act or renewed under section 39—

(a) shall be in the form prescribed in Form 5 of Schedule 2; and

(b) be issued or renewed on payment of the registration fee or the annual fee prescribed in Schedule 1, as the case may be.

9. CERTIFICATE OF REGISTRATION AS AUTHORISED SELLER OF POISONS

A certificate of registration for registration of a person as an authorised seller of poisons issued under sections 36 and 38 of the Act or renewed under section 39—

(a) shall be in the form prescribed in Form 6 of Schedule 2; and

(b) shall be issued on payment of the registration fee or annual fee prescribed in Schedule 1, as the case may be.

Schedule 1

(Regulations 3-9)

FEES

	Fee
Application fee for registration or renewal of registration Application fee for registration or renewal of registration as a pharmacist	$25
Application fee for registration or renewal of registration of a pharmacy	$25
Application fee for registration or renewal of registration as an authorised seller of poisons	$25
Certificate of registration of a person as a pharmacist	$250 – registration fee $200 – annual fee
Certificate of registration of premises as a pharmacy	$500 – registration fee $500 – annual fee
Certificate of registration of a person as an authorised seller of poisons	$350 – registration fee $350 – annual fee

Schedule 2

Form 1

(Regulation 4)

Pharmacy Council

[Address]

Saint Lucia

INSTRUCTIONS: Applicant: Fill out the following blanks. Type or print in ink. Return to the PHARMACY COUNCIL at the address listed above.	*FOR OFFICE USE ONLY*			One Photograph Required. Recent head and shoulder photograph must be attached to the application. Photograph must be of passport quality.
	Receipt number			
	Fee Date			
	Certificate number			
	Date issued			

APPLICATION FOR REGISTRATION AS A PHARMACIST

APPLICANT INFORMATION

Name of applicant (first, middle, last)			Maiden name (if applicable)	
Address			Email address	
City/Town			Social Security number	
Date of birth (day, mo., yr.)	Place of birth	Country	Telephone number	
Name and address of school or college of pharmacy	No. of years attended		Qualifications Obtained	Date graduated

I _____, above named, hereby swear or affirm under the penalties of perjury that the statements made by me in this application for license as a pharmacist by examination are true and correct. I further pledge myself to practice the profession of pharmacy with dignity, integrity and honor and to comply at all times with the rules and regulations governing the profession, should I be granted the privilege of licensure as a pharmacist in the country of Saint Lucia.

Signature of applicant	Date signed (day, mo., yr.)

If your answer is "Yes" to any of the following, explain fully in a sworn affidavit, including all related detail. Describe the event including the location, date and disposition. If you have had a malpractice judgment, provide the name of the plaintiff. Falsification of any of the following is grounds for permanent revocation of a license or permit issued pursuant to the application.

1. Has disciplinary action ever been taken regarding any Yes No health license, certificate or permit you hold or have held in any country?
2. Have you ever been denied a licence, certificate, Yes No registration or permit to practice as a pharmacist or any regulated health occupation in any country?
3. Are there any charges pending against you regarding a Yes No violation of any State law relating to the use, manufacturing, distribution or dispensing of controlled substances, alcohol or other drugs?
4. Have you ever been convicted or pled guilty or nolo contendre to: A. A violation or any State law relating to the use, manufacturing, distribution or dispensing of controlled substances, alcohol or other drugs? Yes No B. To any offense, misdemeanor or felony in any country? (Except for minor violations of traffic laws resulting in fines) Yes No
5. Have you ever been denied staff membership privileges in Yes No any pharmacy or have any privileges been revoked, suspended or subjected to any restrictions, probation or other type of discipline or limitations?
6. Have you ever had a malpractice judgement against you Yes No or settled any malpractice action?
AUTHORIZATION FOR RELEASE OF INFORMATION
I hereby authorize, request and direct any person, firm, officer, corporation, association, organization or institution to release to the Pharmacy Council any files, documents, records or other information pertaining to the undersigned requested by the Pharmacy Council or any of its authorised representatives in connection with processing application for licensure as a pharmacist. I hereby release the aforementioned person, firms, officers, corporations, association, organizations, and institutions from any liability with regard to such inspection or furnishing of any information. I further authorize the Pharmacy Council to disclose the aforementioned persons, firms, officer, corporations, associations, organizations, from any and all liability in connection with such disclosures. A photostatic copy of this authorization has the same force and effect as the original. I hereby swear or affirm that I have read the above statements and agree to same.

Signature of applicant	Date (day, mo. yr.)

Form 2

(Regulation 5)

Application for Registration of premises as pharmacy

Pharmacy Council

[Address]

Saint Lucia

INSTRUCTIONS: Applicant: Fill out the following blanks. Type or print in ink. Return to the PHARMACY COUNCIL at the address listed above.

FOR OFFICE USE ONLY
Receipt number
Fee Date
Certificate number
Date issued

APPLICATION FOR REGISTRATION AS A PHARMACY		
PHARMACY INFORMATION	PHARMACY OWNER INFORMATION	
Name of pharmacy	Name of pharmacy (If corporation or partnership attach a list of officers on a separate sheet including, name, address or title)	
Address of pharmacy	Address of owner	
Phone	Phone	Fax
Fax	Social Security Number	
Email	Email	
Mailing address	Mailing address	
Has the owner, or any corporate officer or partner ever been convicted of an offence involving moral turpitude, a felony offence, or any drug-related offence or has any currently pending felony or drug-related charges, and if so, indicate charge, conviction date, jurisdiction and location. Yes No		

Name of pharmacist in charge		
Name of school or college of pharmacy of pharmacist in charge	Qualifications obtained	Date obtained
License number of pharmacist in charge	Expiration date	Tel No.
Address		
Mailing address (If applicable)		
Email		

I,_____ hereby swear or affirm under (Signature of owner) the penelites of perjury that the statements made in this application for Registration as a Pharmacy are true and correct in all respects.

Form 3

(Regulation 6)

Application for Registration of premises as pharmacy

Pharmacy Council

[Address]

Saint Lucia

INSTRUCTIONS: Applicant: Fill out the following blanks. Type or print in ink. Return to the PHARMACY COUNCIL at the address listed above.

FOR OFFICE USE ONLY
Receipt number
Fee Date
Certificate number
Date issued

APPLICATION FOR REGISTRATION AS AN AUTHORISED SELLER OF POISONS

Name of Business

Address of Business

Phone Fax

Email Mailing Address

Are you a Chain Corporation

Ownership

☐ Corporation (Name and address of Corporation officers and registered agent) ☐ Individual owner, trustee or receiver (Enter name, title and address below) ☐ Partnership (List below names and addresses of the share holders)

Name	Title	Mailing Address	Phone Number	Social Security Number

List of poisons to be sold

_____

Has the owner, or any corporation officer or partner been convicted of an offence involving moral turpitude, a felony offence, or any drug-related offence or has any currently pending felony or drug-related charges, and if so indicate charge, conviction date, jurisdiction and location.

☐ Yes ☐ N o

I, _____ hereby swear or affirm under the penalties (Name of owner) of perjury that the statements made in this application for a Seller of Poisons are true and correct in all respects. Authorised Signature_____ Date _____ Title_____

FORM 4

(Regulation 7)

Certificate of Registration as a Pharmacist

Pharmacy Council

Saint Lucia

Certificate of Registration as a Pharmacist

Registration No. _____

This is to certify that

_____ has

been licensed as a Pharmacist under the Pharmacy Act, for the period

1 January _____ to 31 December _____.

_____ _____

Chairperson, Pharmacy Council Registrar

FORM 5

(Regulation 8)

Certificate of Registration as a Pharmacy

Pharmacy Council

Saint Lucia

Certificate of Registration as a Pharmacy

This is to certify that the Pharmacy_____

situated at _____ in the quarter of _____

managed by _____ is duly licensed as a Pharmacy

for the period ending _____ and that _____

is duly registered as the owner of the pharmacy.

_____ _____

Chairperson, Pharmacy Council Registrar

FORM 6

(Regulation 9)

Certificate of Registration as an Authorised Seller of Poisons

Pharmacy Council

Saint Lucia

Certificate of Registration as an Authorised Seller of Poisons

This is to certify that _____ of _____ is hereby licensed as an authorised seller of poisons and is authorised to sell the poisons set out in Part 2 of the Schedule _____ of the Act for the period ending _____.

_____ _____

Chairperson, Pharmacy Council Registrar

Revision Date: 31 Dec 2008

CHAPTER 11.21

PHARMACY REGULATIONS

ARRANGEMENT OF REGULATIONS

Regulation

PHARMACY REGULATIONS – SECTION 68

(Statutory Instrument 138/2007)

Commencement [20 August 2007]

PRELIMINARY

1. CITATION

These Regulations may be cited as the Pharmacy Regulations.

2. INTERPRETATION

In these Regulations —

"**Act**" means the Pharmacy Act, Cap. 11.21;

"**care giver**" means a patient's spouse, next of kin, legal guardian, attorney or third party insurer where permitted by law;

"**compounding**" means the act of preparing pharmaceutical components into medications pursuant to a prescription or medication order, including but not limited to prescription compounding and intravenous admixture preparation;

"**controlled drug**" means any drug listed in Schedule 1;

"**controlled paraphernalia**" means drug paraphernalia which is under the direct supervision of a pharmacist;

"**device**" includes any apparatus, similar or related article, mechanical, electronic or otherwise including any component part or accessory dispensed by a pharmacies in the usual scope of pharmacy practice;

"**drug**" includes –

(a) articles recognized in the official British Pharmacopoeia, United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States or any other recognized text;

(b) articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in human beings or animals;

(c) articles, other than food intended to affect the structure and any function of the body of human beings or animals; and

(d) articles intended for use as components of any article specified in paragraphs (a), (b) or (c), but not including devices or their components, parts or accessories;

"**drug paraphernalia**" means all equipment, products, and materials of any kind which are used, intended for use or designed for use in introducing a drug into the human body;

"**expiration date**" means the date placed on a drug packaged by the manufacturer or repacker beyond which the product may not be dispensed or used;

"**extern**" means any person who is in final college year or 3rd or 4th professional year at an approved school or college of pharmacy who is assigned to a pharmacy for the purpose of acquiring accredited practical experience under the supervision of the school or college at which he or she is enrolled;

"**intern**" means any new graduate from an approved school or college of pharmacy or a foreign pharmacy graduate or any person who has satisfied the requirements and who is employed in an approved pharmacy for training for the purpose of acquiring accredited practical experience and who has first registered for those purposes with the Pharmacy Council;

"**over the counter**" means a drug approved for the conditions set out in Schedule 2;

"**pharmacy technician**" means a qualified person who assists the pharmacist in performing his or her tasks and responsibilities;

"**pharmacist**" means a person who is registered as a pharmacist pursuant to Part 2 of the Act;

"**pharmacist assisted drug**" means a drug listed in Schedule 3;

"**Pharmacy Council**" means the Pharmacy Council established pursuant to section 5 of the Act;

"**prescriber**" means a health practitioner or veterinarian authorized by law to write prescriptions in Saint Lucia;

"**prescription**" means an order for drugs or medical supplies, written and signed or transmitted by any means of communication by a duly licensed physician to a pharmacist, authorized by law to prescribe and administer such drugs or medical supplies;

"**prescription drug**" means a drug listed in the Schedule 4;

"**professional judgment**" means judiciousness and discretion based upon thorough knowledge and sound application of the specialized body of knowledge peculiar to the practice of pharmacy, and an understanding of the relationship of this knowledge and its application to the well being of the patient and to the judgment of the prescriber;

"**storage temperature**" means the specific directions stated in some monographs with respect to the temperatures at which pharmaceutical articles are stored, where it is considered that storage at a lower or higher temperature may produce undesirable results;

"**supportive personnel**" means those persons, excluding interns, externs and pharmacy technicians who perform functions under the direct supervision of a registered pharmacist.

PART I

STANDARDS

3. PHYSICAL STANDARDS

A pharmacy shall —

(a) be constructed of permanent and secure materials;

(b) be of sufficient size to allow for safe and proper storage of drugs, for compounding, preparation and dispensing of prescriptions, and for provision of patient-oriented and administrative pharmacy service, taking into account the

volume of business, the nature of the patients and their particular needs, and the nature of the pharmacy's business;

(c) be dry, well-lighted, well-ventilated and maintained in a clean, sanitary and orderly condition;

(d) be physically separated from adjacent areas in the same premises by any means that ensures that no one has unsupervised access to any drugs when a pharmacist is not present;

(e) contain a prescription department under regulation 5.

4. TEMPORARY OR MOVEABLE PREMISES

(1) A person may use a temporary or moveable premises as a pharmacist to rural districts if there are no fixed pharmacies in that district.

(2) A pharmacist of a temporary or moveable premises shall not keep a narcotic drug or poison on the temporary or moveable premises.

5. STANDARDS FOR PRESCRIPTION DEPARTMENT

The prescription department of a pharmacy —

(a) may contain an area used for devices, cosmetics, and proprietary drugs;

(b) shall contain a patient waiting area;

(c) shall not be less than 60 square feet and the patient waiting area or the area used for devices, cosmetics, and proprietary drugs are not to be considered a part of the 60 square feet;

(d) shall be provided with a prescription counter –

(i) constructed in such a manner that it prevents unauthorized entry, unsupervised access to any drugs, and pilferage at all times whether or not a pharmacist is on duty;

(ii) fitted with doors with locking devices which will prevent unauthorized entry in the absence of the pharmacist;

(iii) with a prescription area of not less than 18 inches in width and not less than 6 total feet in length to be kept clear at all times for the compounding of prescriptions, dispensing of drugs, necessary record keeping and other pharmaceutical manufacturing;

(e) shall include a sink with running water in the prescription area of retail and institutional pharmacies which is easily accessible to the prescription counter;

(f) shall have sufficient shelf, drawer or cabinet space within the prescription area for proper storage of stock of prescription labels, an assorted stock of prescription containers, an adequate stock of prescription drugs and chemicals and the required equipment;

(g) may contain a rest room to be used exclusively by the pharmacist and supportive personnel if there is another restroom outside the prescription department available to other employees and the public;

(h) shall include adequate refrigeration facilities for the storage of drugs, requiring cold storage temperature to meet manufacturers' specifications for drug storage;

(i) shall contain a private or semi-private area for patient/pharmacist consultation.

6. ACCESS TO PRESCRIPTION DEPARTMENT

(1) The prescription department is restricted to the pharmacist and supportive personnel.

(2) Clerical assistants and other persons designated by the pharmacist may be allowed access by the pharmacist but only at such time as the pharmacist is present.

7. ACCESS TO OTHER AREAS

Access to stock rooms, rest rooms, and other areas other than an office that is exclusively used by the pharmacist shall not be through the prescription department.

8. KEYS TO PRESCRIPTION DEPARTMENT

The keys for the door to the prescription department are to remain in the possession of the pharmacist or a person authorized by the pharmacist.

9. EQUIPMENT IN PRESCRIPTION AREA

(1) The prescription area to be maintained under regulation 5(d)(iii) shall include the following at all times —

(a) an up-to-date, comprehensive pharmaceutical reference text and suitable current reference texts encompassing the general practice of pharmacy, drug interactions, drug product composition and patient counseling and unabridged computerized versions of reference texts;

(b) a permanent prescription filing device and patient profile, record system;

(c) a prescription balance or equivalent electronic weighing device;

(d) a device capable of measuring 0.3ml to 500ml;

(e) a mortar, stet pestle, glass and porcelain;

(f) glass funnels;

(g) a spatula;

(h) a refrigerator to be used only for the storage of pharmaceuticals;

(i) a minimum or maximum refrigerator thermometer with record;

(j) a hard copy of temperature record;

(k) suitable counting trays or an approved counting device;

(l) labels including auxiliary labels and poison labels;

(m) a copy of the Act and Regulations.

(2) The equipment kept pursuant to sub-regulation (1) shall be kept and stored in a clean and readily accessible part of the prescription department.

PART 2

STORAGE, DISPENSING AND DISPOSAL OF DRUGS

10. STORAGE OF DRUGS

(1) All drugs requiring the supervision of a pharmacist including dispensed drugs shall remain within the confines of the prescription department.

(2) All poisons shall be stored within a locked cabinet or draw and the key shall be kept by the pharmacist.

(3) The conditions of storage for all drugs shall be governed by the following terms —

(a) "**Cold**" means any temperature not exceeding 8ÚC (46ÚF).

A refrigerator is a cold place in which temperature is maintained thermostatically between 2Ú and 8ÚC (36ÚF and 46ÚF). A freezer is a cold place in which the temperature is maintained thermostatically between -20ÚC and -10ÚC (-4ÚF and 14ÚF);

(b) "**Room temperature**" means 27ÚC;

(c) "**Controlled room temperature**" is a temperature maintained thermostatically that encompasses the usual and customary working environment of 20ÚC to 25ÚC (68ÚF to 77ÚF), that results in a mean kinetic temperature calculated to be not more than 25ÚC and that allows for excursions between 15ÚC and 30ÚC (59ÚF and 86ÚF) that are experienced in pharmacies, hospitals and warehouse;

(d) "**Warm**" means any temperature between 30ÚC and 40ÚC (86ÚF and 104ÚF);

(e) "**Excessive heat**" means any temperature above 40ÚC (*104ÚF);*

(f) "**Protection from freezing**" means where, in addition to the risk of breakage of the container, freezing subjects a product to loss of strength or potency or to the destructive alteration of its characteristics, the

container label bears an appropriate instruction to protect the product from freezing;

(*g*) "**Cool**" means any temperature between 8ÚC and 15ÚC (46ÚF and 59ÚF).

(4) Outdated, misbranded, deteriorated or adulterated drugs, or any drug marked "sample" or with any like designation or meaning shall not be placed or maintained in active stock for use or sale.

11. PRESCRIPTIONS AWAITING DELIVERY

(1) A prescription which is prepared for delivery to the patient may be placed in a secure place outside of the prescription department and access to the prescriptions restricted by the pharmacist to designated health care personnel.

(2) Prepared prescriptions may be transferred, with the permission of the pharmacist, to the patient at a time when the pharmacist is not on duty.

(3) If a prescription is delivered at a time when the pharmacist is not on duty, written procedures which detail a method of compliance with counseling requirements shall be established and followed by the pharmacy.

12. CONTROLLED PARAPHERNALIA

Controlled paraphernalia shall not be placed on open display or in an area completely removed from the prescription department where the public will have free access to the controlled paraphernalia or where the pharmacist cannot exercise reasonable supervision and control over the controlled paraphernalia.

13. EXPIRED DRUGS

Any drug which has exceeded the expiration date shall be separated from the stock for dispensing and shall be maintained in a designated area within the prescription department until proper disposal.

14. RESTRICTION ON DISPENSING DRUGS

(1) A pharmacist shall not dispense a prescription drug and an authorized seller of poisons shall not dispense a poison unless that pharmacist or authorized seller of poisons receives a prescription or medication order which complies with regulation 15, from a patient or care giver.

(2) A pharmacist shall not dispense any drug to a patient or care giver —

(a) in the case of a pharmacist assisted drug, under the age of 18 years;

(b) in any other case, under the age of 16 years.

15. PRESCRIPTIONS

(1) A prescription shall contain —

(a) the date;

(b) the RX icon before the items are written-items should be bulleted;

(c) the prescriber's information, such as, the name, address, telephone and fax number of the presciber which shall be either pre-printed on the prescription blank, electronically printed, typewritten, rubber stamped, or printed by hand;

(d) the name, strength, frequency, duration, quantity and formulation of drug;

(e) the first and last name of the patient for whom the drug is prescribed;

(f) the address of the patient, which shall either, be placed on the written prescription by the prescriber or his or her agent;

(g) specific information about the patient, such as, height, weight and age so that the correct dose for the patient can be calculated;

(h) refill section should be indicated and if not utilized should be crossed out;

(i) signature of the prescriber;

(j) unapproved non standard abbreviations should not be used as well as those that may lead to error in interpretation by the pharmacist and put the patient at risk;

(k) expression of weights and volumes and units;

(l) decimals:

(i) "500mg" should be used in place of "0.5" or "125mcg" instead of "0.125mg";

(ii) decimal expressions of less than 1 should always be preceded by a zero to enhance the visibility of the decimal;

(m) there should be a space between the name of the medication and the dose as well as between the dose and the units.

(2) A non refill prescription is valid for 7 days from the date it was written.

(3) Where the prescription is made by a dentist or veterinarian for a poison, the words "for dental treatment only" or "for treatment of animals only" should be used.

(4) If not otherwise prohibited by law, the pharmacist may record the address of the patient in an electronic prescription dispensing record for that patient in lieu of recording it on the prescription.

(5) The prescription may be prepared by an agent for the precriber's signature.

(6) This regulation shall not prohibit a prescriber from using preprinted prescriptions for pharmacist assisted drugs if all requirements concerning dates, signatures, and other information specified above are otherwise fulfilled.

(7) This provision shall not apply to prescriptions written as chart orders for patients in hospitals and long-term-care facilities, patients receiving home infusion services or hospice patients, or to a prescription ordered through a pharmacy operated by or for Bordelais Prisons, or the central outpatient pharmacy operated by the Psychiatric Hospital.

16. REFUSAL TO DISPENSE PRESCRIPTION

A pharmacist has the right to refuse to dispense a prescription drug or poison if, in his or her professional judgment —

(a) the prescription is outside the scope of practice of the health practitioner or veterinarian;

(b) there is sufficient reason to question the validity of the prescription; or

(c) it is necessary to protect the health and welfare of the patient.

17. DISPENSING BY INTERN OR EXTERN

A pharmacy intern or extern shall not prepare, compound or dispense a prescription drug except under the direct supervision of a pharmacist.

18. PHARMACY TECHNICIAN, INTERN OR EXTERN

(1) A Pharmacy technician or an intern shall not interpret a prescription order or consult with an prescriber or the agent of the prescriber but may, count, weigh, measure, or pour prescription medication and offer limited advise under the direct supervision of the pharmacist as long as the contents and finished-product are verified by the pharmacist.

(2) A Pharmacy technician, intern and extern shall wear an identification tag, which shall include at least their first name, the first initial of their last name, and their title.

19. SUPERVISION BY PHARMACIST

(1) A pharmacist shall not supervise more than three pharmacy technicians, interns or externs and the personnel who do computer processing of prescriptions are to be included in the 3 to 1 ratio.

(2) The pharmacist supervising the activities of supporting personnel shall be physically present in the compounding or dispensing area and shall be responsible for the accuracy of the dispensed prescription.

20. ELECTRONIC PRESCRIPTIONS AND MEDICATION ORDER

(1) Where a pharmacy accepts a prescription or medication order electronically —

(a) the receiving machine shall be in the prescription department of the pharmacy to protect patient, pharmacy, practitioner confidentiality and security;

(b) the electronic prescription or medication order must originate from the prescriber and another pharmacist;

(c) the pharmacist shall verify the transmission directly with the prescribing practitioner in all cases where a pharmacist has reason to question the accuracy or authenticity of a prescription or medication order transmitted electronically.

(2) Any pharmacist who uses an electronical device to circumvent his or her responsibilities with regard to documenting, authenticating and verifying medication orders and prescriptions or to circumvent other standards of pharmacy practice commits an act of professional misconduct.

(3) A pharmacist shall not accept an electronic device from any health practitioner.

(4) A pharmacist shall not enter into any agreement with any health practitioner or veterinarian which denies the patient the right to have his or her prescription transmitted electronically to a pharmacy of the patient's choice.

21. LACK OF DIRECTIONS ON PRESCRIPTION

(1) A pharmacist shall make a documented attempt to contact the health practitioner or veterinarian to obtain directions in all cases where the health practitioner or veterinarian fails to include directions for use of the drug on the prescription.

(2) Where a health practitioner or veterinarian cannot be contacted, the pharmacist shall instruct the patient as to the appropriate instructions from a recognized reference text.

(3) The pharmacist may add directions or cautionary messages to those indicated by the health practitioner or veterinarian on the prescription, when, in the judgment of the pharmacist, directions to the patient or cautionary messages are

necessary, either for clarification or to ensure proper administration of the drug.

22. RENEWAL OF PRESCRIPTIONS

(1) A prescription for medication or devices which pursuant to these Regulations may be dispensed or furnished only on prescription, shall not be renewed without specific authorization of the prescriber, and the prescription may not be refilled after 6 months from the date of the original prescription.

(2) Prescriptions marked "PRN" or other letters or words meaning refill as needed shall not be renewed beyond 6 months past the date of original prescription.

(3) When the renewals listed on the original prescription have been depleted, no additional renewals may be added to the original prescription.

(4) Additional dispensing must be under a new prescription which must be authorized by the prescriber.

23. GENERIC SUBSTITUTION

(1) Subject to sub-regulation (2), a pharmacist may, when filling any prescription —

(a) inform the person requesting the drug of the availability of any bioequivalent generic drug which is interchangeable with the named drug and which is less costly; and

(b) supply the generic equivalent drug instead of the named drug.

(2) A pharmacist may dispense a brand-name drug product where a suitable generic equivalent drug product is available in cases where –

(a) the health practitioner or veterinarian indicates such substitution is not authorized by specifying on the prescription the words, "brand medically necessary" or some form of emphasis on the brand name such as underline, asterisk or the symbol ®; or

(b) the patient insists on the dispensing of the brand-name drug product.

24. PHARMACIST ASSISTED DRUGS

(1) A pharmacist shall conform to the following standards of professional judgment and care when selling a pharmacy assisted drug —

(*a*) he or she shall ensure that the sale of a specified controlled substance is limited in quantity during any forty eight hour period;

(b) he or she shall obtain suitable identification, including proof of age where appropriate, from every purchaser not known personally to him or her;

(c) if he or she has any doubts regarding the proprietary of a sale of a pharmacist assisted drug, he or she shall resolve thedoubt against the making of the sale.

(2) The pharmacist shall determine, through direct communication with a purchaser who makes a second request for a pharmacist assisted drug within a period of 2 to 4 days or any short period after the initial dispensing, whether the substance is being used correctly and in that regard, the pharmacies shall ascertain how many people are using the substance and whether the condition that the substance is being used to treat is improving.

(3) The pharmacist shall, in all cases where a patient makes a third request for a pharmacist assisted drug within a period of 2 to 4 days or any short period subsequent to the second purchase —

(a) advise the patient or care giver of the substance's abuse potential; and

(b) caution the patient or care giver to consult a physician if the condition for which the substance is being used does not improve.

(4) A pharmacist may be disciplined for professional misconduct if he or she dispenses a pharmacist assisted drug over-the-counter controlled when —

(a) in his or her professional judgment, he or she knows or ought reasonably to know that the requested substance will be used for unauthorized or illicit consumption or distribution; or

(b) in his or her professional judgment, he or she knows or ought reasonably to know that the person requesting the substance previously used it for unauthorized or illicit consumption or distribution.

25. CONTROLLED DRUGS

(1) Subject to sub-regulations (2) and (3), a pharmacist may dispense on a single prescription for a poison, an amount limited to a 28 day supply.

(2) A pharmacist may dispense an emergency supply of a chronic maintenance drug or device in the absence of a current valid prescription, if in his or her professional judgment refusal would endanger the health or welfare of the patient but the pharmacist shall not, in any case, prescribed more than a 72 hour supply.

(3) The pharmacist shall, before dispensing drugs in accordancewith sub-regulation (1), ascertain to the best of his or her ability, by direct communication with the patient, that the drug or device was prescribed for that patient by order of a licensed medical practitioner.

26. POISONS

(1) A pharmacist may dispense any poison contained in the list of poisons.

(2) An authorized seller of poisons may dispense poisons specified in Part II of the list of poisons.

(3) A pharmacist or an authorized seller of poisons shall not dispense any linament, embrocation, lotion or similar caustic substance containing a poison unless such substance is in a container —

(*a*) which is so constructed as to prevent leakage arising from the ordinary risks of handling and which is impervious to poison; and

(*b*) to which is affixed a label giving notice that the contents shall not be taken orally.

(4) Where a pharmacist or authorized seller of poisons dispenses any poison in a bottle of a capacity of not more than one hundred and twenty fluid ounces, the outer surface of that bottle shall be fluted vertically with ribs or grooves easily discernable by touch.

(5) A pharmacist or authorized seller of poisons who dispenses a poison shall —

(*a*) ensure that the poison is packed to avoid leakage arising from the ordinary risks of handling;

(*b*) adequate precautions are taken to prevent the risk of contaminating food.

(6) A pharmacist or authorized seller of poisons shall not dispense one pound of arsenic unless it is mixed with at least one ounce of soot or half an ounce of indigo.

(7) Notwithstanding sub-regulation (6), a pharmacist or authorized seller of poisons shall not dispense one pound of arsenic if —

(*a*) the arsenic is an ingredient of any medicine required to be made up or compounded in accordance with a prescription of a medical practitioner, dentist or veterinary surgeon;

(*b*) it is stated by the person receiving the arsenic that it is required for some purpose other than use in agriculture, and it is established that such mixture would render arsenic unfit for the purpose for which it is being obtained and the arsenic is dispensed in quantities of not less than 10 pounds on each occasion.

27. COUNSELLING

(1) A pharmacist shall make reasonable efforts to counsel a patient or caregiver before dispensing a new prescription.

(2) Counselling pursuant to sub-regulation (1) shall include the following information:

(*a*) the name and description of the drug;

(*b*) the dosage form, dosage route of administration and duration of drug therapy;

(*c*) special directions and precautions for preparation, administration and use by the patient;

(d) common adverse or sever side effects or interactions and contraindications that may be encountered, including their avoidance an the action required if they occur;

(e) techniques for self-monitoring drug therapy;

(f) proper storage;

(g) prescription refill information; and

(h) action to be taken in the event of a missed dose.

(3) An offer to counsel may be made by ancillary personnel but the pharmacist shall perform the counseling.

(4) A pharmacist is not required to counsel a patient or caregiver when the patient or caregiver refuses counseling.

(5) The offer to counsel may be made by telephone or in writing on a separate document accompanying the prescription in all cases where the patient or caregiver is not physically present.

(6) A written offer to counsel shall be in bold print, legible and shall include the hours a pharmacist is available and a telephone number where a pharmacist may be reached and the telephone service shall be available at no cost to the patient.

28. LABELLING

(1) When dispensing a drug a pharmacist shall affix a label to the container in which the drug is dispensed which shall include the following information:

(a) the pharmacy's name and address;

(b) the pharmacy's telephone number;

(c) the brand name or generic name of the dispensed drug;

(d) if generic, the name of the manufacturer;

(e) the strength and quantity of drug dispensed;

(f) the date on which the drug is dispensed;

(g) any cautionary or auxiliary label;

(h) the patient's name;

(i) the initials of the dispensing pharmacist;

(j) the prescriber's name;

(k) the prescription number;

(l) directions for use;

(m) the expiration date, if dispensed in any packaging other than the manufacturer's original packaging; and (n) the caution: **"KEEP OUT OF THE REACH OF CHILDREN"**;

(o) any auxiliary labeling as recommended by the manufacturer or as deemed appropriate in the professional judgment of the dispensing pharmacist.

(2) Where a poison is dispensed, the pharmacist or authorized seller of poisons shall include the information in sub-regulation (1) and the following additional information on the container:

(a) the address, telephone number and signature of the pharmacist or authorized seller of the poisons;

(b) signature of the person receiving the poison;

(c) the purpose for which the poison is required;

(d) where the poison is an ingredient of a preparation, the proportion of the poison;

(e) a notice indicating that the poison is to be kept separate from food and food containers.

(3) In this regulation "**expiration date**" means the earlier of 6 months from the date of dispensing or the expiration date on the manufacturers' container.

29. PATIENT PROFILE RECORD SYSTEMS

(1) A pharmacist shall maintain a patient profile record system of persons to whom prescription drugs are dispensed.

(2) The patient profile record system maintained pursuant to subregulation (1) may be in electronic form and shall —

(a) be devised so as to enable the immediate retrieval of information necessary to enable the dispensing pharmacist to identify previously dispensed drugs at the time a prescription is presented for dispensing;

(b) include the following information:

(i) the family name and the first name of the patient;

(ii) the address and telephone number of the patient;

(iii) the patient's age, birth date or age group and gender;

(iv) the original or refill date on which the drug is dispensed and the initials of the dispensing pharmacist, if the initials and the date are not already recorded on the back of the original prescription or in any other record approved by the Pharmacy Council;

(v) the number or designation identifying the prescription;

(vi) the prescriber's name;

(vii) the name, strength and quantity of the drug dispensed;

(viii) the pharmacist's comments relevant to the patient's drug therapy, including any failure of the patient to accept the pharmacist's offer to counsel; and

(ix) the patient's national insurance number, if any;

(x) whether or not the patient suffers from any allergies and idiosyncrasies or any medical condition which may relate to drug utilization as communicated to the pharmacist by the patient.

(3) If the pharmacist uses an electronic patient profile record system, the pharmacist shall —

(a) establish an auxiliary record keeping system in case the electronic patient profile record system becomes inoperative for any reason;

(b) enter the patient profile information and number of refills authorized during the time the electronic patient

profile record system was inoperative within seventy two hours from the time the electronic patient profile record system is restored to operation;

(c) provide adequate safeguards against manipulation and alteration of records to protect the confidentiality of the information contained in the data bank; and

(d) make arrangements with the supplier of data processing services or materials to ensure that the pharmacy will continue to have adequate and complete prescription and dispensing records if the relationship with such supplier terminates for any reason.

(4) A pharmacist shall maintain one profile record for members of a family living at the same address and possessing the same family name.

(5) The pharmacist shall use his or her professional judgment to review and monitor the patient profile record to determine if there should be any adjustment in the original patient information and indicate the appropriate change in the patient profile record.

(6) Upon receipt of a new or refill prescription, a pharmacist shall examine the patient's profile record before dispensing the drug to determine the possibility of a potentially significant drug interaction, reaction or misuse of the prescription and if the pharmacist detects a potentially significant drug interaction, reaction or misuse, the pharmacist shall take the appropriate action to avoid or minimize the problem, which shall, if necessary, include consultation with the patient and the prescriber.

(7) A pharmacist shall maintain a patient profile record for each patient for a period of not less than 5 years from the date of the last entry in the profile record.

(8) The oldest 4 years of record information must be maintained in such a manner so as to be sight-readable within 2 weeks.

(9) The most recent one year of record information must be immediately retrievable.

30. OVER-THE-COUNTER RECORD

(1) A pharmacist shall maintain a record of every dispensation of a pharmacist assisted drug which shall be clearly labeled "Over the-counter Pharmacist Assisted Drug Record".

(2) A record maintained pursuant to sub-regulation (1) shall include the following information:

(a) the patient's first and last name and address;

(b) the name and quantity of the pharmacist assisted drug sold;

(c) the date of the sale;

(d) the name or initials of the pharmacist who dispensed the drug.

31. SUPPORTIVE PERSONNEL

Supportive personnel may assist the pharmacist in a clerical manner such as the retrieving of prescription files, profile cards, and other such records, the typing of labels and the completing of prescription receipts and other such form.

32. REFILLS

(1) Upon receipt of a refill prescription, a pharmacist shall determine if a substantial time, as is appropriate for that drug in the reasonable and prudent pharmacist's professional judgment, has elapsed from the last filling and when necessary, the pharmacist shall consult with the prescriber and the patient to assure himself or herself that continued use is appropriate.

(2) The pharmacist shall consult with the patient and the prescriber to determine if continued use of a drug is appropriate in cases where the patient profile records indicate sporadic, erratic or irrational use of the drug by a patient.

(3) A pharmacist shall maintain a profile record of all prescription patients who patronize a pharmacy as specified in regulation and the pharmacist shall inquire as to whether other prescription drugs are being concomitantly utilized in order to establish a current drug history for the patient.

33. PROHIBITION OF STEERING

A pharmacist shall not enter into an arrangement with a health practitioner or other person who is authorized to issue prescriptions, or with any health care facility for the purpose of directing or diverting patients to or from a specified pharmacy or restraining in any way a patient's freedom of choice to select a pharmacy.

34 COPIES OF PRESCRIPTION

(1) A pharmacist shall provide a copy of a prescription if the patient or care giver requests a copy of the prescription from the pharmacist.

(2) Copies of prescriptions issued directly to the patient by the pharmacy where the drug was dispensed, pursuant to the receipt of the prescription, shall state in letters at least equal in size to those describing the medication dispensed, the highlighted statement: "COPY FOR INFORMATION ONLY".

(3) Presentation of a prescription marked "COPY FOR INFORMATION ONLY" shall be for information purposes only and have no legal status as a valid prescription.

35. TRANSFER OF PRESCRIPTION

(1) A pharmacist shall transfer a prescription to anotherpharmacist if the patient or care giver requests such transfer.

(2) When a request is made for the transfer of a prescription pursuant to sub-regulation (1) the pharmacist shall make a copy of the prescription marked with the words "COPY FOR INFORMATION ONLY".

(3) Upon making the copy pursuant to sub-regulation (2), the pharmacist —

(a) may issue the copy to the patient; or

(b) send the copy to the other pharmacist by fax.

(4) The pharmacist who sends the copy of a prescription shall invalidate the original prescription on file together with the refill authorizations as of the date the copy is transferred by writing "VOID" on their face and shall record on the back of the invalidated prescription and refill authorizations that a

copy has been issued, the date of issuance of such copy, the name of the pharmacy and pharmacist the prescription is being transferred, and the initials of the pharmacist issuing the transferred prescription.

(5) The pharmacist who receives the copy of the prescription shall on receiving the copy record the following information —

(a) the name, address and original prescription number of the pharmacy from which the copy of the prescription was transferred;

(b) the name of the pharmacist who sent the copy;

(c) the date of issuance of the original prescription;

(d) the number of refills authorized on the original prescription;

(e) the complete refill record from the original prescription;

(f) the date of original dispensing;

(g) the number of valid refills remainint.

(6) The pharmacist who receives a copy of a prescription shall inform the patient that the original prescription has been cancelled at the pharmacy from which it was obtained.

36. RETURN OF PRESCRIPTION DRUG

(1) Subject to sub-regulation (2), a pharmacist shall not accept any drug for return to inventory after that drug has been previously dispensed.

(2) A pharmacist may accept a drug for return to inventory after it has been dispensed if in the pharmacist's professional judgment it is appropriate to do so and if the following conditions are met —

(a) the lot number and expiry date of the drug, where applicable, are directly attached to the dispensed container;

(b) each dose of the drug is individually sealed and the seal is intact at the time of the return to the pharmacy;

(c) the pharmacist has a personal knowledge of the storage conditions of the drug subsequent to its being dispensed

or the length of time between dispensing and return is of such short duration that storage conditions would not be material;

(d) the patient has not been in possession of the drug;

(e) the drug has been under the supervision of the pharmacist directly or indirectly between the time of dispensing and the time of return to a sufficient degree to permit the exercise of professional judgment;

(f) the prescription drug was incorrectly dispensed to the patient.

37. DISPOSAL OF UNWANTED DRUGS

A pharmacist shall dispose of an unwanted drug in a manner that does not cause that drug to become a health hazard and in accordance with the law.

SCHEDULE 1

(Regulation 2)

CONTROLLED DRUGS

Part I

Acetorphine(O-acetyl-7,8 dihydro-7-alpha[1R - hydroxy-1-methylbutyl]- o-methyl-6,14endoethenomorphine or 3-o-acetyltetrahydro-7 alpha-(1- hydroxy-1-methylbutyl)-6, 14-endoetheno-oripavine or 5-acetoxy- 1,2,3,3a,8,9-hexahydro-2 alpha-[1(R) - hydroxy-1-methylbutyl]-3- methoxy-12-methyl-3, 9a-etheno-9, 9b-iminoethano-phenanthro [4,5- bed] furan

Acetyldihyrocodeine

Acetylmethadol (3-acetoxy-6-dimethylamino-4,4-diphenyl-heptane)

Allylprodine (3-ally-1-methyl-4-phenyl-4-propionoxy-piperidine)

Alphacetylmethadol (alpha-3-acetoxy-6-dimethylamino-4,4-diphenylheptane)

Alphameprodine (alpha-3-ethyl-1-methyl-4-phenyl-4-propionoxypiperidine)

Alphamethadol (alpha-6-dimethylamino-4,4-diphenyl-3-heptanol)

Alphaprodine (alpha-1,3-dimethyl-4-phenyl-4-propionoxy-piperidine)

Anileridine (1-para-aminophenethyl-4-phenylpiperidine-4-carboxylic acid ester or 1-[2-(para-aminophenyl)-ethyl]-4-phenylpiperidine-4-carboxylic acid ethyl ester)

Benzethidine (1-(2-benzyloxyethyl)-4-phenylpiperidine-4-carboxylic acid ethyl ester

Benzylmorphine (3-benzylmorphine)

Betacetylmethadol (beta-3-acetoxy-6-dimethylamino-4,4-diphenylheptane)

Betameprodine (beta-3-etyly-1-methyl-4-phenyl-4-propionoxypiperidine)

Betamethadol (beta-6-dimethylamino-4,4-diphenyl-3-heptanol)

Betaprodine (beta-1,3-dimethyl-4-phenyl-4-propionoxy-piperidine)

Bezitramide(1-(3-cyano-3,3-diphenylprophyl)-4-(2-oxo-3 propionyl-1- benzimidazolinyl)-piperidine)

Clonitazene (2-para-chlorbenzyl-1-diethylaminoethyl-5-nitrobenzimidazole)

Cocaine

Codiene (3-methylmorphine)

Codoxime (dihydrocodeinone-6-carboxymethyloxime)

Concentrate of poppy straw (The material arising when poppy straw has entered into a process for the concentration of its alkaloids when

such material is made available in trade)

Desmorphine (dihydrodeoxymorphine)

Dextromoramide ((+)-4-[2-methyl-4-oxo-3,3-diphenyl-4(1-pyrrolidinyl) butyl] morpholine or (+)-3-methyl-2,2-diphenyl-4-morpholino-butyrl-pyrrolidine)

Diampromide (N-[(2-methylphenethylamino) propyl] propionanilide) Diethylthiambutene (3-diethylamino-1,1-di(2'-thienyl)-i-butene)

Difenoxim (1-(3 cyano-3,3 diphenylpropyl)-4phenylisonipecotic acid)

Difenoxin

Dihydrocodeine

Dihydromorphine

Dimenoxadol (2-dimethylaminoethyl-1-ethoxy-1,1-diphenylacetate or dimethylaminoethyl1-ethoxy-1,1-diphenylacetate or dimethylaminoethyl diphenyl-alpha-ethoxyacetate)

Dimepheptanol (6-dimethylamino-4,4-diphenyl-3-heptanol)

Dimethylthiambutene (3-dimethylamino-1,1-di(2thienyl)-1-butene)

Dioxyaphetyl Butyrate (ethyl 4-morpholino-2,2-diphenyl-butyrate)

Diphenoxylate (1-(3-cyano-3,3-diphenylpropyl)-4-phenyl-piperidine4-carboxylic acid ethyl ester or 2,2-diphenyl-4[4-carbethoxy-4-phenyl) piperidino]butyronitril)

Dipipanone (4,4-diphenyl-6-piperidine-3-heptanone)

Drotebanol (3,4-dimethoxy-17-methylmorphinan-6 beta, 14 diol)

Ecgonine, its esters and derivatives which are convertible to ecgonine and cocaine. Ethylmethylthiambutene (3-

ethylmethylamino-1, 1-di-(2'-thienyl)-1-butene) Ethylmorphine (3-ethylmorphine)

Etonitazene (1-diethylaminoethyl-2-para-ethoxybenzyl-5-nitrobenzimidazole)

Etorphine (7,8-dihydro-7 alpha-[1(R)-hydroxy-1-methylbutyl]-O -methyl-6,14-endoethanomorphine or tetrahydro-7alpha-(1-hydro-1-methyl-butyl)-6,14-endoetheno-oripavine or 1,2,3,3a,8,9-hexahydro-5-hydroxy-2-alpha[1(R)-hydroxy-1-methylbutyl]-3-methoxy-12met

Etoxeridine (1-[2-(2-hydroxyethoxy) ethyl]-4-phenylpiperidine 4-carboxylic acid ethyl ester)

Fentanyl (1-phenethyl-4-N-propionylanilinopiperidine)

Furethidine (1-(2-tetrahydrofurfuryloxyethyl)-4-phenylpiperidine-4-carboxylic acid ethyl ester)

Heroine (diacetylmorphine)

Hydrocodone (dihydrocodeinone)

Hydromorphinol (14-hydroxydihydromorphine)

Hydromorphone (dihydromorphinone)

Hydroxypethidine (4-meta-hydroxyphenyl-1-methylpiperidine-4-carboxylic acid ethyl ester or 1-methyl-4-(3-hydroxy-phenyl)-piperidine- 4-carboxylic acid ethyl ester

Isomethadone(6-dimethylamino-5-methyl-4,4-diphenyl-3-hexanone)

Ketobemidone (4-meta-hydroxyphenyl)-methyl-4-propionyl-piperidine or 4-(3-hydroxyphenyl)-1-methyl-4-piperidyl ethyl ketone or 1-methyl- 4-metahydroxyphenyl-4-propionyl-piperidine)

Levomethorphan ((-) -3-methoxy-N-methylmorphinan), but not

Dextromethorphan((+)-3-methoxy-N-methylmorphinan)

Levomoramide ((-)-4-[2-methyl-4-oxo-3,3 diphenyl-4-(1-pyrrolidinyl)butyl] morpholine or (-)-3-methyl-2,2-diphenyl-4-morpholino-butyryl-pyrrolidine)

Levophenacylmorphan ((-)-3-hydroxy-N-phenacylmorphinan)

Levorphanol ((-)-3-hydroxy-N-methylmorphinan), but not

Dextrophan ((+)-3-hydroxy-N-methylmorphinan)

Medicinal Opium

Metazocine (2'-hydroxy-2,5,9-trimethyl-6,7-benzomorphan) or 1,2,3,4,5,6-hexahydro-8-hydroxy-3,6,11-trimethyl-2,6-methano-3-benzazocine)

Methadone (6-dimethylamino-4,4-dophenyl-3-heptanone)

Methadone-Intermediate (4-cyano-2-dimethylamino-4,4-diphenylbutane or 2-dimethylamino-4-diphenyl-4-cyano butane)

Methyldesorphine (6-methyl-delta 6-deoxymorphine)

Methyldihydromorphine (6-methyldihydromorphine)

Metaphon (5-methyldihydromorphinone)

Moramide-Intermediate (2-methyl-3-morpholino-1,1-diphenylpropanecarboxylic acid or 1-diphenyl-2-methyl-3-morpholinopropanecarboxylic acid)

Morpheridine (1-(2-morpholinoethyl)-4-phenylpiperidine-4-carboxylic acid ethyl ester)

Morphine

Morphine Methobromide and other pentavalent nitrogen morphine derivatives, including in particular the morphine N-oxide derivatives, one of which is Codeine-N-Oxide.

Morphine-N-Oxide

Myrophine (myristylbenzylmorphine)

Nicocodeine (6-nicotinylcodeine or 6-(pyridine-3-carboxylic acid)-codeine ester)

Nicomorphine (3,6-dinicotinycodeine or di-nicitinic acid ester of morphine)

Noracymethadol 9 (+)-alpha-3-acetoxy-6-methylamino-4,4-diphenylheptane)

Norcodeine (N-demethylcodeine)

Norlevorphanol ((-)-3-hydroxymorphinan)

Normethadone (6-dimethylamino-4,4-diphenyl-3-hexanoneor 1,1-diphenyl-1-dimethylaminoethyl-butanone-2 or 1-dimethyl-amino-3,3- diphenyl-hexanon-(4))

Normorphine (demethylmorphine or N-demethylated morphine)

Norpipanone (4,4-diphenyl-6-piperidino-3-hexanone)

Oxycodone (14-hydroxydihydrocodeinone or dihydrohydroxycodeinone)

Oxymorphone (14-hydroxydihydrocodeinone or dihydrohydroxymorphinone)

Pethidine (1-methyl-4-phenylpiperidine-4-carboxylic acid ethyl ester)

Pethidine-Intermediate-A (4-cyano-1-methyl-4-phenyl-piperidine or 1-methyl-4-cyanopiperidine

Pethidine-Intemediate-B (4-phenylpiperidine-4-carboxylic acid ethyl ester or ethyl 4-phenyl-4-piperidine-carboxylate)

Pethidine-Intermediate-C (1-methyl-4-phenylpiperidine-4-carboxylic acid)

Phenadoxone (6-morpholino-4,4-diphenyl-3-heptanone)

Phenampromide (N-(1-methyl-2-piperidinoethyl) propionanilide or N-[2-(1-methylpiperid-2'yl) ethyl]-propionanilide)

Phenazocine (2'-hydroxy-5,9-dimethyl-2-phenethyl-6,7-benzomorphan or 1,2,3,4,5,6-hexahydro-8-hydroxy-6,11-dimethyl-3-phenethyl-2,6- methano-3-benzazocine)

Phenomorphan (3-hydroxy-N-phenethylmorphinan) Phenoperidine (1-(3-hydroxy-phenylpropyl)-4-phenyl-piperidine-4-carboxylic acid ethyl ester or 1-phenyl-3-(4-carbethoxy-4-phenylpiperidine)-propanol)

Pholcodine (morpholinyethylmorphine or beta-4-morpholinyethylmorphine)

Piminodine (4-phenyl-1-(3-phenylaminopropyl) piperidine-4-carboxylic acid ethyl ester)

Piritramide (1-(3-cyano-3,3-diphenylpropyl)-4-(1-piperidino) piperidine-4-carboxylic acid amide or 2,2-diphenyl-4-[1-(4-carbamoyl-4-piperidino)-] butyronitrile)

Prophetazine 1,3-dimethyl-4-phenyl-4-propionoxyazacy-cloheptane or 1,3-dimethyl-4-phenyl-4-propionoxy-hexamethyleneimine)

Properidine (1-methyl-4-phenylpiperidine-4-carboxylic acid isopropyl ester)

Propiram

Racemethorphan ((+)-3-methoxy-N-methylmorphinan)

Racemoramide ((+)-4-[2-methyl-4-oxo-3,3-diphenyl-4-(1-pyrrolidinyl) butyl] morpholine or (+)3-methyl-2,2-diphenyl-4-morpholinobutyrlpyrrolidine)

Racemorphan ((+)-3-hydroxy-N-methylmorphinan)

Tetrahydrocannabinol

Thebacon (acetyldihydrocodeinone or acetyldemethylodihydrothebaine)

Thebaine

Trimeperidine (1,2,5-trimethyl-4-phenyl-4-propionoxypiperidine).

Part 2

The isomers, unless expressly excepted, and the esters, ethers and salts, including the salts of isomers, esthers of the substances specified in I above.

Part 3

Any extract or tincture of Cannabis

Part 4

Any-

(a) preparation, mixture, extract, or other substance containing any portion of a substance; or

(b) substance that is chemically equivalent or chemically identical to any preparation, mixture, extract, derivative or other substance containing any portion of a substance, specified in I, II and III.

SCHEDULE 2

(Regulation 2)

OVER THE COUNTER MEDICINES AND DIAGNOSTICS

Over the counter's are only approved for the conditions below
Allergic Response
Allergy

Analgesics
Analgesics (oral)
Analgesics (Topical)

Cardiovascular
Cardiovascular

CNS
Sleep disturbance (temporary)
Smoking cessation
Travel Sickness

Cough, colds and flu
Colds & flu
Coughs
Sore throats

Ears & Eyes
Ear problems
Eye problems

Female Health
Cystitis
Period Pain and PMS
Thrush and Vaginitis

Gastro-intestinal
Constipation
Diarrhea
Hemorrhoids
Indigestion

Irritable Bowel Syndrome
Worms

Infants
Colic
Cradle Cap
Nappy rash
Teething

Nutrition
Iron preparations
Tonics
Vitamins and Minerals

Oral
Oral hygiene

Scalp conditions/infestations
Hair loss
Lice
Scalp conditions

Sexual health
Intercourse
Skin Conditions

Acne
Antiseptics
Athletes foot
Cold sores
Corns and calluses
Scabies
Skin problems
Warts and verrucas

Herbal medicines
Bladder conditions
Colds, flu and sore throats
Constipation
Coughs
First aid

Hemorrhoids
Indigestion
Nausea and Diarrhea
Pain relief
Scalp and hair care
Shin conditions

Sleeplessness
Slimming
Stress
Tonic

Homeopathic remedies

Diagnostics
Blood glucose meters
Pregnancy or ovulation tests
Blood pressure meters

SCHEDULE 3

(Regulation 2)

PHARMACIST ASSISTED DRUGS

1. Anti-Fungals Clotrimazole (Vaginal) and similar Derivatives, Pessaries, Creams, Solution, Nystatin Suspension and cream Topical-all Imidazole derivatives e.g. Econazole

2. Antibiotics Muciprocin

3. Anticholinergics Diphenoxylate/Atropine Hyoscine, Propantheline Baralgin

4. Analgesics Dihydroergotamine Aminiphenazone, Caffeine Orphenadrine, Mefenamic Acid 250mg & 500mg, Ibuprofen 400mg

5. EENT Polysporin and similar preparations Naphazoline/Anatazoline Oxytetracycline eye ointment

6. Antidotes/Metal Antagonists Ipecac Syrup

7. Adrenal Hormones Triamcinolone 0.025% cream Fluocinolone and similar cream or ointment

8. Contraceptives Levonorgestrel 0.75mg

SCHEDULE 4

(Regulation 2)

PRESCIPTION ONLY DRUG

1 Antihelmintics
Thiabendazole (all forms)

2 Antifungals for systemic use
Ketaconazole
Amphoteracin B
Oral Nystatin (tablet)
Griseofulvin
Itraconazole and similar derivatives
All other systemic preparations

3 Antibiotics
Penicillin derivatives e.g. Penicillin G, Pennicillin V
Cloxacillin, Amoxicillin etc.
Erythromycin and other macrolides
Cephalosporins (1st, 2nd, and 3rd generations)
Chloramphenicol
Gentamicin and other aminoglycosides
Tetracyclines and derivatives
Sulphonamides e.g. Co-Trimoxazole
All Anti-Virals e.g. AZT, Acyclovir

4 Anti-Tuberculosis
Ethambutol
Isonaizid
Pyrazinamide
Rifampicin
Any combination thereof and other systemic preparations

5 Anti-Trichomonal
Metronidazole and Derivatives

6 Urinary Tract Anti-Septics
Nitrofurantoin
Nalidixic Acid and derivatives

4-Quinolones e.g. Norfloxacillin, Ciprofloxacillin

7 Anti-Leprotics
Clofazimine
Dapsone
Any other Anti-Leprotic drugs

8 Anti-Neoplastics and Immunosuppressants
Tamoxifen
All other Anti-Cancer

9 Cholinergic Agents
All cholinergic agents

10 Anti-Cholinergics
Atropine
Benzhexol (trihexiphenidyl)
Benztropine and its derivatives

11 Adrenergic Agents
Adrenaline
Dopamine
Isoprenaline

12 Adrenergic Blocking Agents
Ergot Alkaloids
Phenoxybenzamine HCl
Phentolamine Mesylate

13 Skeletal Muscle Relaxants
Skeletal Muscle Relaxants, whether injectable or oral preparations.

14 Iron Preparations
Iron Dextran Injection
Sustained Released high potency iron preparation

15 Anti-Coagulants/Coagulants
Heparin
Warfarin
Protamine Sulphate
Vitamin K1

16 Cardiac Drugs
All Drugs used in cardiac conditions.

17 Hypotensive Drugs
All Hypotensive Drugs

18 General Anesthetics
All General Anesthetics

19 Analgesics and Anti-Inflammatory Agents
All agents, except the following
Ibuprofen 200mg and 400mg (and derivatives of equivalent analgesic potency)
Codeine 8mg
Paracetamol 500mg
Mefenamic Acid 250mg and 500mg

20 Narcotic Antagonists

21 Anti-Convulsants
All anti-convulsants

22 Psychotherapeutics
1All Anxiolytics
All Hypnoitics
All Anti-deprassants
All drugs used in psychosis and related disorders

23 Diuretics

24 Anti-Gout Agents

25 Eye-Ear-Nose-Throat
All of those agents except, wax softners, artificial tears, eye cleaners, normal saline and EENT vasoconstrictors.

26 Carbonic Anhydrase Inhibitors
Acetazolamide

27 Anti-Emetics
All, except oral and rectal preparations of dimenhydrinate.

28 Miscellaneous G. I. Drugs
H2 Antagonists
Omeprazole
Metoclopropamide,
Sucralfate
Misoprostol

29 Antidotes/Metal Antagonists
All except Fuller's Earth and activated Charcoal

30 Adrenal Hormones (oral, Injectable and Inhalation)
Beclomethasone
Dexamethasone
Hydrocortisone
Prednisolone
Prednisone
Triamcinolone

31 Contraceptives
Oral Preparations
Injectables
Dermal Preparations
IUD

32 Estrogens
Norethisterone

33 Androgens

34 Gonadotropins

35 Pituitary Hormones
Vasopressin

36 Progestins
Medoxyprogesterone
Progesterone

37 Anti-Diabetic Drugs

38 Thyroid/Anti-Thyroid Preparations

39 Local Anesthetics

40 Oxytocics

41 Anti-Asthmatics

42 Injectable Vitamins

43 Anti-Parkinsons.