ANTIGUA AND BARBUDA

THE PHARMACY REGULATIONS, 2012

STATUTORY INSTRUMENT

2012, No. 45

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THE PHARMACY REGULATIONS, 2012

ARRANGEMENT

Regulations

ANTIGUA AND BARBUDA

THE PHARMACY REGULATIONS, 2012

2012, No. 45

THE PHARMACY REGULATIONS made in exercise of the powers contained in section 28 of the Pharmacy Act, 1995.

PART I

PRELIMINARY

1. Short title.

These Regulations may be cited as the Pharmacy Regulations, 2012.

2. Interpretation.

In these Regulations—

"Act" means the Pharmacy Act, 1995;

"approved" means approved by the Council;

"Board of Inspectors" means the Board of Inspectors constituted under section 16 of the Act;

"College" means the Antigua State College, or any other institution approved by the Council for the training of pharmacists;

"Community" means the Caribbean Community including the CARICOM Single Market and Economy established by the Treaty;

"Council" means the Council established under section 3 of the Act;

"generic drug" means any unpatented drug and includes a drug whose patent has expired or one that has never been patented;

"generic name" means the official name or international non-proprietary nomenclature;

"Member State" means a Member State of the Community listed in Schedule 1;

"pharmacy programme" means the programme for pharmacy studies offered at the College;

"registered medical practitioner" means a person registered under the Medical Practitioners Act, 2009 No. 3 of 2009;

"Treaty" means the Revised Treaty of Chaguaramus establishing the Caribbean Community including the CARICOM Single Market and Economy signed at Nassau, The Bahamas on the 5th day of July, 2001; and

"University" means an institution, at which a person may read for a degree in pharmacy, that

is approved by the Council.

PART II

APPLICATION FOR REGISTRATION

3. Application.

An application under the Act shall be made in the prescribed form and accompanied by the prescribed fees.

4. Registration as a pharmacy student.

The Council shall approve the registration of an applicant as a pharmacy student where the applicant—

(a) has been accepted for the pharmacy programme of a College for a course of studyin pharmacy; and

(b) has made an application in Form A of Schedule 3 and paid the prescribed fee.

5. Registration as a pharmacist.

(1) The Council shall approve the registration of an applicant as a pharmacist where the applicant—

(a) is the holder of a degree or diploma in Pharmacy from a University or College recognized by the Council;

(b) has produced a Medical Certificate of fitness from a registered medical practitioner stating that he is physically fit and mentally sound to perform the duties of a pharmacist;

(c) has satisfied the requirements of section 7 of the Act;

(d) has produced the documents required under section 8 (2) of the Act;

(e) has made an application in Form B of Schedule 3 and paid the prescribed fee; and

(f) in the case of a newly trained applicant has satisfied a period of internship for six months supervised by the Council.

(2) A person registered as a pharmacist shall pay the annual licence fee as prescribed in Schedule 2.

(3) After the initial licence is granted and prior to the issue of each licence thereafter, a pharmacist applying for a licence is required to complete twelve (12) hours of a continuing education programme approved by or facilitated by the Council.

6. Registration as a pharmacy technician.

(1) The Council shall approve the registration of an applicant as a pharmacy technician, if the Council is satisfied that the applicant—

(a) has a qualification that entitles him to be registered as a pharmacy technician from an institution approved by the Council;

(b) has undergone a period of practical training approved by the Council; and

(c) has produced a Medical Certificate of fitness from a registered medical practitioner stating that he is physically fit and mentally sound to perform the duties of a pharmacy technician;

(d) has produced the documents required under section 8 (2) of the Act;

(e) has made an application in Form D and paid the prescribed fee.

(2) A person registered as a pharmacy technician shall pay the annual licence fee as prescribed in Schedule 2.

7. Notification.

(1) The Council shall, within forty five days of receipt of an application for registration, notify the applicant whether his application has been approved.

(2) An applicant, upon being notified of the approval of his application shall pay the fee prescribed for registration in Schedule 2.

8. Particulars of registration.

(1) The Registrar shall cause the following particulars of every pharmacist to be entered in the Register of Pharmacists—

(a) his name and address;

(b) his age, date of birth and country of origin;

(c) his qualification and the institution from which he received his training; and

(d) the date of his registration in Antigua and Barbuda;

(2) The Registrar shall cause—

(a) a notice of the registration of each pharmacist, who is being registered for the first time in Antigua and Barbuda, to be published in the *Gazette* within one month after the date of registration; and

(b) a complete list of the Register of Pharmacists, containing the names and the dates of registration of each pharmacist registered in Antigua and Barbuda, to be published in the *Gazette* once in the first quarter of each calendar year.

9. Registration certificate and Licence.

(1) The certificate of registration issued by the Council—

(a) for a pharmacist shall be that prescribed in Form C of Schedule 3;

(b) for pharmacy technician shall be that prescribed in Form E of Schedule 3; and

(2) The licence issued by the Council to operate a wholesale pharmaceutical business shall be that prescribed in Form K of Schedule 3.

(3) The licence issued by the Minister—

(a) for premises to be used to operate a pharmacy shall be that prescribed in Form L of Schedule 3;

(b) to be an authorised seller of poisons shall be that prescribed in Form H of Schedule 3.

PART III

LICENSING OF PREMISES AND SALE OF POISONS

10. Application for licence for pharmacy.

An application for a licence to use premises to operate a pharmacy on any premises shall be made to the Registrar in Form F by the owner of the pharmacy or where a body corporate or partnership is making the application, by an officer of the body corporate or a partner and shall be accompanied by—

(a) two passport sized photographs of the applicant taken within the six month period immediately prior to the submission of the application, which are duly certified by an attorney at law registered to practice law in Antigua and Barbuda, or Notary Public to be a true photograph of the applicant; and

(b) the prescribed fees.

11. Application for licence for wholesale pharmaceutical business.

An application for a licence to operate a wholesale pharmaceutical business on any premises shall be made to the Registrar in Form J of Schedule 3 by the owner of the wholesale pharmaceutical business and where the owner of the wholesale pharmaceutical business is a body corporate or partnership, by a partner or officer of the body corporate and shall be accompanied by—

(a) two recently taken passport sized photographs of the applicant, duly certified by an attorney at law registered to practice law in Antigua and Barbuda, or notary public to be a true photograph of the applicant; and

(b) the prescribed fees.

12. Application for licence to sell poison.

(1) An application to be licensed as an authorised seller of poisons shall be made to the Council in Form M of Schedule 3 by a person registered to sell poisons in accordance with regulation 30 and shall be accompanied by—

(a) two recently taken passport sized photographs of the applicant, duly certified by an attorney at law registered to practice law in Antigua and Barbuda, or notary public to be a true photograph of the applicant; and

(b) the prescribed fees.

(2) Where the applicant under regulation 12(1) is a body corporate or partnership the application shall be made by a partner or officer of the body corporate.

13. Inspection of premises.

(1) The Registrar shall, within thirty days of receipt of an application for a licence to operate a pharmacy or wholesale business or to sell poisons containing all the necessary particulars, cause to be forwarded to the Board of Inspectors the application so that an inspection can be conducted to determine whether the premises may be licensed for the operation of a pharmacy or wholesale pharmaceutical business or to sell poisons.

(2) The Board of Inspectors shall within forty-five days of receipt of an application under paragraph (1) visit the premises and carry out all necessary inspections and shall submit to the Council a written report indicating its findings.

14. Licensing of premises.

(1) If the report of the Board of Inspectors indicates that the premises satisfy the requirements to be licensed as a pharmacy or to sell poisons, the Council shall notify the Minister of the report and Recommend that the Minister may approve the licence.

(2) If the report of the Board of Inspectors indicates that the premises satisfy the requirements to be licensed as a wholesale pharmaceutical business, the Registrar shall notify the Council of the report and the Council shall approve the licence.

(3) A certificate issued by the Minister under this Regulation shall be in Form L of Schedule 3.

15. Register of pharmacies.

The Registrar shall, where premises have been approved for use as a pharmacy or wholesale pharmaceutical business, enter the following particulars on the Register of Pharmacies—

(a) the name and address and occupation of the applicant;

(b) the business name and address of the premises;

(c) the nature of business conducted on the premises, and all purposes for which the premises are used or intended to be used;

(d) the name and address and registration particulars of any registered pharmacist employed on the premises; and any changes thereto

(e) the registration number of the premises;

(f) the date of first registration and any records; and

(g) the expiry date of the current registration.

PART IV

PROFESSIONAL MISCONDUCT

16. Complaints.

(1) A person who alleges that a registered pharmacist, pharmacy student or pharmacy technician is guilty of professional misconduct may make a complaint to the Registrar in writing setting out the full circumstances giving rise to the complaint and shall include his name, address and telephone number.

(2) On receipt of a complaint the Registrar shall within twenty one days thereafter, forward the details of the complaint to the Council and the Council shall direct the Board of Inspectors to investigate the complaint.

(3) The Board of Inspectors shall conduct all investigations, as directed by the council within three months of receipt of those directions and shall submit for the consideration of the Council a written report of its findings of the investigations.

17. Professional misconduct.

(1) Professional misconduct includes the following—

(a) stealing or being in unlawful possession of drugs or poisons;

(b) conspiring to procure or unlawfully procuring or attempting to procure an abortion;

(c) being under the influence of drugs or alcohol while performing the duties of a pharmacist, pharmacy student or a pharmacy technician;

(d) tampering with, altering or causing to be altered in any way the prescription of a registered medical practitioner, a registered dentist, a registered veterinary surgeon or veterinary practitioner;

(e) entering into an arrangement with a registered practitioner for the sharing of profits derived from the filling of prescriptions issued by the practitioner;

(f) the wilful or grossly negligent failure to comply with substantial provisions of any laws, rules or regulations governing the practice of the pharmacy profession;

(g) exercising undue influence on a patient or client by promoting the sale of services, goods, appliances or drugs in such manner so as to exploit the patient or client for the financial gain of a pharmacist or of a third party;

(h) permitting a person to share in the fees for professional services, other than: a partner, employee or associate in a professional firm or corporation, professional subcontractor or consultant authorized to practice as a pharmacist, or a pharmacy student, or pharmacy technician;

(i) wilfully making or filing a false report, failing to file a report required to be filed by law or wilfully impeding or obstructing such filing, or inducing another person to impede or obstruct such filing;

(j) failing to make available to a patient or client, upon request, copies of documents in the possession or under the control of the licensee which have been prepared for and paid for by the patient or client;

(k) revealing of personally identifiable facts, data or information obtained in a professional capacity without the prior consent of the patient or client, except as authorized or required by law;

(l) practicing or offering to practice beyond the scope permitted by law, accepting the task of performing professional responsibilities or performing professional responsibilities which the licensee has not the competence to perform or without adequate supervision performing professional services which the licensee is authorized to perform only under the supervision of a licensed professional, except in an emergency situation where a person's life or health is in danger;

(m) delegating professional responsibilities to an unlicensed person or a person who by virtue of insufficient training or insufficient experience is not qualified to perform those responsibilities;

(n) performing professional services which have not been duly authorized by the patient or client or his legal representative;

(o) dispensing a written prescription which does not bear the name of the patient for whom it is intended; the date on which it was written; the name and strength of the drug prescribed, the quantity of the drug prescribed and the directions for use;

(p) failing to maintain a current form which provides for ready retrieval of prescriptions, the patient for whom the prescription is intended, the signature or readily identifiable initials of the pharmacist who filled the prescription, and the number assigned to the prescription ;

(q) holding for sale, offering for sale, or selling—

(i) any drug later than the date marked upon the label as indicative of the date beyond which the contents cannot be expected to be safe and effective; provided, however, that when the drug is identified as an outdated drug by segregation from regular stock or by other means, the holding of that drug beyond its expiration date shall not be deemed a violation of this paragraph; or

(ii) any drug, the nature of which requires storage under special conditions of temperature control as indicated either on the labelling, in the directions for storage of said drug contained in an official compendium, or as directed by common prudence, unless the special condition of temperature control shall have been complied with during the entire period of time in which that drug has been held for sale;

(r) aiding and abetting an unlicensed person to dispense drugs provided that an unlicensed person may assist a pharmacist in the dispensing of drugs by—

(i) receiving written, verbal or electronically transmitted prescriptions, except that in the case of electronically transmitted prescriptions the pharmacists shall review the prescription to determine whether in his professional judgment it shall be accepted by the pharmacy, and if accepted, the pharmacist shall enter his initials into the records of the pharmacy;

(ii) typing prescription labels;

(iii) keying prescription data for entry into a computer-generated file or retrieving prescription data from the file, provided that the computer-generated file shall provide for verification of all information needed to fill the prescription by a pharmacist prior to the dispensing of the prescription, meaning that the pharmacist shall review and approve the information and enter his initials or other personal identifier into the record-keeping system prior to the dispensing of the prescription or of the prescription refill;

(iv) getting drugs from stock and returning them to stock;

(v) getting prescription files and other manual records from storage and locating prescriptions;

(vi) counting dosage units of drugs;

(vii) placing dosage units of drugs in appropriate containers;

(viii) affixing the prescription label to the containers;

(ix) preparing manual records of dispensing for the signature or initials of the pharmacist; or

(x) handing or delivering completed prescriptions to the patient or the person authorized to act on behalf of the patient after the pharmacist has handled the prescription in accordance with the Act and these regulations;

(s) aiding and abetting an unlicensed person to—

(i) receive oral prescriptions from prescribers;

(ii) interpret and evaluate a prescription for conformance with legal requirements, authenticity, accuracy and interaction of the prescribed drug with other known prescribed and over-the-counter drugs;

(iii) make determinations of the therapeutic equivalency as such determinations apply to generic substitution;

(iv) measure, weigh, compound or mix ingredients;

(v) sign or initial a record of dispensing required to be maintained by law;

(vi) counsel patients; or

(vii) perform any other function involving the exercise of professional judgment.

(2) Where the expiration date on a drug is expressed by month and year, the expiration date shall be the last day of the month indicated.

(3) Notwithstanding regulation (1)*(q)*(i), in the event that a drug is not available, a registered medical practitioner may in writing request from a registered pharmacist an out of date drug but the drug shall not be outdated for more than three months and in the case of a registered veterinary practioner the drug shall not be outdated more than six months

(4) A complaint of professional misconduct may not be made against a registered pharmacist who, in good faith, complies with regulation (3).

18. Board to investigate complaint.

(1) The Board of Inspectors in investigating a complaint shall provide the pharmacist, pharmacy student or pharmacy technician with a written statement of the complaint and all the allegations therein and shall invite the Pharmacist, student, or technician to furnish the Board within thirty days

of receipt the particulars of complaint a statement in writing relating to the allegations.

(2) Upon receipt of a written statement from the pharmacist, student, or technician the Board of Inspectors shall consider the matter and shall submit a report of its findings to the Council, within thirty days.

(3) The Board of Inspectors in investigating a complaint may at any stage consult with an attorney-at-law appointed by the Council for the purpose.

(4) The Board of Inspectors may at any stage of its investigation decline to proceed further with the investigation if it determines that the allegations are fraudulently made or where the allegations cannot be substantiated and where the Board of Inspectors so determines, it shall include a statement of its reason for the termination in its report to the Council.

19. Notification when evidence is insufficient.

(1) The Council shall consider the findings of the Board of Inspectors and shall determine within forty five days whether there is sufficient evidence to institute disciplinary proceedings against pharmacist or student, or pharmacy technician.

(2) Where the Council determines that there is insufficient evidence to institute disciplinary proceedings the Council shall forthwith direct the Registrar to notify the complainant and the pharmacist or student, or pharmacy technician, in writing, of the findings of the Council.

20. Procedure where evidence is sufficient.

(1) The Council shall, where the report of the Board of Inspectors recommends that disciplinary action be taken, constitute a committee pursuant to sections 24 and 25 of the Act and fix a date for the hearing and may direct an attorney-at-law retained for the purpose—

(a) to take all steps as may be relevant,

(b) to take steps as may be necessary to obtain or verify any documentary or other evidence that may be relevant, and

(c) to take steps to ensure the attendance of witnesses at the hearing.

(2) On fixing of a hearing date by the Council, the Registrar shall notify the complainant and the pharmacist, student or pharmacy technician of the date and shall specify in the notice—

(a) the nature of the charge to be determined including full particulars of the complainant; and

(b) the time and place of the hearing.

(3) A notice from the Registrar shall also include a statement informing the pharmacist or

student, or technician of the right to be represented by an attorney or other person at the hearing.

(4) Notices under this regulation shall be posted or delivered no later than one month before the date set for the hearing and shall be sent by registered post to the address or to the last known address of the pharmacist or student or technician entered in the register or in the student records or technician records.

21. Rights of accused.

A party against whom disciplinary proceedings have been instituted—

(a) may give evidence, call witnesses and may make submissions orally or in writing on his own behalf;

(b) shall be allowed access to any documentary evidence used in the proceedings and shall upon payment of reasonable costs of copying be entitled to obtain copies of all relevant documents;

(c) shall upon reasonable request having regard to all the circumstances be entitled to an adjournment provided that exceptional circumstances the Council shall permit no more than three adjournments before determining any disciplinary matter before it; and

(d) is entitled to be represented by legal counsel.

22. Expenses.

Where a finding is made against a pharmacist or student or technician as a result of disciplinary proceedings the Council may order the pharmacist or student or technician to cover expenses incurred in connection with the investigation of an allegation or complaint against him or in connection with any disciplinary proceedings.

23. Ex parte Hearings.

Where the Council is satisfied that notice of a hearing has been duly served on the pharmacist or student or technician, it may proceed with the hearing in the absence of the pharmacist or student or technician.

24. Council's decision.

(1) The Council at the conclusion of a hearing shall consider all evidence given at the hearing and after due deliberation may decide—

(a) that the evidence given at the hearing is insufficient to support the charge;

(b) that the charge has not been proven; or

(c) that the charge has been proven.

(2) Where the Council decides that the charge has been proven, the Council may impose any of the sanctions or penalties specified in Section 25 (2) of the Act.

25. Notification of decision.

The Council shall within fourteen days, upon making a determination notify the complainant and the pharmacist or student or technician in writing of its findings and the reasons therefore, and shall where the charge is proven indicate in the notice the sanction or penalty that may have been imposed.

26. Right of appeal.

A person who is aggrieved by a decision of the Council in disciplinary proceedings shall have the right to appeal that decision to a judge in chambers within three months of being notified of the Council's decision.

27. Removal of convicted Pharmacist from register.

Where a complaint against a pharmacist includes a charge of a criminal offence involving dishonesty, fraud or moral turpitude the Council, upon written confirmation under the hand of the Registrar of the High Court, or the Chief Magistrate that the person was convicted of such an offence and that the conviction was not subsequently quashed, may without further inquiry direct the Registrar to remove the name of the pharmacist from the register.

PART V

AUTHORIZED SELLERS OF POISONS

28. Schedule of Poisons.

The substances in Part II of Schedule 4 are poisons for the purposes of the Act.

29. Seller of poisons.

A person shall not sell any poison unless that person is a registered pharmacist or a person duly authorized by these regulations to sell poison.

30. Registration as seller of poison.

(1) A person other than a registered pharmacist may apply to be registered as an authorized seller of poisons by submitting an application to the Council in Form G of Schedule 3.

(2) An application under regulation (1) may be registered as an authorized seller of poisons if he satisfies the Council that he is over twenty one years and that he is of good character and that—

(a) the fee prescribed has been paid; and

(b) he is able to comply with the provisions of the Act relating to the sale of poisons.

(3) For the purposes of regulation (2) an applicant shall submit to the Council documentary evidence proving of his age as well as two recent photographs of the applicant and two testimonials of his good character.

31. Certificate of Registration.

(1) Where satisfied that an applicant has met the requirements to be an authorized seller of poisons, the Council shall recommend to the Minister that a Certificate be issued to the applicant.

(2) A certificate issued by the Minister pursuant to regulation 31(1) shall be in Form H.

32. Register of authorized sellers.

The Council shall cause the Registrar to keep a register of authorized seller of poisons and shall include in the register particulars including the name, address of the authorized seller, and the premises from which he operates, as the Council thinks fit.

33. Display of certificate and licence.

(1) A registered seller of poisons shall display the certificate of registration and licence at all times in a conspicuous place on the premises where poisons are sold.

(2) A register of poisons in Form I shall be maintained by the seller of poisons in such a manner that the same may be produced when requested by the Registrar or the Council and a request may be made without notice.

34. Annual fee.

An authorized seller of poisons shall pay the annual licence fee prescribed in Schedule 2.

35. Cancellation of registration.

(1) The Council may at any time cancel or suspend for such time as it thinks fit, a certificate of registration, if it is satisfied that the holder of the certificate has failed to comply with provisions of the Act or with these Regulations.

(2) The holder of a certificate of registration which has been cancelled or suspended shall forthwith return the certificate to the Council and shall cease forthwith to engage in the business of selling poisons.

36. Sale and labelling of poisons.

(1) A person shall not sell, dispense or deliver to any other person any poison unless the bottle, vessel, box, wrapper or cover in which the poison is contained is labelled, in addition to the requirements of subsection (1) *(d)* of section 18 of the Act with—

(a) adequate directions for use and words of caution in respect of the poison; and

(b) where the poison is an ingredient of a preparation, proportion of poison in that preparation.

(2) Before the sale, dispensing or delivery of any poison, the person selling, dispensing or delivering the poisons, shall ensure that the words of caution in paragraph (1) *(a)* of regulation 18 are understood by the person receiving the poison, and shall cause the person receiving the poison to sign his name beside the relevant entry in a register in which shall be recorded the following—

(a) the date of the transaction;

(b) the name, address and occupation of the person to whom the poison is being sold, dispensed or delivered;

(c) the name and quantity of poisons sold, dispensed or delivered, or where the poison is an ingredient of a preparation, the proportion, of poison;

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

(e) where the person to whom the poison is being delivered is not known to the person selling, dispensing or delivering same, the name and address of a witness to the transaction, and where there is no witness to the transaction, the name and address of person giving a recommendation in respect of the transaction; and

(f) the signature of the person receiving the poison, and signature of the person selling, dispensing or delivering the poison.

37. Handling of poisons.

(1) A person shall not sell, dispense or deliver any liniment embrocation, lotion or similar caustic substances containing poison unless that 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.

(2) Where a person sells, dispenses or delivers any substance mentioned in paragraph (1) in a bottle of not more than 120 fluid ounces, that substance shall be in ribbed or grooved bottles which

are easily discernable by touch.

38. Transport of poisons.

(1) A person shall not transport any poison unless—

(a) it is adequately packed to avoid leakage arising from the ordinary risks of handling;

(b) the outside of the package containing the poison is labelled conspicuously with the name and description of the poison and with a notice indicating that it is to be kept separate from food and food containers; and

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

39. Sale of Arsenic.

(1) A person shall not sell arsenic unless—

(a) that person is authorised under the Act to sell arsenic; and

(b) before sale, the arsenic is mixed with soot or indigo in the proportion of at least an ounce of soot or half an ounce of indigo to one pound of arsenic, and so in proportion for any greater or lesser quantity.

(2) This provision shall not apply—

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

(b) to wholesale pharmaceutical businesses supplying arsenic upon orders in writing in the ordinary course of wholesale pharmaceutical business dealing; or

(c) where arsenic is stated by the person receiving same to be required for some purpose other than use in agriculture, and it is established that the mixture would render the arsenic unfit for the purpose for which it is obtained and the arsenic is delivered in quantities of not less than ten pounds on each occasion.

40. Prescription.

Every prescription for a poison shall be in writing and shall include the following—

(a) the date;

(b) the name and address of the person for whom the prescription is issued;

(c) the name and quantity of the substance to be supplied;

(d) adequate directions for the use of the substance prescribed;

(e) legible signature of the prescriber; and

(f) where the prescription is given by a dentist or registered veterinary surgeon, the words "for dental treatment only" or "for the treatment of animals only" as the care may be.

PART VI

DISPENSING

41. Compounding and dispensing.

(1) A person who dispenses compounds and retails or supplies a drug other than in accordance with the prescription of a registered medical practitioner, registered dentist or registered veterinary surgeon, shall deliver that drug in a container labelled with—

(a) the name of the drug;

(b) the pharmaceutical form and strength;

(c) quantity;

(d) adequate directions for use; and

(e) words of caution respecting the drug, if necessary.

(2) A person who dispenses, compounds, retails or supplies a drug whether over the counter or in accordance with the prescription of a registered dentist, registered medical practitioner or registered veterinary surgeon shall, where there is available a bioequivalent generic drug which is interchangeable with the named drug and which is less costly, inform the person requesting the drug those facts, and shall supply the generic equivalent instead of the named drug except where the person objects or declines to accept the generic form.

(3) A person who dispenses, retails or supplies an over-the-counter drug which carries a brand name shall erect and maintain a prominent sign informing persons of the availability of the generic drug which is the bioequivalent of the drug carrying the brand name.

42. Number of times of dispensing.

(1) No prescription shall be dispensed more than once unless it is dispensed in accordance with the directions of the prescriber included in the prescription to the effect that it may be dispensed at a stated number of times or wherever necessary.

(2) Where a prescription—

(a) includes a direction that it may be dispensed a stated number of times but does not include any direction as to the intervals at which it may be dispensed that prescription shall not be dispensed before the stated duration except where the pharmacist is satisfied that the patient has a legitimate reason;

(b) includes a direction that it may be dispensed at stated intervals but does not include any direction as to the number of times it may be dispensed, that prescription shall not be dispensed more than three times;

(c) has not been dispensed after the period of six months from the date that the prescription was issued, the prescription will cease to be valid.

43. Prescription verbal, or electronic communication.

(1) A prescription for a drug may be communicated verbally by a registered practitioner, registered dentist or registered veterinary surgeon.

(2) A person to whom a prescription for a drug has been verbally or electronically communicated shall forthwith reduce the prescription, after it has been validated by a practitioner under regulation 43(1), into writing and shall, upon the filling thereof, retain that validated prescription for a period of not less than two years from the date of filling same.

(3) A prescription communicated verbally or electronically under regulation 43(2) shall be reduced into writing within thirty-six hours of the verbal or electronic communication.

(4) A person selling a drug pursuant to a written prescription shall retain the prescription for at least two years from the date of filling thereof.

(5) Every prescription for a drug shall include the following—

(a) the date;

(b) the name, age, and address of the person for whom the prescription is issued;

(c) the name, the generic name, pharmaceutical form and strength and the quantity of the substance to be supplied;

(d) adequate directions for the use of the substance prescribed;

(e) the usual signature of the prescriber and his name in legible print form;

(f) the address, telephone number and registration number of the prescriber; and

(g) where the prescription is given by a registered practitioner, registered dentist or registered veterinary surgeon, the words, "for dental treatment or "for treatment of animals only as the case may require".

(6) A person filling a prescription shall note on the prescription at the time of dispensing, the date of dispensing, prescription number and the signature of the person by whom it was dispensed,

an indication of the items dispensed and the prescription shall be retained by the person in charge of the pharmacy in which the prescription was filled for a period of not less than two years from the date on which the prescription was last dispensed.

44. Prescription record.

A person filling a prescription shall—

(a) number each prescription;

(b) file the prescription, or a true copy thereof the person for whom the prescription was given desires to retain the original prescription and the prescription does not contain a controlled substance or quantity of a substance which would make it inadvisable for the pharmacist to part with the same, and

(c) record in a prescription register the number and date of each prescription, the name of the persons for whom it is prescribed, age and address and the name of the registered medical practitioner, registered dentist and registered veterinary surgeon, by whom the same was given, the particulars of every prescription and the directions which accompanied the medicine

45. Arranged storage.

Every antibiotic and other drug or poison which requires special storage arrangements shall be stored in accordance with the temperature and other storage requirements specified by the manufacturer in respect of the antibiotic, drug or poison.

46. Opium Tincture.

(1) A person who sells, dispenses or delivers Tincture Opic Carmph (Camphorated Opium Tincture), shall not sell more than four ounces of that drug at any one time unless the transaction is—

(a) to a registered medical practitioner, registered dentist or registered veterinary surgeon for the purposes of his profession;

(b) for use in a hospital or other medical institution; or

(c) to a registered pharmacist for use in a registered pharmacy.

(2) Every sale, dispensing or delivery of camphorated Opium Tincture shall be recorded by the person making the sale, dispensing or delivery in a book kept for the purpose, in which shall be entered the following particulars—

(a) the date and quantity of the drug taken in stock;

(b) the date and quantity of any sale, dispensing or delivery of the drug;

(c) the name, address and occupation of the person who acquired the drug;

(d) the purpose for which the drug was acquired; and

(e) the name of the person authorizing the transaction, if any.

47. Repeat prescriptions.

(1) A repeat prescription shall not be dispensed after the period of six months from the date that the prescription was issued.

(2) A repeat prescription that has not been dispensed within six months of the date when it was issued, ceases to be valid.

48. Sale of therapeutic substances.

(1) Subject to paragraph (2), a person shall not sell any therapeutic substance by retail, except by prescription.

(2) Paragraph (1) shall not apply—

(a) to the supply of a therapeutic substance which is an antibiotic where it is made on production of a written requisition from one pharmacist to another; or

(b) to a therapeutic substance sold—

(i) by a wholesale pharmaceutical business;

(ii) for export;

(iii) to an authorised person;

(iv) to the owner or master of a ship or aircraft for medical use on board;

(v) to any institution or business which proves to the satisfaction of the Board that it carries on scientific education or research;

(vi) to Government; or

(vii) to a person in charge of a hospital, clinic or nursing home, or of any other institution which is approved by the Board and provides medical, dental, surgical or veterinary treatment.

49. Emergency prescriptions.

(1) A drug may be dispensed by a pharmacist in case of emergency where the supply is made at the request of the patient and the following conditions apply—

(a) the pharmacist under whose supervision the prescription only medicine is to be sold or supplied has interviewed the person requesting the medicine and shall satisfy himself—

(i) that there is an immediate need for the prescription only medicine requested to be sold or supplied and that it is impracticable in the circumstances to obtain a prescription without undue delay;

(ii) that treatment with prescription only medicine requested has been prescribed previously by a doctor for the person requesting it; and

(iii) as to the dose which in the circumstances it would be appropriate for that person to take.

(b) that the pharmacist provides no more than 5 days' treatment of the presription only medicine in question except, where the medicine in question is an ointment, a cream or a preparation in an aerosol dispenser for the relief of asthma, which has been made up for sale in a container elsewhere than at the place of sale or supply, the smallest pack that the pharmacist has available for sale or supply;

(c) that the pharmacist by or under whose supervision the medicine is sold or supplied ensures that an entry in the prescription only register is made stating—

(i) the date on which the prescription only medicine was sold or supplied;

(ii) the name, quantity and, except where it is apparent from the name, the pharmaceutical form and strength of the medicine;

(iii) the name, age and address of the person requiring the medicine and,

(iv) the nature of the emergency.

(d) that the container or package of the medicine is labelled with—

(i) the date on which the prescription only medicine was sold or supplied;

(ii) the name, quantity and, except where it is apparent from the name, the pharmaceutical form and strength of the prescription only medicine;

(iii) the name of the person requiring the prescription only medicine;

(iv) the name and address of the registered pharmacy from which the prescription only medicine was sold or supplied; and

(v) the words "Emergency Supply".

(e) that the prescription only medicine—

(i) is not a controlled drug specified in Schedule 3 Section 5, or in the Mis use of Drugs Regulation;

(ii) is restricted in relation to the Psychotropic Substances, in which case record

of these shall be kept according to the provisions of the Misuse of Drugs Act and its Regulations; or

(iii) is not an antibiotic.

(2) An emergency sale or supply of prescription only medicine which contains or consists of Phenobarbitone or Phenobarbitone Sodium is permitted to be prescribed under regulation (1) if it is for use in the treatment of epilepsy and does not contain any of the substances in Schedule 3 relative to the Controlled Drugs and Psychotropic Substances.

(3) The prescription only medicine to which this regulation applies should not contain one or more of the following substances—

(a) Ammonium Bromide;

(b) Calcium Bromide;

(c) Calcium Bromidolactobionate;

(d) Embutramide;

(e) Fencamfamin Hydrochloride;

(f) Fluanisone;

(g) Hydrobromic Embutramide;

(h) Fencamfamin Phydrochloride;

(i) Methohexitone Sodium;

(j) Pemoline; or

(k) Phenobarbitone.

50. Public notification and recovery of drugs.

(1) The Chief Drug Inspector may, by notice in writing, impose requirements relating to any drug regulated by the Act, on a person registered to sell, supply or distribute drugs where—

(a) the drug does not conform with a standard applicable to the drug or have been found or suspected to be tainted;

(b) the manufacturing principles have not been observed in the manufacture of the drug; or

(c) the drug is supplied in contravention of any law or enactment.

(2) The notice under paragraph (1) may specify one or more of the following requirements—

(a) the steps to be taken to recover the drugs;

(b) the manner in which the steps are to be taken; or

(c) a reasonable period within which the steps are to be taken.

(3) The Chief Drug Inspector shall, as soon as practicable after giving the notice, cause particulars of it to be published in the *Gazette.*

(4) The requirements that may be imposed upon a person under this regulation may include one or more of the following—

(a) to take specified steps, in the specified manner and within period specified, to recover drugs that have been distributed;

(b) to inform the public or a specified class of persons, in the specified manner and within the period specified, to the effect that the circumstances referred to in paragraph (1)*(a)* have occurred in relation to drugs; or

(c) to publish, in the specified manner and within the period specified, specified information, or information of a specified kind, relating to the manufacture or distribution of drugs.

(5) If the circumstances referred to in paragraph (1) apply only to a batch of drugs, the Chief Drug Inspector may limit the imposition of the requirements to the drugs included in that batch.

(6) A requirement to recover drugs under this regulation does not apply to drugs that cannot be recovered because they have been administered to, or applied in the treatment of, a person.

(7) A person commits an offence if—

(a) he does not comply with a notice under this regulation from the Chief Drug Inspector; or

(b) as a result of his failure to comply with the requirements imposed by the Chief Drug Inspector, the use of the drugs for which the requirements were imposed result in or will result in harm or injury to any person.

(8) A person who commits and offence under subparagraph (7) is liable to a fine of fifty thousand dollars and to imprisonment for 4 years or to both.

PART VII

MISCELLANEOUS

51. Certificate lost or destroyed.

(1) Where a certificate of registration or authorization issued under the Act is lost, destroyed or defaced, the person to whom that certificate was originally issued may apply to the Council for a duplicate certificate.

(2) An application for a duplicate certificate shall be made in the relevant application form set out in Schedule 2 in respect of an application for registration or authorization as the case may be required, and shall be accompanied by—

(a) an explanation as to why the duplicate certificate is required; and

(b) the same number of photographs (if any) required in the case of an application for an original certificate.

(3) The Registrar may issue to a person applying for a duplicate certificate, a certificate in the relevant form set out in Schedule 2, clearly marked in bold lettering with the word "DUPLICATE".

(4) A fee of one hundred fifty dollars shall be paid for a duplicate certificate issued under this regulation.

(5) All records and books required by these regulations to be kept by any person, shall be open to inspection by the Board of Inspectors, at all reasonable times and it shall be lawful for the inspectors to make a copy or extract from any record or books.

52. Fees paid into the consolidated fund.

Monies collected from fees prescribed under the Act and these Regulations shall be paid into the Consolidated Fund.

53. Penalty.

A person who contravenes any provision of these Regulations commits an offence and shall be liable, on summary conviction to a fine of ten thousand dollars or to imprisonment for three years or to both.

SCHEDULE 1

(i) Antigua and Barbuda

(ii) Bahamas

(iii) Barbados

(iv) Belize

(v) Commonwealth of Dominica

(vi) Grenada

(vii) Guyana

(viii) Haiti

(ix) Jamaica

(x) Montserrat

(xi) St. Kitts; Nevis and Anguilla

(xii) St. Lucia

(xiii) St. Vincent and the Grenadines

(xiv) Trinidad and Tobago

SCHEDULE 2

FEES

1.	Annual Licence fee for the operation of a Pharmacy	$1000.00
2.	Annual Licence fee for the operation of a wholesale pharmaceutical business	$2000.00
3.	Registration of authorized seller of poisons and annual fee	$250.00
4.	Registration of Pharmacy Student	$50.00
5.	Registration of Pharmacist and annual licence fee	$350.00
6.	Registration of Pharmacy Technician and annual licence fee	$100.00

FORMS A-G

1. Application for registration as a Pharmacy Student ..... Form A

2. Application for Registration as a Pharmacist ..... Form B

3. Certificate of Registration as a Pharmacist ..... Form C

SCHEDULE 3

FORM A *Regulation 4*

The Pharmacy Act

APPLICATION FOR REGISTRATION AS A PHARMACY STUDENT

TO: The Pharmacy Council

Name of Applicant .....

(Block Letters)

Date of Application .....

Address of Applicant .....

.....

.....

(Block Letters)

Age of Applicant .....

(certified copy of Birth Certificate should be attached)

Qualification of Applicant .....

.....

(copies of certificate to be attached)

Testimonials (3 to be attached)

Name of Parent/Guardian (if under 21) .....

(Block Letters)

Address of Parent/Guardian (if applicable) .....

.....

(Block Letters)

Address of Parent/Guardian (if applicable) .....

.....

(Block etters) L

.....

Signature of Applicant

To be completed by the College at which applicant has been admitted as pharmacy student

Date of Admission .....

Recommendation .....

.....

.

To be completed by the Registrar

Date approved/refused by the Council .....

Date Registered, if registered .....

Reason for refusal, if refused .....

.....

Signature of Registrar

FORM B *Regulation 5*

THE PHARMACY ACT

APPLICATION FOR REGISTRATION AS A PHARMACIST

To the Pharmacy Council

Applicant's Surname.....

(Block Letters)

Applicant's Christian Name(s).....

(Block Letters)

Gender: Male ☐ Female ☐

Date of Application .....

Address of Applicant.....

.....

(Block Letters)

Telephone contact information:

e-mail address:

Date of Birth:

Country of birth:

EMPLOYMENT RECORD

Present Employer (if applicable) .....

Employer's address .....

.....

Phone / Fax .....

Email address .....

YEARS OF EXPERIENCE

0-2 ☐	3-5 ☐	6-10 ☐
11-15 ☐	16-20 ☐	21-25 ☐
26-30 ☐	>31 ☐	

QUALIFICATIONS

PharmD ☐	MSc ☐
BSc ☐	Dip Pharm ☐
Ass. Degree ☐	Other (please specify).....

No. of Credits.....

(copies of Diplomas and Certificates to be attached)

Testimonials (2) (to be attached)

Names of Referees (2):

Present or Proposed Employment:.....

DECLARATION

I declare that the information provided herein is a truthful, complete and accurate representation of the information required.

.....
Date

.....
Signature of Applicant

To be completed by the Registrar

Date registered or refused .....

Registration No: .....

Date and No. of Gazette Notice in which registration is published .....

.....

Proof of payment:

Receipt No.

Reason refused, if refused .....

.....

.....
Signature of Registrar

FORM C *Regulation 9*

THE PHARMACY ACT

CERTIFICATE OF REGISTRATION AS A PHARMACIST

Registration No: .....

This is to certify that .....

of .....

has been duly registered as a pharmacist under the Pharmacy Act.

Given under my hand this _____ day of _____ 20 _____

.....
President, Pharmacy Council

Registered

....
Registrar

FORM D *Regulation 6*

THE PHARMACY ACT 1995

APPLICATION FOR REGISTRATION AS A PHARMACY TECHNICIAN

To the Pharmacy Council

Name of Applicant .....
(Block Letters)

Date of Application: .....

Address of Applicant .....

Age of Applicant .....
(copies of Diploma to be attached)

Testimonials (2) (to be attached)

.....
Signature of Applicant

To be completed by the Registrar

Date registered or refused .....

Registration No: .....

Reason refused, if refused .....

.....

.....
Signature of Registrar

FORM E *Regulation 9*

THE PHARMACY ACT 1995

CERTIFICATE OF REGISTRATION AS A PHARMACY TECHNICIAN

Registration No._____

THIS IS TO CERTIFY THAT

.....

NAME

Of .....

has been duly registered as a Pharmacist Technician under the Pharmacy Act

Given under my hand this _____ _____ day of _____ 20 ____

Expired Date: .....

.....

President, Council

.....

Registrar

FORM F *Regulation 10*

THE PHARMACY ACT 1995

APPLICATION FOR LICENCE TO OPERATE A PHARMACY

APPLICATION IS HEREBY MADE FOR A CERTIFICATE OF REGISTRATION OF A PHARMACY, PARTICULARS OF WHICH ARE AS FOLLOWS:

APPLICANT IS A CORPORATION? YES_____ NO _____

OWNER OF PHARMACY:
(OR CORPORATION) _____

ADDRESS OF OWNER:
(OR CORPORATION) _____

NAME OF PHARMACIST: _____

ADDRESS OF PHARMACIST: _____

PHARMACIST REGISTRATION#: _____

PHARMACIST TELEPHONE#: _____

PHARMACIST HOURS OF WORK:

FROM _____ (AM/PM) TO _____ (AM/PM) _____

FROM _____ (AM/PM) TO _____ (AM/PM) _____

FROM _____ (AM/PM) TO _____ (AM/PM) _____

(IF MORE THAN ONE PHARMACIST IS EMPLOYED, PLEASE WRITE THE NAME(S) NEXT TO THEIR RESPECTIVE WORKING HOURS).

TRADING NAME OF PHARMACY: _____

(AS KNOWN TO THE PUBLIC)

ADDRESS OF PHARMACY: _____

_____

_____

TEL#: _____ FAX#: _____

E-MAIL ADDRESS:

_____

THE PHARMACY IS:

(A) A NEW OPENING

(B) BEING ACQUIRED

(C) BEING RELOCATED

(D) ALREADY IN OPERATION

(TICK THE CORRECT RESPONSE)

STATE DATE OF PURCHASE AND/ OR COMMENCEMENT OF OPERATION:

_____

STATE DATE THAT PHARMACY WILL BE READY FOR INSPECTION, PRIOR TO COMMENCEMENT OF OPERATION: _____

_____

THE OWNER(S) OR A DIRECTOR OF THE CORPORATION OPERATING THE ABOVE MENTIONED IS REQUIRED TO SIGN THE FORM.

NAME: _____ PHARMACY REGISTRATION # _____

(IF REGISTERED BEFORE)

POSITION WITH CORPORATION: _____

SIGNATURE: _____

DATE: _____

_____

FOR OFFICIAL USE ONLY

_____

FORM G *Regulation 30*

THE PHARMACY ACT

APPLICATION FOR REGISTRATION AS AN AUTHORIZED SELLER OF POISONS

To the Pharmacy Council

I the undersigned .....
Name of Applicant

of .....
Address of Applicant

hereby make application for registration as an authorized seller of poisons.

I hereby certify that I am over twenty-one years of age and that the particulars of the Business where the selling of poisons will be carried out as follows:-

Name of Business.....

Address of Business.....

3. If partnership, give names and titles of all active partners:

.....

.....

4. If individually owned, give name and address of owner:

.....

.....

6. Phone Number .....

8. I enclose two testimonials from the following persons:-

1.

2.

and enclose –

(i) a fee of .....

(ii) a certified copy of my birth certificate

(iii) two recent photographs of myself

Dated this ..... day of ..... 20.....

.....
Signature of Applicant

FORM H *Regulations 9 & 31*

THE PHARMACY ACT 1995

No. _____

THIS IS TO CERTIFY THAT

.....

Name

IS

Registered as an authorized Seller of Poisons in Antigua and Barbuda

Dated: ....

President, Council

Expired Date: ....

Registrar

FORM I *Regulation 33*

THE PHARMACY ACT 1995

Register of Poison

DATE	Name and quantity of Poison sold	Purpose for which it is sold	Name and Address of purchaser	Signature of Purchaser	Comments

Made by the Pharmacy Council this _____ day of _____ 20_____

.....

President

FORM J *Regulation 11*

THE PHARMACY ACT, 1995

APPLICATION FOR LICENCE TO OPERATE A WHOLESALE PHARMACEUTICAL BUSINESS

APPLICATION IS HEREBY MADE FOR A LICENCE TO OPERATE A WHOLESALE PHARMACEUTICAL BUSINESS, PARTICULARS OF WHICH ARE AS FOLLOWS:

NAME OF APPLICANT: .....

ADDRESS OF APPLICANT: .....

TEL # ..... FAX # ..... EMAIL .....

IF BUSINESS IS A COMPANY:

NAME OF COMPANY: .....

CHAIRMAN OF COMPANY: .....

GENERAL MANAGER OF COMPANY: .....

MANAGING DIRECTOR OR CEO (IF ANY): .....

IF INDIVIDUAL OR FAMILY OWNED:

GENERAL MANAGER: .....

OWNER (S): .....

PHARMACIST NAME: .....

SIGNATURE OF PHARMACIST: .....

PHARMACIST REGISTRATION #: ..... DATE: .....

EMPLOYMENT – FULL TIME: .....

-- PART TIME: ..... HOURS OF WORK: .....

TRADING NAME OF WHOLESALE BUSINESS: .....
(AS KNOWN TO THE PUBLIC)

NORMAL BUSINESS HOURS: .....

ADDRESS OF WHOLE SALE BUSINESS ACTIVITY: .....

.....

THIS WHOLE SALE IS: (A) A NEW OPENING { }
(B) BEING ACQUIRED { }
(C) BEING RELOCATED { }
(D) ALREADY IN OPERATION { }
(TICK THE CORRECT RESPONSE)

STATE DATE THAT THIS UNIT WILL BE READY FOR INSPECTION, PRIOR TO COMMENCEMENT OF OPERATION: .....

.....

STATE DATE OF COMMENCEMENT OF OPERATION: .....

THE OWNER (S) OR A DIRECTOR OF THE COMPANY OPERATING THE ABOVE MENTIONED IS REQUIRED TO SIGN THIS FORM.

NAME: ..... REGISTRATION # OF BUSINESS.....

POSITION WITH COMPANY: .....

SIGNATURE: .....

DATE: .....

FOR OFFICIAL USE ONLY

FORM K *Regulation 9*

THE PHARMACY ACT, 1995

No. _____

THIS IS TO CERTIFY THAT

.....

NAME

IS

LICENSED TO OPERATE A WHOLESALE PHARMACEUTICAL BUSINESS IN ANTIGUA AND BARBUDA

DATED ....

President, Council

EXPIRED DATE ....

Registrar

This Certificate of License is for
the purpose of the Pharmacy Act 1995 and
is the property of the Pharmacy Council
of Antigua and Barbuda.

FORM L *Regulation 14*

THE PHARMACY ACT, 1995

No. _____

THIS IS TO CERTIFY THAT

.....

NAME

IS

LICENSED TO OPERATE A PHARMACY IN ANTIGUA AND BARBUDA

DATED ....

Minister with responsibility
for the administration of the
Pharmacy Act, 1995

EXPIRED DATE ....

Registrar

**This Certificate of License is for
the purpose of the Pharmacy Act 1995 and
is the property of the Pharmacy Council
of Antigua and Barbuda.**

FORM M *Regulation 12*

THE PHARMACY ACT, 1995

APPLICATION FOR LICENCE TO SELL POISONS

APPLICATION IS HEREBY MADE FOR A LICENCE TO SELL POISONS, PARTICULARS OF WHICH ARE AS FOLLOWS:

NAME OF APPLICANT: .....

ADDRESS OF APPLICANT: .....

TEL # ..... FAX # ..... EMAIL .....

IF BUSINESS IS A COMPANY:

NAME OF COMPANY: .....

CHAIRMAN OF COMPANY: .....

GENERAL MANAGER OF COMPANY: .....

MANAGING DIRECTOR OR CEO (IF ANY): .....

IF INDIVIDUAL OR FAMILY OWNED:

GENERAL MANAGER: .....

OWNER (S): .....

PHARMACIST NAME: .....

SIGNATURE OF PHARMACIST: .....

PHARMACIST REGISTRATION #: ..... DATE: .....

EMPLOYMENT – FULL TIME: .....

– PART TIME: ..... HOURS OF WORK: .....

TRADING NAME OF WHOLESALE BUSINESS: .....
(AS KNOWN TO THE PUBLIC)

NORMAL BUSINESS HOURS: .....

ADDRESS OF WHOLE SALE BUSINESS ACTIVITY: .....

.....

THIS WHOLE SALE IS: (A) A NEW OPENING { }
(B) BEING ACQUIRED { }
(C) BEING RELOCATED { }
(D) ALREADY IN OPERATION { }

(TICK THE CORRECT RESPONSE)

STATE DATE THAT THIS UNIT WILL BE READY FOR INSPECTION, PRIOR TO COMMENCEMENT OF OPERATION: .....

.....

STATE DATE OF COMMENCEMENT OF OPERATION: .....

THE OWNER (S) OR A DIRECTOR OF THE COMPANY OPERATING THE ABOVE MENTIONED IS REQUIRED TO SIGN THIS FORM.

NAME: ..... REGISTRATION # OF BUSINESS.....

POSITION WITH COMPANY: .....

SIGNATURE: .....

DATE: .....

FOR OFFICIAL USE ONLY

FORM N *Regulation 14*

THE PHARMACY ACT, 1995

No. _____

THIS IS TO CERTIFY THAT

.....

NAME

IS

LICENSED TO SELL POISONS IN ANTIGUA AND BARBUDA

DATED ....

Minister with responsibility
for the administration of the
Pharmacy Act, 1995

EXPIRED DATE ....

Registrar

This Certificate of License is for the purpose of the Pharmacy Act 1995 and is the property of the Pharmacy Council of Antigua and Barbuda.

SCHEDULE 4

Subject to the provisions made under sections 13, 18, 19 and 20 of the Pharmacy Act, the sale or supply of drugs and poisons for the purpose of the Act falls into 2 parts:

Part I – divided into 6 Sections:

Section 1 – deals with sale of vitamins in Supermarkets, Health Food Stores and Shops

Section 2 – Drugs restricted to Pharmacies only.

Section 3 – deals with Prescription only Drugs.

Section 4 – deals with Controlled drugs and Psychotropic substances.

Section 5 – deals with General Sales.

Section 6 – deals with Chemical Precursors.

Part II – deals with poisons which may be sold by authorized sellers of poisons.

PART I

Section 1

Vitamins – Persons already operating a Health Food Store, Supermarket, or Shop may sell vitamins and minerals as Vitamin Supplements but only in un-opened bottles or containers, suitably labelled as to the therapeutic effect of its contents. Vitamins are any of the following: Vitamins A, B1, B2, B6, C, D and E, biotin, nicotinamide, nicotinic acid, pantothenic acid and its salts, biflavanoids, inositol, choline, para-aminobenzoic acid, cyanocobalamin or folic acid. Vitamin preparations mean any medicinal product, the active ingredients of which consist only of vitamins, or vitamins and minerals salts, that is, salts of any one or more of the following: iron, iodine, calcium, phosphorus, fluorine, copper, potassium, manganese, magnesium or zinc.

Vitamins for oral use as follows:

Thiamine or Vitamin B1

Riboflavin or Vitamin B2

Ascorbic Acid or Vitamin C

Vitamin D, no more than 1,000 international units or less per oral dosage form (1,000 i.u.)

Vitamin E, Alpha tocopherol, no more than 200 international units (200 i.u.)

Any vitamin preparation for oral administration as a food in relation to which there are no written particulars or direction as to dosage.

Any medicinal product for oral administration as a food, not being a vitamin preparation to which one or more of the ingredients has been added: - Vitamin A or D, folic acid or cyanocobalamin, and in relation to which product there are written particulars or directions as to the recommended use of that substance which involves a daily intake in excess of the quantities and ingredients specified.

Any vitamin preparation for oral administration as a food in relation to which there are written particulars or directions specifying a recommended daily dosage for adults involving a daily intake in excess of: vitamin A, 2500 units; or antirachitic activity, 250 units; or folic acid, 25 micrograms; or cyanocobalamin, 5 micrograms.

Exemptions:

No Supermarket, Health Food Store, or Shop may sell the vitamins as listed below:

Vitamin A, any preparation for internal and parenteral use in humans containing or represented as containing more than 10,000 i.u. in each oral dosage form, or if the largest recommended daily dosage shown on the label thereof, if consumed would furnish more than 10,000 i.u.

Vitamin B12 or Cyanocobalamin.

Vitamin B5 or Panthothenic Acid.

Vitamin B3 or Niacin or Niacinamide

Vitamin E dosage over 200 i.u.

Vitamin D dosage over 1,000 i.u., any preparation for internal or parenteral use in humans containing or represented as containing more than 1,000 i.u. in each oral dosage form, or if the largest recommended daily dosage shown on the label thereof, if consumed would furnish more than 1,000 i.u.

Vitamin K.

Vitamin B6 or Pyridoxine Acid.

Folic Acid

Section 2

Narcotic controlled Drugs and Psychotropic substances are restricted to prescriptions only. Record of these must be kept according to the provisions of the Misuse of Drugs Act and the Dangerous Drugs Rules.

The drugs which fall under this section are subject to control and should be guided by the following particu-

lars. Under this section, penalties may be determined for offences under the Misuse of Drug Act. Doctors, pharmacists and persons lawfully conducting retail pharmacy businesses may be called upon to give particulars of the quantities of any of these drugs which have been prescribed, administered or supplied over a period of time. It is an offence to fail, without reasonable excuse, to give the information required or to give false information.

Control Drug Registers

Records must be kept by all person(s) or businesses authorized to possess Control Drugs (CD). The following particulars are to be recorded

a) date on which received;

b) name and address of person or firm from whom received;

c) amount received;

d) form in which received.

For CD supplied the following must be recorded

a) date on which the supply was made;

b) name and address of person or firm to whom supplied;

c) particulars as to licence or authority of the person of firm supplied to be in possession of Controlled Drugs;

d) amount supplied;

e) form in which supplied.

NB: The following points are important in relation to the keeping of CD registers—

a) entries must be in chronological sequence;

b) a separate part of the register must be used for each class of drugs. Separate sections are required for amphetamines (which includes dexamphetamine) and mehtylamphetmines;

c) If desired, separate parts of the register can be used for different drugs or strengths of drugs comprised within a class of drugs;

d) The class of drugs must be specified at the head of each page;

e) entries must be made on the day of the transaction;

f) No cancellation, obliteration or alteration may be made; correction must be dated by marginal note or footnote;

g) entries must be in ink or otherwise indelible;

h) the register must not be used for other purposes;

i) the register must be kept at the premises to which it is related and a separate register must be kept for each premises of the business;

j) particulars of stock receipts and supplies must be - furnished to any authorized person on request (this includes drug inspectors and police officers during any investigation). Other documents and stocks of drugs must also be produced if required;

k) no entry need to be made in the prescription-only register, but it is good practice to make these entries.

CD Lic: The possession, production and supplies of these are restricted in the public interest, to purposes of research or any other purpose designated by the Ministry of Health. A licence is required from the Ministry of National Security for possession.

CD POM: A licence is needed to import, or export these drugs. A pharmacist may supply them to a patient only on the authority of a prescription issued by a registered medical practitioner. Requirement as to safe custody applies.

CD No Register (CD NO Reg): The control that applies to CD POM applies to CD NO REG. However, records in the register of control drugs need not be kept in respect of these drugs.

CD Benz: are mainly benzodiazepines and some adrenoreceptor stimulants. An **import and export licence** is required. There are no restrictions on possession once obtained in accordance with a prescription written by a duly registered physician. Recording of their sale in a control drug register is not required and there are no safe custody requirements.

CD Anab: are mainly anabolic and androgenic steroids. An **import and export licence** is required. There are no restrictions on possession once obtained in accordance with a prescription written by a duly registered physician. Recording of their sale in a control drug register is not required and there are no safe custody requirements.

CD Inv: contains preparations of certain controlled drugs, for e.g. Codeine, pholcodine and morphine, which are exempt from full control when, presented in medicinal products of low strength. There are no restrictions on the import, export, possession or administration of these preparations, and safe custody requirements do not apply for duly authorized person(s) or pharmacies. Invoice is required to be kept for two years.

List 1

CD

A

Amphetamine; its salts

Acetylsalicylic acid (aspirin)/ Papaveretum CD Inv POM

Alfentanil CD

Allylprodine CD POM

Alphacetylmethadol; its salts esters & ethers CD POM

Alphameprodine; its salt CD POM

Alprazolam CD Benz POM

Aminorex CD Benz POM

Amylobarbitone CD No Reg. POM

Amylobarbitone Na CD No Reg. POM

Anileridine; its salts CD POM

Amytal tablets CD No reg. POM

Aspirin 500mg/Codeine 8mg P

Aspirin 250mg/Meprobamate 150mg/Ethoheptazine citrate 75mg CD POM

Aspav tablets CD Inv POM

Atamestane CD anab POM

B

Barbitone CD NO Reg

Barbitone Na CD No Reg

Benzethidine; its salts CD

Benzphetamine; its salts CD No Reg

Benzylmorphine; its salts CD POM

Betacetylmethadol; its salts CD POM

Betameprodine; its salts CD POM

Betamethadol; its salts, esters and ethers CD POM

Betaprodine CD POM

Bezitramide; its salts CD POM

Bolandiol CD anab POM

Bolasterone CD anab POM

Bolazine CD anab POM

Boldenone CD anab POM

Bolenol CD anab POM

Bolmantalate CD anab POM

Bromazepam CD Benz POM

Brotizalom CD Benz POM

Buprenorphine CD No Reg POM

Bufotenine; its salts, esters and ethers CD lic

Butalbital CD No Reg POM

Butobarbitone CD No Reg POM

Butobarbitone Na CD No Reg POM

C

Calusterone CD anab POM

Camazepam CD Benz Pom

Camphorated Opium Tincture CD inv POM

Cannabinol derivatives CD inv POM

Cannabis and Cannabis resin CD lic

Carfentanil; its stereoisomers, salts, esters and ethers CD POM

Cathine its salts, stereoisomers (other than phenylpropanolamine) CD No Reg POM

Cathinone; its stereoisomers, salts, esters and ethers CD lic

Chloroform/Morphine Tincture CD inv POM

Chlordiazepoxide CD Benz POM

Chlophentermine; its salts CD No Reg POM

Chorionic gonadotrophin CD anab POM

Choragon inj. CD anab POM

Clenbuterol CD anab POM

Clobazam CD Benz POM

Clonazepam CD Benz POM

Clonitazene; its salts CD POM

Clorazepic or Clorazepate dipotassium CD Benz POM

Clostebol CD anab POM

Clotiazepam CD Benz POM

Coca leaf CD lic

Cocaine; its salts CD lic

Codeine; its salts CD POM

Codeine/Paracetamol CD inv P

Codeine/Aspirin/Paracetamol tablets CD inv P

Codeine 8mg/Paracetamol 500mg tablet CD inv P

Codeine 60mg/Paracetamol 1g CD inv POM

Codeine 8mg/Aspirin 400mg tablet CD inv P

Codeine/Diphenhydramine/Menthol cough CD inv P

Codeine/Diphenhydramine/Na citrate/Menthol CD inv P

Codeine/Pseudoephedrine/Guaifenesin CD inv P

Codeine 20mg/Ibuprofen 300mg CD inv POM

Codeine or hydrocodone/Brompheniramine maleate/Pseudoephedrine inv P

Codeine/Creosote CD inv P

Codeine Linctus 10mg/5ml CD inv P

Codeine Paediatric Linctus P

Codeine/Kaolin CD inv POM

Codeine/Paracetamol/Caffeine/Hyoscine POM

Codeine/Promthazine/Ephedrine cough and cold inv P

Codeine/Paracetamol/Caffeine/Diphenhydramine P

Codeine/Guaiacol POM

Codeine/Paracetamol/Caffeine POM

Codeine/Paracetamol/Caffeine/Doxylamine CD inv P

Cyclobaritone Ca CD No Reg POM

Cyclobaritone CD No Reg POM

D

Danazol CD anab POM

Desomorphine; its salts, esters and ethers CD POM

Dextropropoxyphene HCI 32.5mg/Paracetamol 325mg inv POM

Dexamphetamine CD POM

Dextropropoxphene 32.5mg/Paracetamol 325mg CD inv POM

Dextropropoxphene; its salts, esters and ethers CD POM

Dextromoramide CD POM

Diazepam CD Benz POM

Diamorphine CD POM

Dihydrocodeine/Paracetamol CD No Reg Pom

Dihyrocodeine/Parcetamol CD Inv P

Dihyrocodeine/Grindelia/althaea cough inv P

Dihyrocodeine; its salts CD POM

Dihyrocodeineone O-carboxymethyloxime; its salts, esters and ethers CD POM

Dihydromorphine; its salts, esters and ethers CD POM

Dimepheptanol; its salts, esters and ethers CD POM

Dimenoxadole, its salt, CD POM

Dipipanone HCI 10mg/Cyclizine 30mg injection CD POM

Dipipanone; its salts CD POM

Diethylpropion; its salt CD No Reg POM

Diethylthiambutene; its salts CD POM

Difenoxin CD POM

Dioxaphetyl butyrate; its salts CD POM

Diphenoxylate CD POM

Dronabinol CD POM

Drotebanol; its salts, esters and ethers CD POM

Drostanolone; its salts CD anab POM

Drotebanol; its salts, esters ethers CD POM

E

Ergonine and its derivatives CD POM

Enestebol CD anab POM

Epitiostanol CD anab POM

Estazolam CD Benz POM

Ethchlorvynol CD No Reg POM

Ethinmate CD No Reg POM

Ethyl loflazepate CD Benz POM

Ehtyleostenol CD anab POM

Eticyclidine CD lic

Etonitazene; its salts POM

Etorphine; its salts, esters and ethers CD POM

Etryptamine CD lic

Ethylmethylthiambutene; its salts CD POM

F

Fencamfamin; its salt, stereoisomers CD Benz POM

Fenethylline; its salts and stereoisomers CD POM

Fenproporex; its salts and stereoisomers CD Benz POM

Fentanyl CD

Fluoxymestrone anab POM

Formebolone POM

Flurazepam CD Benz POM

Fludiazepam CD Benz POM

Flunitrazepam CD Benz No Reg POM

Fluoxymesterone CD anab POM

Formebolone CD anab POM

Furazabol CD anab POM

Furethidine; its salts CD POM

G

Genotropin prep CD anab POM

Glutethimide; its salts and stereoisomers; CD POM

Growth Hormone CD anab POM

H

Halazepam CD Benz POM

Haloxazolam CD Benz POM

Heptabarbitone CD No Reg POM