

ANTIGUA AND BARBUDA

DRAFT 3



THE PHARMACY BILL 2026

No. of 2026

DRAFT

**ANTIGUA AND BARBUDA
THE PHARMACY BILL 2026**

ARRANGEMENT OF CLAUSES

CLAUSES

**PART I
PRELIMINARY**

1. Short title and commencement 7
2. Interpretation 7

**PART II
THE PHARMACY COUNCIL**

3. Continuation and constitution of Council 11
4. Functions of the Council 12
5. Appointment of Registrar 13
6. Functions of the Registrar 13
7. Remuneration of Council members and Registrar 14

**PART III
THE PHARMACY COUNCIL ADMINISTRATION FUND**

8. Establishment of the Special Fund 14
9. Administration of the Pharmacy Council Administration Fund 14
10. Purpose of the Fund 15
11. Accounts and Audit 15

**PART IV
REGISTRATION OF PHARMACISTS
AND PHARMACY TECHNICIANS**

12. Qualification for registration as pharmacist 15
13. Qualification for registration as a pharmacy technician 16

14. Application for registration	16
15. Temporary license as a pharmacist	16
16. Registration of pharmacists and pharmacy technicians.....	17
17. Registration and use of upgraded or additional qualifications	17
18. Certificate of registration as a pharmacist.....	17
19. Practicing pharmacy without licence	17

**PART V
LICENCING OF PREMISES**

20. Procedure for licencing premises	18
21. Registration of licensed premises.....	19
22. Prohibition of unlicensed premises	20
23. Cancellation and suspension of licence.....	20

**PART VI
BOARD OF INSPECTORS
OR DRUG INSPECTORATE**

24. Continuation and constitution of the Board of Inspectors or Drug Inspectorate	21
25. Functions of Board of Inspectors or Drug Inspectorate	22
26. Reports of the Board of Inspectors or Drug Inspectorate.....	23
27. Collection of samples.....	23
28. Appeals	24

**PART VII
SALE, IMPORTATION, EXPORTATION,
MANUFACTURING OF DRUGS**

29. Procurement, sale, importation, exportation, possession etc. of drugs.....	24
30. Requirements for importation of pharmaceuticals, vaccines and biologics into Antigua and Barbuda.....	25
31. Courier service providers	26
32. Import, export or manufacturing of controlled drugs used for medical use	27

33. Record keeping	27
34. Supplements	28
35. Cosmetics	28
36. Manufacturers of pharmaceuticals	29

**PART VIII
PROCUREMENT, SALE, LABELLING
AND STORAGE OF POISONS**

37. Procurement, sale, possession and distribution of poisons.....	30
38. Regulating the sale of poisons.....	30

**PART IX
PHARMACEUTICALS, VACCINES AND BIOLOGICS**

39. Application for approval to test or manufacture pharmaceuticals, vaccines or biologics	31
40. Disposal of expired, unused, damaged drugs or cytotoxic pharmaceuticals, vaccines, biologics and poisons.....	32
41. Exemptions	33
42. Restrictions	33
43. Dispensing and compounding.....	34

**PART X
DISCIPLINARY PROCEEDINGS**

44. Complaints	34
45. Disciplinary proceedings.....	35
46. Penalty	36
47. Publication of removal of name in the Gazette	37

**PART XI
MISCELLANEOUS**

48. Offences	37
49. Penalties prescribed by the Council	38

50. Pharmaceutical quality assurance 38
51. Use of titles 39
52. Regulations 39
53. Repeals 40

- SCHEDULE 1
- SCHEDULE 2
- SCHEDULE 3
- SCHEDULE 4
- SCHEDULE 5
- SCHEDULE 6

DRAFT

ANTIGUA AND BARBUDA
THE PHARMACY BILL 2026

No. of 2026

AN ACT to revise the law relating to the control and regulation of the practice of pharmacy, the sale of drugs and poisons and to make provision for the registration and control of persons admitted to practice as pharmacists and engaged in the business of pharmacy and for other connected purposes.

ENACTED by the Parliament of Antigua and Barbuda as follows –

PART I
PRELIMINARY

1. Short title and commencement

This Act may be cited as the Pharmacy Act 2026 and shall come into operation on a day to be appointed by the Minister by Notice published in the *Gazette*.

2. Interpretation

In this Act –

“adverse drug reactions” means any harmful, unintended reactions to medicine that occur at doses normally used for treatment;

“agreed encrypted channel” means an end-to-end encrypted channel agreed upon by the sender and receiver for the transmission of a patient prescription over a secure internet system;

“authorised seller of poisons” means a person -

- (a) licensed by the Pesticides and Toxic Chemicals Board to sell poisons; and
- (b) whose premises has been licensed by the Pharmacy Council for the sale of said poisons;

“Biologics” means medicines that are grown and purified from large-scale cell cultures (bacteria, yeast, plant, or animal) or derived from living systems.

“Chief Drug Inspector” means a pharmacist who is given the responsibility to manage the affairs of the Board of Inspectors;

“Clinical Trial Committee” means a committee that is established for the oversight of clinical trials

“cosmetic” means a product used for beautification, or alteration of the skin without pharmaceutical or therapeutic ingredients;

“controlled drug” means a controlled drug used for a medical use;

"Council" means the Pharmacy Council established under the Pharmacy Act 1995 and continued at section 3 of this Act, and acts on behalf of the Minister of Health;

“courier service providers” means an entity that imports or delivers items on behalf of a business, institution or individual by way of an overseas mailbox;

"compounding" means mixing, putting together or uniting two or more ingredients ordered in a prescription by a duly registered medical practitioner, dentist or veterinary surgeon;

"dentist" means any person who is registered as a dentist under section 32 of the Medical Act or any law in Antigua and Barbuda providing or the registration of persons carrying on the work of a dentist;

"dispensing" means the supplying of drugs on and in accordance with a prescription given by a medical practitioner, a dentist or a veterinary surgeon;

"drug" means –

- (a) any substance or mixture of substances or any article manufactured, sold or represented for use in –
 - (i) the diagnosis, cure, treatment, mitigation or prevention of any disease, disorder, abnormal physical or mental state, or the symptoms thereof in human, animal or fowl;
 - (ii) the restoring, correcting or modifying of organic functions in human, animal or fowl;
 - (iii) the disinfection of premises where food is manufactured, prepared or stored; or
 - (iv) the preparation of cosmetics for producing a drug action as mentioned in paragraphs (i), (ii) and (iii); and
- (b) any substance whether natural or synthetic with therapeutic or medical properties and chiefly used as medicines or ingredients in medicines; or
- (c) any article other than food intended to affect the structure of any function of the body of human, animal or fowl;

“Falsified medical products” means those products that deliberately and/or fraudulently misrepresent their identity, composition or source;

“Global Benchmarking Tool (GBT)” means; the primary means by which the World Health Organization (WHO) objectively evaluates regulatory systems, as mandated by WHA Resolution 67.20 on Regulatory System Strengthening for medical products;

“Good Clinical Practice” means a standard for the planning, initiating, performing, recording, oversight, evaluation, analysis and reporting of clinical trials that provides assurance that the data and reported results are reliable and that the rights, safety and wellbeing of the trial participants are protected;

“Good Manufacturing Practice” or “GMP”–

- (a) means the minimum requirements to assure that the products produced are consistently high in quality, from batch to batch, and are for their intended use; and
- (b) includes mechanisms to ensure that –
 - (i) all particulars of the active pharmaceutical ingredients, and inactive ingredients are recorded;
 - (ii) the end product is free from contaminants;
 - (iii) there is consistency in the manufacturing process;
 - (iv) the manufacturing process is well documented from inputs to outputs;
 - (v) all personnel are well trained; and
 - (vi) the final product has been checked for quality throughout the production phase;

“hospital” refers to a facility that is staffed and equipped for the diagnosis of disease, for the treatment of the sick and injured, and for their housing during the process;

“Independent Pharmaceutical Quality Control Laboratory” means a laboratory authorized by the Pharmacy Council to validate or test each batch of pharmaceuticals, vaccines or biologics produced by a pharmaceutical company to ensure that the products produced are safe and efficacious based on internationally recognized pharmaceutical standards;

“Institutional Review Board” or “IRB” means the body within the Ministry of Health which is responsible for ensuring ethical conduct of scientific research;

“manufacturer” means a company that invents an original drug and makes it under its registered trade name or a company that make generic drugs after the patent for a branded drug has expired or a company that repackage drugs for distribution;

“manufacturing” means the production of pharmaceuticals from active pharmaceutical ingredients, synthetic ingredients or from biologic ingredients or from any other substance or material;

“medical practitioner” means a person who is registered under Part III of the Medical Practitioners Act, 2009;

“Minister”, except where otherwise specified, means the Minister with responsibility for the regulation and control of the practice of pharmacy and the importation, sale, distribution and supply of drugs and poisons;

“Pharmaceuticals” means compounds manufactured for use as medicinal drugs in humans, animals and fowl.

“Pharmaceutical Manufacturing Facility” means a facility that manufactures pharmaceuticals, vaccines or biologicals for humans, animals or fowl;

“Pharmacovigilance” means the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problems;

"pharmacy" means –

- (a) any place or premises registered as a pharmacy under **section 21**; or
- (b) a place for the sale, distribution or compounding of any prescriptive drugs, medicines, chemicals or poisons;

"pharmacist" means a person who is registered in accordance with section 16 and whose name appears in the Register of Pharmacists kept and maintained under section 6;

"pharmacy technician " means a person who is registered in accordance with section 16 and whose name appears in the Register of Pharmacy Technicians kept and maintained under section 6;

"poisons" means any substance, whether a drug or not, that is dangerous to human or animal health or life and is designated a poison by regulation made under this Act;

“Post Marketing Surveillance” is the process of monitoring the safety of drugs once they reach the market, after the successful completion of clinical trials;

"Registrar" means the person appointed as Registrar under **section 5**;

“Repackaging” means the act of taking a finished drug product from the container in which it was distributed by the original manufacturer and placing it into a different container without manipulation of the drug;

“small medical clinic” means a facility that has capacity to treat a maximum of five patients for more than twenty-four (24) hours;

“starting dose” means the dose of a drug that is given to a patient to immediately reduce or relieve the patient’s signs and symptoms of a medical condition;

“Substandard medical products” means out-of-specification products, are authorised products that fail to meet quality standards, specifications or both.

“supplement” means any substance or product except tobacco in pill, tablet, capsule or liquid form containing a vitamin, mineral, herb or other plant product, amino acids, other known dietary substances that is intended as a supplement to normal diet.

“Stringent Regulatory Authority” or “SRA” means a national authority that is considered by WHO to apply stringent standards for quality, safety, and efficacy in its process of regulatory review of drugs, vaccines, and biologicals for marketing authorization;

“Unlicensed/unregistered medical product” means those products that have not undergone evaluation and/or approval by the National Regulatory Authority for the market in which they are marketed, distributed or used subject to permitted conditions under national or regional regulation and legislation.

“Vaccine” means a substance used to stimulate immunity to a particular infectious disease or pathogen, typically prepared from an inactivated or weakened form of the causative agent or from its constituents or products.

"Veterinary Surgeon" means any person registered under section 11 of the Veterinary Act, 1986;

“WHO Listed Authority (WLA)” means a regulatory authority or a regional regulatory system which has been documented to comply with all the relevant indicators and requirements specified by WHO for the requested scope of listing based on an established benchmarking (GBT) and a performance evaluation process

“WHO” means World Health Organization; and

“wholesale pharmaceutical business” means a business engaged in the importation, exportation, purchase, distribution, supply or warehousing of drugs or poisons for wholesale or for the licensed distribution of pharmaceuticals not for sale.

PART II THE PHARMACY COUNCIL

3. Continuation and constitution of Council

- (1) The Pharmacy Council established under section 3 of the Pharmacy Act, 1995 is preserved and shall continue for the purposes of this Act.
- (2) The Council shall consist of seven members, namely –
 - (a) the Director of Pharmaceutical Services, *ex officio*;
 - (b) one Medical Practitioner appointed by the Minister after consultation with the Medical Association of Antigua and Barbuda Inc.;
 - (c) three pharmacists appointed by the Minister after consultation with the Antigua and Barbuda Pharmaceutical Society;
 - (d) one pharmacist who is or has been engaged in the teaching of pharmacy in Antigua and Barbuda and appointed by the Minister; and
 - (e) one person appointed by the Minister who shall represent the interest of the consumer.
- (3) A member of the Council, other than an *ex officio* member shall hold office for a term of three (3) years, but shall at the expiration of such term be eligible for re-appointment.
- (4) Any member of the Council, other than an *ex officio* member, may resign his office by writing to the Minister.

- (5) Where a member ceases to hold office before the expiry of his appointed term, the Minister may, subject to subsection (2), appoint a person to hold office for the un-expired period of that member's term.
- (6) Any person elected at the first sitting of the Council to the posts of President and Deputy President of the Council shall hold the posts for the term of the Council.
- (7) The Council may, subject to the provisions specified in the Schedule, regulate its own procedure.
- (8) The Minister may, after consultation with –
 - (a) the Medical Association of Antigua and Barbuda Inc., revoke the appointment of a member under paragraph (b) of subsection (2); or
 - (b) the Antigua and Barbuda Pharmaceutical Society, revoke the appointment of a member appointed under paragraph (c) of subsection (2).

4. Functions of the Council

- (1) The functions of the Council are –
 - (a) to regulate and control the practice of pharmacy;
 - (b) to control, promote, establish and maintain high professional standards of practice and conduct among pharmacists;
 - (c) to establish, develop and maintain standards of knowledge, skill and professional ethics for persons involved in the profession and practice of pharmacy;
 - (d) to govern and regulate the standards to be observed at all facilities utilized in the practice of pharmacy;
 - (e) to advise the Minister on any matter relating to pharmacy including the purchase, sale dispensing of pharmaceutical products and manufacturing;
 - (f) to examine and approve the curriculum relating to pharmacy education in Antigua and Barbuda, including the making of decisions pertaining to the qualification and examination of persons qualified as pharmacists, pharmacy technicians or pharmacy students;
 - (g) to be responsible for establishing and maintaining high professional standards of practice and conduct among pharmacists;
 - (h) ;
 - (i) to advise the Minister on procedures for examination and approval of pharmaceutical products;
 - (j) to decide on matters relating to the registration of persons as authorised importers, exporters, manufacturers, wholesale pharmaceutical business or sellers of pharmaceutical products;
 - (k) to consider and approve for registration persons who satisfy the requirements prescribed by the Council and who apply to be registered as a pharmacy student, pharmacy technician, or pharmacist or as an entity offering pharmacy education;
 - (l) to establish rules of professional conduct and discipline and to provide procedures for enquiring into breaches of such rules;

- (m) to advise the Minister on matters relating to registration of premises and persons authorised to sell drugs and poisons;
 - (n) to give directions to the Registrar in the performance of his or her duties under this Act;
 - (o) to establish guidelines for the management of drugs in small medical clinics;
 - (p) to charge fees for Continued Education sessions or other short-term educational programs or pharmacy-related activities; and
 - (q) to grant licences to applicants once the requirements in the Act and regulations are satisfied; and
 - (r) to advise the Minister on the reasons for suspending or canceling a license or the closure of a business or other entity in the interest of public health;
 - (s) to make recommendations to the Minister on matters relating to the administration of the Act.
- (2) The Council may issue guidelines.
 - (3) The Council may issue licences for different categories of pharmacists.
 - (4) The Council may recommend to the Minister the removal of an inspector for cause.
 - (5) The Council shall not later than 31st day of March each year, prepare and submit to the Minister a comprehensive report of its activities during the preceding year.

5. Appointment of Registrar

- (1) For the purposes of this Act there shall be a Registrar who shall be appointed by the Minister on the advice of the Council for a period not exceeding four (4) years.
- (2) The Registrar shall be –
 - (a) a person who is a qualified pharmacist; and
 - (b) registered under **section 16** of this Act.

6. Functions of the Registrar

- (1) The Registrar shall perform the general administrative duties of the Council.
- (2) Without prejudice to the generality of subsection (1), the Registrar shall keep and maintain the following –
 - (a) a "Register of Pharmacists" in which shall be recorded the names and particulars of all persons admitted by the Council to practice as pharmacists;
 - (b) "Register of Pharmacy Technicians" in which shall be recorded the names and particulars of all persons licensed by the Council as pharmacy technicians;
 - (c) a "Register of Pharmacies" in which shall be recorded the names and addresses of premises licensed to operate the business of pharmacy; and
 - (d) "Register of Wholesale Pharmaceutical Businesses" in which shall be recorded the business names and addresses of businesses licensed to operate as wholesale pharmaceutical businesses; and

- (e) “Register of Pharmaceutical Manufacturing Facilities” in which shall be recorded the business names and addresses of businesses licensed to operate as pharmaceutical manufacturing facilities.
- (3) The Registrar shall, at the direction of the Council, record the names and particulars as may be prescribed, of all persons approved by the Council to be registered as pharmacists.
- (4) The Registrar shall comply with any direction given to him or her under section 4 (1)(n).

7. Remuneration of Council members and Registrar

The Minister may, after consultation with the Minister of Finance, pay to the members of the Council and to the Registrar such remuneration or allowance as may, from time to time, be prescribed.

PART III THE PHARMACY COUNCIL ADMINISTRATION FUND

8. Establishment of the Special Fund

- (1) There is hereby established a Special Fund pursuant to section 42(1)(a) of the Finance Administration Act 2006 to be known as the Pharmacy Council Administration Fund.
- (2) The revenue of the Fund shall be generated from –
 - (a) licensing fees paid to the Council;
 - (b) application fees paid to the Council;
 - (c) any budgetary allocations from the Government; and
 - (d) any other source deemed appropriate by the Board.
- (3) There shall be paid into the Fund all sums of money received or acquired by the Council under subsection (2).
- (4) With the approval of the Minister of Finance, the Council may open an account with a commercial bank within Antigua and Barbuda into which all monies received under subsection (2) shall be paid.

9. Administration of the Pharmacy Council Administration Fund

- (1) The Pharmacy Council Administration Board, hereinafter referred to as the Board, shall, subject to the approval of the Financial Secretary of the Ministry of Finance, be responsible for the administration of the Fund.
- (2) The Board shall comprise of the following persons –
 - (a) The President of the Council;
 - (b) The Registrar of the Council;
 - (c) the Permanent Secretary for the Ministry with responsibility for Health; and
 - (d) a representative from the Ministry of Finance recommended by the Minister of Finance.
- (3) The signatories of the account shall be –

- (a) the Permanent Secretary or someone designated by him or her within the Ministry of Health;
 - (b) the President of the Council; and
 - (c) the Registrar of the Council.
- (4) Any two (2) of the persons listed at subsection (3) may together lawfully sign and issue cheques for the payment of services rendered to the Council..
 - (5) The Board shall keep and maintain a record of all monies received or paid out of the Fund and shall submit these records to the Auditor General on an annual basis for auditing.

10. Purpose of the Fund

The purpose of the Special Fund is –

- (a) to meet the administrative obligations of the Council; and
- (b) to meet the legal obligations of the Council;

11. Accounts and Audit

- (1) The Board shall keep accounts of its transactions to the satisfaction of the Minister of Finance.
- (2) Such accounts shall be audited annually by the Director of Audit or some other suitable person or auditing firm or company, appointed by the Minister of Finance, after consultation with the Director of Audit.

PART IV REGISTRATION OF PHARMACISTS AND PHARMACY TECHNICIANS

12. Qualification for registration as a pharmacist

- (1) A person is entitled to be registered as a pharmacist if he or she satisfies the Council that–
 - (a) he or she is in possession of the qualifications prescribed by the Council;
 - (b) he or she has attained the age of twenty-one (21) years;
 - (c) he or she has paid the prescribed fee for registration and the biennial licensing fee to practice as a pharmacist; and
 - (d) he or she can read, write and understand the English Language.
- (2) A person who practices in Antigua and Barbuda as a medical practitioner, dentist, veterinary surgeon, registered nurse, clinical nursing assistant, emergency medical technician or paramedic shall not be entitled to be registered as a Pharmacist under this Act.

13. Qualification for registration as a pharmacy technician

A person is entitled to register as a pharmacy technician if he or she satisfies the Council that he or she –

- (a) holds a certificate or diploma as a pharmacy technician from an educational institution recognised by the Council;
- (b) has undergone a period of practical training as a pharmacy technician in a programme approved by the Council;
- (c) is physically and mentally fit to perform the duties of a pharmacy technician;
- (d) is at least eighteen (18) years of age.

14. Application for registration as a pharmacist or pharmacy technician

- (1) A person who satisfies the requirements to be registered as a pharmacist or pharmacy technician may submit an application in the prescribed form to the Registrar to be registered under this Act.
- (2) The application shall be accompanied by the following –
 - (a) a document certifying the applicant's professional qualifications;
 - (b) two testimonials of the applicant's good character and ability from persons who have known the applicant for at least three (2) years;
 - (c) the names of two referees who are qualified pharmacists or medical practitioners;
 - (d) the birth certificate of the applicant; and
 - (e) the prescribed fee.
- (3) The Council may, in writing, request further information from an applicant to determine whether to grant or refuse the application, and upon receipt of the information the Council shall make its decision.

15. Temporary license as a pharmacist

- (1) A person who is part of a team of visiting medical professionals or other overseas mission to Antigua and Barbuda shall be required to register and obtain a temporary license to practice as a Pharmacist before undertaking any work in Antigua and Barbuda.
- (2) An application for temporary registration as a Pharmacist must be –
 - (a) in writing;
 - (b) transmitted to the Council, whether by physical or electronic means, no later than 45 days prior to the arrival of the applicant in Antigua and Barbuda;
 - (c) accompanied by the documents specified in section 14(2); and
 - (d) the prescribed application fee for a temporary licence.
- (3) If the Council is satisfied that the applicant meets the requirements of this Act and the regulations issued hereunder, the Council shall issue the applicant with a temporary license in the prescribed form which shall be valid for a period not exceeding sixty (60) days from the date of issue.

- (4) A person who is granted a temporary license shall observe the conditions attached to the licence.

16. Registration of pharmacists and pharmacy technicians

- (1) The Council may direct the Registrar to—
 - (a) enter the name and particulars of any person whose application is successful in the Register of Pharmacists or the Register of Pharmacy Technicians, as the case may be; and
 - (b) issue to a successful applicant a certificate of registration and a license in the form prescribed by the Council on payment of the registration fee and license fee.
- (2) The Registrar shall publish in the Gazette a notification of the name and particulars of all persons entered in the Register of Pharmacists as directed under subsection (1).
- (3) A licence granted in accordance with the provisions of this section is renewable as stipulated by the Regulations under this Act.

17. Registration and use of upgraded or additional qualifications

- (1) A registered Pharmacist or Pharmacy Technician who has been awarded an advanced degree, diploma or certificate and desires to have this achievement noted on his or her registration, shall apply to the registrar, submitting such documentary proof the Council may require that he or she holds the additional qualification in question.
- (2) If the registrar is satisfied that the additional qualification is a degree, diploma or certificate he or she shall cause such degree, diploma or certificate to be entered in the register.

18. Certificate of registration as a pharmacist or Pharmacy Technician

- (1) No certificate shall be valid unless it is signed by the President of the Council and the Registrar and authenticated with the seal of the Council.
- (2) Every pharmacist registered under this Act is entitled to be issued with one certificate only but in the event of loss or destruction or change of name, he or she may apply to the Council for a replacement certificate on the payment of the prescribed fee.

19. Practicing pharmacy without licence

- (1) No person shall engage in the practice of pharmacy unless such person is registered and license as a pharmacist under this Act.
- (2) A person who contravenes subsection (1) commits an offence and is liable on summary conviction to a fine of twenty-five thousand dollars (\$25,000.00) or to imprisonment for a term of two (2) years or to both such fine and imprisonment.

PART V
LICENCING OF PREMISES

20. Procedure for licencing premises

- (1) A person shall not use any premises or permit any premises to be used to operate a pharmacy, wholesale pharmaceutical business, or pharmaceutical manufacturing facility unless such premises have been approved by the Pharmacy Council and licensed as meeting the requirements of this Act and its regulations.
- (2) A person desirous of operating a pharmacy, wholesale pharmaceutical business or pharmaceutical manufacturing facility on any premises shall submit an application to the Council in the prescribed form.
- (3) The application for a licence shall be accompanied by –
 - (a) the prescribed application fee; and
 - (b) a non-refundable inspection fee of –
 - (i) five hundred dollars (\$500.00) dollars for pharmacies;
 - (ii) one thousand dollars (\$1,000.00) for wholesale pharmaceutical businesses; or
 - (iii) three thousand dollars (\$3,000.00) for pharmaceutical manufacturing facilities.
 - (c) proof that the pharmacy, wholesale pharmaceutical business or pharmaceutical manufacturing facility has in its employment a full time registered and licensed pharmacist present for the duration of the opening hours of the business for the purpose of procuring, dispensing, distributing, exporting, managing, manufacturing and control of all drugs, active and inactive pharmaceutical ingredients, and poisons;
 - (d) a declaration –
 - (i) by the pharmacist responsible; and
 - (ii) by the owner or operator of a pharmacy, wholesale pharmaceutical business or pharmaceutical manufacturing facility,
that the premises to be licensed is under the direct management, direct control or direct supervision of the registered and licensed pharmacist referred to in subparagraph (i); and
 - (e) an undertaking by the owner or operator of the pharmacy, wholesale pharmaceutical business or manufacturing pharmaceutical facility that where the registered and licensed pharmacist is no longer employed by the business, the owner or operator of the pharmacy, wholesale pharmaceutical business or manufacturing pharmaceutical facility will provide the Council within five (5) calendar days of the cessation of the employment of that registered

pharmacist with the name and particulars of the replacement registered pharmacist.

- (4) Where the premises to be licensed as a pharmacy, wholesale pharmaceutical business or pharmaceutical manufacturing facility is also used for any other business activity, the pharmacy, wholesale pharmaceutical business or pharmaceutical manufacturing facility shall –
- (a) have a specific name; and
 - (b) have a business registration certificate that is separate and distinct from the business registration certificate for any other business activity carried on at the premises.
- (5) Where the premises to be licensed is a pharmacy, the dispensing area shall, at a minimum, satisfy the requirements for pharmacy dispensary set out in Schedule 3.
- (a) The Registrar shall submit the application for a licence to the Board of Inspectors who shall inspect the premises and report in writing to the Council stating whether the requirements of this Act and its Regulations have been complied with.
 - (b) The Council may, after considering the report, approve or refuse the application for a licence.
 - (c) Where the Council refuses to approve an application, it shall give reasons for such refusal.
 - (d) Pharmaceutical manufacturers shall designate and report the qualified personnel responsible for compliance with technical standards to the Council

21. Pharmacy premises may be licensed as wholesale business

The owner of a pharmacy may apply for a licence to operate a wholesale pharmaceutical business if the premises satisfy the requirements stipulated in this Act and the regulations for operating a wholesale pharmaceutical business.

22. Registration of licensed premises

- (1) Where, the Council approves any premises for use as a pharmacy, wholesale pharmaceutical business or pharmaceutical manufacturing facility, and has received payment of the prescribed fees, the Council shall direct the Registrar –
- (a) to enter the name of the approved premises in the Register of Pharmacies, Wholesale Pharmaceutical Business or Pharmaceutical Manufacturing Facility, whichever is applicable;
 - (b) to issue the applicant with a certificate of licence in respect of such premises; and
 - (c) to publish the name and address of the approved premises in the Gazette on the 30th day of April and 31st day of October of each year.
- (2) Every licence granted under this section shall remain valid for a period of twenty-four (24) months from the date of issue.

- (3) No certificate shall be valid unless it is signed by the President of the Council and the Registrar and authenticated with the seal of the Council.
- (4) Application for renewal of licensed premises shall be submitted to the Registrar not later than three months before the expiration of the licence.
- (5) The Registrar shall forward such application together with the report of the Board of Inspectors to the Council who shall determine whether or not the licence should be granted or renewed.

23. Prohibition of unlicensed premises

- (1) No person shall operate any premises as a pharmacy, wholesale pharmaceutical business or pharmaceutical manufacturing facility unless the operator has obtained in respect of the premises, a licence granted by the Council bearing the signatures of the President of the Council and the Registrar, and authenticated with the seal of the Council.
- (2) The owner or operator of any pharmacy, wholesale pharmaceutical business or pharmaceutical manufacturing facility licensed under this Act shall at all times, display in a conspicuous place within the licensed premises the certificate of licence in respect of the premises.
- (3) A person who fails to comply with this section commits an offence and is liable on summary conviction to a fine of twenty thousand dollars (\$20,000.00) or to imprisonment for a term of twelve (12) months or to both such fine and imprisonment.

24. Cancellation and suspension of licence

- (1) The Council shall cancel or suspend a licence on the grounds that –
 - (a) the premises in relation to which the licence is issued has ceased to be used as a pharmacy, wholesale pharmaceutical business or pharmaceutical manufacturing facility;
 - (b) the premises is in a state of disrepair or is in an unsanitary condition so as to render it unsuitable to comply with the conditions of this Act;
 - (c) the licence for the premises has not been renewed in accordance with this Act and its regulations;
 - (d) there is no pharmacist associated with the pharmacy or wholesale pharmaceutical business, or pharmaceutical manufacturing facility;
 - (e) the pharmacist on record with the Council as having the management, control or supervision of the pharmacy or wholesale pharmaceutical business is no longer employed by the pharmacy or wholesale pharmaceutical and the name and particulars of the replacement pharmacist has not been provided to the Council or
The pharmacist on record with the Council as part of the pharmaceutical manufacturing facility team is no longer employed by the pharmaceutical manufacturing facility and the name and particulars of the replacement pharmacist has not been provided to the Council

- (f) the owner, operator or registered and licensed pharmacist of the pharmacy, wholesale pharmaceutical business or pharmaceutical manufacturing facility is operating that pharmacy, wholesale pharmaceutical business or pharmaceutical manufacturing facility in contravention of the provisions of this Act and its regulations.
- (2) Where a licensed premises has ceased to be used as a pharmacy, wholesale pharmaceutical business or pharmaceutical manufacturing facility, the holder of the licence to which the premises relates shall deliver up the licence to the Registrar for cancellation.
- (3) The holder of a licence that has been suspended or that is liable to be cancelled or suspended, may, in addition to any other penalty imposed under this Act, be required to pay to the Registrar an administrative penalty not exceeding three thousand dollars (\$3,000.00) before the licence can be renewed.
- (4) The holder of a licence that has been cancelled or suspended under this section shall, as soon as practicable, but not later than fourteen (14) days of the service of the notice of cancellation or suspension on him or her, deliver up the licence to the Registrar to be disposed of in a manner directed by the Council.
- (5) Where a licence has been cancelled in respect of any premises, a new application for a licence shall be made in respect of the premises before another licence can be issued.
- (6) The Council shall notify the Minister forthwith of any suspension or cancellation of a licence.
- (7) The Registrar shall, as soon as a licence is suspended or cancelled under this section, cause to be published in the Gazette –
- (a) a notice of suspension or cancellation of the licence; and
- (b) the removal of the name of the pharmacy, wholesale pharmaceutical business or pharmacy manufacturing facility from the Register of Pharmacies or Wholesale Pharmaceutical Business or Pharmaceutical Manufacturing Facility, as the case may be.

PART VI

BOARD OF INSPECTORS OR DRUG INSPECTORATE

25. Constitution of the Board of Inspectors or Drug Inspectorate

- (1) The Minister may, after consultation with the Council, constitute a Board of Inspectors, which shall function as the Drug Inspectorate for the purposes of this Act.
- (2) The Board of Inspectors or Drug Inspectorate shall consist of a Chief Drug Inspector and any number of registered and licensed pharmacists employed by the Ministry of Health as may from time to time be required to meet the national needs.
- (3) Neither the Chief Drug Inspector nor any inspector on the Drug Inspectorate shall hold the post of Director of Pharmaceutical Services.

- (4) The Chief Drug Inspector reports to the Council and is responsible for coordinating the activities of the Drug Inspectorate
- (5) No member of the Drug Inspectorate shall engage in private practice as a pharmacist.

26. Functions of Board of Inspectors or Drug Inspectorate

- (1) The functions of the Drug Inspectorate are to –
 - (a) conduct pharmacovigilance functions and report their findings to the Council.
 - (b) carry out inspection of any premises in respect of which an application for a licence is being considered. ;
 - (c) enter upon any premises on which a pharmacy, wholesale pharmaceutical business or pharmaceutical manufacturing facility is operating to ensure compliance with the requirements of this Act and the regulations;
 - (d) enforce standards as prescribed or adopted by the Council for handling and storing drugs and poisons; ;
 - (e) enter any premises or visit any location or site where or on which drugs or poisons are administered, sold, stored, manufactured, imported, exported, dispensed or distributed for the purpose of ascertaining the observance by the business of good storage and distribution practices, good manufacturing practices, good clinical practices;
 - (f) enter any premises or visit any location or site and remove any pharmaceuticals that have not been approved for sale within Antigua and Barbuda or that do not meet labelling requirements as set out in this Act or the regulations;
 - (g) enter any premises or visit any location or site and remove any pharmaceuticals that has been recalled from the market by the manufacturer or the Ministry of Health via the office of the Director of Pharmaceuticals;
 - (h) enter any premises, or location or site in respect of which there is reasonable cause to suspect that a breach of this Act or its Regulations has occurred;
 - (i) interception and confiscation of pharmaceuticals not authorized for importation into Antigua and Barbuda or which are not in compliance with the requirements of this Act; and
 - (j) recommend to the Council forthwith the need for closure or for action to be taken against any pharmacy, wholesale pharmaceutical business, pharmaceutical manufacturing facility and any other entity and the rationale thereof.
- (2) Without limiting the generality of the foregoing, the Drug Inspectorate shall have the power to –
 - (a) seize pharmaceuticals, any documents or records to protect the public health as part of its investigations;
 - (b) take copies of records that are required to carry out its investigation;
 - (c) have the power to make such enquires and collect such samples as may be considered necessary for ascertaining compliance with this Act or any regulations made hereunder;

- (d) to seize from any premises, location, site, entity or person any pharmaceutical or shipment of pharmaceuticals that are in their possession without the proper license or permission granted by the Council;
- (e) to inspect any supply of pharmaceuticals entering any Port or location within Antigua and Barbuda;
- (3) Nothing in this section prevents the Drug Inspectorate from entering and inspecting –
 - (a) any premises; or
 - (b) any place of practice of any medical practitioner, dentist, or veterinary surgeon,

where it has reason to believe that storage, dispensing, manufacturing, importation, exportation, sale or the distribution of drugs is being carried out.

27. Reports of the Board of Inspectors or Drug Inspectorate

- (1) The Drug Inspectorate shall after inspection submit to the Council a report stating whether –
 - (a) the premises complies with the standards set out by the Council;
 - (b) any of the provisions of this Act or its regulations has been contravened; or
 - (c) there has been a breach of any professional conduct.
- (2) Where the report of the Drug Inspectorate finds that the premises fail to comply with the standards set out by the Council, the Council may by notice in writing direct the holder of the license to carry out within a specified time such repairs or alterations as considered necessary to comply with the standards set out by the Council.
- (3) If at the expiration of such specified time the holder of the license fails to comply with such direction, the Council shall suspend the licence until such time as there is full compliances with the directive of the Council.
- (4) Where a licence holder fails within three months of the suspension of the licence to comply with the Council direction, the Council may cancel the licence.

28. Collection of samples

- (1) Where a member of the Drug Inspectorate collects any sample from any premises, location, site or person, he or she shall –
 - (a) list the items collected on the Confiscated Item Document Form prescribed in Schedule II;
 - (b) furnish the person or person responsible for the premise, location or site with a copy of the list in paragraph (a);
 - (c) sign the form; and
 - (d) cause the person or person responsible for the premises, location or site to sign the form.
- (2) In the event the person refuses to sign, the Inspector shall indicate on the form –
 - (a) that the person refused to sign;

- (b) the time of the refusal to sign;
 - (c) the names of the persons present, if any; and
 - (d) and date of such refusal.
- (3) If any of the samples collected are required to be tested, the pharmaceutical business, entity or person from whom the samples were taken shall be liable to bear the full cost of testing.
- (4) Where there is a requirement to collect random samples from any person, premises, location or site as part of the Government's quality assurance measures, the Government shall bear the costs associated with the testing of these samples.

29. Appeals

- (1) Any person who is aggrieved by a decision of the Council:
- (a) not to permit him or her to be registered;
 - (b) to suspend or cancel the registration of that person;
 - (c) to remove his or her name from of the Register of Pharmacies or to remove the name of his business from the Register of Wholesale Pharmaceutical Businesses;
 - (d) not to approve an application for licensing a premises for operating as a pharmacy, wholesale pharmaceutical business or pharmaceutical manufacturing facility; or
 - (e) to suspend or cancel the licence in respect of a licensed premises may within thirty (30) days from the date of such decision appeal to a Judge in chambers against the decision.
- (2) The Judge may, after hearing an appeal made to him under subsection (1), grant such relief as he or she considers proper.
- (3) Notwithstanding subsection (2), a decision of the Council continues to have effect unless it is altered, amended or set aside by the Judge in Chambers.

PART VII

MANUFACTURING, SALE, IMPORTATION, EXPORTATION AND POSSESSION ETC. OF DRUGS OR PHARMACEUTICALS

30. Procurement, sale, importation, exportation, possession etc. of drugs or Pharmaceuticals

- (1) No person shall procure, import, export, sell, store, distribute, compound, or have in his or her possession with intent to distribute or dispense by wholesale or retail any drug or pharmaceutical unless –
- (a) the selling, compounding, manufacturing or dispensing by retail is carried out by a licenced and registered pharmacist and on premises registered under **section 17** of this Act;
 - (b) the pharmaceutical activities conducted by a wholesale pharmaceutical is effected under the direct control and management of a registered and licensed pharmacist under this Act;
 - (c) the prescribed requirements relating to the compounding, dispensing or selling of the drugs are complied with;
 - (d) in the case of a drug that is a poison, the selling, compounding or dispensing complies with the provisions of **sections 37 and 38**.

- (2) No person shall procure, import or export, sell, store distribute, compound, or have in their possession with intent to distribute or dispense by wholesale or retail any drug, vaccine, biologic or medical supply that is marked on its internal or external label for export only or for use in a specific country only or manufacture for a specific country only.
- (3) No person shall procure, import, export, sell, store, distribute, compound, or have in his possession with intent to distribute or dispense by wholesale or retail any drug or medical supply that is not labelled in accordance with the National Standards for the Labelling of Pharmaceuticals as set out in Schedule 4.
- (4) The Council may grant an exemption for the procurement, importation, exportation, sale or possession of a specific quantity of a drug after conducting its due diligence in cases of national shortage or national emergency.
- (5) If the Council grants an exemption it is for a specified period as stipulated by the Council, and the jurisdiction where the product originates.
- (6) Licensed importers of pharmaceuticals shall –
 - (a) ensure that the company they are importing from is duly registered and licensed by the relevant authorizing authority in the exporting country; and
 - (b) provide copies of supporting documents to the Chief Drug Inspector.
- (7) Any person or entity that contravenes subsection (6) is liable to pay a penalty as prescribed by the Council.
- (8) Failure to pay the imposed penalty within the stipulated time may result in criminal prosecution.
- (9) Every drug dispensed from a medical prescription shall be placed in a box, bottle, vessel, wrapper or other receptacle bearing a label with such instructions as the medical practitioner may direct.

31. Requirements for importation of drugs, pharmaceuticals, vaccines and biologics into Antigua and Barbuda

- (1) All importers of drugs, pharmaceuticals, vaccines or biologics shall ensure that prior to their importation, they are registered and approved for use in the country of origin and are also approved by one of the listed WHO Listed Authorities.
- (2) Proof of registration by a National Regulatory Authority on WHO listing shall be submitted to the Chief Drug Inspector.
- (3) Notwithstanding subsection (1), importers may import drugs, pharmaceuticals, vaccines and biologics if they are registered or recommended for registration or approval by the Caribbean Regulatory System.
- (4) After submission of the application documentation and/or requirements presented as outlined in guidelines published by competent authority for the importation of any new generic or branded pharmaceuticals, vaccines or biologics, the Council may grant approval after ninety (90) working days upon verifying the veracity of the documentation presented.

32. Registration and Marketing Authorization:

- (1) The registration of a drug shall be based on clinical evidence that the product is efficacious and safe for use
- (2) Marketing authorization of a medical product is based on evidence of quality, safety, and efficacy.
- (3) The Council may after issuing market authorisation, renew, variation, and cancellation of marketing authorizations for all regulated products.
- (4) Prior to Market Registration and Market Authorisation the applicant shall submit to the Council all technical documentation,
- (5) The Council may expedite market authorisation with conditionalities in emergencies, with reliance mechanisms on decisions from trusted regulatory authorities.

33. Courier service providers

- (1) Any individual or entity seeking to import any pharmaceutical, vaccine or biologic not available in Antigua and Barbuda via their services shall –
 - (a) obtain an Import Licence from the Council for the importation of any pharmaceuticals, vaccine or biologic;
 - (b) provide to the Chief Drug Inspector the original copy of the prescription written by a doctor, dentist, or veterinary surgeon registered in Antigua and Barbuda; and
 - (c) provide proof that the drugs are not available locally.
- (2) Courier service providers shall ensure that –
 - (a) individuals or entities importing drugs via their service provide proof of the required Import Licence from the Council;
 - (b) all drugs imported into Antigua and Barbuda comply with the National Labeling Standards for Pharmaceuticals and any other requirement of this Act and its Regulations;
 - (c) The drug, vaccine or biologics are shipped under correct temperature conditions;
 - (d) there is a secure area to store pharmaceuticals at the temperature stipulated by the manufacturer; and
 - (e) Drug Inspectors are permitted to access to the secure area utilized for temporary store of drugs.
- (3) Courier service providers are not allowed to procure, sell, import, distribute, possess pharmaceuticals unless duly licensed by the Council
- (4) Failure comply with these provisions the Council shall prescribe Penalties as stipulated in

34. Import, export or manufacturing of controlled drugs used for medical use

- (1) A pharmacy, pharmaceutical wholesale business, or hospital that is desirous of importing or exporting pharmaceuticals that are controlled drugs for medical use in human, animal, or fowl shall apply to the Director of Pharmaceutical Services.
- (2) The applicant shall provide –
 - (a) all particulars of the controlled drug including, but limited to –
 - (i) dosage form;
 - (ii) strength;
 - (iii) quantity; and
 - (iv) pack size;
 - (b) particulars of the pharmacy, pharmaceutical wholesale business or hospital, as the case may be; and
 - (c) particulars of the supplier.
- (3) An importation licence granted for the importation of a controlled drug may only be utilized once within the period to time stipulated on the licence.
- (4) The Director of Pharmaceutical Services and the Chief Drug Inspector shall approve the application for the importation, exportation and manufacturing of controlled drugs by affixing his or her signature to the form as set out in Schedule 5 or 6, as the case may be.
- (5) A copy of all licences granted shall be kept on record for a period of two (2) years from the time of issuance.
- (6) A copy of the approved license shall be provided to the Minister of Justice within thirty (30) working days for record keeping purposes.

35. Record keeping

- (1) A medical practitioner shall keep a record of the sale of drugs in emergency cases and, in particular shall record –
 - (a) the particular medication sold to the patient;
 - (b) the time and date of the sale;
 - (c) dosage form;
 - (d) directions for use;
 - (e) the quantity of the drug sold; and
 - (f) the cost of the drug.
- (2) A medical practitioner shall furnish to the Chief Drug Inspector or his or her designated representative the record in subsection (1).
- (3) All medical practitioners, veterinary surgeons, dentists, clinics and entities that purchase pharmaceuticals shall record all purchases and quantities of drugs that were provided to patients for immediate or emergency use.

- (4) The manufacturer of pharmaceuticals, vaccines, or biologics shall have a rigid record-keeping system to –
 - (a) record all materials and country of origin in the production supply chain;
 - (b) record the recall of a product and the reason for the recall; and
 - (c) document all adverse events observed or reported according to the degree of severity.
- (5) The manufacturer shall submit to the Council immediately a report on all recalls and adverse events recorded no later than five (5) working days.

36. Supplements

- (1) No person shall advertise a supplement as therapy or treatment for disease in human, animal or fowl unless there is clinical scientific evidence to support the claim.
- (2) Supplements shall be sold in their original sealed containers.
- (3) Any supplement that is in an injectable form shall be prescribed by a doctor or veterinary surgeon.
- (4) Supplements shall be free of pharmaceuticals that are psychotropic substances, steroids, stimulant and other drugs.
- (5) Drug Inspectors may inspect or visit any premises where supplements are stored, sold or manufactured and take samples of the supplements.
- (6) The cost for testing of any samples taken by Drug Inspectors shall be borne by the business.
- (7) The labelling of supplement shall comply with the National Labelling Standards for Pharmaceuticals.
- (8) Any person who breaches this provision commits an offence and may be liable to a fine of twenty thousand dollars (\$20,000.00) or to imprisonment for a period not exceeding twelve (12) months.

37. Cosmetics

- (1) Cosmetics shall be sold in their original sealed containers.
- (2) Cosmetics shall be free of pharmaceuticals and toxic substances that can be harmful to human health.
- (3) Drug Inspectors may –
 - (a) inspect or visit any premises where cosmetics are stored, sold, or manufactured;
 - (b) compulsorily acquire products for testing; and
 - (c) compensate the person or entity for the products.
- (4) If a sample of an item purporting to be a cosmetic
 - (a) found to be inconsistent with its stated chemical composition;
 - (b) is unsuitable for specified use; or
 - (c) is contaminated,

the business shall refund the purchase and testing cost.

- (5) The labelling of cosmetics shall include –
 - (a) all ingredients, their quantity or strength,
 - (b) the manufacturer,

- (c) batch number,
- (d) expiration date
- (e) date of manufacture
- (f) country of origin
- (6) The main display and leaflet of all cosmetics shall be in the English language but may include other languages.
- (7) Any person who breaches this provision commits an offence and may be fined twenty thousand dollars (\$20,000.00) or confined to twelve (12) months in prison.

38. Manufacturers of pharmaceuticals

A manufacturer of pharmaceuticals shall design its facility in such a manner to ensure that –

- (a) Compliance with good manufacturing practices recommended by WHO
- (b) the pharmaceutical facility adheres to strict regulations and standards set by the Council;
- (c) environmental controls are in place to facilitate adequate air filtration and temperature regulations;
- (d) the layout of the facility considers personnel and process flow, equipment and maintenance;
- (e) instrumentation is calibrated regularly to allow for accurate results and reliable data;
- (f) the facility is designed to mitigate the risk of accidental or intentional contamination through controlled access;
- (g) the facility is designed to facilitate the production of high-quality and safe pharmaceuticals;
- (h) all equipment used in the facility are of high quality, reliable, robust and allow for the production of pharmaceuticals that meet regulatory requirements stipulated by this Act and adhere to good manufacturing practice guidelines;
- (i) the location of the facility should prioritise the adequate security of the site;
- (j) the manufacturer shall ensure that standard operating procedures are in place for all activities pertaining to the facility and manufacturing processes;
- (k) The manufacturer shall ensure that all materials used in the production process are documented.
- (l) The manufacturer shall ensure that systems are in place to ensure the compliance with good manufacturing practice, good pharmaceutical manufacturing practice and World Health Organization guidelines for the production of drugs and biologics or vaccines.
- (m) The manufacturer shall ensure that all personnel employed are duly qualified and certified for their position and engage in continuous education.
- (n) The manufacturer shall have a system in place for the recall of pharmaceuticals, vaccines or biologics.
- (o) The Council may provide additional guidelines to the manufacturer as needed.

**PART VIII
PROCUREMENT, SALE, LABELLING
AND STORAGE OF POISONS**

39. Procurement, sale, possession and distribution of poisons

- (1) No person shall carry on the business that includes the procurement, importation, selling by retail or by wholesale of poisons unless –
 - (a) that person is registered as an authorised seller of poisons by the Pesticides and Toxic Chemicals Board; and
 - (b) the business is operated on premises licensed for the sale of poisons by the Council.
- (2) An application to sell poisons shall be made to the Registrar on a form prescribed by regulation.
- (3) The Registrar shall submit such application to the Council who may, after making such enquiries as it considers necessary, approve or refuse to approve such application.
- (4) Where the Council is satisfied that –
 - (a) the applicant is sufficiently knowledgeable and is a fit and proper person to sell poison; and
 - (b) the premises in which he or she proposes to carry on such business is licensed for the sale of poisons under section 20;

it may make a recommendation to the Council to grant to the applicant a certificate of licence.

- (5) The Council may, on the receipt of such recommendation from the Board of Inspectors and, on payment of the prescribed fee, issue to the applicant a licence on the prescribed form as an authorised seller of poisons.
- (6) A licence issued under this section is not transferable and authorises only the licence holder to sell poison in accordance with the provisions of this Act.
- (7) A licence to sell poisons shall remain valid for a period as stated in the license obtained from the Pesticide and Toxic Chemical Board and is renewable on application in the prescribed form as stipulated by the Pesticide and Toxic and Chemical Board.
- (8) A person shall not procure, import, export, supply, distribute or dispense any poison except the poison is labelled in accordance with the National Standard for the Labelling of Pharmaceuticals as set out in Schedule 4 or the applicable standard establish by the Pesticide and Toxic Chemical Board.

40. Regulating the sale of poisons

- (1) Every person authorised under this Act to sell poisons by retail shall keep-
 - (a) a Poisons Book in which shall be recorded the particulars specified in subsections (3) and (4);
 - (b) the poison in a bottle, vessel, box, wrapper or cover, distinctly labelled with the name of the poison and bearing a distinctive mark that it is a poison; and
 - (c) the poison stored in an area set apart exclusively for poisons.

- (2) For the purposes of this section, the Council may, on the advice of the Pesticide and Toxic Chemical Board, prescribe specified poisons and the conditions under which such poisons may be sold to the public.
- (3) The seller of a specified poison shall not deliver the poison until the seller has entered or caused to be entered in the Poisons Book the following particulars –
 - (a) the date and form of poison prescribed;
 - (b) the name, occupation, valid telephone number and the address of the person to whom the poison is supplied;
 - (c) the name and quantity of the poison sold;
 - (d) the purpose for which it is stated by the purchaser to be required; and
 - (e) the signature of the purchaser, the person if any who introduced him to the seller.
- (4) Where the purchaser is a registered medical practitioner, veterinary surgeon or dentist, an order signed by the purchaser may be accepted in place of the signature in the Poisons Book and the seller shall enter the words "signed Order" and retain the Order for a period of two (2) years.
- (5) The seller of a specified poison may, in the case of an emergency and by an undertaking of a registered medical practitioner, veterinary surgeon or dentist to supply a signed order within twenty-four hours, sell without the immediate requirement of the signed order or the purchaser's signature in the book.

PART IX PHARMACEUTICALS, VACCINES AND BIOLOGICS

41. Application for approval to test or manufacture pharmaceuticals, vaccines or biologics

- (1) An inventor or manufacturer of a pharmaceutical, vaccine or biologic that is desirous of conducting testing in animals, human or fowl shall apply to the Council for permission to conduct clinical trials or testing.
- (2) The application shall be accompanied by –
 - (a) all of the particulars of the pharmaceutical, vaccines or biologics to include –
 - (i) chemical structure;
 - (ii) proposed dosage form;
 - (iii) strength;
 - (iv) stability data; and
 - (v) proposed time period for the testing or pre-clinical trials; and
 - (b) other scientific information determined by the Pharmacy Council.
- (3) The Council shall review the application and provide the applicant with a certificate of approval or rejection within six (6) months to conduct the testing or clinical trials.
- (4) The Council shall share the application with the Institutional Review Board and/or Clinical Trial Committee for approval prior to granting the certificate of approval or rejection.

- (5) An inventor or manufacturer that is desirous of manufacturing a pharmaceutical or vaccine or biologics shall submit to the Council all of the scientific and clinical data pertaining to the product for consideration, and any other information requested by the Council.
- (6) The Council shall review the scientific and clinical data and provide the applicant with a certificate to manufacture and a certificate of market authorization or documentation of rejection within six (6) months.
- (7) A manufacturer to whom a certificate of approval granted is required to comply with the requirements set out by the World Health Organization and any WLA prior to the manufacturing of pharmaceuticals, vaccines, or biologics.
- (8) The Council shall provide the applicant with the reasons why the application was rejected.
- (9) The Pharmacy Council may seek additional external expertise from WHO, any NRA or any other relevant regulatory body or its agencies or one of the WHO Listed Authority prior to granting of a certificate of approval or rejection to manufacturing by the applicant.
- (10) The Council may approve batch release for vaccines or biologics that are approved by a WLA once the necessary verifiable documentation are submitted by the applicant

42. Disposal of expired, unused, damaged drugs or cytotoxic pharmaceuticals, vaccines, biologics and poisons

- (1) A person shall not dispose of expired, unused, damaged drugs or cytotoxic pharmaceuticals, biologics, vaccines, or poisons except in accordance with the provisions of this section.
- (2) A person who intends to dispose of expired, unused, damaged drugs or cytotoxic pharmaceuticals or biologics, vaccines or poisons shall give written notice to the Chief Drug Inspector of his intention not less than thirty (30) days prior to the date on which he intends to dispose of the expired, unused, damaged or cytotoxic pharmaceuticals or poisons.
- (3) A notice under subsection (2) shall include a list of all the pharmaceuticals or poisons to be disposed of, listed by name and by the quantity, expressed in millilitres or otherwise.
- (4) A copy of the list referred to in subsection (3) shall be provided to the Chief Health Inspector, who will identify the disposal site based on the disposal specification provided by the Chief Drug Inspector.
- (5) A copy of the disposal certificate shall be provided to the Chief Drug Inspector within five (5) days of the disposal of the expired, unused, damaged drugs or cytotoxic pharmaceuticals or vaccines, biologics and poisons.

PART IX RESTRICTIONS

43. Exemptions

- (1) Subsection (1) of section 29, does not apply to the sale of any drug –
 - (a) to a medical practitioner, veterinary surgeon or dentist for the purpose of practising their profession;
 - (b) to, or for use in, any approved hospital; or
 - (c) to a pharmacist for the purpose of a pharmacy.
- (2) Section 38 does not apply to a drug administered by –
 - (a) a medical practitioner to his patient in his or her office or as a starting does in the case of a home visit;
 - (b) a dental surgeon to his patient in his or her office or as a starting does in the case of a home visit;
 - (c) a veterinary surgeon for any animal under his care or as a starting does in the case of a home visit;
 - (d) a midwife acting under the direction of a registered medical practitioner; or
 - (e) a nurse acting under the direction of a registered medical practitioner.
- (3) Other entities shall not procure, sell, import, export, have in its possession or otherwise deal with, drugs unless an exemption is granted by the Council.
- (4) The Council may grant an exemption with restrictions to small medical clinics.

44. Restrictions

- (1) A medical practitioner may sell to patients –
 - (a) a starting dose of a drug, only for use within his or her office; or
 - (b) other drugs, for emergency use.
- (2) Subject to subsection (1), a medical practitioner may only sell to the patient a maximum of three (3) days' supply upon verification that all pharmacies in Antigua and Barbuda are closed.
- (3) Subject to subsection (1), a medical practitioner, veterinary surgeon or dentist shall not dispense or sell medication to any patients but can provide a patient with drug samples to take away from his or her office.
- (4) Every medical practitioner, veterinary surgeon or dentist shall purchase pharmaceuticals, vaccines, and biologics for use in their practice from local suppliers.
- (5) Notwithstanding the foregoing subsections –
 - (a) the Council may grant to a medical practitioner, veterinary surgeon, dentist or entity a single use licence per order in Schedule 6 for the importation of a specific drug, with a specific quantity, strength, dosage form upon payment of the prescribed fee of fifty dollars (\$50.00).

- (b) a medical practitioner, or veterinary surgeon or dentist shall not purchase or store controlled drugs unless the Council grants an exemption with specific restrictions stipulated in this Act, under its Regulations and any other law.
- (6) A medical clinic or medical facility, hospital or other entity that offers medical services and is desirous of procuring, importing, purchasing, storing or selling drugs to patients shall –
 - (a) apply to the Council for a pharmacy license; and
 - (b) employ a full-time pharmacist for the dispensing, management and control of pharmaceuticals to be supplied to patients.
- (7) The operator of a pharmacy that imports, distributes or sells drugs to other entities without the requisite licence commits an offence and is liable to a fine of five thousand dollars (\$5,000.00).
- (8) Pharmaceutical wholesale businesses and manufacturers shall not supply or dispense pharmaceuticals directly to patients.
- (9) Any person or entity that fails to comply with the provisions of this section commits an offence and is liable to a penalty not exceeding five thousand dollars (\$5,000.00).

45. Dispensing and compounding

- (1) A person who operates a pharmacy, manufacturing or wholesale pharmaceutical business shall not permit the dispensing, and wholesale section thereof to be open unless –
 - (a) a pharmacist that is duly registered and license under this Act is in charge thereof and in actual attendance therein; and
 - (b) all drugs in the dispensing section of a pharmacy or pharmaceutical wholesale section or manufacturing facility required by this Act to be compounded, dispensed, stored for sale or retailed under the direct management of a pharmacist are secured in a place to which the public does not have access.
- (2) In the dispensing area of a pharmacy only pharmacist, pharmacy technicians, pharmacy interns and pharmacy students are the only persons permitted to be in the pharmacy dispensing space.

PART X DISCIPLINARY PROCEEDINGS

46. Complaints

- (1) A person who wishes to make a complaint against a person registered under this Act shall do so to the Council, stating the particulars of the complaint.
- (2) If any person registered under this Act is found, upon enquiry by the Council —
 - (a) to be suffering from any illness rendering him or her unfit to practise pharmacy;

- (b) to be guilty of dishonesty, negligence or incompetence in the performance of his or her functions as a pharmacist or a pharmacy technician, or of serious professional misconduct; or
 - (c) to have procured his or her registration under this Act as a result of any misleading, false or fraudulent representation; or
 - (d) to be in breach of any disciplinary rules made under this Act,
- the Council may impose one of the sanctions prescribed in section 46.

47. Disciplinary proceedings

- (1) The Minister shall after consultation with the Council establish a disciplinary committee to hear and determine, all complaints brought on behalf of the Registrar under subsection (6) against any person for breach of –
 - (a) any disciplinary rules made under this Act; or
 - (b) any professional conduct recognised by the Council.
- (2) The Council may institute disciplinary proceedings against any pharmacist registered under this Act who –
 - (a) has been convicted of an offence under this Act;
 - (b) has been convicted for an offence involving moral turpitude under any other law; or
 - (c) has committed an act of professional misconduct.
- (3) For the purposes of this Act, “professional misconduct” includes violation of any code of conduct of professional standards established or recognised by rules made under this Act, and without limiting the generality of the foregoing includes –
 - (a) any act or thing done by a person registered under this Act that is contrary to the generally recognized duty and responsibility of such a person to his or her patient;
 - (b) the failure to do any act or thing with respect to a patient in accordance with his or her duty
 - (c) improper conduct or association with a patient;
 - (d) wilful or deliberate betrayal of a professional confidence;
 - (e) abandonment of a patient in danger without sufficient cause and without allowing the patient sufficient opportunity to retain the services of another pharmacist;
 - (f) knowingly giving a certificate with respect to any matter relating to pharmacy which the pharmacist or pharmacy technician knows or ought to know is untrue, misleading or otherwise improper;
 - (g) the division with any person who is not a partner or assistant of any fees or profits resulting from the taking or advice from another pharmacist without the patient's knowledge or consent;
 - (h) the abuse of intoxicating liquor or drugs;
 - (i) the impersonation of another pharmacist or pharmacy technician;
 - (j) association with unqualified or unregistered persons whereby such persons are enabled to practise pharmacy;
 - (k) any wilful or negligent misrepresentation as to the curative efficacy possessed by a drug or any other substance, whether inherently or by administration or application thereof;

- (l) knowingly practising pharmacy while under the influence of alcohol or drugs to such an extent as to constitute a danger to the public or a patient;
 - (m) the doing of or failure to do any act or thing in connection with his professional practice, which is in the opinion of the Council unprofessional or discreditable;
 - (n) the wilful or negligent failure to comply with any directive given by the Council with respect to the dispensing of drugs or otherwise; and
 - (o) conviction of an indictable offence.
- (4) For the purposes of paragraph (b) of section (4), any disclosure of confidential information by a person registered under this Act pertaining to any patient shall not be deemed to be wilful or deliberate where such disclosure is required by any law for the treatment of that patient or for the protection of others against serious injury.
- (5) Notwithstanding subsection (3), any person who –
- (a) performs an act under paragraph (d) or (g) of subsection (4); or
 - (b) not being registered and license under this Act, holds out directly or indirectly to the public that he or she is qualified and registered in accordance with the provisions of this Act,

commits an offence and is liable to a fine not exceeding twenty thousand dollars (\$20,000.00) or to imprisonment for a period not exceeding two (2) years or to both fine and imprisonment.

- (6) All disciplinary proceedings under this Act shall be instituted in the name of the Registrar.
- (7) Any person against whom any disciplinary proceedings is brought under this Act may appear in person or may be represented by an attorney-at-law.
- (8) The Minister may, after consultation with the Council, prescribe by regulation the procedure for conducting disciplinary proceedings.

48. Penalty

- (1) The Disciplinary Committee shall at the conclusion of any disciplinary proceedings submit a report of its findings to the Council.
- (2) Where the Council is satisfied that the person against whom proceedings was brought has violated any disciplinary rules or professional standards it may-
 - (a) suspend the licence of such person for a period not exceeding one (1) year;
 - (b) cause the cancellation of the licence of the person;
 - (c) direct the Registrar to remove the name of that person from the register if the breach is so serious as to warrant the imposition of such penalty; or
 - (d) censure that person.
- (3) The Council may direct the Registrar to remove the name of a pharmacist from the register if such pharmacist –
 - (a) is convicted of an offence under this Act which in the opinion of the Council renders the person unfit to practise as a pharmacist;
 - (b) obtained his registration by fraud;
 - (c) is certified to be of unsound mind;
 - (d) is convicted under the Misuse of Drugs Act 1973 or under any other Act controlling or prohibiting the compounding, sale or use of any drugs;

- (e) is guilty of professional misconduct;
- (f) is habitually drunk or is addicted to any drug;
- (g) is negligent in compounding, dispensing or selling of drugs; or
- (h) is convicted of a felony by a court of competent jurisdiction.

49. Publication of removal of name in the Gazette

- (1) The Registrar shall, cause to be published in the Gazette the suspension, cancellation or removal of the name of any pharmacist from the Register of Pharmacists.
- (2) The Registrar shall, as soon as a license of a pharmacy, wholesale pharmaceutical business or a pharmaceutical manufacturing facility is suspended or cancelled under this Act, cause to be published in the Gazette –
 - (a) a notice of suspension or cancellation of the license; and
 - (b) the removal of the name of the pharmacy, wholesale pharmaceutical business or pharmacy manufacturing facility from the Register of Pharmacies or Wholesale Pharmaceutical Business or Pharmaceutical Manufacturing Facility, as the case may be.

PART XI MISCELLANEOUS

50. Offences

Any person who –

- (a) wilfully delays or obstructs the Board of Inspectors in the execution of its duties;
- (b) refuses to allow any sample to be taken in accordance with section 27;
- (c) fails to, or knowingly gives false information to the Board of Inspectors in the performance of its duties or gives information that is likely to mislead the Board of Inspectors in the performance of its duties;
- (d) by the offer of bribes or other inducement prevents or attempts to prevent the Board of Inspectors or any member of the Board from performing the duties imposed on it by this Act;
- (e) with the intent to deceive –
 - (i) forges a certificate purporting to be issued under this Act;
 - (ii) uses a certificate issued to another person under this Act;
 - (iii) lends or allows a certificate that has been issued to him to be used by another person;
 - (iv) uses a licence that has been cancelled or suspended under section 23; or
 - (v) makes a false declaration in any application or other document submitted to the Council or the Registrar.
- (f) accepts bribes in connection with any matter relating to the performance of his functions; or
- (g) contravenes a provision of this Act or of the regulations for which no specific penalty is provided,

is guilty of an offence and is liable on summary conviction to a fine of forty thousand dollars (\$40,000.00) and to a term of imprisonment for a period of twelve (12) months or to both such fine and imprisonment.

- (h) Any person who knowingly supplies substandard or falsified drugs or pharmaceuticals or vaccines or biologics is guilty of an offence and is liable on summary conviction to minimum fine of \$500,000.00 or a fine equivalent to the market value of the products seized, and the cost of storage and destruction, and/or up to five (5) years imprisonment

51. Penalties prescribed by the Council

- (1) Any person or entity found to be in contravention of this Act and its Regulations shall be subject to –
 - (a) an administrative fine; or
 - (b) a fine for the appropriate disposal of any items seized by Inspectors in the execution of their duties in accordance with this Act.
- (2) The penalties for noncompliance with this Act and its Regulations shall be equal to –
 - (a) the value of the items seized; and
 - (b) a ten per cent (10%) fine for disposal of the items seized.
- (3) All penalties imposed shall be paid within ten (10) days.
- (4) Where a person fails pay the imposed fee and an accrued fifty per cent (50%) interest per day within forty (40) days, the Council shall refer the matter for legal proceedings according to this Act and regulations made hereunder.

52. Pharmaceutical quality assurance

- (1) The manufacturer of drugs, pharmaceuticals, vaccines, or biologics shall ensure that there is a tracking system for all ingredients utilized in the production of each batch.
- (2) The Pharmaceutical manufacturer shall ensure proper maintenance logs of the facility are kept.
- (3) The Pharmaceutical manufacturer shall keep all records of pest control and mitigation methods utilized.
- (4) The manufacturer shall ensure that there are Standard Operating Procedures Manuals that cover all activities of its operations.
- (5) The Pharmacy Council shall authorize the government analytical laboratory service and/or an external laboratory to validate the safety, efficacy, composition, dissolution, bioavailability, strength, stability and other standards that may be necessary to ensure that pharmaceuticals, vaccines, or biologics produced by a manufacturer meet local and international standards.
- (6) The manufacturer of pharmaceuticals, vaccines or biologics shall not sell or distribute any batch unless a certificate of approval from the Pharmacy Council has been issued.

53. Use of titles

- (1) No person shall, unless registered under this Act as a pharmacist or seller of poisons, as the case may be, assume or make use of the following titles –
 - (a) Pharmacist;
 - (b) Chemist or Druggist;
 - (c) Pharmaceutical Chemist;
 - (d) Dispensing Chemist;
 - (e) Dispensing Druggist; or
 - (f) Authorised seller of poisons or drugs or any other title or name implying that he or she is registered as such under this Act.
- (2) No person shall, unless he or she is registered as a pharmacist under this Act, use in connection with any business, any sign, title or emblem or any description which implies that he or she or any other person employed by him possesses any qualification with respect to the selling, compounding for dispensing of any drug or poisons.
- (3) No person shall, unless premises upon which a sign, emblem or representation is displayed are appropriately registered under this Act, display on the premises the sign, emblem or representation that includes the description "drug store", "drug dispensary" or "pharmacy" or "sale of pharmaceuticals" or the other sign, title, emblem, or representation that implies or from which the public may infer that those premises are registered as such under this Act.

54. Regulations

- (1) The Minister may, after consultation with the Council, make regulations –
 - (a) prescribing –
 - (i) the qualifications necessary for registration as a pharmacist, pharmacy technician or pharmacy student; and
 - (ii) the requirements necessary for licensing premises, pharmacies, wholesale pharmaceutical businesses and pharmaceutical manufacturing facility;
 - (b) prescribing the period for which any certificate given under the provisions of this Act is to remain in force;
 - (c) respecting the manner in which disciplinary proceedings or enquiries are to be instituted and the procedure to be followed in the conducting of these proceedings or enquiries;
 - (d) prescribing the period for which any books or registers required under this Act are kept and preserved;
 - (e) respecting the addition to poisons of specified ingredients for the purpose of rendering them readily distinguishable as poisons;
 - (f) controlling the sale whether wholesale or retail, or the supplying of poisons by or to any person or classes of persons;
 - (g) specifying the substances that are poisons for the purposes of this Act;
 - (h) prohibiting the sale by retail of any specified poison except on a prescription given by a medical practitioner, dentist or veterinary surgeon and regulating the use of such prescriptions;

- (i) respecting the compounding, dispensing, labelling, storing, packaging, sale and retailing of drugs, registration, market authorisation, and poisons;
 - (j) respecting the containers in which poisons may be sold or supplied;
 - (k) prescribing those places, other than pharmacies in which poison included in the list referred to in section 20 (2) may be stored for sale or may be sold by retail and the requirements to be satisfied in relation to the storing and retailing in those places of those poisons;
 - (l) prescribing the qualification of persons to be put in control of the manufacture of pharmaceutical preparations containing poisons;
 - (m) prescribing the fees to be paid for anything to be done under this Act; and
 - (n) prescribing anything that is by this Act authorised or required to be prescribed.
- (2) The Council may, from time to time, by publication in the Gazette restrict the sale of a non-prescription drug by requiring the drug to be issued by a licenced pharmacist.

55. Repeals.

- (1) The Pharmacy Act, 1995 is hereby repealed.
- (2) The Antibiotic and Therapeutic Substance Act, Cap. 17 is hereby repealed.

SCHEDULE 1

(Section 3)

Procedure of Council

- (1) The council shall elect from amongst its members a president and a deputy president.
- (2) The president shall preside at all meetings of the Council, but in his absence the deputy president shall preside.
- (3) Where for any reason both the president and the deputy president are absent from any meeting, the members present and forming a quorum shall elect one of their number to preside at that meeting.
- (4) For the purposes of any official meeting of the Council, four members shall constitute a quorum.
- (5) The Council shall, for the proper conduct of its business, hold its meetings at such places and at such times as it may, from time to time, determine.
- (6) All decisions of the Council shall be by a majority of the votes of the members present and voting.
- (7) In the event of the votes being equal the person presiding at such meeting shall have a casting vote.
- (8) The Council may appoint a secretary after consultation with the Ministry.
- (9) The secretary shall keep a minutes book in which, shall be recorded, the proceedings and decisions of the Council.
- (10) All decisions of the Council shall be signed by the president and the secretary.
- (11) The Minister may revoke the appointment of any member appointed under section 3(2)(e).
- (12) The Council shall appoint an Expert Committee to evaluate and analyse specific documents and information that are submitted to the Council and advise the Minister of such appointment.
- (13) The Minister may approve remuneration for the Committee after consultation with the Council.
- (14) If a member of the Council is absent without valid reason for five (5) consecutive meetings, the President shall notify the Minister that the seat is vacant.

DRAFT

**SCHEDULE 2
ANTIGUA AND BARBUDA PHARMACY COUNCIL
CONFISCATED ITEMS DOCUMENT FORM**

(Section 27)

Name of Person/Entity:

Location of Operation:

Date:

Line #	Product name.	Expiry date	Manufacturer	Lot or batch number	Dosage Form	Quantity

Drug Inspector:

Name:

Signature:

Person/Entity

Name:

Signature:.....

SCHEDULE 3

MINIMUM REQUIREMENTS FOR PHARMACY DISPENSARY

(Section 20(4))

MINISTRY OF WORKS
ST. JOHN'S STREET, ST. JOHN'S
ANTIGUA & BARBUDA

Design & Control
Division

Tel: (268) 562-6503
Fax: (268) 562-6160
Email: div@p-wkbarb.com

REFERENCE SET
NOT FOR CONSTRUCTION

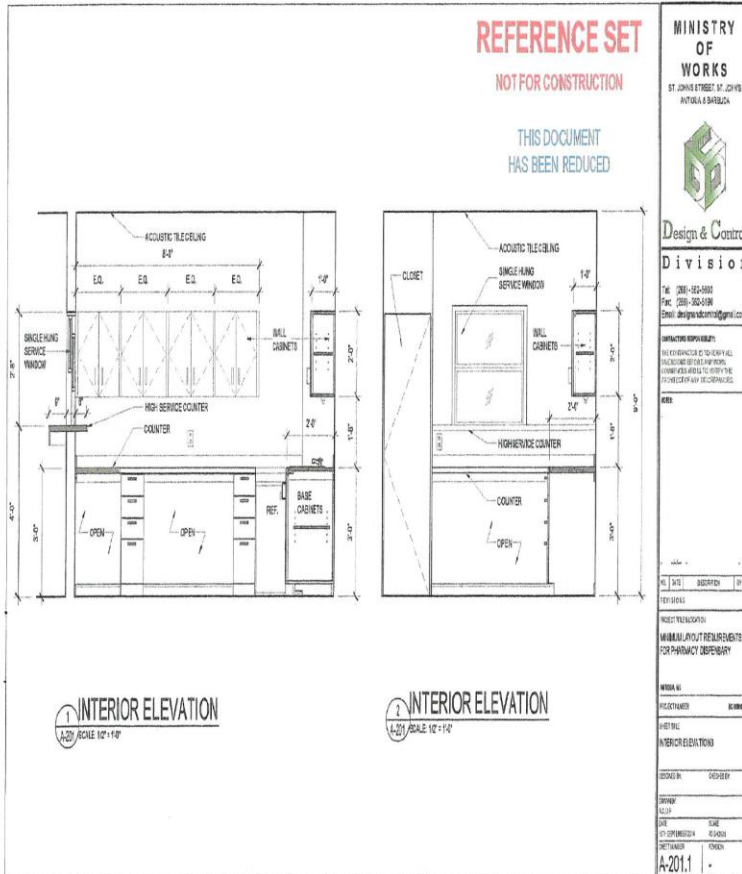
THIS DOCUMENT
HAS BEEN REDUCED

**MINIMUM REQUIREMENTS FOR
PHARMACY DISPENSARY**

ANTIGUA, WI

ARCHITECTURAL CONSULTANT	ENGINEER	STRUCTURAL CONSULTANT	ELECTRICAL CONSULTANT	MERCHANDISE CONSULTANT	PLUMBING CONSULTANT	PROJECT MANAGEMENT CONSULTANT





MINISTRY OF WORKS
ST. JAMES STREET, 17, 201 V.S.
PORTAU PRINCE

Design & Control
Division

Tel: (202) 452-5900
Fax: (202) 502-5198
Email: designandcontrol@gmail.com

CONTRACT RESPONSIBILITY
THE CONTRACTOR IS TO VERIFY ALL DIMENSIONS OF ALL WORKS. DIMENSIONS ARE TO BE TAKEN FROM THE EXTERIOR FACE UNLESS OTHERWISE SPECIFIED.

DATE:

NO.	REV.	DESCRIPTION	BY

PROJECT TITLE: **MINIMUM AVAILABILITY REQUIREMENTS FOR PHARMACY OBSERVATORY**

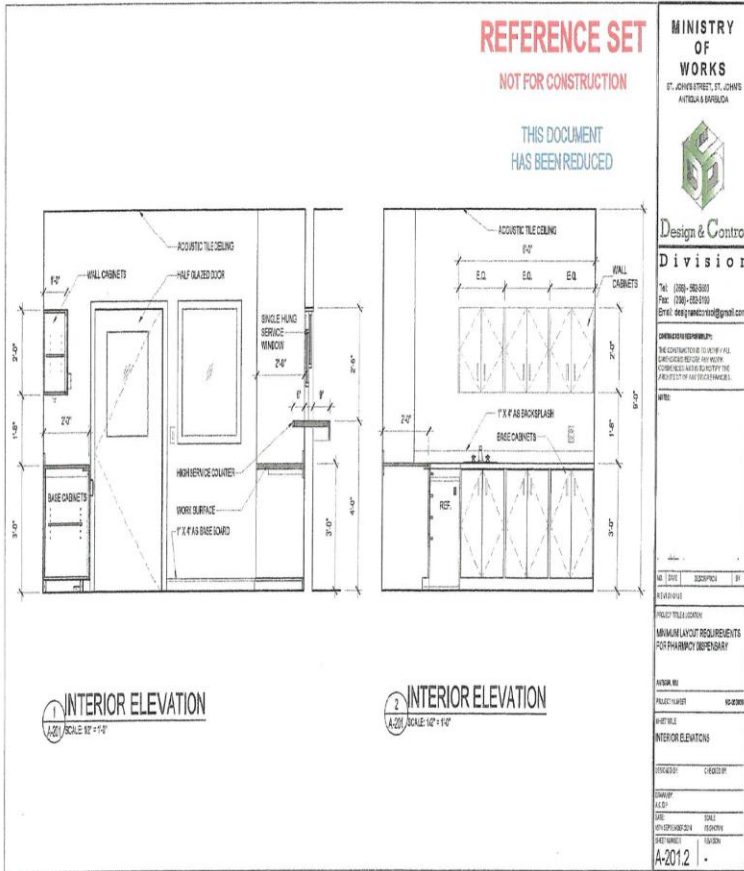
WORK NO. _____
REGISTERED: ARCHITECT ENGINEER

DRAWING: **INTERIOR ELEVATION**

DESIGNED BY: **DESIGNER**

DRAWN BY: _____
SCALE: _____
DATE: _____
CHECKED BY: _____
DATE: _____
APPROVED BY: _____
DATE: _____

A-201.1



SCHEDULE 4
NATIONAL STANDARD FOR LABELLING OF PHARMACEUTICALS

(Sections 29 and 37)

1. Scope

This standard described general labelling requirement for drugs. It is applicable to all drugs which are manufactured, imported, sold or distributed within Antigua and Barbuda.

2. Terms and definitions

For the purpose of this standard, the following definitions shall apply:

2.1 Country of origin means the country where the drug was manufactured and or repackaged for distribution or sale.

2.2 Drug means any substance or mixture of substances manufactured, sold or represented for use in the:

- the diagnosis, cure, treatment, mitigation or prevention of any disease, disorder, abnormal physical or mental state, or the symptoms thereof in human, animal or fowl;
- the restoring, correcting or modifying of organic functions in human, animal or fowl;
- any substance whether natural or synthetic with therapeutic or medical properties and chiefly used as medicines or ingredients in medicines; and
- any article other than food intended to affect the structure of any function of the body of man or animal.

2.3 Pharmaceuticals means compounds manufactured for use as medical drugs in humans, animals and fowl.

2.4 Label means any tag, ticket, brand, mark, pictorial or other descriptive matter, written, printed, stenciled, marked, embossed, impressed on, accompanying or attached to a package or container.

2.5 Secondary label means any label or leaflet on, inserted or affixed to an immediate package or container of the drug.

2.6 Principal display panel means the principal label affixed to the package or container, identifying its contents by stating the name (generic and brand name) of the drug, the ingredients, strength, weight, volume, dosage form, manufacturer, lot number/ batch number, expiry date, manufacturing standard, address of manufacturer and where applicable the repackaging entity or product license holder

2.7 Main panel means the principal label affixed to the package or container, identifying its contents by stating the name (generic and brand name) of the drug, the ingredients, strength, weight, volume, dosage form, manufacturer, lot number/ batch number,

expiry date, manufacturing standard, address of manufacturer and where applicable the repacking entity or product license holder.

- 2.8** Manufacturer means a person who, under his own name, or under a trade, design, or word mark, trade name or other name, word or mark controlled by him, sells a drug to the general public or to a wholesaler or other distributor for resale to the general public; and includes a body of persons, whether corporate or incorporate.
- 2.9** Repacking entity refers to a company which under license by a manufacturer, repackages a drug for distribution or sale.
- 2.10** Product license holder refers to a company which manufactures and or packages a drug under license for the product patent holder.
- 2.11** Package includes any container, wrapper, confining band or card in which the good intended for sale to the retailer purchaser or distribution to the public is wholly contained, placed or packed.
- 2.12** Legible means that the written or printed matter that can be read without difficulty under the conditions in which the label is normally displayed to a consumer.
- 2.13** Weight means the same as the term 'mass' in physics

3. Labelling Requirements

3.1 A label affixed to the inner or main display panel of the package or container of a drug shall be legible and contain the following information:

3.1.1. Main display panel

- (a) Brand or trade name, and generic name;
- (b) Weight, volume, strength, quantity therein;
- (c) Active and inactive ingredients;
- (d) Dosage form;
- (e) Batch number/ lot number;
- (f) Expiry date (stating the month and year) in clear terms;
- (g) Date of manufacture;
- (h) Manufacturing standard;

- (i) Name and address of manufacturer, repackaging agent, product license holder, or any person who legally assumes the responsibility for the manufacturer, along with his/her address
- (j) Indication (s) and recommended dosage and dosage interval; and
- (k) Handling and Storage conditions

3.1.2 Secondary label:

- (a) Full description of the drugs;
- (b) Indications;
- (c) Contraindications;
- (d) Recommended dosage and interval;
- (e) Route of administration;
- (f) Side effects;
- (g) Adverse effects;
- (h) Precautions and cautions;
- (i) Drug interactions;
- (j) Warnings and relevant symbols;
- (k) Manufacturer, address, and trademark;
- (l) Handling and Storage conditions; and
- (m) Any special precautions for the disposal of any unused drug or waste material derived from the drug.

3.2 A claim shall not be made on the label unless it can be substantiated scientifically. A drug or drug label shall not be described or presented in a manner that is false, misleading or deceptive to create an erroneous impression regarding its character in any respect.

3.3 The labelling requirements specified in this standard shall be in the English language on the main display panel and secondary label from the manufacturer, but may include other languages.

3.4 It is the responsibility of any person who procures, sells or distributes any drugs to ensure that they are labelled as required by this standard.

4. Approval of Labels

The Bureau of Standards shall, on request, approve labels conforming to this standard.

DRAFT

SCHEDULE 5

FORM A

ANTIGUA AND BARBUDA PHARMACY COUNCIL

THE PHARMACY ACT 2026

IMPORT LICENSE

ISSUED BY THE GOVERNMENT OF ANTIGUA AND BARBUDA

The Pharmacy Council, being the body charged with the administration of the law relating to controlled drugs for medical use hereby certify that it has approved the importation by:

- (a) Name, Address and business of importer
.....
.....
- (b) Exact description and amount of drugs to be imported.
.....
.....
- (c) Name and Address of firm in exporting country from which the drugs are to be obtained.
.....
.....
- (d) State any special conditions to be observed, e.g. not to be imported through the post. Subject to the following conditions
.....
.....
.....
- (e) State, if possible, Customs Office through Which the goods will be imported.
.....
.....
- (f) State, if possible, the route to be followed
.....

by the goods.

(g) Period within which
the import is to be
effected.

I am satisfied that the consignment proposed to be imported is required: –

- (1) for legitimate purposes;
- (2) Solely for medical purposes

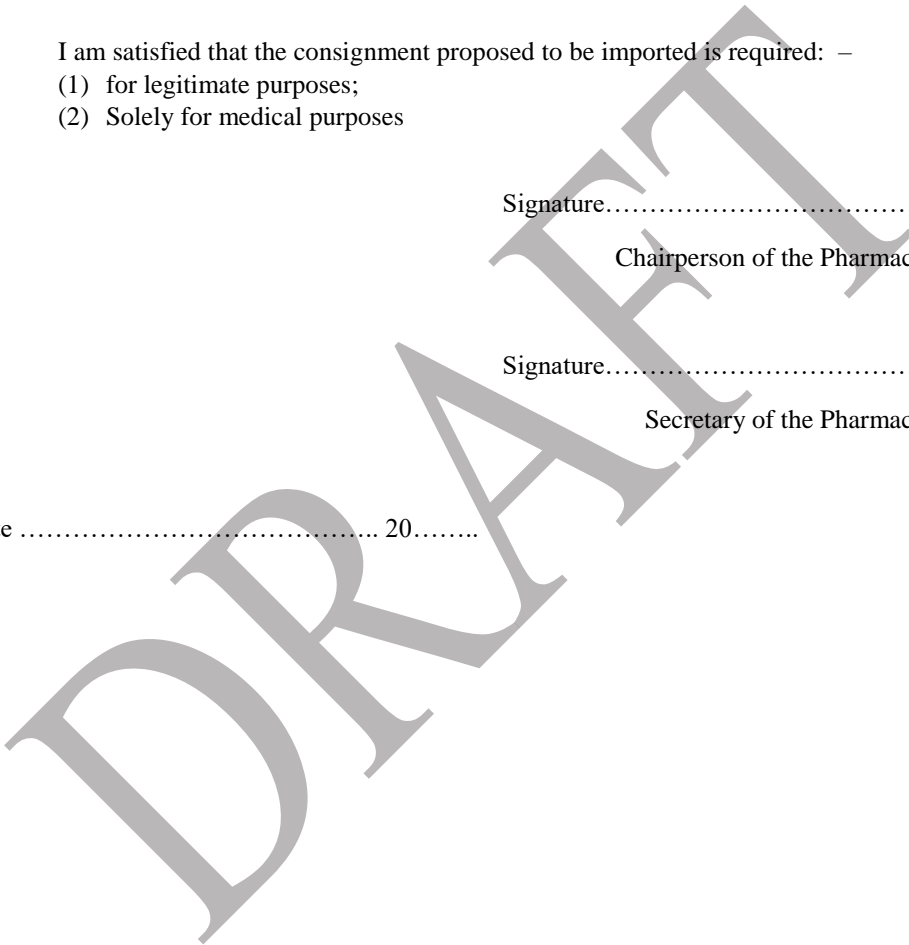
Signature.....

Chairperson of the Pharmacy Council

Signature.....

Secretary of the Pharmacy Council

Date 20.....



FORM B

ANTIGUA AND BARBUDA PHARMACY COUNCIL

THE PHARMACY ACT 2026

EXPORT LICENSE

ISSUED BY THE GOVERNMENT OF ANTIGUA AND BARBUDA

The Pharmacy Council, being the body charged with the administration of the law relating to controlled drugs for medical use hereby certify that it has approved the exportation by:

- (a) Name, Address and business of exporter
- (b) Exact description and amount of drugs to be exported.
- (c) Name and Address of firm in importing country at which the drugs are to be collected.
- (d) State any special conditions to be observed, e.g. not to be exported through the post. Subject to the following conditions
- (e) State, if possible, Customs Office through which the goods will be exported.
- (f) State, if possible, the route to be followed by the goods.

(g) Period within which
 the export is to be
 effected.

I am satisfied that the consignment proposed to be exported is required: –

- (1) for legitimate purposes;
- (2) solely for medical purposes.

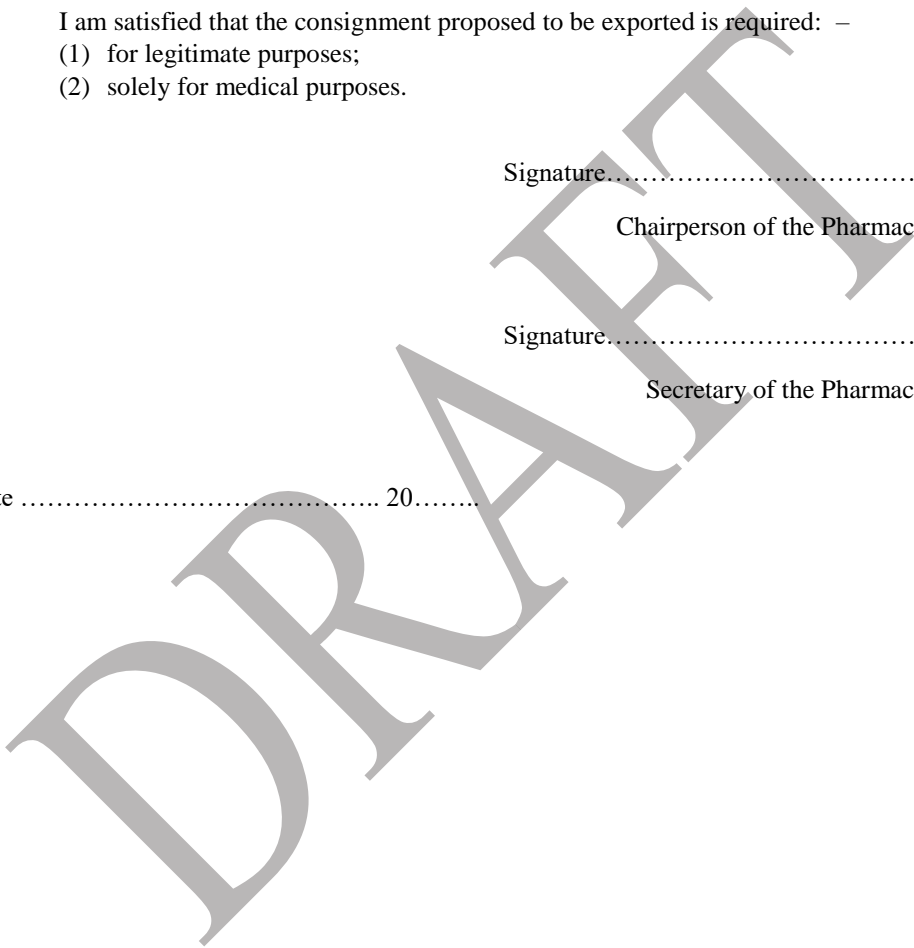
Signature.....

Chairperson of the Pharmacy Council

Signature.....

Secretary of the Pharmacy Council

Date 20.....



SCHEDULE 6

FORM A

ANTIGUA AND BARBUDA

THE PHARMACY ACT 2026

ANTIGUA AND BARBUDA PHARMACY COUNCIL

(Section 42)

**APPLICATION FORM FOR SINGLE USE
LICENSE TO IMPORT PHARMACEUTICALS**

Institution or Entity, or Individual Information

Name

(Block Letters)

Address

(Block letters)

Date of incorporation

Telephone number

Date of Application

Generic Name of Drug to be imported

.....

Dosage form

Strength

Quantity requested

Manufacturer

Country of Origin

Name and Address of the exporting company

.....

A declaration that the drug(s) are/is not available in Antigua and Barbuda

.....

.....

.....

.....

.....

NB: For an individual:

- a. a prescription must be attached to the application.
- b. If permission is granted, the maximum quantity that will be allowed is three months for personal use.

NB: The Chief Drug Inspector may request additional information to support your application.

.....

Signature of Applicant

