ANTIGUA AND BARBUDA

THE PHARMACY (AMENDMEANT) ACT, 2019

No. 13 of 2019

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ANTIGUA AND BARBUDA

THE PHARMACY (AMENDMENT) ACT, 2019

ARRANGEMENT OF SECTIONS

SECTIONS

[L.S.]

I Assent,

Hayden Thomas,
Governor-General's Deputy.

31st October, 2019.

ANTIGUA AND BARBUDA

THE PHARMACY (AMENDMENT) ACT, 2019

NO. 13 OF 2019

AN ACT to amend the Pharmacy Act, 1995, No. 11 of 1995 and for incidental and connected purposes.

ENACTED by the Parliament of Antigua and Barbuda as follows:

1. Short title and commencement

(1) This Act may be cited as the Pharmacy (Amendment) Act, 2019.

(2) This Act shall take effect as from the 1st day of November 2019.

2. Interpretation

In this Act—

"principal Act" means the Pharmacy Act, 1995, No. 11 of 1995.

3. Amendment of section 2 – Interpretation

The principal Act is amended in section 2 by repealing the definition of the term "wholesale pharmaceutical business" and replacing it as follows –

"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 .

4. Amendment of section 3 – Establishment and constitution of the Council

Section 3 of the principal Act is amended in subsection (2) by repealing the words "Director of Pharmacy" and replacing these words with the words "Director of Pharmaceutical Services"

5. Amendment of section 4 – Functions of the Council

The principal Act is amended in subsection (1) of section 4 by –

(i) repealing paragraph *(b)* and replacing it as follows –

"(b) to examine and approve the curriculum relating to pharmacy education in Antigua and Barbuda and to decide on matters relating to the qualification and examination of persons qualified as pharmacist, pharmacy technicians or pharmacy students;"

(ii) repealing paragraph *(f)* and replacing it as follows –

"*(f)* 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"

6. Insertion of new section 7A – Qualification for registration as a Pharmacy technician

The principal Act is amended by inserting immediately after section 7 the following new section 7A as follows –

"7A. 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 years of age.**"**

7. Insertion of new section 8A – Temporary registration as a Pharmacist

The principal Act is amended by inserting immediately after section 8 the following new section 8A as follows –

"8A. Temporary registration as a Pharmacist

(1) A person shall, as part of a team of visiting medical professionals or other overseas mission to Antigua and Barbuda, be registered and granted a temporary license to practice as a Pharmacist.

(2) An application for temporary registration as a Pharmacist must be made in writing to the Council no later than 45 days prior to the arrival of the applicant in Antigua and Barbuda and must be accompanied by the documents specified in section 8.

(3) If the Council is satisfied that the applicant meets the requirements of this Act and the regulations issued hereunder, the Council shall on receipt of payment of the prescribed fee, issue the applicant with a 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 granting of the licence.**"**

8. Amendment of section 11 – Practicing pharmacy without a licence

Section 11 of the principal Act is amended by repealing subsection (2) and replacing it as follows –

"(2) A person who contravenes this section commits an offence and is liable on summary conviction to a fine of twenty thousand dollars or to 2 years imprisonment or to both such fine and imprisonment."

9. Amendment of section 12 – Procedure for licensing premises

Section 12 of the principal Act is repealed and replaced as follows –

"12. Procedure for licensing premises

(1) No premises shall be used or be permitted to be used to operate as a pharmacy or wholesale pharmaceutical business unless such premises have been approved by the Minister and licensed as having met the requirements of this section.

(2) Every application for a licence to operate a pharmacy or a wholesale pharmaceutical business on any premises shall –

(a) be in the prescribed form;

(b) be accompanied by –

(i) the prescribed application fee; and

(ii) a non-refundable inspection fee of three hundred ($300.) dollars

(3) Where the premises to be licensed as a pharmacy or wholesale pharmaceutical business is also used for any other business activity, the pharmacy or wholesale pharmaceutical business 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.

(4) 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 2.

(5) No licence shall be granted in respect of any premises to be used for a pharmacy or a wholesale pharmaceutical business unless there is submitted with the application for a licence –

(a) proof that the pharmacy or wholesale pharmaceutical business has in its employ a registered pharmacist for the purpose of dispensing, managing and controlling all drugs and poisons;

(b) a declaration by the owner or operator of the pharmacy or wholesale pharmaceutical business that the premises to be licenced is one of not more than two pharmacies or wholesale pharmaceutical businesses under the management, control or supervision of the registered pharmacist referred to in paragraph *(a)*;

(c) an undertaking by the owner or operator of the pharmacy or wholesale pharmaceutical business that in the event that the registered pharmacist is no

longer in the employ of the pharmacy or wholesale pharmaceutical business, the owner or operator of the pharmacy or wholesale pharmaceutical business 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.

(6) 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 Minister stating whether the requirements of this Act have been complied with.

(7) The Minister may, after considering the report, approve or refuse the application for a licence.

(8) Where the Minister refuses to approve an application, he shall give reasons for so refusing.**"**

10. Amendment of section 14 – Prohibition of unlicensed premises as pharmacy

Section 14 of the principal Act is amended by repealing subsection (3) and replacing it as follows –

"(3) A person who fails to comply with this section commits an offence and is liable on summary conviction to a fine of four thousand dollars or to imprisonment for 12 months or to both such fine and imprisonment."

11. Amendment of section 15 – Cancellation and suspension of licence

Section 15 of the principal Act is repealed and replaced as follows –

"15. Cancellation and suspension of licence

(1) The Minister may, on the advice of the Council, 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;

(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 or the regulations made under this Act;

(d) there is no registered pharmacist associated with the pharmacy or wholesale pharmaceutical business, or the registered pharmacist on record with the Council as having the management, control or supervision of the pharmacy or wholesale pharmaceutical business is no longer in the employ of the pharmacy or wholesale pharmaceutical business and the name and particulars of a replacement registered pharmacist has not been provided to the Council; or

(e) the owner, operator or registered pharmacist of the pharmacy or wholesale pharmaceutical business is operating the pharmacy or wholesale pharmaceutical business in contravention of the provisions of this Act or the regulations made under this Act."

(2) Where a licensed premises has ceased to be used as a pharmacy, 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 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 days of the service of the notice of cancellation or suspension on him, 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.

12. Amendment of section 16 – Constitution and functions of the Board of Inspectors

Section 16 of the principal Act is amended by repealing subsection (1) and replacing it as follows –

"(1) The Minister may, after consultation with the Council, constitute a Board of Inspectors which shall consist of the Director of Pharmaceutical Services or his representative and any number of registered pharmacists to meet the national needs."

13. Repeal and replacement of section 18

Section 18 of the principal Act is repealed and replaced with the following –

"18. Sale, importation, exportation, possession etc. of drugs

"(1) No person shall import, export, sell, distribute, compound, or have in his possession with intent to distribute or dispense by wholesale or retail any drug unless –

(a) the selling, compounding or dispensing by retail is carried out by a registered pharmacist and on premises registered under section 13 of this Act;

(b) the selling by wholesale is effected under the control or supervision of a registered pharmacist;

(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 19 and 20;

(2) 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.

(3) No person shall import, export, sell, distribute, compound, or have in his possession with intent to distribute or dispense by wholesale or retail any drug or medical supply except the labelling of the drug or medical supply is in accordance with the National Standard for the Labelling of Pharmaceuticals as set out in Schedule 3."

14. Amendment of section 19 – Sale, possession and distribution of poison

Section 19 of the principal Act is amended by inserting after subsection (7) a new subsection (8) as follows –

"(8) A person shall not 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 3"

15. Insertion of new section 20A – Disposal of expired, unused, damaged or cytotoxic pharmaceuticals and poisons

The principal Act is amended by inserting immediately after section 20 a new section 20A to read as follows –

"20A. Disposal of expired, unused, damaged or cytotoxic pharmaceuticals and poisons

(1) A person shall not dispose of expired, unused, damaged or cytotoxic pharmaceuticals or poisons except in accordance with the provisions of this section.

(2) A person who intends to dispose of expired, unused, damaged or cytotoxic pharmaceuticals or poisons shall give written notice to the Director of Pharmaceutical Services of his intention not less than 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 millilitre or otherwise.

(4) A copy of the list referred to in subsection (2) shall be provided to the Chief Health Inspector, who will identify the disposal site based on the disposal specification provided by the Director of Pharmaceutical Services.

(5) A copy of the disposal certificate shall be provided to the Director of Pharmaceutical Services within 5 days of the disposal of the expired, unused, damaged or cytotoxic pharmaceuticals or drugs."

16. Amendment of section 27 – Offences

Section 27 of the principal Act is amended as follows –

(a) in paragraph *(e)* thereof

(i) by removing the full stop at the end of sub-paragraph (iv) and replacing this with a semi-colon;

(ii) by inserting immediately after sub-paragraph (iv) a new sub-paragraph (v) to read as follows –

"(v) makes a false declaration in any application or other document submitted to the Council or the Registrar."

(b) by repealing paragraph *(g)* and replacing it as follows –

"(g) contravenes a provision of this Act or of the regulations for which no specific penalty is provided,"

17. Amendment of Schedule 1 to the principal Act

Schedule 1 to the principal Act is amended by replacing the words "Chief Pharmacist" with the words "Director of Pharmaceutical Services"

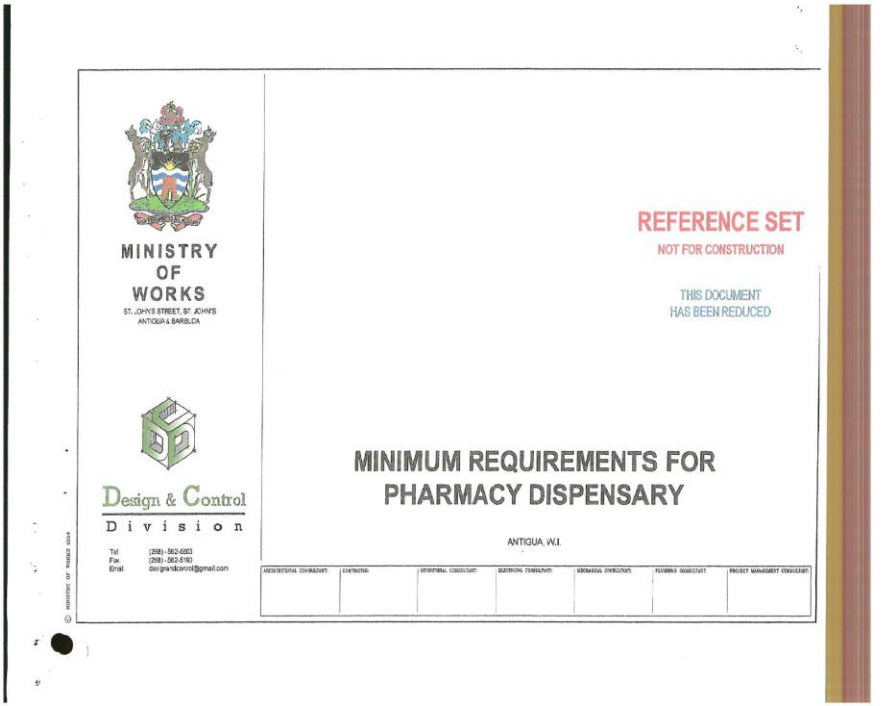
18. Amendment of the principal Act - Insertion of Schedules 2 and 3 into the principal Act

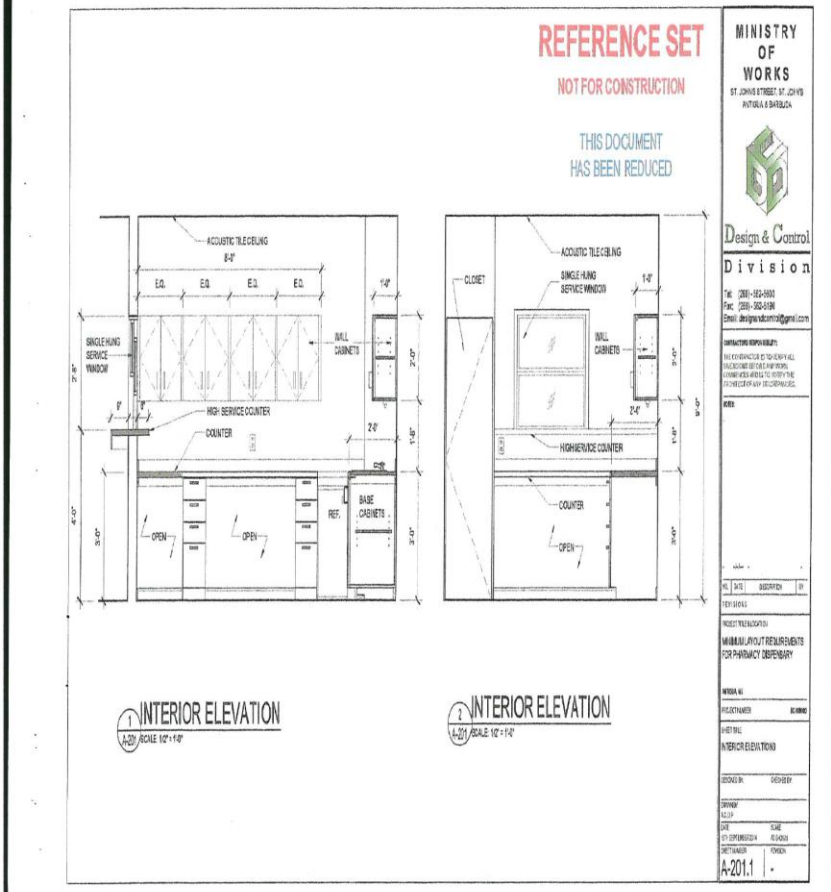
The principal Act is amended by inserting two new Schedules marked Schedule 2 and Schedule 3 as follows –

SCHEDULE 2

MINIMUM REQUIREMENTS FOR PHARMACY DISPENSARY

(Section 12(4))

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Design & Control
Division
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SERVICE WINDOW
WALL
CABINETS
HIGH SERVICE COUNTER
COUNTER
BASE
CABINETS
REF.
OPEN
CLOSET
HIGH SERVICE COUNTER
INTERIOR ELEVATION
SCALE: 1/2" = 1'-0"
INTERIOR ELEVATION
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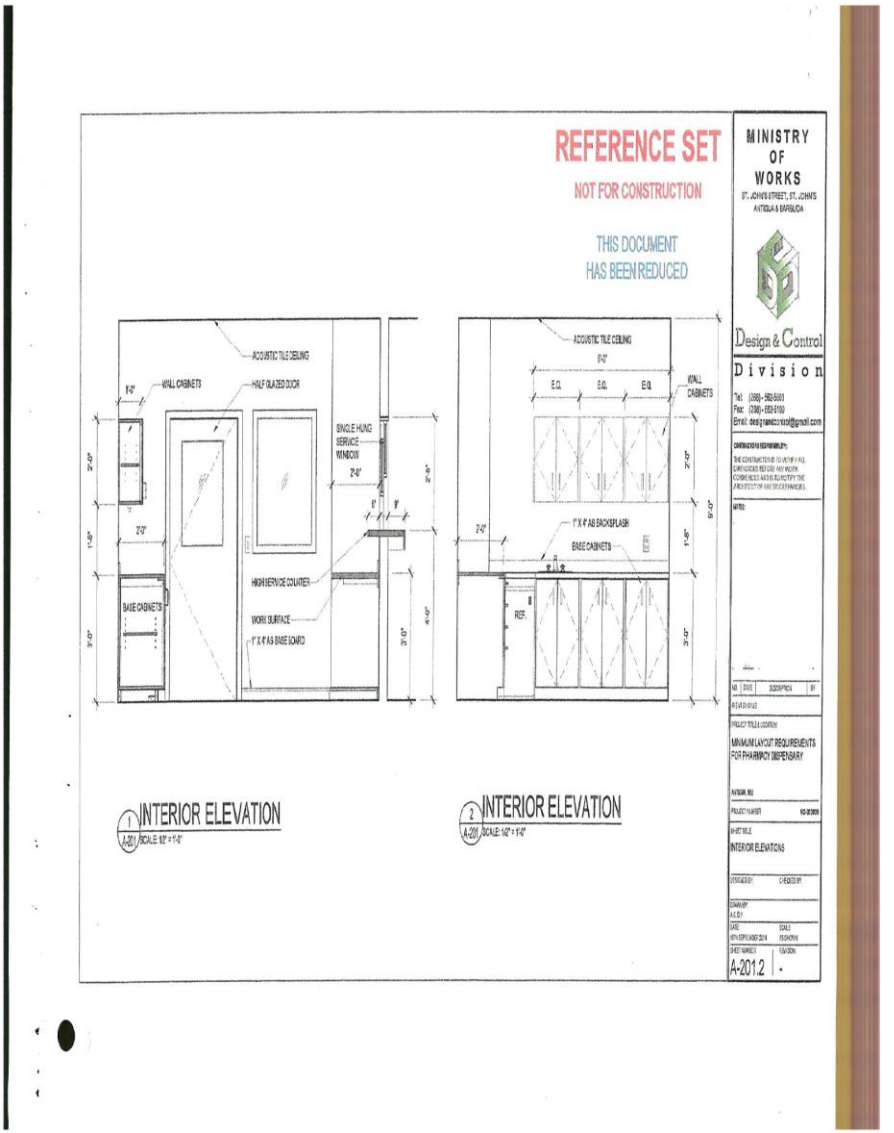
MINIMUM LAYOUT REQUIREMENTS
FOR PHARMACY DISPENSARY
A-201.1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BASE CABINETS
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REF.
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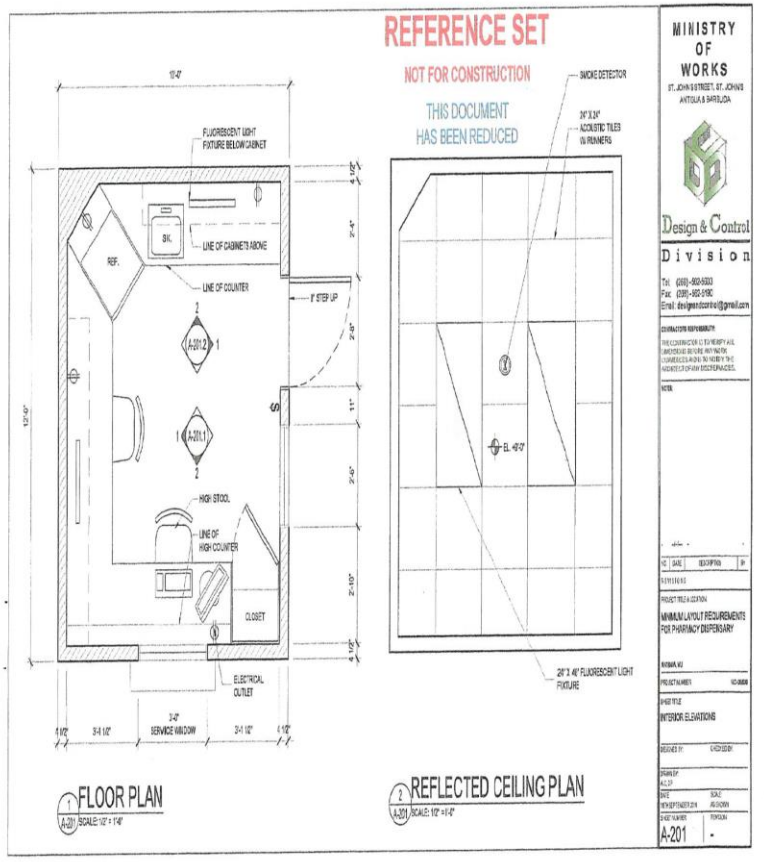
A-201 SCALE: 1/2" = 1'-0"
2 INTERIOR ELEVATION
A-201 SCALE: 1/2" = 1'-0"
MINISTRY OF WORKS
ST. JOHN'S STREET, ST. JOHN'S
ANTIGUA & BARBUDA
Design & Control
Division
MINIMUM LAYOUT REQUIREMENTS FOR PHARMACY DISPENSARY
INTERIOR ELEVATIONS
A-201.2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LINE OF CABINETS ABOVE
LINE OF COUNTER
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LINE OF HIGH COUNTER
CLOSET
ELECTRICAL OUTLET
SERVICE WINDOW
SMOKE DETECTOR
ACOUSTIC TILES
EL. -9'-0"
2'-0" X 4'-0" FLUORESCENT LIGHT FIXTURE
1 FLOOR PLAN
SCALE: 1/2" = 1'-0"
2 REFLECTED CEILING PLAN
SCALE: 1/2" = 1'-0"
MINISTRY OF WORKS
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Design & Control
Division
MINIMUM LAYOUT REQUIREMENTS FOR PHARMACY DISPENSARY
INTERIOR ELEVATIONS
A-201

SCHEDULE 3

NATIONAL STANDARD FOR LABELLING OF PHARMACEUTICALS

(Sections 18 and 19)

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. 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.

— Any article other than food intended to affect the structure of any function of the body of man or animal

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

2.4 Inner label means the label on or affixed to an immediate package or container of the drug.

2.5 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.

2.6 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, weather corporate or incorporate.

2.7 Repacking entity refers to a company which under license by a manufacturer repackages a drug for distribution or sale.

2.8 Product license holder refers to a company which manufactures and or package a drug under license for the product patent holder.

2.9 Package includes anything in which any drug is wholly contained, placed or packed.

2.10 Legible mean that the written matter can be read and understood without difficulty under the conditions in which the label is normally displaced to a consumer.

3. Labelling Requirements

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

3.1.1. Main 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 Date of manufacture

(g) Manufacturing standard

(h) 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

(i) Indication *(s)* and recommended dosage and dosage interval

(J) Handling and Storage conditions

3.1.2 Inner panel:

(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 trade mark

(l) Handling and Storage conditions

(m) Any special precautions for the disposal of any unused drug or waste material derived from the drug

3.1.3 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.

3.1.4 The labelling requirements specified in this standard shall be in the English language on the main display panel, but may include other languages.

3.1.5 Its is the responsibility of any person who sells or distributes any drugs to ensure that they are labelled as required by this standard.

4. Approval of Labels

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

Passed the House of Representatives on the 23rd day of July, 2019.

Gerald Watt, Q.C,
Speaker.

A. Peters,
Acting Clerk to the House of Representatives.

Passed the Senate on the 31st day of July, 2019.

Alincia Williams Grant,
President.

A. Peters,
Acting Clerk to the Senate.