

PHARMACY

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Pharmacy Act 2025

TABLE OF AMENDMENTS

The Pharmacy Act 2025 No 34 was certified and commenced on 29 August 2025.

Amending Legislation	Certified	Date of Commencement
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An Act to provide for the registration of pharmacists, the registration of pharmacies, the regulation of the practice of pharmacy and for related purposes.

Enacted by the Parliament of Nauru as follows:

PART 1 — PRELIMINARY

1 Short title

This Act may be cited as the *Pharmacy Act 2025*.

2 Commencement

This Act commences on the date it is certified by the Speaker.

3 Interpretation

In this Act:

‘Board’ means the Pharmacy Board established under Section 7;

‘Chairperson’ means the chairperson of the Board;

‘dispense’, in relation to a medicinal product, includes:

- (a) the supply of a medicinal product in accordance with a prescription;
- (b) the preparation of a medicinal product for supply or sale to the public, whether in response to the issue of a prescription or a request by an individual to be supplied with the medicinal product; or
- (c) the packaging, labelling, recording and delivery of a medicinal product;

‘International Non-proprietary Name’ means the generic name of a medicinal product;

‘medicinal product’ means any substance whether of animal, plant or synthetic origin, which is used internally or externally and includes any substance or mixture of substances manufactured, sold or represented for use for:

- (a) diagnosing, preventing, alleviating or curing an ailment, injury, defect or disease;
- (b) restoring, correcting or modifying organic functions;
- (c) testing susceptibility to a disease or ailment; or
- (d) the diagnosis, treatment, mitigation or prevention of a disease or mental or physical impairment, or the symptoms of the disease or impairment;

‘member’ means a member of the Board;

‘Minister’ means the Minister for Health and Medical Services;

‘narcotic drugs and psychotropic substances’ means substances whether natural or synthetic, listed in the *United Nations Single Convention of Narcotic Drugs 1961* and in the *United Nations Convention on Psychotropic Substances 1971*;

‘Nauru Customs Service’ means the office established under Section 4(1) of the *Customs Act 2014*;

'pharmaceutical product' means a product sold or supplied by a pharmacy, which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means, and includes:

- (a) any substance or combination of substances:
 - (i) presented as having properties for treating or preventing a disease; or
 - (ii) which may be used for the treatment or prevention of a disease by medical diagnosis or by modifying, restoring or correcting physiological functions by exerting a pharmacological, immunological or metabolic action;
- (b) a product which the average person considers as cosmetic, beauty and skin care, sunscreen, toothpaste, deodorant and anti-perspirant, or a hair styling or hair colouring product; and
- (c) a medical device generally known as any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article intended by the manufacturer to be used alone or in combination, for human beings for any of the following purposes:
 - (i) diagnosis, prevention, monitoring, treatment or alleviation of a disease;
 - (ii) diagnosis, monitoring, treatment or alleviation of, or compensation for, an injury;
 - (iii) investigation, replacement, modification or support of the anatomy or of a physiological process;
 - (iv) supporting or sustaining life;
 - (v) control of conception including contraception;
 - (vi) disinfection of medical devices; or
 - (vii) providing information for medical purposes through in vitro examination of specimens derived from the human body;

'pharmacist' means a person who is registered for the practice of pharmacy under this Act;

'pharmacy' means any approved premises in which any service pertaining to the practice of pharmacy is provided;

'pharmacy licence' means a licence issued under Section 26;

'practice of pharmacy' includes:

- (a) compounding and dispensing of prescription medicinal products;
- (b) supply of a medicinal product by a pharmacist to suit the needs of a particular person;
- (c) sale of prescription medicinal products;
- (d) preparing or breaking up a manufacturer's original package of medicinal products for the purpose of repackaging the medicinal product in larger or smaller quantities for distribution or sale; or
- (e) importation, storage, retail or wholesale supply of medicinal products;

'prescription' means a written instruction by a practising health practitioner listed in Schedule 1 to a pharmacist to dispense a particular medicinal product at a particular quantity with directions to the patient on the means, frequency and duration of the taking of the medicinal product, which shall be printed on a label by the pharmacist;

‘restricted medicine’ or *‘restricted medicinal product’* means a medicine or medicinal product that:

- (a) may be purchased from a pharmacist without a prescription;
- (b) is not available for self-selection from a pharmacy;
- (c) is kept behind a counter or in the dispensary; and
- (d) is sold by a pharmacist;

‘RON Hospital’ means the Republic of Nauru Hospital; and

‘Secretary’ means the Secretary for Health and Medical Services.

4 Objectives

The objectives of this Act are to:

- (a) provide for the registration of pharmacists;
- (b) provide for the registration of pharmacies;
- (c) provide for the standards required for pharmacy premises;
- (d) provide for the importation of medicinal products;
- (e) provide for the standards of medicinal products to be imported, sold or supplied in the Republic;
- (f) provide for the supply of medicinal products by pharmacies; and
- (g) ensure primary and secondary availability of prescription and non-prescription medicinal products in the Republic apart from the Government pharmacy.

[The next page is 990,501]

PART 2 — ADMINISTRATION

5 Functions and responsibilities of the Secretary

The Secretary shall:

- (a) register pharmacists on the recommendation of the Board;
- (b) maintain a register of pharmacists;
- (c) issue licences for the practice of pharmacy;
- (d) maintain a register of licensed pharmacies;
- (e) keep and maintain a register of all approved medicinal products for prescription and non-prescription medicinal products;
- (f) carry out or cause to be carried out, inspections of pharmacies;
- (g) facilitate the receipt of complaints in relation to the practice of pharmacy;
and
- (h) do all other things as may be necessary or convenient to achieve the objectives of this Act.

6 Powers of the Secretary

The Secretary shall have the power to do all things necessary or convenient to be done for the performance of his or her functions under this Act.

[The next page is 990,701]

PART 3 — PHARMACY BOARD

7 Pharmacy Board

- (1) The Pharmacy Board is established.
- (2) The Board consists of the following members:
 - (a) the Secretary who shall be the Chairperson;
 - (b) the Director of Medical Services or with the concurrence of the Minister the Director may nominate a health practitioner employed by the RON Hospital;
 - (c) a Government pharmacist; and
 - (d) a member of the community appointed by the Minister.
- (3) The Minister shall, on the recommendation of the Board, appoint the secretary to the Board.
- (4) The secretary to the Board shall perform all the functions, duties and responsibilities that the Board may assign to him or her.
- (5) The member appointed under subsection (2)(d) shall:
 - (a) hold office for a term of 2 years; and
 - (b) be eligible for re-appointment.

8 Functions of the Board

The Board shall:

- (a) advise the Minister on matters relating to the practice of pharmacy;
- (b) regulate the practice of pharmacy;
- (c) develop a policy for the sale and supply of medicinal products;
- (d) establish, develop and maintain standards of knowledge, skill and professional ethics of persons involved in the practice of pharmacy;
- (e) consider complaints in relation to the practice of pharmacy referred to the Board by the Secretary;
- (f) monitor and enforce compliance with this Act; and
- (g) have other functions or duties which the Minister may from time to time assign to the Board.

9 Powers of the Board

The Board shall have the power to do all things necessary or convenient to be done for the performance of its functions under this Act or any other written law.

10 Meetings of the Board

- (1) Subject to this Act, the Board shall determine its own procedure for meetings.
- (2) The Board shall hold meetings at least 4 times in a year.
- (3) The Chairperson shall determine the time and place for any meeting of the Board and the secretary to the Board shall serve written notice of the meeting to all the members.
- (4) The quorum for a meeting of the Board shall be 3 members.
- (5) The Chairperson, or in his or her absence any member appointed by the Minister, shall preside at the meeting of the Board.

- (6) The decision of the majority of the members present at the meeting shall be the decision of the Board and where there is a tie in the number of votes, the Chairperson has a casting vote in addition to his or her deliberative vote.
- (7) The secretary to the Board shall maintain records of all the minutes and proceedings of the meetings.

11 Obligations of the members of the Board

- (1) The members shall severally and jointly at all times:
 - (a) act *bona fide* in the best interests of the practice of pharmacy and carry out the objectives of this Act;
 - (b) exercise reasonable care and diligence in the performance of their responsibilities, duties and functions;
 - (c) take reasonable steps through the processes of the Board to obtain sufficient information and advice about all matters to be decided by the Board to enable them to make conscientious and informed decisions; and
 - (d) exercise discretion with respect to all matters to be decided by the Board.
- (2) A member does not breach this Section by acting in accordance with a direction or requirement of the Minister under this Act.

12 Vacation of office

- (1) The office of a member becomes vacant:
 - (a) on the expiry of the term of the office of the member;
 - (b) on the death of the member;
 - (c) on the resignation of the member;
 - (d) where the member is adjudged bankrupt;
 - (e) where the member fails to perform his or her duties under this Act;
 - (f) on the removal of the member from office under subsection (2);
 - (g) where the member is absent from 3 consecutive meetings of the Board except on leave granted by the Chairperson;
 - (h) where the member is nominated to be a candidate in an election for the Parliament or elected as a member of the Parliament; or
 - (i) where a member is convicted of a criminal offence.
- (2) The Minister may remove a member from office if the member is considered by a board of not less than 2 health practitioners, appointed by the Minister, to be incapable of performing his or her responsibilities and duties efficiently.
- (3) A vacancy in the office of a member shall not affect the validity of the proceedings or decisions of the Board.
- (4) Where a vacancy occurs, the Chairperson shall, as soon as practicable, inform the Minister in writing of the vacancy so that it can be filled in accordance with this Act.

13 Remuneration of the Board

A member is not entitled to a fixed remuneration but may be paid reasonable allowance as may be determined by the Minister.

14 Disclosure of interest

- (1) Where a member has any interest relating to a matter before the Board including any pharmacist or the practice of pharmacy, the member shall disclose the details of his or her interest as soon as practicable after the member becomes aware that he or she has an interest.
- (2) The disclosure shall be recorded in the minutes of the meeting of the Board and the member shall:
 - (a) after the disclosure, not take part in any deliberation or decision-making of the Board in respect of that matter; and
 - (b) be disregarded for the purposes of constituting a quorum of the Board in that deliberation or decision.

[The next page is 990,901]

PART 4 — REGISTRATION OF PHARMACIST

15 Application to register as a pharmacist

- (1) A person is eligible to be registered as a pharmacist if he or she:
 - (a) holds the prescribed qualifications; and
 - (b) is registered as a pharmacist in a country specified in Schedule 2.
- (2) The Minister may amend Schedule 2 by order notified in the Gazette.
- (3) An application for registration as a pharmacist shall be:
 - (a) made in the prescribed form;
 - (b) accompanied by prescribed particulars;
 - (c) accompanied by evidence of payment of the prescribed fee; and
 - (d) made to the Secretary.

16 Decision on application for registration as pharmacist

- (1) Subject to subsection (2), upon receipt of an application under Section 15, the Secretary shall refer the application to the Board for its consideration.
- (2) The Board shall consider each application and within 30 days from date the application is made under Section 15, the Board shall:
 - (a) register the applicant as a pharmacist and issue a certificate of registration to the applicant; or
 - (b) refuse to register the applicant as a pharmacist.
- (3) Where the Board refuses to register the applicant as a pharmacist, the Board shall notify the applicant in writing of the decision.

17 Practising certificate

- (1) Upon payment of the prescribed fee, the Board shall grant a practising certificate to a registered pharmacist.
- (2) A practising certificate is valid for 12 months.

18 Renewal of practising certificate

- (1) A registered pharmacist shall apply for renewal of his or her practising certificate before the expiration of the practising certificate.
- (2) An application for renewal shall be:
 - (a) made in the prescribed form;
 - (b) accompanied by prescribed particulars;
 - (c) accompanied by evidence of payment of the prescribed fee; and
 - (d) made to the Secretary.
- (3) Upon receipt of an application for renewal under subsection (1), the Secretary shall refer the application for renewal to the Board for its consideration.
- (4) The Board shall consider each application for renewal and upon being satisfied that a pharmacist has been practising in accordance with this Act, the Board shall renew the practising certificate.

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- (5) A practising certificate may only be renewed for a period of 12 months from the date of expiry of the previous practising certificate.

[The next page is 991,001]

PART 5 — COMPLAINTS AGAINST PHARMACIST

19 Complaints against pharmacist

- (1) A person may make a complaint in writing to the Board against a pharmacist for his or her professional conduct.
- (2) The Board shall conduct its investigation and consider and determine the complaint.

20 Dealing with complaints

- (1) The Board may decide at any time in relation to a complaint to:
 - (a) decline to deal with, or dismiss the complaint where the complaint lacks any merit;
 - (b) deal with the complaint at a meeting of the Board; or
 - (c) inquire into the complaint.
- (2) Subject to subsection (3), the Board may determine its own procedures for the purposes of subsection (1).
- (3) The Board shall comply with the rules of natural justice in dealing with a complaint.

21 Decision of the Board on complaints

Where the Board considers that there is merit in a complaint against a pharmacist, it shall:

- (a) caution or reprimand the pharmacist;
- (b) impose conditions on the pharmacist's registration as it deems appropriate;
- (c) require the pharmacist to complete an educational course or training;
- (d) direct the pharmacist to provide reports on the pharmacist's pharmacy practice in the manner specified by the Board;
- (e) order the pharmacist to seek counselling or medical or psychiatric treatment;
- (f) impose a penalty not exceeding \$1,000 on the pharmacist, which shall be paid into the Treasury Fund;
- (g) order that the pharmacist's registration be suspended for a period not exceeding 12 months; or
- (h) order that the pharmacist's name be removed from the register of pharmacists.

[The next page is 991,201]

PART 6 — LICENCE TO OPERATE A PHARMACY

22 Registered pharmacist to have overall responsibility for pharmacy

A registered pharmacist shall be responsible for the day-to-day management, operation and conduct of the business of a pharmacy.

23 Licence to operate a pharmacy

A registered pharmacist may apply to the Board for a pharmacy licence if:

- (a) the pharmacist is the owner of the pharmacy; or
- (b) the pharmacist is employed by the owner of the pharmacy who is not a pharmacist or is not managing the operation of the pharmacy.

24 Application for pharmacy licence

- (1) An application for a pharmacy licence shall be:
 - (a) in the prescribed form;
 - (b) accompanied by a:
 - (i) certificate of business registration issued under the *Business Names Registration Act 2018*;
 - (ii) business licence issued under the *Business Licences Act 2017*;
 - (iii) in the case of a corporation, certificate of incorporation issued under the *Corporations Act 1972*; and
 - (iv) in the case of partnership, certificate of registration of a partnership issued under the *Partnership Act 2018*;
 - (c) accompanied by a copy of the certificate of registration of the pharmacist in charge;
 - (d) accompanied by a valid practising certificate of the pharmacist in charge of the pharmacy; and
 - (e) accompanied by evidence of payment of the prescribed fee.
- (2) The Board may require the applicant to provide additional information as the Board reasonably requires to decide the application.
- (3) Any information required under subsection (2) shall be provided:
 - (a) in writing; and
 - (b) within the specified time.

25 Requirements for pharmacy premises

- (1) A pharmacy premises shall comply with the requirements of this Act and any other written law.
- (2) A pharmacy shall have:
 - (a) at least one doorway allowing direct public access to the premises;
 - (b) secure doors and windows;
 - (c) a secure roof;
 - (d) a secure area for the safekeeping of dangerous drugs or poisonous chemicals accessible only to a pharmacist and authorised persons;
 - (e) a refrigerator suitable for the storage of medicinal products at appropriate temperatures;

- (f) a fireproof area for keeping inflammable medicinal products or any substances required for the preparation of medicinal products;
 - (g) an area where only pharmacists are allowed to enter with a self-closing door with a notice displayed conspicuously stating “entry restricted to pharmacists only”; and
 - (h) a dispensing area.
- (3) The dispensing area referred to in subsection (2)(h) shall:
- (a) have adequate lighting and ventilation;
 - (b) have adequate heating facilities for dispensing and compounding medicinal products;
 - (c) be equipped with a non-crossable sink, supplied with available hot and cold distilled running water; and
 - (d) have a dispensing bench that is at least 40 centimetres wide, and of sufficient length to provide not less than 1 square metre of free working space, with an impervious covering.
- (4) The Minister may prescribe other requirements as may be necessary.

26 Decision on application

- (1) The Board shall consider each application made and inform the applicant of its decision within 30 days from the date the application is made.
- (2) Subject to Section 24(2), the Board may, on receipt of an application:
- (a) issue a pharmacy licence; or
 - (b) refuse to issue a pharmacy licence.
- (3) Where the Board refuses to issue a pharmacy licence, the Board shall notify the applicant in writing of its decision and the reasons for such refusal.

27 Conditions of pharmacy licence

A pharmacy licence is subject to the following conditions:

- (a) the licensee shall comply with all written laws; and
- (b) any other conditions that are specified in the licence or which may be prescribed.

28 Particulars to be provided in the pharmacy licence

- (1) For the purposes of this Act, the Board shall issue a pharmacy licence, with or without any conditions.
- (2) The pharmacy licence shall state the following:
- (a) name of pharmacy;
 - (b) location of pharmacy premises;
 - (c) name of owner of pharmacy;
 - (d) name of pharmacist in charge;
 - (e) category of practice of pharmacist in charge;
 - (f) registration number of pharmacist in charge;
 - (g) trading hours of the pharmacy;
 - (h) date of issue of the pharmacy licence;
 - (i) date of expiry of the pharmacy licence;
 - (j) conditions of the pharmacy licence; and
 - (k) name and signature of the Chairperson.
- (3) The pharmacy licence shall be valid for a period of 12 months from the date on which it is issued unless earlier suspended or cancelled by the Board.

29 Pharmacy licence to be displayed

- (1) A pharmacy licence issued to a pharmacy shall be displayed in a conspicuous place in the pharmacy premises.
- (2) A person who contravenes subsection (1):
 - (a) is liable to pay a fixed penalty of \$1,000; and
 - (b) shall pay the fixed penalty within 7 days after the fixed penalty notice is served on the person by an authorised officer.
- (3) A person who contravenes subsection (2) commits an offence and upon conviction is liable to a fine not exceeding \$5,000 or a term of imprisonment not exceeding 6 months or both.

30 Renewal of pharmacy licence

- (1) A registered pharmacist may apply to the Secretary for renewal of a pharmacy licence if:
 - (a) the pharmacist is the owner of the pharmacy; or
 - (b) the pharmacist is employed by the owner of the pharmacy who is not a pharmacist or is not managing the operation of the pharmacy.
- (2) An application for renewal shall be made in accordance with Section 24(1).
- (3) The Secretary shall, on receipt of an application for renewal, refer the application to the Board for its consideration and decision.
- (4) The Board shall, on receipt of the application and being satisfied that a pharmacy has been operating in accordance with this Act, renew the pharmacy licence.
- (5) A pharmacy licence shall only be renewed for a period of 12 months from the date of expiry of the previous pharmacy licence.
- (6) Where the owner or pharmacist in charge of the pharmacy fails to renew the pharmacy licence before expiry, the owner or pharmacist in charge of the pharmacy shall cease the operation of the pharmacy the day immediately after the date of expiry of the pharmacy licence.

31 Variation of conditions of pharmacy licence

- (1) The Board may at any time vary the conditions of a pharmacy licence on:
 - (a) a written application of the owner of the pharmacy;
 - (b) a written application of the pharmacist in charge of the pharmacy; or
 - (c) its own motion.
- (2) For the purposes of subsection (1)(c), the Board shall consider any representation made by the owner or pharmacist in charge of the pharmacy before varying any pharmacy licence conditions.
- (3) A variation of any condition of the pharmacy licence by the Board shall be endorsed on the pharmacy licence together with the date when it was made and the date the variation takes effect.

32 Suspension of pharmacy licence

- (1) The Board may suspend a pharmacy licence where the Board is of the opinion that:
 - (a) the pharmacy does not meet the requirements of the premises;
 - (b) the pharmacy is operating in breach of any of its pharmacy licence conditions; and

- (c) a suspension is necessary in the public interest.
- (2) Before making a decision under subsection (1), the Board shall by notice in writing:
 - (a) inform the owner or pharmacist in charge of the pharmacy of its intention to suspend the pharmacy licence;
 - (b) provide reasons for its intention to suspend the licence in the notice; and
 - (c) require the owner or pharmacist in charge of the pharmacy to show cause or prove that the licence should not be suspended, within 14 days after the notice is served on the owner or pharmacist in charge of the pharmacy.
- (3) The Board shall, on the day immediately after the 14-day period in subsection (2)(c):
 - (a) make a decision under subsection (1);
 - (b) provide reasons for the suspension in writing including any remedial action that is required to be taken by the owner or pharmacist in charge of the pharmacy; and
 - (c) serve the notice of the suspension to the owner or pharmacist in charge of the pharmacy.
- (4) Where the Board suspends the pharmacy licence, the pharmacy shall immediately cease all of its operations.
- (5) Where the owner or pharmacist in charge of the pharmacy fails to comply with the suspension notice or continues the operation of the pharmacy, the owner and pharmacist in charge of a pharmacy each commit an offence and upon conviction are each liable to a fine not exceeding \$10,000 or a term of imprisonment not exceeding 2 years or both.

33 Restoration of suspended pharmacy licence

- (1) The owner or pharmacist in charge of the pharmacy may apply for the restoration of the pharmacy licence, where a pharmacy whose licence has been suspended:
 - (a) for more than 3 months without any further proceedings or action by the Board; or
 - (b) has complied with the remedial action required to be undertaken under Section 32(3)(b) or rectified any matters for which the pharmacy licence was suspended.
- (2) Where the Board is satisfied with the application in subsection (1), it shall restore the pharmacy licence.
- (3) The pharmacy may continue to operate if the Board restores the pharmacy licence.

34 Cancellation of pharmacy licence

- (1) The Board shall cancel a pharmacy licence where:
 - (a) the owner or pharmacist in charge of the pharmacy fails to comply with any remedial action required to be undertaken under Section 32(3)(b);
 - (b) the pharmacy operates without a pharmacist in charge at any time;
 - (c) the pharmacy operates without a current or with an expired business licence; or

- (d) the pharmacist in charge of the pharmacy is being disciplined or deregistered from practising as a pharmacist.
- (2) The Board shall notify, and provide reasons in writing to, the owner or pharmacist in charge of the pharmacy for the cancellation of the licence within 5 working days after the licence is cancelled.
- (3) A pharmacy whose licence is cancelled under this Section shall immediately cease all of its operations on receipt of the notice under subsection (2).

35 Appeals

- (1) A holder of a licence cancelled under Section 34 may appeal the decision of the Board to the Minister.
- (2) An appeal shall be made with the office of the Minister:
 - (a) in writing; and
 - (b) within 14 days after the receipt of the reasons for the cancellation of the licence under Section 34(2).
- (3) The Minister shall provide his or her decision on the appeal in writing within 14 days after the appeal is made.

[The next page is 991,401]

PART 7 — REGISTER OF MEDICINAL PRODUCTS

36 Register of medicinal products

- (1) The Secretary shall establish a register of medicinal products which are approved for dispensation and use in the Republic.
- (2) The register of medicinal products shall be kept:
 - (a) in writing; and
 - (b) in digital or electronic form.
- (3) The register shall contain the following classes of medicinal products:
 - (a) Class A which may be sold or supplied from licensed retail businesses;
 - (b) Class B which may be sold or supplied from licensed pharmacies under the supervision of a pharmacist;
 - (c) Class C which are available only on prescription; and
 - (d) Class D which are narcotic drugs and psychotropic substances subject to special import controls.
- (4) For the purposes of subsection (3), the register of medicinal products may contain the following information:
 - (a) the brand name of the medicinal product;
 - (b) the International Non-proprietary Name of the medicinal product;
 - (c) the name of the manufacturer; and
 - (d) the country or place of manufacture.
- (5) The Secretary:
 - (a) may review the contents of the register of medicinal products annually; and
 - (b) shall publish the contents of the register of medicinal products in the Gazette in January and July of each year.
- (6) The classes of medicinal products contained in the register of medicinal products shall be prescribed by regulations.
- (7) Upon payment of the prescribed fees:
 - (a) the register of medicinal products shall be made available for inspection by a person during business hours; and
 - (b) certified copies of the entries in the register of medicinal products shall be provided to the person.

[The next page is 991,601]

PART 8 — IMPORTATION OF MEDICINAL PRODUCTS

37 Importation of medicinal products

- (1) Subject to subsections (2) and (3), a person shall not import for sale, supply or distribution a medicinal product contained in Class B, Class C and Class D in the register of medicinal products, unless the person obtains a permit under Section 38.
- (2) The Government pharmacy may import for sale, supply or distribution a medicinal product contained in Class B, Class C and Class D in the register of medicinal products without obtaining a permit under Section 38.
- (3) A person or the Government pharmacy, as the case may be, shall obtain from the Secretary a permit to import medicinal products before placing an order for importation of the medicinal products.
- (4) A person or the Government pharmacy, as the case may be, who intends to import medicinal products under this Act shall provide the following to the Nauru Customs Service:
 - (a) the permit issued under Section 38;
 - (b) certified copies of relevant documents issued by the national regulatory authority of the country from which the medicinal products are being imported;
 - (c) a batch certificate issued by the manufacturer;
 - (d) any other relevant documents relating to the medicinal products; and
 - (e) authorisation for the release of the medicinal products from the Secretary.

38 Application for permit to import

- (1) An application for a permit to import any medicinal product shall be made to the Secretary:
 - (a) in the prescribed form;
 - (b) accompanied by certified copies of relevant documents issued by the national regulatory authority of the country from which the medicinal products are being imported;
 - (c) accompanied by particulars of the medicinal products intended for import; and
 - (d) accompanied by evidence of payment of the prescribed fee.
- (2) The Secretary may require the applicant to provide any additional information as the Secretary deems necessary.
- (3) The Secretary shall consider each application and may issue or refuse to issue a permit to import.
- (4) Where the Secretary issues or refuses to issue a permit, the Secretary shall:
 - (a) notify the applicant in writing of the decision; and
 - (b) in the case of a refusal to issue a permit, provide reasons for the refusal.
- (5) A permit issued under this Section may be subject to:
 - (a) specific conditions to ensure the permit holder imports the medicinal products in accordance with any required or prescribed standards for transport, storage, security or display of the medicinal products;

- (b) conditions imposed by the Secretary to ensure the medicinal products conform to any standards which apply to the medicinal products; and
- (c) other conditions relating to the import of the medicinal products as the Secretary deems appropriate.

39 Restriction on imports

- (1) A person shall only import a medicinal product that is obtained or sourced from a foreign manufacturer or foreign wholesaler, if the medicinal product is manufactured in and eligible for sale in an approved country listed in Schedule 3.
- (2) The Minister may amend Schedule 3 by order notified in the Gazette.
- (3) A person who contravenes subsection (1) commits an offence and upon conviction is liable to a fine not exceeding \$50,000 or a term of imprisonment not exceeding 5 years or both.

40 Quality control

- (1) A person shall not import, procure or arrange or cause another person to import, procure or arrange for the importation of:
 - (a) a counterfeit medicinal product;
 - (b) an adulterated medicinal product; or
 - (c) a medicinal product that has been tampered with.
- (2) A person who contravenes subsection (1) commits an offence and upon conviction is liable to a fine not exceeding \$50,000 or a term of imprisonment not exceeding 5 years or both.
- (3) Where a person imports the medicinal product under subsection (1), the Board may:
 - (a) refer the matter to the Nauru Police Force for investigation;
 - (b) request the Nauru Customs Service or Nauru Police Force to seize the medicinal product;
 - (c) require the destruction of the medicinal product; or
 - (d) suspend or cancel the licence of the pharmacy or pharmacist who is the holder of the permit.
- (4) The Minister may decline or cancel a permit to import for the contravention of this Section.

[The next page is 991,801]

PART 9 — PHARMACY BUSINESS

41 Pharmacy business

- (1) A pharmacy licenced under this Act may:
 - (a) import, supply, sell, dispense and distribute medicinal products for retail or wholesale purposes;
 - (b) import, supply, sell and distribute pharmaceutical products;
 - (c) dispense approved prescription medicinal products; and
 - (d) provide any other goods and services related to the practice of pharmacy which may be approved by the Secretary.
- (2) For the purposes of subsection (1)(c), the Minister shall approve a list of prescribed medicinal products which the pharmacy may import and dispense in the Republic.

42 Trading hours for pharmacy

- (1) The trading hours for a pharmacy shall be:
 - (a) within 9am to 9pm; and
 - (b) for at least 5 days a week.
- (2) The trading hours for a pharmacy under subsection (1) shall be stated on the licence issued to the pharmacy.
- (3) The Minister may by order notified in the Gazette vary the trading hours of a pharmacy.

[The next page is 992,001]

PART 10 — CONTROL OF RETAIL SALE OF MEDICINAL PRODUCTS

43 Retail sale of medicinal products

- (1) A person shall not sell or supply by retail or wholesale any:
 - (a) prescription medicine;
 - (b) restricted medicine; or
 - (c) any pharmacy-only medicine.
- (2) A person may sell or supply by retail, any medicinal product which does not require a prescription to be issued by a health practitioner listed in Schedule 1 and is contained in class A of the register in Section 36.

44 Prescriptions

- (1) A person shall not write or issue a prescription unless the person is a health practitioner listed in Schedule 1 with a valid practising certificate.
- (2) The health practitioner shall issue a prescription in writing and the prescription shall contain information which may be prescribed.
- (3) A pharmacist shall not dispense any prescription medicinal product unless the prescription:
 - (a) is in writing with the date the prescription was issued;
 - (b) is written in terms and symbols which are ordinarily used in professional practice;
 - (c) contains the name, signature and workplace address of the health practitioner who issued the prescription;
 - (d) contains a statement relating to the frequency the prescription is to be dispensed;
 - (e) contains the recommended dosage; and
 - (f) contains the generic name of the medicinal product.
- (4) A pharmacist may, at the request of a person under medical treatment and where circumstances constitute an emergency, supply a medicinal product to the person without a prescription being presented to the pharmacist, upon being satisfied that the request for the medicinal product is appropriate to the need of the person and requires a pending refill.
- (5) The container or package of the medicinal product supplied under subsection (4) shall bear a label showing particulars instructed by a health practitioner or as necessary for the safe usage by a person.
- (6) A person who contravenes this Section commits an offence and upon conviction is liable to a fine not exceeding \$20,000 or a term of imprisonment not exceeding 5 years or both.

45 Automatic vending machine

- (1) The owner or pharmacist in charge of a pharmacy may, with the approval of the Secretary, use an automatic vending machine for the sale or supply of pharmaceutical products specified in the approval given by the Secretary.
- (2) For the purposes of this Section, '*automatic vending machine*' means any machine or mechanical device used or capable of being used for the

purpose of selling or supplying goods without the personal manipulation or attention of the seller or supplier or his or her employee, or other agent at the time of sale or supply.

46 Power of Minister to restrict sale of non-prescription medicinal products

The Minister may, in consultation with the Board, from time to time by notice in the Gazette, restrict the sale of a non-prescription medicinal product by requiring the medicinal product to be dispensed by a pharmacist.

[The next page is 992,201]

PART 11 — RESPONSIBILITIES OF OWNER AND PHARMACIST

47 Responsibilities of owner and pharmacist in charge of pharmacy

The owner and pharmacist in charge of a pharmacy shall ensure:

- (a) that the pharmacy operates in accordance with this Act;
- (b) that records are kept of all pharmacists engaged by or employed by the pharmacy;
- (c) that the Secretary is informed of any changes to the pharmacists engaged by or employed by the pharmacy;
- (d) that due diligence is exercised in the dispensing of medicinal products in accordance with standards of practice which may be prescribed;
- (e) compliance with all registration and pharmacy licence conditions;
- (f) that:
 - (i) a prescription medicinal product dispensed to or for a person, is dispensed pursuant to a prescription provided to the pharmacy;
 - (ii) prescription medicinal products are dispensed by a pharmacist;
 - (iii) records are created and maintained in accordance with this Act; and
 - (iv) the medicinal products dispensed meet the standards as may be prescribed; and
- (g) an explanation is given to the person receiving the medicinal product in the manner and mode of administering or taking the medicinal product.

48 Records of pharmacy to be kept

The owner or pharmacist in charge of a pharmacy shall keep or cause to be kept for a period of not less than 7 years:

- (a) proper records of the daily business conducted by the pharmacy;
- (b) a log book recording the daily transactions of the pharmacy in relation to prescriptions;
- (c) proper records of medicinal products imported, supplied or sold by the pharmacy; and
- (d) other records which may be prescribed.

49 Change of ownership of pharmacy

Where the ownership of a pharmacy changes:

- (a) the owner or pharmacist in charge of the pharmacy shall deliver the pharmacy licence to the Board by the effective date of that change of ownership; and
- (b) the pharmacy licence shall be immediately cancelled by the Board.

50 Cessation of operation of pharmacy

Where a pharmacy ceases to operate as a pharmacy, the owner or pharmacist in charge of the pharmacy shall immediately:

- (a) notify the Board in writing of the cessation;
- (b) ensure all medicinal products are disposed of in accordance with this Act or any other written law;
- (c) ensure the prescription records are securely kept;

- (d) provide any other information in writing as may be requested by the Board;
and
- (e) satisfy any other requirements which may be prescribed.

[The next page is 992,401]

PART 12 — AUTHORISED OFFICERS

51 Authorised officers

- (1) The Secretary and the Government pharmacist shall be an authorised officer for the purposes of this Act.
- (2) The Minister may by order notified in the Gazette appoint authorised officers.
- (3) An authorised officer appointed under subsection (2) shall:
 - (a) act under the directions or instructions of the Secretary;
 - (b) be issued with an identification card that is signed by the Minister at the time of his or her appointment; and
 - (c) produce his or her identification card on request.
- (4) Where an authorised officer fails to produce his or her identification card as required under subsection (3)(c), he or she shall not exercise any powers under this Act.
- (5) Police officers are authorised officers for the purposes of this Act.

52 Power of entry and inspection of pharmacy

- (1) An authorised officer may enter and inspect any pharmacy during normal business hours for the purposes of:
 - (a) ensuring that the pharmacy is operating in accordance with this Act; and
 - (b) ensuring the pharmacy meets the requirements of this Act.
- (2) For the purposes of subsection (1), an authorised officer may:
 - (a) require the production of records or other documents required to be kept and maintained under this Act; and
 - (b) make copies of the documents and records.
- (3) The pharmacist in charge of or any other person employed at the pharmacy shall provide reasonable assistance to an authorised officer.

53 Fixed penalty notice

- (1) An authorised officer may issue a fixed penalty notice to a pharmacy that the authorised officer has reasonable cause to believe has breached the requirements of this Act.
- (2) The fixed penalty notice shall be prescribed and shall:
 - (a) state the name and address of the pharmacy;
 - (b) provide details of the circumstances alleged to constitute the offence; and
 - (c) specify the amount of the fixed penalty.
- (3) Where a pharmacy is served with a fixed penalty notice under this Act:
 - (a) proceedings shall not be taken for the offence before the end of the period of 14 days following the date of service of the notice; and
 - (b) the owner or pharmacist in charge of the pharmacy shall not be convicted of the offence if the fixed penalty is paid before the end of the 14-day period.

54 Offender to be informed

An authorised officer who issues a fixed penalty notice shall inform the owner or pharmacist in charge of a pharmacy, as the case may be:

- (a) of the contents of the notice; and
- (b) that the penalty shall be paid within 14 days after the service of the notice.

55 Fixed penalty notice court appearances

- (1) Where the owner or pharmacist in charge of a pharmacy served with a fixed penalty notice, fails to pay the penalty and pleads guilty on the date of the hearing of the offence contained in the notice, the court:
 - (a) shall impose the penalty for the offence as contained in this Act;
 - (b) shall order court costs of \$100; and
 - (c) may grant other orders that the court deems appropriate to ensure compliance with the order of the court not limited to committal.
- (2) The court may hear and determine any offences under this Act where a person fails to attend court in person or by a legal representative on the date so required by the notice.
- (3) Where the owner or pharmacist in charge of the pharmacy is present or represented by a legal practitioner and pleads not guilty, the matter shall be dealt with in accordance with the procedure of the court.

[The next page is 992,601]

PART 13 — OFFENCES

56 Practice as a pharmacist

- (1) A person shall not represent or hold himself or herself out as a pharmacist unless the person is registered as a pharmacist under this Act.
- (2) A person who contravenes subsection (1) commits an offence and upon conviction is liable to a fine not exceeding \$50,000 or a term of imprisonment not exceeding 5 years or both.

57 Pharmacy operating without pharmacy licence

- (1) A person shall not operate a pharmacy without a valid pharmacy licence.
- (2) A person who contravenes subsection (1) commits an offence and upon conviction is liable to a fine not exceeding \$100,000 or a term of imprisonment not exceeding 5 years or both.

58 Providing false information

- (1) A person shall not provide false information in support of an application under this Act for:
 - (a) registration as a pharmacist;
 - (b) a pharmacy licence; or
 - (c) a permit to import.
- (2) A person who contravenes subsection (1) commits an offence and upon conviction is liable to a fine not exceeding \$20,000 or a term of imprisonment not exceeding 24 months or both.

59 Importing medicinal products without permit

A person who imports medicinal products under Part 8 without a permit issued under Section 38 commits an offence and upon conviction is liable to a fine not exceeding \$100,000 or a term of imprisonment not exceeding 5 years or both.

60 Online practice of pharmacy prohibited

- (1) A person shall not establish or engage in the practice of pharmacy online in any form unless approved by the Minister in writing.
- (2) A person who contravenes subsection (1) commits an offence and upon conviction is liable to a fine not exceeding \$100,000 or a term of imprisonment not exceeding 5 years or both.

61 Dispensing medicine without prescription

- (1) A pharmacist shall not dispense any medicinal product which requires a prescription unless the pharmacy is provided with the prescription.
- (2) A person who contravenes subsection (1) commits an offence and upon conviction is liable to a fine not exceeding \$100,000 or a term of imprisonment not exceeding 5 years or both.

62 Obstructing or hindering authorised officer

- (1) A person shall not obstruct or hinder an authorised officer in the performance of his or her duties and exercise of his or her powers under this Act.
- (2) A person who contravenes subsection (1) commits an offence and upon conviction is liable to a fine not exceeding \$10,000 or a term of imprisonment not exceeding 12 months or both.

63 Offence by corporation

- (1) Where an offence has been committed under this Act by a corporation, firm, society or other body of persons, any person who at the time of the commission of the offence is a director, manager, secretary or officer or a partner of the company, firm, society or other body of persons or is purporting to act in such capacity also commits that offence and shall be liable unless he or she proves that:
 - (a) the offence was committed without his or her consent or collusion; and
 - (b) he or she exercised all diligence to prevent the commission of the offence as he or she ought to have exercised, having regard to the nature of his or her functions in that capacity and to all circumstances.
- (2) Upon conviction, the court may impose:
 - (a) in case of a corporation, firm, society or other body of persons, a fine not exceeding \$100,000; and
 - (b) in case of a director, manager, secretary or officer or a partner of the company, firm, society or other body of persons, a fine not exceeding \$20,000 or a term of imprisonment not exceeding 12 months or both.

[The next page is 992,801]

PART 14 — MISCELLANEOUS

64 Fees for medicinal products

- (1) Subject to subsection (2), the provision and supply of medicinal products and pharmaceutical products by the Government pharmacy shall be a public expense.
- (2) The Cabinet may prescribe:
 - (a) the categories of persons who may be eligible to medicinal products and pharmaceutical products free of charge;
 - (b) the medicinal products which may be provided for a fee and the applicable fee; or
 - (c) the pharmaceutical products which may be provided for a fee and the applicable fee.

65 Protection from liability

The Minister, Board, Secretary, Department, pharmacists and authorised officers shall not be liable for any act done or omitted to be done in good faith in the performance of a function or exercise of a power under this Act or any other written law in furthering the objectives of this Act.

66 Jurisdiction of the District Court for offences

The District Court has jurisdiction to hear and determine all offences under this Act and has the power to impose the penalties for the offences under this Act.

67 Consequential amendments

- (1) Section 3(3)(e) of the *Health Practitioners Act 1999* is amended by deleting 'pharmacists'.
- (2) The *Health Practitioners (Registration Forms and Fees) Regulations 2018* is amended by:
 - (a) deleting '□ Pharmacist' in paragraph 3 in the form in Schedule 1; and
 - (b) deleting 'Pharmacist' and the corresponding registration fee and annual renewal of practising certificate fee in the tenth row in the table in Schedule 5.

68 Regulations

- (1) The Cabinet may make regulations to prescribe matters that are required or permitted by this Act to be prescribed or are necessary or convenient to be prescribed for carrying out or giving effect to this Act and generally for achieving the purposes of this Act.
- (2) Without limiting subsection (1), the Cabinet may make regulations to prescribe:
 - (a) forms and fees required under this Act;
 - (b) the dispensing of medicinal products;
 - (c) the process for approving medicinal products;
 - (d) the standards required for pharmacy premises;
 - (e) the standards of medicinal products to be imported or dispensed;

- (f) the restricting or banning of use of certain medicinal products;
- (g) the substances which are poisons for the purposes of this Act;
- (h) guidelines for the disposal of pharmaceutical products;
- (i) the storage or security of pharmaceutical products;
- (j) the mode of labelling of packages and containers of medicinal products supplied by a pharmacy;
- (k) withdrawal of pharmaceutical products from sale;
- (l) the manner in which prescriptions are to be issued; and
- (m) the documentation to accompany the import of medicinal products.

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PART 15 — SAVINGS AND TRANSITIONAL

69 Savings and transitional

- (1) Any person registered as a pharmacist under the *Health Practitioners Act 1999* immediately before the commencement of this Act continues as a registered pharmacist under this Act.
- (2) Any practising certificate issued to a pharmacist under the *Health Practitioners Act 1999* remains valid until the date of expiry of the practising certificate.
- (3) The Secretary shall enter the names of all the pharmacists under subsection (1) into the register of pharmacists under this Act.
- (4) Sections 23, 25 and 42 shall not apply to the Government pharmacy.

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SCHEDULE 1

[Section 3]

HEALTH PRACTITIONERS TO ISSUE PRESCRIPTIONS

1. General and specialist medical practitioners
2. Dental practitioners
3. Psychiatrists

[The next page is 993,601]

SCHEDULE 2

[Section 15]

PHARMACISTS REGISTERED IN SPECIFIC COUNTRIES

1. Australia
2. Canada
3. Cook Islands
4. Fiji
5. India
6. Kiribati
7. Malaysia
8. New Zealand
9. Palau
10. Papua New Guinea
11. Philippines
12. Republic of China (Taiwan)
13. Republic of Marshall Islands
14. Samoa
15. Solomon Islands
16. Tokelau
17. Tonga
18. United Kingdom
19. United States of America
20. Vanuatu

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SCHEDULE 3

[Section 39]

APPROVED COUNTRIES

1. Australia
2. Canada
3. Fiji
4. India
5. Malaysia
6. Netherlands
7. New Zealand
8. Papua New Guinea
9. Republic of China (Taiwan)
10. Singapore
11. United Arab Emirates
12. United Kingdom
13. United States of America
14. Vanuatu (for International Dispensing Authority Pacific)

