CAYMAN ISLANDS

PHARMACY BILL, 2024

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A BILL FOR AN ACT TO REPEAL AND REPLACE THE PHARMACY ACT, 1979 AND THE PHARMACY ACT, 1991; TO REGULATE THE IMPORTATION, MANUFACTURE, WHOLESALE, DISPENSING AND PRESCRIBING OF MEDICINES; AND FOR INCIDENTAL AND CONNECTED PURPOSES

PUBLISHING DETAILS

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Memorandum of

OBJECTS AND REASONS

This Bill repeals and replaces the Pharmacy Act, 1979 and the Pharmacy Act, 1991 with a new regulatory regime for the import, manufacture, wholesale, dispensing and prescribing of medicines.

The Bill is divided into six parts and contains forty-two clauses.

PART 1 - PRELIMINARY

Part 1 of the Bill deals with preliminary matters.

Clause 1 provides for the short title and commencement of the legislation.

Clause 2 contains definitions used throughout the legislation, including important definitions such as "medicine", "approved medicine", "pharmacy medicine" and "prescription-only medicine". An "approved medicine" is a medicine that is approved in a country prescribed by the regulations, approved by the Pharmacy Council or taken to be approved under an exceptional use authorization or an emergency use authorization. The regulations will prescribe each medicine that is a "pharmacy medicine" or a "prescription-only medicine".

PART 2 - LICENCES AND AUTHORIZATIONS

Part 2 of the Bill provides for the various licences that allow a person to import, manufacture and sell by wholesale a medicine. This Part also provides for the authorizations that render a medicine approved for the purposes of the legislation.

Division 1 of Part 2 specifies who requires a licence for various activities.

Clause 3 specifies who may import approved medicines. An approved medicine may be imported as follows —

(a) by a pharmacist, for the purpose of dispensing it;

(b) by a registered practitioner acting within the scope of the registered practitioner's practice, for the purpose of administering the medicine to patients;

(c) by the holder of a manufacturing licence, for the purpose of manufacturing medicine;

(d) by the holder of a wholesale licence, for the purpose of selling by wholesale;

(e) by the holder of a dispensing licence, for the purpose of dispensing it;

(f) by a person, for self-administration in specified circumstances; and

(g) by the Chief Medical Officer or the Director of Agriculture.

Clause 4 creates an offence for manufacturing a medicine without a manufacturing licence. It also specifies that a manufacturing licence authorizes the holder of the licence to import the ingredients required for the manufacture, and also to sell by wholesale the resulting product.

Clause 5 creates an offence for selling by wholesale a medicine without a wholesale licence. It also specifies that a wholesale licence authorizes the holder of the licence to import the medicine for the purposes of wholesale, and reiterates that the holder of a manufacturing licence may sell by wholesale medicine manufactured under the licence without a wholesale licence.

Clause 6 provides that a person who dispenses a pharmacy medicine or a prescription-only medicine commits an offence unless the person is a pharmacist, is acting under the supervision of a pharmacist or holds a dispensing licence. It also specifies that a dispensing licence authorizes the holder of the licence to import the medicines that the holder is authorized to dispense under the licence. Clause 6 applies in addition to clause 26, which contains additional requirements for dispensing prescription-only medicines.

Division 2 of Part 2 provides for the procedure for obtaining a manufacturing, wholesale or dispensing licence.

Clause 7 provides for licence applications to be made to the Pharmacy Council, in the form approved by the registrar and accompanied by the prescribed fee and any documents prescribed by the regulations.

Clause 8 specifies the criteria for issuing each type of licence. The criteria are in addition to any criteria that may be prescribed by the regulations. They include requirements about premises, equipment, supervision and record-keeping.

Clause 9 requires the Pharmacy Council to either issue (if satisfied that the applicant meets the criteria for the licence and is otherwise a fit and proper person) or refuse a licence application. Written notice of a refusal, including the reasons for the refusal, must be given.

Clause 10 provides for the duration and conditions of a licence. A licence may be issued for up to three years and is subject to the conditions prescribed by the regulations and any other conditions specified in the licence itself.

Clause 11 allows the Pharmacy Council to vary, suspend or revoke a licence. The clause specifies the circumstances in which the Council may do each of these things, and the procedural fairness requirements to be accorded to the licensee.

Division 3 of Part 2 deals with the circumstances in which a medicine may be approved or authorized for use.

Clause 12 allows the Pharmacy Council to approve a medicine for use in the Cayman Islands if satisfied it meets specified requirements. This is an additional avenue for a medicine to become an approved medicine for the purposes of the legislation. The primary way in which a medicine becomes an approved medicine is if a corresponding authority of a country prescribed by the regulations approves it. This means the Pharmacy Council will not be required to individually approve each medicine that may be used in the Islands.

Clauses 13 and 14 establish two mechanisms by which a non-approved medicine may be authorized for use in the Islands. This does not mean the non-approved medicine becomes an approved medicine – rather, the authorization results in the non-approved medicine being treated as an approved medicine for the duration of the authorization only.

Clause 13 provides for an exceptional use authorization to be issued by the Pharmacy Council on application by a prescriber if the Council is satisfied that the medicine is safe and effective and exceptional circumstances exist that require the medicine to be made available, even though it is not an approved medicine. The exceptional use authorization is subject to the conditions and limitations specified in it, including as to the duration of the authorization.

Clause 14 provides for an emergency use authorization to be issued by the Cabinet if the medicine is required due to a national health emergency. The emergency use authorization is subject to the conditions and limitations specified in it, including as to the duration of the authorization.

PART 3 - DEALING WITH MEDICINES

Part 3 of the Bill contains provisions regulating how medicines are dealt with.

Division 1 of Part 3 contains requirements that apply to all medicines, including medicines that are neither pharmacy medicines nor prescription-only medicines.

Clause 15 creates an offence for importing, selling by wholesale, dispensing, prescribing, administering or manufacturing a non-approved medicine. This would not apply to a non-approved medicine for which an exceptional use or emergency use authorization has been issued, as those medicines are taken to be approved medicines for the purpose of the legislation.

Clause 16 prohibits a person from supplying a medicine by retail unless the person is a pharmacist or is acting under the supervision of a pharmacist and supplies the medicine from a certified pharmacy, or unless the person is acting in accordance with a dispensing licence. A certified pharmacy is one that is certified under section 5 of the Health Practice Act (2021 Revision). An exception to this prohibition is for medicines other than pharmacy medicines, prescription-only medicines or narcotics, which may be supplied from premises capable of being closed to the public such as supermarkets and gas stations.

Clause 17 provides that it is an offence for a person to compound a medicine unless the person is a pharmacist, is acting under the supervision of a pharmacist, is acting in accordance with a dispensing licence, or is a registered practitioner or veterinary surgeon acting within their scope of practice. The word “compound” is defined in clause 2 to mean to prepare, mix, alter or assemble ingredients to make a medicinal product.

Clause 18 provides that it is an offence to alter the composition of a medicine with the intention of supplying it to another person. This clause also provides that it is an offence to supply, or possess with the intention of supplying, a medicine with an altered composition.

Clause 19 provides that it is an offence to supply, or possess with the intention of supplying, a medicine that is labelled in a false or misleading way.

Clause 20 provides that it is an offence to supply with a medicine, or possess with the intention of supplying with a medicine, written information (such as that contained in a leaflet) that describes the medicine in a false or misleading way. It also requires medicine to be supplied with a patient information leaflet written in English.

Clause 21 prohibits a person from installing a vending machine on the person's premises for the purpose of supplying a pharmacy medicine, prescription-only medicine or narcotic, from dispensing a pharmacy medicine, prescription-only medicine or narcotic using a vending machine, or allowing another person to install a vending machine on the person's premises for these purposes.

Clause 22 bans internet and mail order pharmacies. An internet or mail order pharmacy is defined in clause 2 as one that operates by internet or mail order sales and has no physical premises at which in-person services are provided to patients. This means that a traditional pharmacy would be able to provide online services to patients in addition to its traditional in-person service.

Division 2 of Part 3 contains requirements that apply to pharmacy medicines and prescription-only medicines.

Clause 23 restricts the wholesale of pharmacy medicines and prescription-only medicines. It requires holders of wholesale and manufacturing licences to only sell such a medicine to a pharmacist operating a certified pharmacy, the holder of a dispensing licence, a registered practitioner (a prescriber in the case of a prescription-only medicine) acting within the scope of the prescriber's practice or a Government entity.

Clause 24 prohibits a person from issuing a prescription unless the person is a prescriber. However, a ship's physician (who is a registered practitioner in another jurisdiction but not in the Islands) may issue a prescription for up to a seven-day supply of a medicine other than a narcotic. This ensures that passengers and crew of visiting military and cruise ships are able to have a prescription filled without visiting a prescriber in the Islands.

Clause 24 also requires a prescriber to comply with any requirements specified in the regulations when prescribing a narcotic.

Clause 25 provides that it is an offence to alter a prescription unless the person altering it is a pharmacist acting under the instruction of the prescriber or acting within the pharmacist's scope of practice.

Clause 26 creates restrictions on dispensing a prescription-only medicine. An authorized dispenser (defined in clause 2 as a pharmacist or a person acting in accordance with a dispensing licence) may only dispense a prescription-only medicine if they do so in accordance with a prescription issued within the previous twelve months (or another prescribed period), and, in the case of a narcotic, in compliance with the requirements of the regulations.

Clause 26 contains exceptions for prescribers dispensing to patients under a dispensing licence, for veterinary surgeons dispensing within their scope of practice and pharmacists dispensing an emergency supply of medicine in specified, restricted circumstances.

Clause 27 allows an authorized dispenser to substitute an interchangeable and bio-equivalent generic medicine for the product specified in a prescription if the patient is informed and the medicine is accurately labelled. This applies unless the substitution is prohibited by the regulations.

Clause 28 prohibits the dispensing of samples of prescription-only medicines except in accordance with the regulations.

Clause 29 prohibits anyone other than a prescriber, a person acting in accordance with the written directions of a prescriber or a registered practitioner from administering a prescription-only medicine to another person.

Clause 30 prohibits a person from possessing a prescription-only medicine unless the person holds a prescription for the medicine, is acting under the directions of the person holding the prescription, is an authorized dispenser, is a veterinary surgeon or registered practitioner acting within their scope of practice, is acting under the written directions of a prescriber or holds a manufacturing or wholesale licence for the medicine.

Clause 31 regulates the supply and labelling of poisons. This only applies to poisons that are prescribed by the regulations.

PART 4 - ENFORCEMENT

Part 4 of the Bill contains provisions relating to enforcement of the legislation.

Clause 32 provides for the registrar to appoint inspectors. Inspectors are subject to the directions of the registrar in carrying out their duties.

Clause 33 specifies the powers of inspectors. These powers include powers of entry, search and inspection. An inspector is also empowered to take samples of anything found during a search of a place, and seize anything the inspector reasonably believes is connected with the commission or intended commission of an offence under the legislation, or provides evidence of the commission of an offence.

Clause 34 restricts an inspector's power to enter a place that is a residence. If the owner of the residence does not consent to the entry, the inspector must obtain a warrant to enter, and a warrant will only be given if it is reasonably required for the enforcement of the legislation.

Clause 35 requires an inspector to give a receipt for anything seized from a person, and specifies that the registrar has control over any such item and may retain it for the purpose of proceedings for an offence.

Clause 36 creates an offence for obstructing or failing to comply with a requirement of an inspector.

PART 5 - MISCELLANEOUS

Part 5 of the Bill contains miscellaneous provisions.

Clause 37 empowers the registrar to approve forms for the legislation. Approved forms are used for licence applications.

Clause 38 protects the registrar, an inspector, members of the Pharmacy Council and the Chief Medical Officer from liability and indemnifies them for anything done in good faith in the exercise of a power or performance of a function under the legislation.

Clause 39 provides that it is an offence to disclose information obtained in the course of performing a function connected with the administration of the legislation or exercising a power under the legislation.

Clause 40 provides for a person who is aggrieved by a decision of the Pharmacy Council under the legislation (such as a decision relating to a licence) to appeal to the Health Appeals Tribunal.

Clause 41 provides for the Cabinet, acting on the advice of the Pharmacy Council, the Chief Medical Officer or the Chief Nursing Officer, to make regulations prescribing all matters that are required, permitted or necessary to be prescribed to give effect to the purposes of the legislation.

PART 6 - REPEALS

Part 6 of the Bill provides for repeals.

Clause 42 repeals the Pharmacy Act, 1979 and the Pharmacy Act, 1991, the latter of which never commenced. There are no transitional matters arising from the repeal of these laws.

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A BILL FOR AN ACT TO REPEAL AND REPLACE THE PHARMACY ACT, 1979 AND THE PHARMACY ACT, 1991; TO REGULATE THE IMPORTATION, MANUFACTURE, WHOLESALE, DISPENSING AND PRESCRIBING OF MEDICINES; AND FOR INCIDENTAL AND CONNECTED PURPOSES

ENACTED by the Legislature of the Cayman Islands.

PART 1 - PRELIMINARY

Short title and commencement

1. (1) This Act may be cited as the Pharmacy Act, 2024.

(2) This Act comes into force on such date as may be appointed by Order made by the Cabinet and different dates may be appointed for different provisions of this Act and in relation to different matters.

Interpretation

2. In this Act —

"**administer**", in relation to a substance, means to apply, inject, insert or otherwise introduce the substance to the body of a human being or animal, in its existing state or after it has been dissolved, dispensed in, diluted or mixed with another substance;

"**animal**" means a mammal, bird, reptile, amphibian or fish, but does not include a human being;

"**approved form**" means a form approved by the registrar under section 37;

"**approved medicine**" means a medicine —

(a) approved by a corresponding authority of a country prescribed by the regulations;

(b) approved by the Council under section 12; or

(c) taken to be an approved medicine under section 13 or 14;

"**assemble**", in relation to a medicine, means —

(a) to enclose the medicine, with or without other medicines, in a container that is labelled before the medicine is supplied; or

(b) if the medicine is already enclosed in the container in which it is to be supplied, to label the container before it is supplied;

"**authorized dispenser**" means a person who is permitted to dispense a pharmacy medicine or prescription-only medicine under section 6(1);

"**certified pharmacy**" means a pharmacy that is a certified health care facility under section 5 of the *Health Practice Act (2021 Revision)*;

"**Chief Medical Officer**" means the person appointed to the position of that title in the ministry responsible for health;

"**Chief Nursing Officer**" means the person appointed to the position of that title in the ministry responsible for health;

"**compound**", in relation to a medicine, means to prepare, mix, alter or assemble multiple ingredients to make the medicine in order to dispense the medicine;

"**constable**" has the meaning assigned by section 2 of the *Police Act (2021 Revision)*;

"**corresponding authority**" means the authority of another country that performs corresponding functions to those of the Council under this Act;

"**Council**" means the Pharmacy Council established under section 21 of the *Health Practice Act (2021 Revision)*;

"**dispense**", in relation to a medicine, means to supply the medicine, in the course of business or of providing professional services, to a person for the purpose of the medicine being self-administered by the person or administered to an animal;

"**dispensing licence**" means a licence referred to in section 6 and issued under section 9;

"**emergency use authorization**" means an authorization issued by the Cabinet under section 14;

"**exceptional use authorization**" means an authorization issued by the Council under section 13;

"**Government entity**" means any body of Government and includes a ministry, portfolio, statutory authority, company, board, department or office;

"**import**" means import into the Islands;

"**inspector**" means a person appointed to be an inspector under section 32;

"**internet or mail-order pharmacy**" means a pharmacy that —

(a) operates by way of online or mail-order sales; and

(b) does not have a physical premises where in-person pharmacy services are provided;

"**licence**" means a dispensing licence, a manufacturing licence, a product licence or a wholesale licence;

"**manufacturing licence**" means a licence referred to in section 4 and issued under section 9;

"**medicine**" means —

(a) a substance or combination of substances —

(i) presented as having properties of preventing or treating disease in human beings or animals; or

(ii) that may be administered to human beings or animals with a view to restoring, correcting or modifying a physiological function by exerting a pharmacological, immunological or metabolic action, or making a medical diagnosis; or

(b) a preparation developed from autologous or allogeneic biological materials;

"**narcotic**" means any of the following —

(a) a drug included on the Yellow List of Narcotic Drugs Under International Control prepared by the International Narcotics Control Board; or

(b) a controlled drug under the *Misuse of Drugs Act (2017 Revision)*;

"**non-approved medicine**" means a medicine other than an approved medicine;

"**pharmacist**" means a person who, under the *Health Practice Act (2021 Revision)* —

(a) is registered to practice the profession of pharmacy; and

(b) holds a practising licence to do so;

"**pharmacy medicine**" means a medicine prescribed as a pharmacy medicine by the regulations;

"**poison**" means a substance prescribed to be a poison by the regulations;

"**prescriber**" means —

(a) a registered practitioner who is a medical doctor or dentist;

(b) any other registered practitioner prescribed by the regulations; or

(c) a veterinary surgeon;

"**prescription**" means a verbal or written instruction (including an instruction issued electronically) authorizing the dispensing of a medicine;

"**prescription-only medicine**" means medicine prescribed as a prescription-only medicine by the regulations;

"**registered practitioner**" has the meaning assigned by section 2 of the *Health Practice Act (2021 Revision)*;

"**registrar**" has the meaning assigned by section 2 of the *Health Practice Act (2021 Revision)*;

"**scope of practice**", in relation to a registered practitioner, means the practitioner's scope of practice under a code mentioned in section 35 of the *Health Practice Act (2021 Revision)*;

"**ship's physician**" means a medical doctor employed to practise on board a commercial cruise ship or military vessel;

"**supply**" includes sell;

"**veterinary surgeon**" has the meaning assigned by section 2 of the *Veterinary Act (1997 Revision)*; and

"**wholesale licence**" means a licence referred to in section 5 and issued under section 9.

PART 2 - LICENCES AND AUTHORIZATIONS

Division 1 - Licence requirements

Importing medicines

3. (1) A person may import an approved medicine as follows —

(a) a pharmacist may import an approved medicine for the purpose of dispensing it;

(b) a registered practitioner who is authorized to administer an approved medicine within the registered practitioner's scope of practice may import the medicine for the purpose of administering the medicine to the practitioner's patients in quantities that are appropriate for the size of the practitioner's practice;

(c) under section 4(2)(a), the holder of a manufacturing licence for the manufacture of an approved medicine may import the ingredients (which

may be medicines) specified in the licence for the purpose of manufacturing the medicine;

(d) under section 5(2), the holder of a wholesale licence to sell an approved medicine by wholesale may import the medicine for the purpose of selling it;

(e) under section 6(2), the holder of a dispensing licence to dispense an approved medicine may import the medicine for the purpose of dispensing it;

(f) a person may import an approved medicine for self-administration if the following conditions are met —

(i) the quantity of the medicine is not of commercial value;

(ii) the medicine is contained in the original manufacturer's packaging or the container in which it was dispensed by a pharmacy and is labelled with a full description of the contents; and

(g) the Chief Medical Officer or the Director of Agriculture may import an approved medicine.

(2) A person who imports a medicine except as specified in this section commits an offence and is liable on conviction to a fine of ten thousand dollars or to imprisonment for a term of two years, or to both.

Manufacturing licence

4. (1) Subject to subsection (3), a person shall not manufacture a medicine except in accordance with a manufacturing licence.

(2) A manufacturing licence authorizes the holder of the licence to do any of the following in addition to manufacturing each medicine specified in the licence without an additional licence —

(a) import the ingredients specified in the licence for the purpose of manufacturing the medicine; and

(b) sell the medicine by wholesale.

(3) A person specified in section 17(1) does not require a manufacturing licence to compound a medicine.

(4) A person who contravenes subsection (1) commits an offence and is liable on conviction to a fine of twenty thousand dollars or to imprisonment for a term of five years, or to both.

Wholesale licence

5. (1) Subject to subsection (3), a person shall not sell an approved medicine by wholesale except in accordance with a wholesale licence.

(2) A wholesale licence authorizes the holder of the licence to import, for the purpose of selling by wholesale, each medicine or class of medicines permitted to be sold by wholesale under the licence without an additional licence.

(3) The holder of a manufacturing licence may sell a medicine specified in the licence by wholesale without a wholesale licence.

(4) A person who contravenes subsection (1) commits an offence and is liable on conviction to a fine of twenty thousand dollars or to imprisonment for a term of five years, or to both.

Dispensing licence

6. (1) A person shall not dispense a pharmacy medicine or a prescription-only medicine unless —

(a) the person is a pharmacist or acting under the supervision of a pharmacist; or

(b) the person does so in accordance with a dispensing licence.

(2) A dispensing licence authorizes the holder of the licence to import, for the purpose of dispensing, each medicine or class of medicines permitted to be dispensed under the licence without an additional licence.

(3) Section 26 contains additional requirements for dispensing prescription-only medicines.

(4) A person who contravenes subsection (1) commits an offence and is liable on conviction to a fine of twenty thousand dollars or to imprisonment for a term of five years, or to both.

Division 2 - Licence applications

Application for licence

7. (1) A person may apply to the Council for a licence.

(2) The application shall be —

(a) made in the approved form; and

(b) accompanied by the prescribed fee and any documents prescribed by the regulations.

Criteria for issuing licence

8. (1) The criteria for issuing a manufacturing licence are as follows —

(a) that the premises and equipment to be used for manufacturing operations under the licence are suitable for purpose;

(b) that the manufacturing operations are to be supervised by a person who holds the qualifications prescribed by the regulations;

(c) that adequate records are to be kept of the operations and output; and

(d) any other criteria prescribed by the regulations.

(2) The criteria for issuing a wholesale licence are as follows —

(a) that the premises and equipment to be used for storing and distributing medicines under the licence are suitable for purpose;

(b) that a pharmacist is to supervise the storage and distribution of medicines;

(c) that adequate records are to be kept of the storage and distribution of medicines; and

(d) any other criteria prescribed by the regulations.

(3) The criteria for issuing a dispensing licence are as follows —

(a) that the premises and equipment to be used for storing and dispensing medicines under the licence are suitable for purpose;

(b) that a registered practitioner acting within the registered practitioner's scope of practice is to supervise the storage and dispensing of medicines;

(c) that adequate records are to be kept of the storage and dispensing of medicines;

(d) that adequate arrangements are in place for providing appropriate information to patients to whom medicines are dispensed;

(e) that a pharmacist, acting as a consultant, is to be available to advise the licence holder on dispensing medicines and to consult with patients when required; and

(f) any other criteria prescribed by the regulations.

Decision on licence application

9. The Council shall assess an application under section 7 and —

(a) issue the licence if satisfied that the applicant —

(i) meets the criteria for the issue of the licence specified in section 8; and

(ii) is otherwise a fit and proper person to hold the licence; or

(b) refuse the application and give the applicant written notice of the refusal, including the reasons for it.

Duration and conditions of licence

10. (1) A licence may be issued for the period, not exceeding three years, specified in it and may be renewed.

(2) A licence is subject to any conditions prescribed by the regulations and any additional conditions and limitations specified in it.

Variation, suspension and revocation of licence

11. (1) The Council may vary the conditions of a licence if —

(a) the Council becomes aware of information that, had it been known when the licence was issued, would have resulted in different or additional conditions being imposed on the licence; or

(b) the holder of the licence has breached a condition of the licence and the Council believes the variation is necessary to reduce the risk of a further breach.

(2) Before deciding to vary the conditions of a licence, the Council shall —

(a) give written notice to the holder of the licence —

(i) of the reasons for, and particulars of, the proposed variation; and

(ii) that the holder may make written submissions to the Council about the proposed variation within a reasonable period of at least twenty-one days stated in the notice; and

(b) have regard to any written submissions made by the holder within the stated period.

(3) The Council may revoke a licence if —

(a) the Council becomes aware of information that, had it been known when the application for the licence was made, would have resulted in the application being refused; or

(b) the holder of the licence has breached a condition of the licence in such a serious manner that the Council believes the licence should be revoked.

(4) Before deciding to revoke the licence, the Council —

(a) shall give written notice to the holder of the licence —

(i) of the reasons for the proposed revocation; and

(ii) that the holder may make written submissions to the Council about the proposed revocation within a reasonable period of at least twenty-one days stated in the notice; and

(b) may suspend the licence during the period stated in the notice; and

(c) shall have regard to any written submissions made by the holder within the stated period.

(5) If the Council decides to vary, suspend or revoke a licence, the Council must give the holder written reasons for the decision.

Division 3 - Medicine approval and authorization

Medicine approval

12. The Council may approve a medicine for the purposes of this Act if the Council is satisfied that the medicine —

(a) is safe and effective for the purpose for which it is intended to be administered;

(b) is of good quality, according to the specification and method or proposed method of manufacture, and will be of good quality when sold and dispensed; and

(c) meets any other criteria prescribed by the regulations.

Exceptional use authorization

13. (1) The Council may, on application by a prescriber, issue an exceptional use authorization for a non-approved medicine if the Council is satisfied that —

(a) exceptional circumstances exist requiring the medicine to be made available; and

(b) the medicine is safe and effective for the purpose for which it is intended to be administered.

(2) The non-approved medicine is taken to be an approved medicine for the purposes of this Act for the duration of the exceptional use authorization.

(3) The exceptional use authorization —

(a) may be issued for the use of the medicine generally or be limited to the administration of the medicine to a specified patient or class of patients; and

(b) is subject to the conditions and limitations specified in it.

Emergency use authorization

14. (1) The Cabinet may, by notice published in the *Gazette*, issue an emergency use authorization for a non-approved medicine.

(2) The non-approved medicine is taken to be an approved medicine for the purposes of this Act for the duration of the emergency use authorization.

(3) The emergency use authorization is subject to the conditions and limitations specified in it.

PART 3 - DEALING WITH MEDICINES

Division 1 - Medicines generally

Dealing with non-approved medicine

15. (1) A person shall not —

(a) import;

(b) sell by wholesale;

(c) dispense;

(d) prescribe;

(e) administer; or

(f) manufacture,

a non-approved medicine.

(2) A person who contravenes subsection (1) commits an offence and is liable on conviction to a fine of twenty thousand dollars or to imprisonment for a term of five years, or to both.

Supplying a medicine

16. (1) Subject to subsection (2), a person shall not supply a medicine by retail unless —

(a) the person —

(i) is a pharmacist, or is acting under the supervision of a pharmacist; and

(ii) supplies the medicine from a certified pharmacy; or

(b) the person does so in accordance with a dispensing licence.

(2) Subsection (1) does not apply to the supply of a medicine in the following circumstances —

(a) the supply is made from premises capable of being contained and locked so as to exclude the public; and

(b) the medicine —

(i) has been prepared for retail supply and placed in a container or package that has not been opened since the medicine was prepared;

(ii) is supplied under the authority of the person holding a manufacturing or wholesale licence for the medicine; and

(iii) is not a pharmacy medicine, prescription-only medicine or narcotic.

(3) A person who contravenes subsection (1) commits an offence and is liable on conviction to a fine of twenty thousand dollars or to imprisonment for a term of five years, or to both.

Compounding a medicine

17. (1) A person shall not compound a medicine unless the person is —

(a) a pharmacist;

(b) acting under the supervision of a pharmacist;

(c) the holder of a dispensing licence who is authorized to compound the medicine under the licence;

(d) a registered practitioner acting within the registered practitioner's scope of practice; or

(e) a veterinary surgeon acting within the veterinary surgeon's scope of practice.

(2) A person who contravenes subsection (1) commits an offence and is liable on conviction to a fine of twenty thousand dollars or to imprisonment for a term of five years, or to both.

Altering a medicine

18. (1) A person shall not —

(a) alter the composition of a medicine with the intention of supplying the medicine to another person; or

(b) supply, or possess with the intention of supplying, a medicine with an altered composition.

(2) A person who contravenes subsection (1) commits an offence and is liable on conviction to a fine of twenty thousand dollars or to imprisonment for a term of five years, or to both.

(3) Subsection (1) is not contravened only because a medicine contains extraneous matter as a result of the process of manufacturing or compounding the medicine.

Labelling of medicine

19. (1) A person shall not supply, or possess with the intention of supplying, a medicine in a container that is labelled in a way that —

(a) falsely describes the medicine;

(b) is likely to be misleading in relation to the nature, efficacy or quality of the medicine; or

(c) does not meet the requirements prescribed by the regulations for the labelling of the medicine.

(2) A person who contravenes subsection (1) commits an offence and is liable on conviction to a fine of ten thousand dollars or to imprisonment for a term of two years, or to both.

Information accompanying medicine

20. (1) A person shall not supply with a medicine, or possess with the intention of supplying with a medicine, written information (whether contained in a leaflet or otherwise) that —

(a) falsely describes the medicine;

(b) is likely to be misleading in relation to the nature, efficacy or quality of the medicine; or

(c) does not meet the requirements prescribed by the regulations or specified in the *Misuse of Drugs Act (2017 Revision)* for information accompanying the medicine.

(2) Subject to subsection (3), a person shall not supply a medicine unless the medicine is supplied with a patient information leaflet written in English.

(3) The Chief Medical Officer may, on a case-by-case basis, issue an exemption from the requirement to supply a medicine with a patient information leaflet written in English if it is not reasonably practicable to comply with the requirement.

(4) A person who contravenes subsection (1) or (2) commits an offence and is liable on conviction to a fine of ten thousand dollars or to imprisonment for a term of two years, or to both.

Vending machines

21. (1) A person ("person A") shall not —

(a) install a vending machine on premises occupied by person A for the purpose of supplying a pharmacy medicine, prescription-only medicine or narcotic;

(b) dispense a pharmacy medicine, prescription-only medicine or narcotic using a vending machine; or

(c) allow another person to install a vending machine on premises occupied by person A for the purpose of supplying a pharmacy medicine, prescription-only medicine or narcotic.

(2) A person who contravenes subsection (1) commits an offence and is liable on conviction to a fine of ten thousand dollars or to imprisonment for a term of two years, or to both.

(3) In this section, "**vending machine**" means a machine or device from which a product can be obtained, including by —

(a) electronic funds transfer; or

(b) inserting money, a token or something else.

Internet and mail order pharmacies

22. (1) A person shall not dispense a pharmacy medicine or prescription-only medicine from an internet or mail-order pharmacy.

(2) A person who contravenes subsection (1) commits an offence and is liable on conviction to a fine of twenty thousand dollars or to imprisonment for a term of five years, or to both.

Division 2 - Pharmacy medicines, prescription-only medicines and other restricted products

Wholesale of pharmacy or prescription-only medicine

23. (1) The holder of a wholesale licence or a manufacturing licence shall not sell a pharmacy medicine or a prescription-only medicine by wholesale except to —

(a) a pharmacist operating a certified pharmacy;

(b) the holder of a dispensing licence;

(c) in the case of a pharmacy medicine, a registered practitioner who is authorized to administer the medicine within the registered practitioner's scope of practice;

(d) in the case of a prescription-only medicine, a prescriber who is authorized to administer the medicine within the prescriber's scope of practice; or

(e) a Government entity that is authorized by law to use the medicine.

(2) A person who contravenes subsection (1) commits an offence and is liable on conviction to a fine of twenty thousand dollars or to imprisonment for a term of five years, or to both.

Prescribing medicine

24. (1) Subject to subsection (2), a person shall not issue a prescription unless —

(a) the person is a prescriber acting within the prescriber's scope of practice; and

(b) if the prescription is for a narcotic, the prescriber complies with the requirements prescribed by the regulations for prescribing narcotics.

(2) A ship's physician who is not a registered practitioner may issue a prescription for the supply (not exceeding a seven-day supply or, if the medicine is packaged in units that each exceed a seven-day supply, a single unit), of a medicine other than a narcotic, but may not authorize a refill of the prescription.

(3) A person who contravenes subsection (1) or (2) commits an offence and is liable on conviction to a fine of twenty thousand dollars or to imprisonment for a term of five years, or to both.

Altering a prescription

25. (1) A person shall not alter a prescription unless the person is —

(a) the prescriber who issued the prescription;

(b) a pharmacist acting under the instruction of the prescriber who issued the prescription; or

(c) a pharmacist acting within the pharmacist's scope of practice.

(2) A person who contravenes subsection (1) commits an offence and is liable on conviction to a fine of ten thousand dollars or to imprisonment for a term of two years, or to both.

Dispensing a prescription-only medicine

26. (1) Subject to subsection (2), an authorized dispenser shall not dispense a prescription-only medicine unless —

(a) the person does so in accordance with a prescription issued within —

(i) twelve months before the date of dispensing the medicine; or

(ii) if the regulations prescribe a different period, that period; and

(b) if the medicine is a narcotic, the person complies with the requirements prescribed by the regulations for dispensing narcotics.

(2) Notwithstanding subsection (1) —

(a) a prescriber may dispense a prescription-only medicine to the prescriber's patients in accordance with a dispensing licence;

(b) a veterinary surgeon may dispense a prescription-only medicine within the scope of the veterinary surgeon's practice; or

(c) a pharmacist may dispense a supply of a prescription-only medicine without a prescription ("emergency supply") if the following conditions are satisfied —

(i) the medicine is not a narcotic;

(ii) the medicine is essential to maintaining the patient's life or continuing therapy and, in the professional opinion of the pharmacist, interrupting the therapy would be detrimental to the patient's well-being;

(iii) the request for the emergency supply has not been made immediately after a previous emergency supply of the medicine was given and used;

(iv) the pharmacist makes a complete record of the particulars of the supply; and

(v) the amount dispensed does not exceed a fourteen-day supply or, if the medicine is packaged in units that each exceed a fourteen-day supply, a single unit.

(3) A person who contravenes subsection (1) commits an offence and is liable on conviction to a fine of ten thousand dollars or to imprisonment for a term of two years, or to both.

Interchangeable and bio-equivalent generic medicines

27. (1) Subject to subsection (3), an authorized dispenser may substitute an interchangeable and bio-equivalent generic medicine for a product specified in a prescription if the authorized dispenser —

(a) informs the patient; and

(b) labels the container of the medicine with the name of the medicine dispensed rather than the brand name of the medicine prescribed.

(2) A medicine is an interchangeable and bio-equivalent generic medicine in relation to a specified product if it —

(a) is an approved medicine; and

(b) has the same active ingredient, in the same strength and the same dosage, as the specified product.

(3) An authorized dispenser shall not substitute an interchangeable and bio-equivalent medicine if the substitution is prohibited by the regulations.

(4) A person who contravenes subsection (1) or (3) commits an offence and is liable on conviction to a fine of five thousand dollars or to imprisonment for a term of one year, or to both.

Dispensing samples

28. (1) An authorized dispenser shall not dispense a prescription-only medicine by way of a sample except in accordance with the regulations.

(2) A person who contravenes subsection (1) commits an offence and is liable on conviction to a fine of five thousand dollars or to imprisonment for a term of one year, or to both.

Administering a prescription-only medicine

29. (1) A person shall not administer a prescription-only medicine to another person unless the person is —

(a) the prescriber of the medicine;

(b) acting in accordance with the written directions of the prescriber of the medicine; or

(c) a registered practitioner acting within the registered practitioner's scope of practice.

(2) A person who contravenes subsection (1) commits an offence and is liable on conviction to a fine of ten thousand dollars or to imprisonment for a term of two years, or to both.

Possessing a prescription-only medicine

30. (1) A person shall not possess a prescription-only medicine unless the person —

(a) has a prescription for the medicine in the person's name;

(b) is acting under the directions of a person who holds a prescription for the medicine;

(c) is an authorized dispenser;

(d) is a registered practitioner who, acting within the registered practitioner's scope of practice, may dispense the medicine;

(e) is a veterinary surgeon who, acting within the veterinary surgeon's scope of practice, may dispense the medicine;

(f) is acting under the written directions of a prescriber; or

(g) holds a manufacturing or wholesale licence for the medicine.

(2) A person who contravenes subsection (1) commits an offence and is liable on conviction to a fine of five thousand dollars or to imprisonment for a term of one year, or to both.

Supply and labelling of poison

31. (1) The Council may, in accordance with the requirements of the regulations, certify a person to be a person who may possess a poison.

(2) A person ("person A") shall not supply another person ("person B") with a poison unless —

(a) person A is a pharmacist who supplies the poison from a certified pharmacy; and

(b) person B is certified by the Council under subsection (1).

(3) A person who contravenes subsection (2) commits an offence and is liable on conviction to a fine of ten thousand dollars or to imprisonment for a term of two years, or to both.

(4) A person shall not supply a poison, or possess a poison with the intention of supplying it, unless the container of the poison is labelled as follows —

(a) with the name of the poison;

(b) with the word "poison";

(c) with the name and address of the certified pharmacy from which the poison is supplied;

(d) with an indication of the general or specific risk taken in its use, together with any safety precautions to be taken; and

(e) in accordance with any other requirements prescribed by the regulations.

(5) A person who contravenes subsection (4) commits an offence and is liable on conviction to a fine of five thousand dollars or to imprisonment for a term of one year, or to both.

PART 4 - ENFORCEMENT

Appointment of inspectors

32. (1) The registrar may, in writing, appoint a person to be an inspector.

(2) An inspector shall assist the Council and has the functions and powers conferred on an inspector by this Act, subject to any restrictions specified in the inspector's instrument of appointment.

(3) In exercising powers or performing functions, an inspector shall comply with the directions of the registrar.

(4) The registrar shall issue each inspector with an identity card —

(a) stating the inspector's name and the expiry date of the card;

(b) showing a recent photograph of the inspector; and

(c) signed by the Chief Medical Officer or a person designated by the Chief Medical Officer.

(5) An inspector exercising a power or performing a function in relation to a person shall, if asked by the person, produce the inspector's identity card.

Powers of inspectors

33. (1) An inspector may exercise any of the powers specified in subsection (2) if the inspector reasonably believes it is necessary to do so for the administration or enforcement of this Act.

(2) Subject to section 34, the inspector may do any of the following in relation to a place —

(a) enter, inspect and search the place;

(b) require a person at the place to give the inspector specified information (including documents) or assistance to access anything at the place;

(c) inspect and take samples of anything found in the place that appears to the inspector to be —

(i) a medicine;

(ii) a container or package used or intended to be used to contain a medicine or a document used or intended to be used to provide information to accompany a medicine; or

(iii) anything used in connection with the manufacture or assembly of a medicine, including an ingredient of the medicine;

(d) seize anything the inspector reasonably believes —

(i) is connected with the commission, or intended commission, of an offence under this Act; or

(ii) provides evidence of the commission of an offence under this Act; and

(e) make a record relating to the exercise of a power under this subsection (including, for example, by making a copy of a document, taking a photograph or making a video recording).

Restrictions on powers of entry

34. (1) This section applies if an inspector intends to enter a place under section 33(2).

(2) If the place is not a residence, the inspector shall, as far as practicable, give notice to the owner of the place of the inspector's intention to enter the place before doing so.

(3) If the place is a residence, the inspector shall not enter the place unless —

(a) the inspector has given written notice to the owner of the place of the inspector's intention to enter the place; and

(b) the inspector —

(i) is permitted by the owner (whether orally or in writing) to enter the place; or

(ii) is authorized to enter the place under a warrant issued by a Magistrate.

(4) A Magistrate may issue the warrant only if satisfied that the warrant is reasonably required in the circumstances for the enforcement of this Act.

(5) The warrant may authorize the inspector, with the assistance of a constable, to use force to enter the place.

Dealing with seized items

35. (1) An inspector shall give a receipt to a person for anything the inspector seizes from the person under this Act.

(2) The registrar has control of anything seized under this Act.

(3) The registrar may retain anything seized that is relevant to the prosecution of an offence under this Act until the proceedings for the offence have ended.

Obstructing an inspector

36. (1) A person who obstructs an inspector who is exercising a power or performing a function under this Act, including by destroying any document or thing during the course of a search conducted under section 33(2), commits an offence and is liable on conviction to a fine of five thousand dollars or to imprisonment for a term of one year, or to both.

(2) A person who fails to comply with a requirement given to the person by an inspector who is exercising a power or performing a function under this Act commits an offence and is liable on conviction to a fine of five thousand dollars or to imprisonment for a term of one year, or to both.

PART 5 - MISCELLANEOUS

Approved forms

37. The registrar may approve forms for use under this Act.

Protection from liability and indemnity

38. (1) Each of the following persons is not civilly or criminally liable for an act done or omitted to be done by the person in good faith in the exercise of a power or performance of a function under this Act —

(a) the registrar;

(b) an inspector;

(c) a member of the Council; or

(d) the Chief Medical Officer.

(2) The Government shall indemnify each of the following persons against all claims, damages, costs, charges or expenses incurred for an act done or omitted to be done in good faith in the exercise of a power or performance of a function under this Act —

(a) the registrar;

(b) an inspector;

(c) a member of the Council; or

(d) the Chief Medical Officer.

Confidentiality of information

39. (1) A person commits an offence if —

(a) the person obtains information in the course of performing a function connected with the administration of this Act or exercising a power under this Act;

(b) the person recklessly or intentionally discloses the information to another person; and

(c) the disclosure is not —

(i) for a purpose connected with the administration of this Act, including a legal proceeding arising out of the operation of this Act; or

(ii) to a person who is otherwise entitled to the information.

(2) A person who contravenes subsection (1) commits an offence and is liable on conviction to a fine of ten thousand dollars or to imprisonment for a term of one year, or to both.

Appeals

40. Where a person is aggrieved by a decision of the Council under this Act —

(a) the person may appeal against the decision to the Health Appeals Tribunal established by section 4 of the *Health Practice Act (2021 Revision)*; and

(b) Schedule 2 to the *Health Practice Act (2021 Revision)* applies to the conduct of the appeal.

Regulations

41. (1) The Cabinet, on the advice of the Council, the Chief Medical Officer or the Chief Nursing Officer, may make regulations prescribing all matters that are required or permitted by this Act to be prescribed, or are necessary to be prescribed to give effect to the purposes of this Act.

(2) Without limiting subsection (1), the Cabinet may make regulations —

(a) controlling, regulating or prohibiting the manufacture, sale, supply, possession, export or import of any medicine;

(b) regulating the issue of prescriptions;

(c) regulating the storage and disposal of medicines;

(d) prohibiting or regulating the advertising of medicines;

(e) regulating the keeping of records relating to the supply of medicines; and

(f) prescribing fees and providing for the waiver, refund and discount of fees.

(3) Regulations made under this Act may —

(a) make different provision in relation to different cases or circumstances;

(b) apply in respect of particular persons or particular cases or particular classes of persons or particular classes of cases, and define a class by reference to any circumstances whatsoever; or

(c) contain such transitional, consequential, incidental or supplementary provisions as appear to the Cabinet to be necessary or expedient for the purposes of the regulations.

(4) Regulations made under this Act may create an offence punishable by a penalty not exceeding the maximum penalty prescribed under this Act.

PART 6 - REPEALS

Repeals

42. The following are repealed —

(a) the *Pharmacy Act, 1979*; and

(b) the *Pharmacy Act, 1991*.

Passed by the Parliament the day of , 2024.

Speaker

Clerk of the Parliament