

BERMUDA

PHARMACY AND POISONS ACT 1979

1979 : 26

TABLE OF CONTENTS

PART I PRELIMINARY

1	Short title
2	Interpretation
	PART II
	THE PHARMACY COUNCIL
3	The Pharmacy Council
4	Membership of the Council
4A	Functions of the Council
4B	Protection from personal liability
4C	Annual Report
5	Proceedings of the Council, etc
	PART III
	REGISTRATION OF PHARMACISTS
6	Offence to practise pharmacy if not registered
7	Registration as a pharmacist
7A	Re-registration as non-practising member
7AA	Period of validity of registration
8	Code of Conduct
9	Pharmacy Profession Complaints Committee
10	Investigation of complaint by Committee
10A	Inquiry into complaint by Council
10B	Inquiry by Council of its own initiative
11	Surrender of registration
12	Restoration of name to register

PHARMACY AND POISONS ACT 1979

13 14 14A 14B 15	Proof of registration Appeals Fees Amendment of Seventh Schedule Regulations for this part
	PART IV REGISTRATION OF PHARMACIES
16 17 18 19 20 21	Register of pharmacies Registration of premises as registered pharmacies Unfit premises: new applications Unfit premises: registered pharmacies Appeals When certificates of unfitness take effect Regulations for this Part
	PART V CONTROL OF PRESCRIPTIONS AND IMPORTATION
23 23A 24 25 26	Prescriptions to be in a certain form Validity of a prescription Supply by registered pharmacist of equivalent medicines Restrictions on the importation of medicines Declaration relating to imported medicines [repealed]
	PART VI CONTROL OF DRUGS
27 28 29 30 31 31A 31B 31C 31D 31E	Certain substances to be sold on prescription only Certain substances to be available at pharmacies only Restrictions on dispensing Prohibition on giving away Schedule 3 or Schedule 4 drugs Unfit drugs [repealed] Health and safety requirements Orders and notices to prohibit supply of a drug or drug product Suspension notices Application to set aside a suspension notice Power to obtain information
	PART VII CONTROL OF POISONS
32 33 34 35 36 37 38	Prohibition of sale of poison without licence Poisons Licences to sell poisons Revocation of licences Appeals Poisons Book Sale of poisons to unknown persons prohibited Sale of poisons to persons under 18 prohibited

PHARMACY AND POISONS ACT 1979

40	Labelling of poisons
41	Sale of poisons to intoxicated persons etc. prohibited
42	Method of keeping poisons
43	Statement of proportion of poison in preparations
44	Liquid preparations containing poison
	PART VIII
	MISCELLANEOUS
45	Wholesale transactions
46	Dispensing records
46A	Prescription drug pricing
47	Dishonest sales
48	Regulations for Parts VI and VII
48A	Minister may by order amend the Third or Fourth Schedule
48B	Minister may provisionally add or remove drugs in the Third or Fourth Schedule
49	Minister may obtain reports on drugs and poisons
50	Minister may obtain information on prices
51	Inspections
51A	Notice of test
51B	Compensation
52	Service of documents
53	Transitional
54 	Student pharmacists
55 56	Offences Repeal [omitted]
57	Commencement [omitted]
31	Commencement fortunear
	FIRST SCHEDULE
	SECOND SCHEDULE
	List of Practitioners
	WHIPD COHEDINE
	THIRD SCHEDULE
	Drugs obtainable only on prescription except whereSpecified in the Fourth Schedule (part I and Part II)
	Schedule (part I and I art II)
	FOURTH SCHEDULE
	PART I
	FIFTH SCHEDULE
	Pharmacy Profession Complaints Committee
	•
	SIXTH SCHEDULE Prohibition Orders Prohibition Notices and Nations to Warre
	Prohibition Orders, Prohibition Notices and Notices to Warn

 $[preamble\ and\ words\ cf\ enactment\ omitted]$

SEVENTH SCHEDULE

PART I

PRELIMINARY

Short title

This Act may be cited as the Pharmacy and Poisons Act 1979.

Interpretation

- 2 In this Act, unless the context otherwise requires—
 - "appropriate fee" means a fee referred to in section 14A;
 - "Association" means the professional association representing pharmacists in Bermuda;
 - "Bermuda Health Council" means the Bermuda Health Council established under section 3 of the Bermuda Health Council Act 2004;
 - "certificate of competence" means a certificate of competence granted by the Council under regulations made under section 15(1)(b);
 - "Code" means the code of conduct referred to in section 8;
 - "continuing professional development" means the minimum hours of continuing professional development required under section 7(5A)(d);
 - "the Council" means the Pharmacy Council established by section 3;
 - "dentist" means a dental practitioner registered under the Dental Practitioners Act 1950 [title 30 item 4] or an exempted dental practitioner within the meaning of that Act;
 - "dispense," with its grammatical variations, in relation to a medicine or a poison, means the preparation and supplying in such manner of a medicine or a poison on and in accordance with a prescription given by a duly qualified practitioner as to ensure the pharmaceutical and therapeutic suitability to the circumstances for which it is prescribed;
 - "drug" means a substance or combination of substances used, or for use in or on the body of a person or animal—
 - (a) to prevent, diagnose, treat or mitigate a disease, disorder or abnormal physical or mental state or symptom of them; or
 - (b) to restore, correct or modify organic functions, and includes a prescribed substance or combination of substances;
 - "drug product" means a manufactured product that contains a drug including tablets, pills, capsules, caplets, creams, powders, transdermal patches or liquids;
 - "functions" includes powers and duties;
 - "medicinal use" means-

- (a) use by being administered to one or more human beings or animals; or
- (b) use as an ingredient in the preparation of a substance or article which is to be administered to one or more human beings or animals;

for-

- (i) treating or preventing disease;
- (ii) diagnosing disease or ascertaining the existence, degree or extent of a physiological condition;
- (iii) contraception;
- (iv) inducing anaesthesia; or
- (v) otherwise preventing or interfering with the normal operation of a physiological function, whether permanently or temporarily, and whether by way of terminating, reducing or postponing, or increasing or accelerating, the operation of that function or in any other way;
- "Minister" means the Minister responsible for Health;
- "non-practising pharmacist" means a person who is registered as a pharmacist section 7A but who is not practising pharmacy in Bermuda;
- "physician" means a medical practitioner registered under the Medical Practitioners Act 1950 [title 30 item 8] or an exempted medical practitioner within the meaning of that Act;
- "poison" has the meaning assigned thereto in section 33;
- "practitioner" includes any of the professions listed in the Second Schedule;
- "prescribed" means prescribed by regulations;
- "prescription" means a prescription issued by any of the practitioners listed in the Second Schedule;
- "register" means the register of pharmacists kept under section 7(2);
- "registered pharmacist" means a person registered pursuant to section 7(4) and (4B);
- "registered pharmacy" has the meaning assigned thereto in section 17(3);
- "Registrar" means-
 - (a) with respect to pharmacists, the official for whose appointment section 7(1) provides;
 - (b) with respect to pharmacies, the Chief Medical Officer;
- "regulation" means regulation made under section 15, 22 or 48;
- "relevant professional body", in relation to registered pharmacists, means the Bermuda Pharmaceutical Association;

"Schedule 3 drug" has the meaning assigned thereto in section 25(6);

"Schedule 4 drug" has the meaning assigned thereto in section 28(1);

"veterinary practitioner" means a person who holds a certificate issued under the Veterinary Practitioners Act 2008.

[Section 2, "veterinary practitioner" amended by 2008: $20 \text{ s.} 17 \text{ \& Sch. } 2 \text{ e}_{\text{i}}$ fective 9 July 2010; Section 2, "Schedule 3 drug" amended by 2011: $31 \text{ s. } 2 \text{ e}_{\text{i}}$ fective 10 August 2011; Section 2 'Association", "drug", "drug product", "non-practising pharmacist" inserted, "practitioner" and "a prescription" deleted and substituted and "registered pharmacist" amended by 2013: $48 \text{ s. } 2 \text{ e}_{\text{i}}$ fective 24 December 2013; Section 2 definition "Registrar" repealed and replaced, definitions "appropriate fee", "Bermuda Health Council", "Code", "continuing professional development" and "register" inserted by 2020: $47 \text{ s. } 105 \text{ e}_{\text{i}}$ fective 11 December 2020]

PART II

THE PHARMACY COUNCIL

The Pharmacy Council

3 There shall be established a body called the Pharmacy Council, whose general function shall be to secure high standards of professional competence and conduct in the practice of pharmacy in Bermuda, and who shall have such other functions as may be assigned to the Council by any statutory provision.

Membership of the Council

- 4 (1) The Council shall consist of—
 - (a) a chairman appointed by the Minister;
 - (aa) one member, who shall be a representative of the Association, appointed by the Minister;
 - (ab) one member, who shall not be a registered pharmacist, appointed by the Minister as a person appearing to him to be qualified by his training or experience or both to assist the Council in matters of a legal or ethical nature:
 - (b) one member, who shall be a practitioner, appointed by the Minister; and
 - (c) four members elected by registered pharmacists from among themselves.
- (2) The Council may co-opt a representative of the Bermuda Pharmacy Owners Association to any of their meetings but such a representative shall not have a vote.

[Section 4 subsection (1)(aa) inserted and subsection (1)(c) amended by 2013: 48 s. 3 e)fective 24 December 2013; Section 4 subsection (1) amended by 2018: 66 s. 2 e)fective 10 January 2019; Section 4 subsection (1)(ab) inserted by 2022: 3 s. 2 e)fective 9 March 2022]

Functions of the Council

4A The Council shall, in addition to any other function under this Act, make periodic reviews of the Act for the purpose of making recommendations to the Minister as to any

necessary amendments to the Act generally, and with particular reference to the Third and Fourth Schedules.

Protection from personal liability

4B A member of the Council shall not be personally liable for damages for anything done or omitted to be done in the discharge or purported discharge of the Council's functions under this Act unless the act or omission was in bad faith.

[Section 4B inserted by 2013: 48 s. 4 e]fective 24 December 2013]

Annual Report

4C The Council shall submit to the Minister, at such time as the Minister may determine after the end of each year, an annual report concerning such activities of the Council as the Minister may prescribe.

[Section 4C inserted by 2020 : 47 s. 106 e] fective 11 December 2020]

Proceedings of the Council, etc

5 The provisions in the First Schedule shall have effect with respect to the Council.

PART III

REGISTRATION OF PHARMACISTS

Offence to practise pharmacy if not registered

- 6 (1) It shall be unlawful for an individual to practise pharmacy unless at the time—
 - (a) he is a registered pharmacist; and
 - (b) he operates, or is employed at, premises which are a registered pharmacy.
- (2) A person shall be deemed to be practising pharmacy for the purposes of this Act if, in the way of trade or business in Bermuda, he takes or uses a title, or holds himself out as engaging in a profession, being a title or profession to which this subsection applies.
- (3) The titles and professions to which subsection (2) applies are those of pharmacist, chemist, druggist, chemist and druggist, dispensing chemist and dispensing druggist, and any other suggesting a connexion with the business of compounding or dispensing medicines.

Registration as a pharmacist

- 7 (1) There shall be a Registrar, for the purposes of this Act to be known as the Registrar of Pharmacists.
- (1A) The Chief Executive Officer of the Bermuda Health Council shall be the Registrar of Pharmacists.

- (1B) The Registrar may, subject to such conditions as he may consider appropriate, in writing delegate such functions conferred on him on such terms as he considers appropriate to an officer of the Bermuda Health Council.
 - (1C) A delegation under subsection (1B) may—
 - (a) be made subject to such conditions, qualifications and exceptions as the Registrar may specify in the instrument of delegation;
 - (b) be revoked or varied by a subsequent instrument.
- (1D) The Statutory Instruments Act 1977 does not apply in respect of an instrument made under this section.
- (2) The Registrar shall establish and maintain a register of pharmacists for the purposes of this Act.
- (3) The register of pharmacists shall be kept at the offices of the Registrar, and be available for inspection by the public at all reasonable times without charge.
- (4) Where a person applies in the required form to the Registrar and pays the appropriate fee the Council shall, if the person is qualified for registration as a pharmacist under this Act, direct the Registrar to register him as a pharmacist under this Act by causing his name and the prescribed particulars relating to him to be entered in the register of pharmacists and giving him a certificate of registration in the prescribed form.
- (4A) A person who has been registered under subsection (4) shall apply for reregistration every two years after the first registration or within such longer period than two years but not exceeding three years as may be specified in the certificate of registration issued to him pursuant to section 7AA.
- (4B) The Council may approve an application for re-registration under subsection (4A) and issue a certificate of re-registration to the person applying.
- (5) Any individual other than a disqualified person shall, for the purposes of subsection (4), be qualified for registration as a pharmacist under this Act if he—
 - (a) is fit and proper and possesses the appropriate qualifications and experience; and
 - (b) possesses a certificate of competence granted to him by the Council for passing a written exam in pharmacy set by the Council; and
 - (c) has had a minimum of six months' practical experience of which not less than one month after graduation has been spent under the supervision in Bermuda of a registered pharmacist.
 - (5A) A person applying for re-registration under subsection (4A) shall—
 - (a) apply in the form required by the Council;
 - (b) pay the appropriate fee;

- (c) continue to meet the qualifications, experience and conduct as required in subsection (5);
- (d) meet the minimum amount of continuing professional development as required by the Council; and
- (e) meet the number of practice hours as required by the Council.
- (6) Where the Council refuses or fails to register a person who makes an application under subsection (4), or refuses or fails to re-register a person who makes an application under subsection (4A) (hereinafter in this section called "applicant"), the applicant may appeal to the Supreme Court.
- (7) An applicant may appeal to the Supreme Court under subsection (6) within 28 days after the decision is made (in this section referred to as "the appeal period").
 - (7A) [Repealed by 2020: 47 s. 107]
 - (8) [Repealed by 2020: 47 s. 107]
- (9) A list of registered pharmacists shall be published annually in the Gazette so soon as may be after the 1st day of January, and particulars of any alteration made in the register of pharmacists on or after that date in any year shall also be published in the Gazette.

[Section 7 subsections (1),(3),(4) and (5) amended, subsections (6) and (8) deleted and substituted, subsection (7) deleted and inserted and subections (4B),(5A) and (7A) inserted by 2013 : 48 s. 5 $\epsilon_{\rm j}$ fective 24 December 2013; Section 7 amended by 2020 : 47 s. 107 $\epsilon_{\rm j}$ fective 11 December 2020]

Re-registration as non-practising member

- 7A (1) A person who is registered under section 7(4) and is not practising pharmacy in Bermuda may re-register as a non-practising pharmacist in a form required by the Council and by paying the appropriate fee.
- (2) The Registrar shall establish and maintain a register of non-practising pharmacists for the purposes of this Act.
- (3) A person registered as a non-practising pharmacist shall not practise pharmacy in Bermuda.
- (4) A non-practising pharmacist applying for re-registration to practise pharmacy shall—
 - (a) apply in the form required by the Council;
 - (b) pay the appropriate fee;
 - (c) continue to meet the qualifications, experience and conduct requirements in section 7(5); and
 - (d) meet the minimum amount and type of continuing professional development and practice hours as required by the Council.

(5) [Repealed by 2020: 47 s. 108]

[Section 7A inserted by 2013 : 48 s. 6 ϵ] fective 24 December 2013; Section 7A subsection (5) repealed by 2020 : 47 s. 108 ϵ] fective 11 December 2020]

Period of validity of registration

- 7AA (1) Unless sooner cancelled and subject to subsections (2) and (3), the registration of a pharmacists shall have effect for a period of two years from the date of his registration or such shorter period as may be specified in the certificate of registration issued to him.
- (2) Subsection (3) applies where a person is registered as a pharmacist on a date that falls between the start, and end, of the applicable registration cycle for pharmacists.
- (3) Where this subsection applies, the registration of the pharmacist may, if the Council so determines appropriate, have effect for such longer period than two years but not exceeding three years as may be specified in the certificate of registration issued to him.

|Section 7AA inserted by 2020 : 47 s. 108 ejfective 11 December 2020|

Code of Conduct

- 8 (1) It shall be the duty of the Council to prepare, and from time to time as they think fit amend, a code of conduct which the Council considers to be conduct that is proper for registered pharmacists in a professional respect (hereinafter in this Act called "the Code").
- (2) The Council shall send to each registered pharmacist at his address on the register of pharmacists a copy of the Code and of any amendment made to the Code.
- (2A) The Code may contain guides to ethical conduct, standards of practice or scopes of practice.
- (3) In exercise of their powers under section 10A the Council shall, subject to subsection (4), be guided by any relevant provision of the Code.
- (4) Where an inquiry has been conducted by the Council under sections 10A or 10B, the Council may find a person guilty of negligence, incompetence or other improper conduct nothwithstanding that the conduct in question is not prohibited by the Code, but they shall not find a person guilty of improper conduct if that conduct is authorized by the Code.

[Section 8 repealed and replaced by 2013 : 48 s. 7 ϵ] fective 24 December 2013; Section 8 amended by 2020 : 47 s. 109 ϵ] fective 11 December 2020]

Pharmacy Profession Complaints Committee

- 9 (1) There shall be established, in accordance with the Fifth Schedule, a committee to be known as the "Pharmacy Profession Complaints Committee" (hereinafter in this Act called "the Committee").
 - (2) The functions of the Committee are—

- (a) to receive and investigate, or cause to be investigated, complaints against any registered pharmacist including any allegation that—
 - (i) the pharmacist's registration was improperly obtained;
 - (ii) the pharmacist is guilty of professional misconduct;
 - (iii) the pharmacist is unfit to practise by reason of conviction of an indictable offence or adverse physical or mental health; or
 - (iv) the pharmacist is otherwise unfit to practise or to be registered; and
- (b) to perform such other functions as may be prescribed.
- (3) The Committee may investigate any complaint based on matters alleged to have occurred—
 - (a) inside or outside Bermuda; or
 - (b) at any time, whether or not at a time when the person complained against was registered as a pharmacist.
 - (4) A complaint referred to in subsection (2)(a)—
 - (a) shall be made by the complainant—
 - (i) if the complainant is a child or is physically or mentally unable to make the complaint, by the parent or guardian, friend or a person acting on behalf of the complainant; and
 - (ii) if the conduct complained of relates to a person who is dead, by the person's executor or personal representative;
 - (b) shall be in writing and addressed to the Committee;
 - (c) shall set out the matters alleged to constitute grounds for disciplinary action to be taken against the pharmacist who is the subject of the complaint;
 - (d) may be required by the Committee to be in a form approved by the Committee.
- (5) If the Committee considers that a complaint arose from a misunderstanding by the complainant or between the complainant and the pharmacist complained of, the Committee may, before proceeding further with the investigation of the complaint, require the parties to appear before it in order to discuss the matter with a view to clarifying the misunderstanding and resolving the matter informally.
- (6) The Fifth Schedule has effect as to the appointment and proceedings of the Committee and other matters relating to the Committee.

[Section 9 repealed and replaced by 2013: 48 s. 7 e) fective 24 December 2013]

Investigation of complaint by Committee

- 10 (1) Where a complaint under section 9(4) is not resolved informally as provided in section 9(5), the Committee shall investigate the complaint and determine whether, in its opinion, the complaint—
 - (a) is frivolous or vexatious, is made in bad faith, is an abuse of process, or for any other reason, ought not to be referred to the Council; or
 - (b) ought to be referred to the Council for decision.
 - (2) The Committee—
 - (a) shall give written notice to the pharmacist who is the subject of the complaint that a complaint has been made, together with a summary of the matters alleged in the complaint;
 - (b) shall request that the pharmacist who is the subject of the complaint show cause in writing, within a specified time after the notice is given, explaining why the matter should not be placed before the Council for determination; and
 - (c) may take evidence from witnesses on oath or affirmation, administered by the Chairman.
- (3) If the Committee determines that a complaint is frivolous or vexatious, is made in bad faith, is an abuse of process or otherwise ought not to be considered by the Committee, it shall dismiss the complaint and give written notice to the complainant of the dismissal and the reasons for the dismissal.
- (4) If the Committee determines that a complaint ought to be referred to the Council for decision, the Committee shall, as soon as practicable, refer the matter to the Council.

[Section 10 repealed and replaced by 2013: 48 s. 7 effective 24 December 2013]

Inquiry into complaint by Council

- 10A (1) If, pursuant to an investigation under section 10, the Committee places the matter before the Council for determination, the Council shall inquire into the matter.
 - (2) For the purposes of an inquiry of this section, the Council—
 - (a) may take evidence from witnesses on oath or affirmation, and for that purpose the Chairman of the Council may administer an oath or affirmation;
 - (b) shall afford the registered pharmacist and the Committee, or a member of the Committee, every facility—
 - (i) to appear before the Council;
 - (ii) to be represented by a barrister and attorney;
 - (iii) to call or cross-examine witnesses; and

- (iv) generally to make a full defence or explanation in the matter of the complaint.
- (3) Following its inquiry, the Council shall make a decision as to whether the complaint is proved or not proved, in whole or in part, together with reasons for its decision.
- (4) If the Council decides that a complaint is not proved, in whole or in part, it shall dismiss the complaint to the extent that it is not proved.
- (5) If the Council decides that a complaint is proved, in whole or in part, it shall record a finding to that effect and it may make any order of a disciplinary nature that it sees fit in respect of a pharmacist against whom the complaint is made, including an order—
 - (a) admonishing the pharmacist;
 - (b) suspending the pharmacist from practice as a pharmacist for such period as it sees fit or for an indefinite period;
 - (c) striking the name of the pharmacist off the register;
 - (d) imposing conditions or limitations with regard to the pharmacist's practice as a pharmacist.
- (6) The Council shall give written notice, to the pharmacist against whom a complaint is made, of its decision under subsection (3) and any order made by the Council under subsection (5), together with reasons.
- (7) The pharmacist against whom the complaint is made may appeal against a decision or order of the Council in the manner provided in section 14.
- (8) Any proceedings in connection with the holding of an inquiry by the Council under this section shall, for the purpose of the provisions of the Criminal Code Act 1907 relating to perjury, be deemed to be judicial proceedings.
- (9) A member of the Council who was involved in the matter complained of may not participate in an inquiry by the Council under this section.
- (10) A person who is suspended from practice under this section shall, for the duration of the suspension, be deemed not to be registered.

[Section 10A inserted by 2013: 48 s. 8 e] fective 24 December 2013]

Inquiry by Council of its own initiative

- 10B (1) In the absence of a complaint, the Council may, of its own initiative, hold an inquiry into any matter referred to in section 9(2) that could have formed the subject of an investigation by the Committee.
- (2) The provisions of section 10A that apply in respect of an inquiry by the Council under that section shall apply to an inquiry under this section with any necessary modification.

[Section 10B inserted by 2013: 48 s. 8 effective 24 December 2013]

Surrender of registration

11 The Council may order the Registrar to erase from the register of pharmacists the name of a registered pharmacist against whom no matter of complaint is pending under sections 10A and 10B, if the registered pharmacist applies to the Council for the purpose and surrenders to him his certificate of registration.

[Section 11 amended by 2013 : 48 s. 9 ϵ] fective 24 December 2013; Section 11 amended by 2020 : 47 s. 110 ϵ] fective 11 December 2020]

Restoration of name to register

- 12 (1) A person whose name has been removed from the register under section 11, or whose name has been struck from the register, or who has been suspended from practice under section 10A or 10B, may make an application to the Council, in a form determined by the Council, for his name to be restored to the register or for his suspension to be terminated.
- (2) An application under subsection (1) for the restoration of a name to the register of pharmacists shall not be made to, or be considered by, the Council—
 - (a) within twelve months after the date of removal, striking off or suspension;
 - (b) within twelve months after a previous application under that subsection; or
 - (c) where the Council in the direction ordering the erasure appointed a period within which another application should not be made under that subsection, within that period.
- (3) On receipt of an application, the Council shall decide whether to restore the applicant's name to the register or to terminate his suspension, after considering the following matters—
 - (a) the character and professional ability of the applicant;
 - (b) the nature of the matter in respect of which the applicant's name was struck from the register or for which the applicant was suspended;
 - (c) the conduct of the applicant after his name was struck from the register or after he was suspended;
 - (d) any other circumstances appearing to the Council to be relevant.
- (4) The Council shall give written notice to the applicant of its decision, together with reasons.
- (5) An applicant may appeal against the decision of the Council in the manner provided in section 14.

[Section 12 repealed and replaced by 2013 : 48 s. 10 e]fective 24 December 2013]

Proof of registration

13 A certificate signed by the Registrar certifying that a person named in the certificate is or, as the case may be, is not, a registered pharmacist and, in the case of a person to whom the certificate refers as being a registered pharmacist, specifying the date of registration, shall be admissible in any proceedings as prima facie evidence of the facts stated in the certificate.

[Section 13 amended by 2020 : 47 s. 110 ϵ] fective 11 December 2020]

Appeals

- 14 (1) A person aggrieved by any decision of the Council referred to in subsection (2) may, within 28 days after the date on which the decision is given to the person by the Council, appeal to the Supreme Court against the decision.
- (2) The person referred to in subsection (1) may appeal against the following decisions— $\,$
 - (a) a decision not to issue or renew a registration certificate;
 - (b) a decision not to issue a re-registration certificate;
 - (c) a decision to remove the name of a person from the register;
 - (d) a decision to remove, or alter, any entry in the register in respect of a person;
 - (e) a decision not to restore a person's name to the register;
 - (f) a decision not to terminate a person's suspension.
- (3) On an appeal under this section the Supreme Court may make such order in the matter as it thinks proper, including an order as to the costs of the appeal.
 - (4) An order of the Supreme Court under subsection (2) is final.
- (5) The practice and procedure to be followed in relation to an appeal under this section are as prescribed by rules of court.
- (6) The Council may appear as respondent on such appeal and, whether they appear at the hearing of the appeal or not, they shall be deemed to be a part to the appeal for the purpose of enabling directions to be given as to the costs or expenses of the appeal.

|Section 14 repealed and replaced by 2013: 48 s. 11 e₁ fective 24 December 2013|

Fees

- 14A (1) The appropriate fees shall be payable to the Bermuda Health Council.
- (2) A person applying to register as a pharmacist shall at the time of filing of the application for registration, in respect of that application pay to the Bermuda Health Council the appropriate fee

- (3) A person applying to be re-registered shall, within every two years after the date when the person is first registered, or such longer period as may be applicable pursuant to section 7AA, pay to the Bermuda Health Council the appropriate fee.
- (4) In this section, "appropriate fee" means the fee set forth in the Seventh Schedule.
- (5) The Seventh Schedule shall have effect as to fees that are payable by registered persons under this Act.

[Section 14A inserted by 2020: 47 s. 111 ejfective 11 December 2020]

Amendment of Seventh Schedule

- 14B (1) The Minister may by order amend the Seventh Schedule to vary any fee specified therein or to add or revoke fees.
- (2) An order made by the Minister under subsection (1) shall be subject to the affirmative resolution procedure.

[Section 14B inserted by 2020 : 47 s. 112 e) fective 11 December 2020]

Regulations for this part

- 15 (1) The Minister may make regulations—
 - (a) regulating the making of applications for registration as a pharmacist under this Act and providing for the evidence to be produced in support of such applications;
 - (b) prescribing professional standards that are to be met by registered pharmacists;
 - (c) prescribing the procedure to be followed on an inquiry held pursuant to sections 10A and 10B.
- (2) Regulations made under subsection (1) shall be subject to the negative resolution procedure.

[Section 15 amended by 2013 : 48 s. 9 ϵ] fective 24 December 2013]

PART IV

REGISTRATION OF PHARMACIES

Register of pharmacies

- 16 (1) The Registrar shall establish and maintain a register of pharmacies for the purposes of this Act.
- (2) The register of pharmacies shall be kept at the offices of the Registrar, and be available for inspection by the public at all reasonable times without charge.

[Section 16 subsection (2) amended by 2013 : 48 s. 12 ϵ] fective 24 December 2013]

Registration of premises as registered pharmacies

- 17 (1) Where an application for the registration of premises as a registered pharmacy is made by any person (hereafter in this Part called an "applicant") to the Registrar on the prescribed form accompanied by the appropriate fee, the Registrar shall, subject to sections 18, 20 and 21(1), enter the prescribed particulars relating to those premises in the register of pharmacies.
- (2) In subsection (1) "the appropriate fee" means the relevant fee prescribed in the Government Fees Regulations 1976.
- (3) In this Act "to register premises as a registered pharmacy" means to enter the prescribed particulars relating to them in the register of pharmacies pursuant to subsection (1), and any premises in relation to which the prescribed particulars are so entered are in this Act referred to as a "registered pharmacy".
- (4) A list of registered pharmacies shall be published annually in the Gazette so soon as may be after the 1st day of January, and particulars of any alteration made in the register of pharmacies on or after that date in any year shall also be published in the Gazette.
- (5) It shall be an offence for any premises to bear any sign or other representation that it is a pharmacy, drug-store, dispensary or other words representing any such premises as being registered as a pharmacy under this Act unless such premises are in fact so registered, or for any person to represent himself as being a pharmacist, apothecary, druggist, dispenser or any other description, whether of the foregoing classes or not, calculated to represent that he is registered as a pharmacist under this Act, unless he is so registered.

[Section 17 subsection (2) amended by 2013 : 48 s. 13 ϵ] fective 24 December 2013]

Unfit premises: new applications

- 18 (1) If it appears to the Minister that premises in respect of which an application under section 17 has been made fail in a material respect to comply with the requirements of regulations made under section 22(1)(a) which are for the time being in force, he may determine to issue to the applicant a certificate of unfitness under this section certifying that the premises are unsuitable for registration as a registered pharmacy.
- (2) Before the Minister issues a certificate of unfitness under this section, he shall serve on the applicant a notice stating what he proposes and his reasons therefor.
- (3) If within fourteen days after receipt of a notice under subsection (2) the applicant makes representations in writing to the Minister, or gives notice in writing to the Minister of his desire to be heard with respect to the Minister's proposal to issue such a certificate, the Minister shall not issue the certificate before he has considered the applicant's representations in writing or, where the applicant gave notice of his desire to be heard, his oral representations if made within a reasonable time.
- (4) Where the Minister, after considering any such representations as aforesaid, determines not to issue a certificate of unfitness under this section in respect of the

premises in question, he shall notify the applicant and the Registrar of his decision, and the Registrar shall forthwith register the premises as a registered pharmacy.

- (5) Where the Minister, after considering any such representations as aforesaid, determines that a certificate of unfitness ought to be issued in respect of the premises in question, he shall issue the certificate by serving it on the applicant, and he shall also serve a copy of the certificate on the Registrar.
- (6) A certificate of unfitness issued under this section shall state the reasons for its issue.
- (7) Except in accordance with the directions of the Supreme Court given under section 20(2), the Registrar shall not register as a registered pharmacy premises in respect of which a certificate of unfitness has been issued under this section.

Unfit premises: registered pharmacies

- 19 (1) Where the Minister is of opinion that a registered pharmacy fails in a material respect to comply with the requirements of regulations made under section 22(1)(a) which are for the time being in force, the Minister shall serve on the operator of the pharmacy a notice stating his intention to issue a certificate of unfitness under this section in respect of the pharmacy, and the Minister's reasons therefor; and section 18(3) to (6) shall have effect mutatis mutandis in relation to notices and certificates under this section as they have effect in relation to notices and certificates of unfitness under that section.
- (2) Where a certificate of unfitness is issued under this section, the registered pharmacy to which the certificate relates shall cease to be a registered pharmacy with effect from the date of the taking effect of the certificate under section 21.

Appeals

- 20 (1) Any person aggrieved by the issue of a certificate of unfitness under section 18 or 19 may, at any time within twenty-eight days after the service of the certificate upon him, appeal under this section to the Supreme Court, and upon any such appeal that Court shall have power to confirm or revoke the issue of the certificate.
- (2) Where the Supreme Court revokes a certificate of unfitness issued under section 18, the Court shall give such directions as the case requires with regard to the registration of the premises as a registered pharmacy under section 17.
- (3) The powers of the Chief Justice to make rules under section 62 of the Supreme Court Act 1905 [title 8 item 1] shall extend to the making of rules regulating the practice and procedure to be followed on, and the fees to be paid in connexion with, any such appeal.
- (4) The Registrar may appear as the respondent on any such appeal and, whether he appears at the hearing of the appeal or not, he shall be deemed to be a party to the appeal for the purpose of enabling directions to be given as to the costs or expenses of the appeal.

When certificates of unfitness take effect

- 21 (1) Without prejudice to section 18(7), where an appeal is not brought against the issue of a certificate of unfitness under that section, or where such an appeal is brought but is withdrawn or struck out for want of prosecution, the certificate shall take effect on the expiration of the time for appealing or, as the case may be, on the withdrawal or striking out of the appeal; but otherwise such a certificate shall take effect if and when the appeal is dismissed and not otherwise.
- (2) Where an appeal is not brought against the issue of a certificate of unfitness under section 19, or where such an appeal is brought but is withdrawn or struck out for want of prosecution, the certificate shall take effect on the expiration of thirty days after the expiration of the time for appealing or, as the case may be, upon the expiration of thirty days after the withdrawal or striking out of the appeal; but otherwise such a certificate shall take effect upon the expiration of thirty days after the dismissal of the appeal and not otherwise.

Regulations for this Part

- 22 (1) The Minister may make regulations under this section with respect to registered pharmacies—
 - (a) prescribing standards for their maintenance and operation, including provision for space, equipment and facilities;
 - (b) imposing requirements as to the circumstances in which a registered pharmacist must, or (as the case may require) need not, be present in a registered pharmacy;
 - (c) prescribing the books and records to be kept, and providing for the examination by or on behalf of the Minister of such books and records;
 - (d) prescribing the returns to be made, and information to be forwarded, to the Minister.
- (2) Regulations made under this section shall be subject to the negative resolution procedure.

PART V

CONTROL OF PRESCRIPTIONS AND IMPORTATION

Prescriptions to be in a certain form

- 23 (1) Subject to the provisions of this section, a prescription of any substance shall not be made by a practitioner unless it is on a valid prescription form which includes the information as provided in regulation 5 or 6 of the Pharmacy and Poisons (Control of Prescriptions) Regulations 2022.
- (2) Nothing in subsection (1) shall make it unlawful for a registered pharmacist to execute a prescription that is transmitted to him by telephone by a practitioner where

the practitioner's voice is known to him and he honestly believes the voice of the person transmitting the prescription to be that of the practitioner.

- (3) Subsection (1) shall not apply to a practitioner who transmits a prescription to a registered pharmacist by telephone if the prescription is for a ten-day supply of the medicine prescribed; so, however, that in no case such a prescription be refilled by the registered pharmacist.
- (4) The original of every prescription dispensed by him shall bear a number and shall be preserved by the registered pharmacist on a file kept for that purpose in the pharmacy and he shall, where requested to do so by another registered pharmacist, furnish a copy thereof to that other registered pharmacist unless the prescribing practitioner has forbidden the furnishing of such a copy.
- (5) A copy of a prescription furnished to another registered pharmacist shall contain the following information:
 - (a) the name and address of the prescribing practitioner and of the person for whom the substance has been prescribed;
 - (b) the name of the substance prescribed, its strength and quantity, and directions for its use;
 - (c) the dates of the first and last dispensing of the substance prescribed and the number of refills (if any) remaining; and
 - (d) the number of the prescription and the name and address of the pharmacy.
- (6) Where a request is made for a prescription to be refilled at a pharmacy other than that at which the substance prescribed was first dispensed, the registered pharmacist to whom the request is made shall communicate with the pharmacy at which the substance was first dispensed for the purpose of obtaining a copy of the prescription and the pharmacy at which the substance prescribed was first dispensed shall make a record of the date, the name and address of the pharmacy where the prescription is refilled. In the event that a third pharmacy is in possession of the original prescription, that pharmacy must be informed as well of the fact of the refilling of the prescription and of the date, name and address of the pharmacy where the prescription is refilled. A registered pharmacist who refills a prescription shall make a record of the date and quantity of the substance dispensed and he shall initial the record.
- (7) A registered pharmacist may, at the request of a person under medical treatment and where the circumstances constitute an emergency, supply a Schedule 3 drug in relation that person without a prescription being presented to him:

Provided that in no circumstances whatever shall he supply a drug which is also specified in Schedule 2 of the Misuse of Drugs Regulations 1973.

(8) Before a registered pharmacist may supply a Schedule 3 drug under subsection (7) he must satisfy himself by means of questions put to the person requesting the drug—

- (a) that there is a genuine and urgent need by the person for the Schedule 3 drug;
- (b) that it is not practicable in the circumstances of the particular case for a prescription to be obtained from a practitioner immediately;
- (c) that treatment with the particular Schedule 3 drug has been previously prescribed by a practitioner for the person requesting it; and
- (d) that the dose which he will supply is appropriate to the need of the person.
- (9) The supply of a Schedule 3 drug in the circumstances specified in subsection (8) shall not in any case exceed five days' supply except—
 - (a) where the drug is in the form of an ointment or cream, or is a preparation in an aerosol container for the relief of asthma, and in these cases the supply shall consist of the smallest package or container available;
 - (b) an oral contraceptive in which case the full cycle may be dispensed; or
 - (c) an antibiotic in liquid form for oral administration, in which case the smallest quantity that will provide a full course of treatment may be supplied.
- (10) The container or package of a Schedule 3 drug supplied pursuant to subsection (7) shall bear a label showing—
 - (a) an identification number;
 - (b) the date of supply;
 - (c) the name of the person to whom supplied
 - (d) the name and address of the supplying pharmacy;
 - (e) the name, quantity, directions for use, and where appropriate, the pharmaceutical form and strength of the drug;
 - (f) the words EMERGENCY SUPPLY marked thereon; and
 - (g) the initials of the registered pharmacist.
- (11) The registered pharmacist shall also keep a book entitled "Emergency Supply Book" in which shall be entered the particulars at subsection (10)(a) to (f) (inclusive).

[Section 23 subsection (1) repealed and replaced and subsections (3)-(7) (10) and (11) amended by 2013: 48 s. 14 effective 24 December 2013]

Validity of a prescription

23A A prescription shall be valid for one year from the date as shown on a valid prescription form.

[Section 23A inserted by 2013: 48 s. 15 effective 24 December 2013]

Supply by registered pharmacist of equivalent medicines

- 24 (1) Where a registered pharmacist receives for execution a prescription which does not prohibit an alternative equivalent drug or drug product from being supplied under the prescription—
 - (a) it shall be required for the registered pharmacist to supply under the prescription any drug or drug product available to the pharmacist at the location of sale—
 - (i) which is in his opinion the chemical and therapeutic equivalent of the drug or drug product specified in the prescription; and
 - (ii) if taking all relevant factors into account, the price that he charges and accepts for the drug or drug product he supplies is less than that which he would have charged and accepted for the drug or drug product specified;
 - (b) it shall be lawful for the registered pharmacist to supply under the prescription any drug or drug product—
 - (i) which is in his opinion the chemical and therapeutic equivalent of the drug or drug product specified in the prescription; and
 - (ii) if taking all relevant factors into account, the prices that he charges and accepts for the drug or drug product he supplies is the same as that which would have charged and accepted for the drug or drug product specified.
- (2) A drug or drug product supplied by a registered pharmacist under subsection (1) must be a drug or drug product accepted by the Council as the chemical and therapeutic equivalent of the drug or drug product specified in the prescription in question.

[Section 24 repealed and replaced by 2013: 48 s. 16 e] fective 1 February 2014]

Restrictions on the importation of medicines

- 25 (1) A person shall only import into Bermuda for medicinal use medicines that are obtained from foreign manufacturers or foreign wholesalers if those medicines are eligible for sale in the United States of America, Canada, the United Kingdom or a country in the European Union in accordance with the regulatory standards of the relevant country.
- (2) A person who acquires medicine from abroad for distribution or sale in Bermuda shall register with the Minister in accordance with regulations made under this Act by the Minister.
- (3) Any person who fails to comply with this section or any regulations made under this Act commits an offence.
- (4) A person who fails to comply with this section or any regulations made under this Act may have any medicines being imported by him forfeited to the Crown.
 - (5) The Minister may make regulations to prescribe the requirements for—

- (a) the registration of a person under subsection (2); and
- (b) the importation of medicines.
- (6) In this section—

"manufacturer" means a person involved in the production, preparation, propagation, conversion, processing, packaging or labelling of medicine;

"medicine" means any substance specified in the Third Schedule (in this Act referred to as a "Schedule 3 drug");

"wholesaler" means a person who obtains medicine for distribution or delivery to persons other than consumers.

(7) The negative resolution procedure shall apply to regulations made under this section.

[Section 25 repealed and replaced by 2011 : 31 s. 3 ejfective 10 August 2011; Section 25 subsection (1) amended by 2020 : 4 s. 2 ejfective 31 January 2020]

Declaration relating to imported medicines

26 |Repealed by 2011 : 31 s. 4|

[Section 26 repealed by 2011:31 s. 4 exfective 10 August 2011]

PART VI

CONTROL OF DRUGS

Certain substances to be sold on prescription only

- 27 (1) Subject to any provision made by any regulation, no person shall for medicinal use sell any Schedule 3 drug otherwise than under a prescription.
 - (2) In this section and section 28 "sell" or "sale" means sell or sale by retail.

Certain substances to be available at pharmacies only

- 28 (1) Subject to subsection (3) and to any provision made by any regulation, no person shall for medicinal use keep for sale, or sell, any substance specified in Part I or Part II of the Fourth Schedule (in this Act referred to as a "Schedule 4 drug") elsewhere than at a registered pharmacy.
- (2) Subject to subsection (3) and to any provision made by any regulation, no person shall for medicinal use keep for sale, or sell, any substance specified in Part II of the Fourth Schedule unless he is a registered pharmacist.
- (3) Subsection (1) or (2) shall not apply to a practitioner as respects anything done by him in the course of his practice as such.

[Section 28 substituted by 1989:56 effective 15 January 1990]

Restrictions on dispensing

29 Subject to any provision made by any regulation no person other than a registered pharmacist or a practitioner acting in the course of his practice as such shall manufacture or compound or dispense any Schedule 3 or Schedule 4 drug.

Prohibition on giving away Schedule 3 or Schedule 4 drugs

- 30 (1) Subject to subsection (2), no person shall make a gift of any Schedule 3 or Schedule 4 drug to any person who is not a practitioner or a registered pharmacist.
 - (2) Subsection (1) shall not apply—
 - (a) to a practitioner who makes a gift of a Schedule 3 or Schedule 4 drug; or
 - (b) to a registered pharmacist who makes a gift of a Schedule 4 drug,

to another person for use by that person for the medical or dental treatment of a human being or animal.

Unfit drugs

31 |Repealed by 2013 : 48 s. 17|

[Section 31 repealed by 2013: 48 s. 17 e) fective 24 December 2013]

Health and safety requirements

- 31A (1) For the purposes of sections 31B, 31C, 31D and 31E, a drug or drug product fails to comply with a general health and safety requirement if it is not reasonably safe having regard to all the circumstances including—
 - (a) the manufacturer of a drug or drug product, or any regulatory authority that granted a drug or drug product marketing authorisation, issuing a recall or any form of notice of warning for the drug or drug product;
 - (b) marketing authorisation of a drug or drug product granted by the regulatory authority in the United States, Canada, the United Kingdom or the European Union, or another jurisdiction that the United States, Canada, the United Kingdom or the European Union has a mutual recognition agreement with, is denied, suspended or discontinued due to reasons of quality, safety or efficacy;
 - (c) the storage, distribution, supply, security, or handling of the product compromised its safety, quality or efficacy due to standards set by the manufacturer or regulatory authority that granted marketing authorization for the drug or drug product;
 - (d) the drug or drug product is not properly labelled to allow for—
 - (i) its safe consumption;
 - (ii) the determination of—
 - (A) the amount of active ingredients;

- (B) its proper use;
- (C) the content;
- (e) any other risk to public or individual health as specified by the Minister after consultation with the Chief Medical Officer.
- (2) A person is guilty of an offence under this section if he-
 - (a) supplies any drug or drug product which fails to comply with the health and safety requirement or any prescribed standard;
 - (b) offers or agrees to supply any such drug or drug product; or
 - (c) exposes or possesses such drug or drug product for supply,

and is liable on summary conviction to a fine of \$10,000 or imprisonment for 6 months, or both.

[Section 31A inserted by 2013 : 48 s. 18 ϵ] fective 24 December 2013; Section 31A subsection (1)(b) amended by 2020 : 4 s. 2 ϵ] fective 31 January 2020]

Orders and notices to prohibit supply of a drug or drug product

- 31B (1) The Minister may—
 - (a) make orders ("prohibition orders") prohibiting persons from supplying, or offering to supply, exposing for supply or possessing for supply any drug or drug product which the Chief Medical Officer considers is not safe and which are described in the orders;
 - (b) serve on any person a notice ("prohibition notice") prohibiting the person from supplying, or offering to supply, agreeing to supply, exposing for supply or possessing for supply any drug or drug product which the Chief Medical Officer considers is not safe and described in the notice;
 - (c) serve on any person a notice ("notice to warn") requiring the person to publish, in a form and manner and on occasions specified in the notice and at his own expense a warning about any drug or drug product so specified which the Chief Medical Officer considers is not safe and which the person supplies or has supplied.
- (2) A person who contravenes a prohibition order, a prohibition notice or a notice to warn is liable on summary conviction to a fine of \$10,000 or to imprisonment for 6 months, or both.

[Section 31B inserted by 2013: 48 s. 18 ϵ] fective 24 December 2013]

Suspension notices

31C (1) Where the Minister has reasonable grounds for suspecting that any health and safety requirement provided in section 31A has been contravened in relation to any drug or drug product, he may serve a notice ("a suspension notice") prohibiting the person on whom it is served, for such period ending not more than six months after the date of the notice as specified therein, from supplying the drug or drug product, offering

to supply them, agreeing to supply them or exposing them for supply without the consent of the Minister.

- (2) A suspension notice shall—
 - (a) describe the drug or drug product in a manner to sufficiently identify it;
 - (b) set out the grounds on which the Minister suspects that a safety provision has been contravened in relation to the drug or drug product; and
 - (c) state that the person on whom the notice is served may apply under section 31D for an order setting aside the notice.
- (3) The consent of the Minister under subsection (1) may impose such conditions on the doing of anything for which the consent is required as the Minister considers appropriate.
- (4) Any person who contravenes a suspension notice is guilty of an offence and is liable on summary conviction to a fine of \$10,000 or to imprisonment for 6 months, or both.

[Section 31C inserted by 2013: 48 s. 18 ejfective 24 December 2013]

Application to set aside a suspension notice

- 31D (1) Any person having an interest in any drug or drug product in respect of which a suspension notice is in force may apply to a magistrate for an order setting aside the notice.
- (2) On an application under subsection (1), the magistrate shall not make an order setting aside the suspension notice unless he is satisfied that there has been no contravention of any safety provision in relation to any drug or drug product.

[Section 31D inserted by 2013: 48 s. 18 e) fective 24 December 2013]

Power to obtain information

- 31E (1) If the Minister considers that, for the purpose of deciding whether to make, vary or revoke a prohibition order or to serve, vary or revoke a prohibition notice or to serve or revoke a notice to warn, he requires information which another person is likely to be able to furnish, the Minister may serve on the other person a notice requiring the person—
 - (a) to furnish to the Minister within a period specified in the notice, such information as is so specified;
 - (b) to produce such documents as are specified in the notice at a time and place so specified and to permit a person appointed by the Minister for the purpose of taking copies of the documents at that time and place.
 - (2) A person is guilty of an offence if he—
 - (a) fails, without reasonable cause, to comply with a notice served on him under subsection (1); or

- (b) in purporting to comply with a requirement which by virtue of subsection (1)(a) is contained in a notice served on him under that subsection, furnishes information which he knows is false in a material particular or recklessly furnishes information which is false in a material particular.
- (3) A person guilty of an offence under-
 - (a) subsection 2(a) of that subsection, is liable on summary conviction to a fine of \$10,000 or to imprisonment for 6 months; and
 - (b) subsection 2(b) of that subsection, is liable on summary conviction to a fine of \$15,000 or to imprisonment for 12 months.
- (4) No information obtained by virtue of this section shall be disclosed except—
 - (a) for the purpose of any criminal proceedings or any investigation with a view to such proceedings;
 - (b) for the purpose of enabling the Minister to decide whether to make, vary or revoke safety regulations or a prohibition order or whether to serve, vary or revoke a prohibition notice or to serve or revoke a notice to warn; or
 - (c) in a prohibition notice, a notice to warn or a warning published as required by a notice to warn or in a warning about goods which is published by the Minister;

but the prohibition on disclosure imposed by this subsection does not apply to publicised information.

(5) A person who discloses information in contravention of subsection (4) is liable on summary conviction to a fine of \$10,000 or to imprisonment for 6 months, or both.

[Section 31E inserted by 2013: 48 s. 18 e) fective 24 December 2013]

PART VII

CONTROL OF POISONS

Prohibition of sale of poison without licence

32 Subject to the provisions of this Part, it shall be unlawful for a person to offer for sale, or sell, any poison unless he holds a licence for the purpose under section 34.

Poisons

33 Any substance specified in the Fifth Schedule shall be a poison for the purposes of this Act.

Licences to sell poisons

34 (1) Any person who makes application to the Minister in the prescribed form and pays the appropriate fee provided for under the Government Fees Act 1965 [title 15 item

- 18] may be granted a licence by the Minister under this section, and a person holding such a licence is in this Act referred to as a "licensed seller of poisons".
- (2) The Minister may refuse to grant a licence under this section to any person who for any reason relating to that person or his premises and appearing to the Minister to be sufficient is not fit to hold such a licence.
- (3) A licence under this section shall not entitle the holder to sell any poison for a use that is a medicinal use, and it shall accordingly be an offence against this Act for a licensed seller of poisons to sell a poison if he knows or has reason to believe that the poison will be applied to a use that is a medicinal use.
- (4) The licence of a licensed seller of poisons shall lapse if he does not on or before the 31st day of December pay to the Minister the appropriate annual fee provided for under the Government Fees Act 1965 [title 15 item 18].
- (5) A list of the licensed sellers of poisons shall be published annually in the Gazette so soon as may be after the 1st day of January, and particulars of any alterations made in the number of licensed sellers of poisons on or after that date in any year shall also be published in the Gazette.

Revocation of licences

35 Subject to section 36, the Minister may revoke a licence granted under section 34 for any reason such as is mentioned in section 34(2), and shall give notice in writing to the holder of the licence of his decision to revoke the licence and the reasons for the decision.

Appeals

- 36 (1) Any person aggrieved by the revocation of a licence under section 35 may within twenty-eight days after receiving notice of the decision appeal to the Supreme Court, and upon any such appeal that Court shall have power to confirm or revoke the Minister's decision.
- (2) The powers of the Chief Justice to make rules under section 62 of the Supreme Court Act 1905 [title 8 item 1] shall extend to the making of rules regulating the practice and procedure to be followed on, and the fees to be paid in connexion with, any such appeal.
- (3) The Minister may appear as respondent on any such appeal and, whether he appears at the hearing of the appeal or not, he shall be deemed to be a party to the appeal for the purpose of enabling directions to be given as to the costs or expenses of the appeal.
- (4) Where an appeal is not brought against the decision of the Minister to revoke a licence under section 35, or where an appeal is brought but is withdrawn or struck out for want of prosecution, the decision shall take effect on the expiration of the time for appealing or, as the case may be, on the withdrawal or the striking out of the appeal; but otherwise such a decision shall take effect if and when the appeal is dismissed and not otherwise.

Poisons Book

- 37 (1) Every person who sells poison shall maintain a book (in this Act called the "Poisons Book") in such form as the Minister may approve for the purpose of keeping the records called for by subsection (2).
- (2) Every such person shall enter and keep in the Poisons Book, in relation to every sale by him of a poison, a record of—
 - (a) the date of the sale;
 - (b) the kind and quantity of the poison sold;
 - (c) the name and address of the purchaser; and
 - (d) the purpose stated by the purchaser for the purchase,

and he shall obtain the signature of the purchaser to, and himself sign, the entry in the Book.

Sale of poisons to unknown persons prohibited

- 38 A person shall not sell poison to any person that is not known to him, except in the presence of a third person who—
 - (a) is known to the seller; and
 - (b) declares to the seller that the purchaser is known to him; and
 - (c) in confirmation of his declaration signs the entry in the Poisons Book.

Sale of poisons to persons under 18 prohibited

- 39 (1) Subject to subsection (2), it shall be an offence against this Act for any person to sell poison to a person under 18 years of age.
- (2) It shall be a defence for a person charged with an offence against subsection (1) that he believed on reasonable grounds (the proof whereof shall be on him) that the purchaser was 18 years or over.

Labelling of poisons

Subject to any provision made by any regulation, no person shall sell any poison to any other person unless the word "poison" and the name and business address of the seller and the date of the sale are displayed in clear and legible writing on the surface of the receptacle in which the poison is contained.

Sale of poisons to intoxicated persons etc. prohibited

41 It shall be an offence against this Act for any person to sell poison to another person whom he knows, or has cause to believe, to be intoxicated by drink or drugs or to be of unsound mind.

Method of keeping poisons

- 42 In the keeping of poisons it shall be the duty of every licensed seller of poisons to ensure—
 - (a) that every bottle, vessel, box or package containing poison has attached to it a label bearing the name of the article and also some distinctive mark to show that poison is contained therein;
 - (b) that poison is kept in accordance with one or other of the following systems, that is to say,—
 - in a bottle or vessel tied over, capped, locked or otherwise secured in a manner different from that in which vessels containing articles that are not, or do not contain, poison are secured in the same premises;
 - (ii) in a bottle or vessel rendered distinguishable by touch from bottles or vessels in which articles that are not, or do not contain, poison are kept in the same premises;
 - (iii) in a bottle, vessel, box or package kept in a room or cupboard set apart for dangerous articles.

Statement of proportion of poison in preparations

- 43 (1) Subject to subsections (2) and (3), it shall be the duty of every person selling a preparation containing poison to ensure that there is set out on a label attached to the preparation the proportion, whether expressed as a percentage or otherwise, which such poison bears to the total content of the preparation.
- (2) In the case of a preparation listed in the official British Pharmacopoeia or the British Pharmaceutical Codex or any supplement thereto, it shall be a sufficient compliance with subsection (1) if that preparation—
 - (a) when sold either with or without dilution or admixture, is described by its name or synonym or abbreviated name used in the Pharmacopoeia, Codex or supplement with the addition of the letters B.P. or B.P.C., as the case may be; and
 - (b) when sold with dilution or admixture, is described by the proportion which the preparation bears to the mixture of which it forms a part.

Liquid preparations containing poison

- 44 It shall be the duty of every person selling any liquid preparation containing poison to ensure—
 - (a) that the preparation is not sold otherwise than in bottles, tins, drums or casks sufficient to withstand without leakage the ordinary risks of transit;
 - (b) that every such bottle, tin, drum or cask has the legend "Poison not to be taken internally" indelibly printed, marked or branded in easily legible

- letters in a conspicuous position apart from the label, and that there is thereon a label bearing the same legend; and
- (c) when such a liquid is sold in bottles, that such bottles are of a distinctive character so as to be easily distinguishable by touch from other bottles.

PART VIII

MISCELLANEOUS

Wholesale transactions

- 45 (1) Subject to any provision made by any regulation, no person shall by wholesale sell or otherwise dispose of any schedule 3 or Schedule 4 drug or poison to any person that is not entitled to sell that drug or poison by retail.
- (2) A sale or disposal of a drug or poison is a sale or disposal by wholesale for the purposes of this Act if it is a sale or disposal to a person who buys or receives the drug or poison for the purpose of selling or disposing of the drug or poison to some other person; and in this Act "sale by retail" or "sell by retail" means sale or sell otherwise than by wholesale.

Dispensing records

- Where any person supplies a Schedule 3 or Schedule 4 drug or poison (hereafter in this section referred to as a "substance") under a prescription—
 - (a) he shall mark in clear and legible writing on a paper accompanying the substance—
 - (i) his initials;
 - (ii) his name, address and telephone number (if any) or, where the substance is supplied from a registered pharmacy, the name, address and telephone number (if any) of the registered pharmacy;
 - (iii) the name of the customer to whom the substance is supplied;
 - (iv) the directions for using the substance;
 - (v) the number assigned to the prescription;
 - (vi) the quantity of the substance supplied;
 - (vii) the brand or trade name, the generic name, the name of the manufacturer and the strength of the substance supplied;
 - (viii) whether the prescription is to be refilled, and if so, the number of times;
 - (ix) the date when the prescription is filled; and
 - (x) the name of the practitioner who issued the prescription;

(b) he shall, or, where the substance is supplied from a registered pharmacy, the operator of the pharmacy shall, for the period of two years (or, where the prescription was repeated, two years after the last time it was repeated) retain the original of the prescription.

[Section 46(a)(x) inserted by 2013: 48 s. 19 ϵ] fective 24 December 2013]

Prescription drug pricing

- 46A (1) Where any person supplies a prescription drug to another person, he shall inform the person purchasing the drug of—
 - (a) the cost of the drug—
 - (i) covered by insurance, in the case where the person purchasing the drug is insured; and
 - (ii) payable by the person purchasing the drug; and
 - (b) the amount of the dispensing fee charged by the person supplying the drug.
- (2) A person who contravenes subsection (1) commits an offence against this Act. |Section 46A inserted by 2021:15 s. 4(a) ϵ_i fective 10 September 2021|

Dishonest sales

- 47 It shall be an offence against this Act for any person keeping for sale, or offering for sale, or selling, any Schedule 3 or Schedule 4 drug or poison falsely to represent to any person—
 - (a) that it is a substance that it is not; or
 - (b) that it contains a substance that it does not contain; or
 - (c) that it is unadulterated when it has been adulterated.

Regulations for Parts VI and VII

- 48 (1) The Minister may make regulations under this section—
 - (a) prescribing the amount or proportion of any substance that is to be contained in a Schedule 3 or Schedule 4 drug or a poison;
 - (b) prescribing the types of, and labelling for, containers to be used for containing a Schedule 3 or Schedule 4 drug or a poison;
 - (c) regulating the manner in which, and the conditions subject to which, Schedule 3 or Schedule 4 drugs or poisons are to be prescribed by practitioners, including the conditions under which Schedule 3 or Schedule 4 drugs or poisons may be supplied on a second or subsequent occasion without a further prescription having to be prepared;
 - (d) regulating the manner in which records are to be kept of the purchase and sale of Schedule 3 or Schedule 4 drugs or poisons;

- (e) designating poisons that may be sold by persons not otherwise authorized by this Act for the purpose, and authorizing and regulating the sale of such poisons by such persons or by classes of such persons;
- (f) designating Schedule 3 or Schedule 4 drugs and poisons that may be sold by persons not otherwise authorized by this Act for the purpose, and authorizing and regulating the sale without prescription by such persons or by classes of such persons of such drugs and poisons to owners of birds or animals for the treatment of the birds or animals;
- (g) [deleted]
- (h) generally for carrying out the purposes of sections 31A, 31B, 31C, 31D, 31E, 51, 51A and 51B.
- (2) Regulations made under this section shall be subject to the negative resolution procedure.

[Section 48 subsection (1) amended by 2013 : 48 s. 20 ϵ] fective 24 December 2013; subsection (1)(g) deleted by 2014 : 36 s. 2 ϵ] fective 22 December 2014]

Minister may by order amend the Third or Fourth Schedule

- 48A (1) The Minister may, on the recommendation of the Chief Medical Officer or the Council, by order amend the Third or Fourth Schedule.
- (2) The negative resolution procedure shall apply to an order made under subsection (1).

[Section 48A inserted by 2014 : 36 s. 2 ϵ] fective 22 December 2014]

Minister may provisionally add or remove drugs in the Third or Fourth Schedule

The Minister may, on the recommendation of the Chief Medical Officer or the Council, by Notice in the Gazette, provisionally list, or remove, the drugs in the Third or Fourth Schedule and such drugs shall be considered listed in, or removed from, the Third or Fourth Schedule for a period not exceeding 30 days or until the Minister issues an order either adding to, or deleting from, the Third or Fourth Schedule such drugs, whichever occurs earlier.

|Section 48B inserted by 2014: 36 s. 2 effective 22 December 2014|

Minister may obtain reports on drugs and poisons

- 49 (1) The Minister may by notice in writing served upon any practitioner or any registered pharmacist require him to report to the Minister in writing the quantity of any Schedule 3 or Schedule 4 drug or any poison that he has purchased or sold or, in the case of a practitioner, prescribed, as the case may be, during the period stated in the notice.
 - (2) Where—
 - (a) the Minister has reason to believe (whether or not because of a report made to him pursuant to a notice served under subsection (1)) that a

practitioner or a registered pharmacist has purchased or sold, or a practitioner has prescribed, excessive or otherwise unreasonable amounts of a Schedule 3 or Schedule 4 drug or a poison during a particular period; or

- (b) a practitioner or registered pharmacist fails to make a report that he has been properly required under subsection (1) to make; or
- (c) a report such as aforesaid appears to the Minister to be incomplete,

then, but without prejudice to any other power that is available to the Minister or any other person, the Minister may report the matter to the Council in the case of a registered pharmacist, or to the relevant professional body in the case of a practitioner, for such action as the Council or that body may think fit to take.

(3) In subsection (2) "relevant professional body", in relation to a practitioner, means the body appearing to the Minister to be the body having professional disciplinary control over the practitioner.

[Section 49 subsection (2) amended by 2013: 48 s. 21 e]fective 24 December 2013]

Minister may obtain information on prices

- 50 (1) The Minister may by notice in writing under this section served upon any practitioner or the operator of any registered pharmacy require him to supply to the Minister in writing such information as may be specified pursuant to subsection (2).
 - (2) A notice under this section may demand information relating to—
 - (a) the price at which any substance was purchased by any person; and
 - (b) the price at which any substance was sold by any person to any member of the public,

in the conduct, or for the purposes, of the practice of the practitioner or the business of the registered pharmacy as the case may be during the period specified in the notice, and may demand any other information relating to, or connected with, the prices of substances so purchased or sold which the Minister may consider is required for establishing whether the prices charged to the public for such substances during the period were fair and reasonable.

Inspections

- 51 (1) It shall be the duty of the Minister, by means of inspection and otherwise, to take all reasonable steps to enforce, and secure compliance by registered pharmacists and others with the provisions of this Act or any regulation, and the Minister shall for that purpose appoint such number of inspectors as in his opinion is required.
- (2) Any inspector may, for the purposes of enforcement of this Act or any regulations, make test purchases or otherwise ascertain whether any provisions of this Act or any regulations or of an order under this Act are being complied with.

- (3) An inspector appointed under this section who has reasonable cause to believe that an offence under this Act or regulations has been committed shall, for the purpose of enforcing and securing compliance with the said provisions have power—
 - (a) at all reasonable times and on production, if required, of his credentials, enter any registered pharmacy or place of business (other than premises or parts of premises used as a dwelling house) and while there he may—
 - (i) inspect any drug or drug product found;
 - (ii) examine any procedure;
 - (iii) seize and detain drugs or drug products for testing;
 - (iv) seize and detain goods or documents which he believes may be required as evidence in proceedings under this Act;
 - (v) for the purpose of exercising his powers to seize drugs or drug products under this section and to the extent that it is reasonably necessary in order to ensure compliance with any provision of this Act, require any person having authority to do so to break open any container, and if the person does not comply, the inspector may do so himself.
- (4) An inspector who seizes drugs, drug products or documents in exercise of his powers under subsection (3) shall, in a written statement specifying the nature and amount of items seized, inform the person from whom they are seized.
- (5) For the purpose of proceedings taken or transactions made under this Act, the written statement of an inspector given under subsection (4) has effect as a receipt for the drug, drug products or documents seized.
- (6) A magistrate who is satisfied by sworn information in writing that there are reasonable grounds to believe that—
 - (a) goods, books or documents which an inspector has power to inspect are on any premises and that their inspection is likely to disclose evidence of the commission of an offence under this Act or the regulations; or
 - (b) an offence under this Act or the regulations has been, is being, or is about to be committed on any premises;

and that-

- (c) admission to the premises has been or is likely to be refused and that notice of intention to apply for a warrant under this subsection has been given to the occupier; or
- (d) an application for admission or the giving of the notice mentioned in paragraph (c) would defeat the object of the entry or that the premises are unoccupied or that the occupier is temporarily absent and it might defeat the object of the entry to await his return,

may by warrant under his hand, which shall continue in force for a period of one month, authorise any inspector to enter the premises, if need be by force.

(7) An inspector who enters premises by virtue of this section may take with him such other persons and equipment as appears necessary to him, and on leaving premises which he enters by virtue of a warrant under subsection (6), where either the premises are unoccupied or the occupier is temporarily absent, he shall affix a notice in a conspicuous place stating that the premises were entered for the purpose of this section, and as far as practicable shall leave the premises as effectively secured against trespassers as he found them.

(8) A person who—

- (a) wilfully obstructs an inspector acting in the exercise of any power conferred on him under subsections (3) to (7);
- (b) wilfully fails to comply with any requirement properly made to him by an inspector under subsections (3) to (7);
- (c) without reasonable cause fails to give an inspector acting under subsections (3) to (7), such assistance or information as he may reasonably require of the person for the performance of the inspector's functions;
- (d) in giving information as mentioned in paragraph (c) makes a statement which he knows to be false;
- (e) not being an inspector purports to act as an inspector under this Act;
- (f) discloses to another person, where the disclosure is not made in the performance of his duty—
 - (i) information with respect to a manufacturing process or trade secret obtained by him in premises which he has entered by virtue of subsections (3) to (7); or
 - (ii) information otherwise obtained by him under this Act,
 - is guilty of an offence and is liable on summary conviction to a fine of \$10,000 or imprisonment for 6 months, or both.
- (9) An inspector appointed under this section shall have power with the consent of the Minister to institute summary proceedings in respect of an offence against this Act or any regulation, and to conduct any such proceedings notwithstanding that he is not a barrister and attorney.
- (10) If a person wilfully delays or obstructs an inspector in the exercise of any of his powers under this section, or refuses to allow any sample to be taken in accordance with the provisions of this section, or fails without reasonable excuse to give any information which he is duly required under this section to give, he is guilty of an offence against this Act.

[Section 51 repealed and replaced by 2013 : 48 s. 22 e]fective 24 December 2013]

Notice of test

- 51A (1) Where drugs or drug products seized or purchased by an inspector in pursuance of this Act are submitted to a test, the inspector shall—
 - (a) if the drugs or drug products were seized, inform the person from whom they were seized of the result of the test;
 - (b) if the drugs or drug products were purchased and the test leads to proceedings for an offence under this Act, inform the person from whom the goods were purchased of the result of the test;

and where as a result of the test proceedings for an offence are instituted against a person, the inspector shall allow the person to have the goods tested independently if it is reasonably practicable to do so.

(2) The Minister may by order provide for the testing of drugs or drug products seized or purchased by an inspector in pursuance of this Act and in particular may in those orders provide that the test be carried out at the Ministry's expense in a manner, by a person, and at a laboratory or testing facility specified in the order.

[Section 51A inserted by 2013: 48 s. 23 effective 24 December 2013]

Compensation

- 51B (1) Where in the exercise of his powers under section 51 an inspector seizes and detains any drugs or drug products, and the owner suffers loss by reason of the goods being seized or by reason that, during the detention, the goods are lost or damaged or deteriorate, unless the owner is convicted of an offence under this Act committed in relation to the goods, the owner is entitled to compensation for the loss so suffered.
- (2) Any disputed question as to the right to or the amount of any compensation payable under this section shall on the written application of the owner or of the Attorney-General be determined as follows—
 - (a) if the amount of the compensation claimed does not exceed \$10,000, by a magistrate; or
 - (b) if the amount of the compensation claimed exceeds \$10,000, by a judge of the Supreme Court,

in like manner as if the magistrate or the judge were a single arbitrator appointed pursuant to the provisions of the Arbitration Act 1986, and the provisions of that Act shall apply accordingly.

[Section 51B inserted by 2013 : 48 s. 23 ϵ] fective 24 December 2013]

Service of documents

- 52 Any notice or other document required or authorized by any provision of this Act to be served on any person, or to be given or sent to any person, may be served, given or sent—
 - (a) by delivering it to him; or

- (b) by sending it by post to him at his usual or last-known residence or place of business in Bermuda; or
- (c) in the case of a body corporate, by delivering it to the secretary or clerk of the body corporate at its registered or principal office or sending it by post to the secretary or clerk of that body corporate at that office.

Transitional

- 53 (1) Every person who immediately before 1 January 1980 was registered as a pharmacist under the Pharmacists Registration Act 1928 (now repealed) shall be deemed on and after that date to be a registered pharmacist within the meaning of this Act, but subject to the provisions of this Act.
- (2) For such period (and no longer) beginning on 1 January 1980 as the Minister may appoint for the purpose by notice made under this subsection and published in the Gazette every set of premises which immediately before that date was being operated as a pharmacy, being premises to which this subsection applies, shall be deemed to be a registered pharmacy within the meaning of this Act.
- (3) Subsection (2) applies to premises in respect of which the operator of those premises notifies the Minister in writing by 1 February 1980 of his wish to have the benefit of that subsection apply to those premises.
- (4) Every person who immediately before 1 January 1980 was the holder of a licence granted to him under section 2 of the Poisons Act 1930 (now repealed) shall be deemed on and after that date to be a licensed seller of poisons within the meaning of this Act, but subject to the provisions of this Act.

Student pharmacists

- 54 (1) Nothing in section 6 shall have effect in relation to a student pharmacist acting in accordance with a permit granted to him under this section.
- (2) The Minister may grant a permit under this section to a student pharmacist to compound or dispense any substance specified in the Third, Fourth or Fifth Schedule, subject to the conditions specified in the permit.
- (3) A permit under this section must contain a condition that the permit-holder when acting under the permit shall do so under the direct personal control and supervision of a registered pharmacist who is named in the permit and who has endorsed the permit in acknowledgement of his responsibility thereunder; and (but without prejudice to any liability of the permit-holder apart from this Act) any act done by the permit-holder under, or in reliance upon, the authority of the permit shall for the purposes of this Act be deemed to be the act of that registered pharmacist.
- (4) The Minister may without notice at any time in writing revoke a permit granted under this section.
- (5) In this section "student pharmacist" means a person who has satisfied the Minister that he is undergoing a course of training that will qualify him in due course to receive a certificate of competence from the Council.

Offences

- 55 (1) Any person who contravenes or fails to comply with any duty or prohibition imposed upon him by or under any provision to which this section applies commits an offence against this Act.
- (2) The provisions to which this section applies are sections 23, 25, 27 to 30, 32, 37, 38, 40, 42 to 46, 46A, 49 and 50.
- (3) Subject to subsection (3A), any person committing an offence against this Act may be proceeded against either summarily or on indictment—
 - (a) Punishment on summary conviction: imprisonment for 12 months or a fine of \$20,000, or both such imprisonment and fine;
 - (b) Punishment on conviction on indictment: imprisonment for 3 years or a fine of \$50,000, or both such imprisonment and fine;
- (3A) A person who contravenes section 6 commits an offence and is liable on summary conviction to fine of \$10,000 or a term of imprisonment of six months or to both for a first offence, and to a fine of \$20,000 or a term of imprisonment of one year or to both for a second or subsequent offence.
- (4) The power to make regulations under section 15, 22 or 48 includes the power to constitute offences for contravention of, or failure to comply with, any such regulation and to fix punishments, including imprisonment (but not exceeding the scale of punishments for which subsection (3) of this section provides), for any such offence.
- (5) Where an offence committed against this Act or any regulation by a body corporate is proved to have been committed with the consent or connivance of, or to be attributable to any neglect on the part of, any director, manager, secretary or other similar officer of the body corporate, or any person who was purporting to act in any such capacity, he, as well as the body corporate, commits an offence against this Act and is liable to be proceeded against and punished accordingly.

[Section 55 amended by 2020 : 47 s. 113 ϵ] fective 11 December 2020; Section 55 amended by 2021 : 15 s. 4(a) ϵ] fective 10 September 2021]

Repeal

56 [omitted]

Commencement

57 [omitted]

FIRST SCHEDULE

(Sections 5 and 7(1))

THE PHARMACY COUNCIL

- 1 A member of the Council shall hold office for the period of one year or for such longer or shorter period as the Minister may determine.
- 2 A member of the Council shall be eligible for re-appointment or re-election to membership of the Council.
- A person appointed or elected to fill the place of a member of the Council who vacates office before the expiry of his term of office shall hold office for so long only as the member whose place he fills would have held the office.
- Where a member of the Council vacates his office three months or less before the expiry of his term of office, the vacancy need not be filled.
- 5 A member of the Council may resign his office at any time by giving notice in writing to the Minister of his resignation.
- The Minister may declare the office of a member of the Council vacant if—
 - (a) the Minister is satisfied that the member is unable through mental or physical incapacity to perform the functions of his office; or
 - (b) the member has failed without adequate cause to attend three successive meetings of the Council.
- The Council may act notwithstanding any vacancy in their membership, and no act of the Council shall be invalid by reason only of a defect in the appointment of a member.
- 7A Every question or matter to be determined by the Council at any meeting shall be decided by a majority of the members present at the meeting but, in the event of an equality of votes, the Chairman shall have the casting vote.
- 8 Subject to the foregoing provisions of this Schedule the Council may regulate their own procedure.
- 9 (1) The Council may, in its discretion, appoint from among its own members or from among other persons, such number of committees as it thinks fit for purposes which, in the opinion of the Council, would be more expediently carried out or managed by such committees.

(2) The Chairman of any committee appointed under subsection (1) shall be a member of the Council.

10 [deleted]

[First Schedule amended by 2013 : 48 s. 24 ϵ] fective 24 December 2013; First Schedule paragraph 10 deleted by 2014 : 36 s. 2 ϵ] fective 22 December 2014; First Schedule paragraph 7A inserted by 2022 : 3 s. 3 ϵ] fective 9 March 2022]

SECOND SCHEDULE

(Section 2)

LIST OF PRACTITIONERS

Physician- for the purposes of medical treatment of human beings

Dentist- for the purposes of dental treatment of human beings

Veterinary Practitioner- for the purposes of animal treatment

Optometrist- subject to the restrictions and requirements under section 10 and Schedule 2 of the Optometrists and Opticians Act 2008

Advanced Practice Nurse or Midwife- subject to the restrictions and requirements under 8B(1) and (2) of the Nursing and Midwifery Act 1997

[Second Schedule repealed and replaced by 2013 : 48 s. 25 ϵ] fective 24 December 2013; Second Schedule amended by 2018 : 58 s. 17 ϵ] fective 17 December 2018]

THIRD SCHEDULE

(Sections 25(6); 27(1)))

DRUGS OBTAINABLE ONLY ON PRESCRIPTION EXCEPT WHERE SPECIFIED IN THE FOURTH SCHEDULE (PART I AND PART II)

Note: The following annotations used in this Schedule have the following meanings:

md (**maximum dose**) i.e. the maximum quantity of the substance contained in the amount of a medicinal product which is recommended to be taken or administered at any one time.

mdd (maximum daily dose) i.e. the maximum quantity of the substance that is contained in the amount of a medicinal product which is recommended to be taken or administered in any period of 24 hours.

mg milligram

ms (maximum strength) i.e. either or, if so specified, both of the following:

- (a) the maximum quantity of the substance by weight or volume that is contained in the dosage unit of a medicinal product; or
- (b) the maximum percentage of the substance contained in a medicinal product calculated in terms of w/w, w/v, v/w, or v/v, as appropriate.

external use means for application to the skin, teeth, mucosa of the mouth, throat, nose, eye, ear, vagina or anal canal when a local action only is necessary and extensive systemic absorption is unlikely to occur. Note: the following are not regarded as for external use: throat sprays, throat pastilles, throat lozenges, throat tablets, nasal drops, nasal sprays, nasal inhalations or teething preparations.

parenteral use means administration by breach of the skin or mucous membrane.

_			
1			
Abacavir			
ABC Liniment			
Acamprosate			
Acarbose			
Acebutolol			
Acepifylline			
Acepromazine			
Acetanilide			
Acetarsol			

Acetazolamide

Acetohexamide

Acetorphine

Acetrizoic Acid

Acetyl Sulphafurazole

Acetyl Sulphamethoxypyridazine

Acetylcarbromal

Acetylcholine

Acetylcysteine

Acetyldigitoxin

Acetyldihydrocodeine

Acetylpromazine

Acetylstrophanthidin

Acitretin

Aconiazide

Aconite Belladonna and Chloroform

Liniment BP 1968

Aconite Root

Aconitine

Actinomycin C

Actinomycin D

Acyclovir

Adalimumab

Adapalene

Adefovir

Adicillin

Adiphenine

Admune Influenza Vaccine

Adrenaline

Adrenocortical Extract

Adriamycin

Aerosoxacin

Aesculin

Aflibercept

Agomelatine

Albamycin preparations

Albamycin T preparations

Albumin Human

Albumin Microspheres Human (3M)

Albuterol, Salbutamol

Amiloride

Alclofenac Alcuronium Chloride Aldosterone Alendronate Alfacalcidol Alfentanil Alfuzosin Algestone Algestone Acetonide Algestone Acetophenide Aliskiren Alitretinoin Alkavervir Allobarbitone Allopurinol Allyloestrenol Allylprodine Almotriptan Alphacetylmethadol Alphadolone Acetate Alphameprodine Alphamethadol Alphaprodine Alphaxalone Alprazolam Alprenolol Alprostadil Alseroxylon Amantadine Ambenonium Chloride Ambrisentan Ambuside Ambutonium Bromide Amcinonide Ametazole Amethocaine for local ophthalmic use Amikacin

Apixaban Apomorphine

Aminocaproic Acid Aminodarone Aminoglutethimide Aminophylline Aminopterin Aminorex (and Methyl Derivative) Aminosalicylic Acid Amiodarone Amiphenazole Amitriptyline Amlodipine Ammonium Bromide Ammonium Chloride in inhalers Amoxycillin, Amoxicillin Amoxycillin Trihydrate Amphetamine Amphomycin Amphotericin Ampicillin Ampicillin Trihydrate Amyl Nitrite Vitrellae BP Amylobarbitone Amylocaine in preparations for local ophthalmic use Anaesthetics all inhalational Anagrelide Anakinra Anastrozole Ancrod Androsterone Aneurine Angiotensin Amide Anileridine Antazoline Anterior Pituitary Extract Anti-lymphocyte Immunoglobulin Antimony Apiol

Apramycin

Apremilast

Aprepitant

Aprobarbitone

Aprotinin

Arecoline

Areocoline-acetarsol

Aripiprazole

Arprinocid

Arsanilic Acid

Arsenic

Arsphenamine

Asparaginase

Astemizole

Atamestane

Atazanavir

Atenolol

Atomoxetine

Atorvastatin

Atovaquone

Atracurium Besylate

Atropine Eye Drops B.P. -

Atropine Eye Ointment B.P. -

Atropine -

Atropine Methobromide -

Atropine Methobromide -

Atropine Oxide -

Atropine Oxide -

Azacyclonol

Azaperone

Azapropazone

Azaribine

Azathioprine

Azelaic Acid

Azidocillin

Azithromycin

Bacampicillin

Bacitracin Methylene Disalicylate

Baclofen

in preparations for local opthalmic use in preparations for local opthalmic use

in inhalers

in preparations for local ophthalmic use

in inhalers

in preparations for local ophthalmic use

in inhalers

Balsalazide

Bambermycin

Bamipine

Barbitone

Barbituric Acid - and derivatives

Barium Carbonate

Barium Chloride

Barium Sulphate

Barium Sulphide

Beclamide

Beclomethasone

Belladonna Herb

Belladonna Root

Bemegride

Benactyzine

Benapryzine

Benazepril

Bendazac

Bendrofluazide, Bendroflumethazide

Benethamine Penicillin

Benoxaprofen

Benperidol

Benserazide

Benzafibrate

Benzathine Penicillin

Benzbromarone

Benzestrol

Benzethidine

Benzhexol

Benzilonium Bromide

Benzocaine -

Benzoctamine

Benzoyl Peroxide -

Benzoylsuphanilamide, N-

Benzphetamine

Benzquinamide

Benzthiazide

Benztrone Injections

Benztropine Mesylate

for local ophthalmic use

in concentrations greater than 10%

Benzyl morphine

Benzylpenicillin

Betacetylmethadol

Betahistine

Betameprodine

Betamethadol

Betamethasone

Betaprodine

Betaxolol

Bethanechol Chloride

Bethanidine

Bevacizumab

Bexarotene

Bezafibrate

Bezitramide

Bicalutamide

Bimatoprost

Biorphen Oral Solution

Biperiden

Bismuth Glycollylarsanilate

Bisoprolol

Bleomycin Sulphate

Bolandiol

Bolasterone

Bolazine

Boldenone Undecylenate

Bolenol

Bolmantalate

Bosentan

Botulinum Toxin

Bretylium Tosylate

Brexpiprazole

Brimonidine

Brinzolamide

Bromazepam

Bromhexine

Bromocriptine

Bromvaletone

Brotizolam

Budesonide
Bufexamac
Bufotenine
Bumetanide
Buphenine

Bupivacaine - in preparations for local ophthalmic use

Buprenorphine Bupropion Buspirone Busulphan

Butacaine - in preparations for local ophthalmic use

Butalbital

Butanilicaine - in preparations for local ophthalmic use

Butaperazine Butobarbitone Butorphanol Butriptyline

Butylchloral Hydrate

Cabergoline Cadexomer Calcipotriol Calcitonin Calcitriol

Calcium 5-allyl-5-N-Butylbarbiturate

Calcium Acetate

Calcium Aminosalicylate Calcium Amphomycin

Calcium Benzamidosalicylate

Calcium Bromide

Calcium Bromolactobionate

Calcium Carbimide Calcium Folinate

Calcium Leucovorin preparations

Calcium Sulphaloxate

Calusterone

Camphorated Opium tincture BP

Camazepam Canagliflozin

Candesartan

Candicidin	
Cannabidiol	
Cannabinol -	and derivatives
Cannabis	
Cannabis resin	
Cantharadin	
Capecitabine	
Capreomycin sulphate	
Captodiamine	
Captopril	
Caramiphen	
Carbachol	
Carbamazepine	
Carbenicillin	
Carbenoxolone	
Carbidopa	
Carbidopa Monohydrate	
Carbimazole	
Carbocisteine	
Carbon Tetrachloride	
Carboxymethylcysteine	
Carfecillin	
Carfentanil	
Carisoprodol	
Carmustine	
Carperidine	
Carphenazine	
Carvedilol	
CCNU, Lomustine	
Cathine	
Cefaclor	
Cefadroxil	
Cefdinir	
Cefixime	
Cefotaxime	
Cefoxitin	
Cefpodoxime Proxetil	

Cefsulodin

Ceftolozane

Cefuroxime

Celecoxib

Centella Asiatica -

extract and active principals thereof (if for

internal use)

Cephalexin

Cephaloglycin

Cephaloram

Cephaloridine

Cephalosporin C

Cephalosporin E

Cephalosporin N

Cephalothin Sodium

Cephamandole

Cephazolin Sodium

Cephradine

Cerium Oxalate

Chemocycline preparations

Chenodeoxycholic Acid

Chloral Antipyrine

Chloral Betaine

Chloral Formamide

Chloral Glycerolate

Chloral Hydrate

Chloralose

Chloralurethane

Chlorambucil

Chloramphenicol

Clorazepic acid

Chlordiazepoxide

Chlorhexadol

Chlorisondamine Chloride

Chlormadinone Acetate

Chlormerodrin

Chlormethiazole

Chlormezanone

Chlorodyne BP

Chloroform -

for inhalational use

Chloroform and Morphine Tincture BP

Chloroquine

Chlorothiazide

Chlorotrianisene

Chlorphenoxamine

Chlorphentermine

Chlorpromazine

Chlorpropamide

Chlorprothixene

Chlortetracycline

Chlorthalidone

Chlorzoxazone

Cholestyramine

Cholic Acid

Choline Magnesium Trisilicate

Choline Theophyllinate

Chorionic Gonadotrophin

Chymotrypsin for parenteral or opthalmic use

Ciclacillin Ciclopirox Cilazapril

Cimetidine Cinacalcet

Cinchocaine -

Cinchophen Cinoxacin

Ciprofloxacin

Cisplatin

Citalopram

Citrated Calcium Carbimide

Clarithromycin

Clavulanic Acid

Clemizole

Clenbuterol

Clidinium Bromide

Clindamycin

Clioquinol

Clobazam

Clobetasol 17-propionate

in preparations for local ophthalmic use

Contraceptives -

Clobetasone Butyrate Clofazimine Clofibrate Clomiphene Citrate Clomipramine Clomocycline Clonazepam Clonidine Clonitazene Clopamide Clopenthixol Clopidogrel Cloprostenol Sodium Clorazepate Clorexolone Clorprenaline Clostebol Acetate Clotiazepam Cloxacillin Cloxazolam Clozapine Cocaine Cocculus Indicus Cocillana Compound Syrup BP 1949 Codeine for non-parenteral use with ms greater than 8mg calculated as base Co-dergocrine Mesylate Colchicine Colesevelam Colestipol Colistin if for implantation under the skin Collagen preparations -Collagenase when sold or recommended as a debriding agent Colocynth and Jalap Compound Tablets BP 1963 Coniine Conium Leaf

oral

Daclizumab

Corticotrophin	
Cortisone	
Cortodoxone	
Cotarnine Chloride	
Co-Trifamole	
Co-trimoxazole, Sulfamethoxazole/ Trimethoprim	
Coumarin derivatives	
Crisaborole	
Cropropamide	
Crotamiton	
Crotethamide	
Croton Oil	
Croton Seed	
Cuemid	
Curare	
Cyclandelate -	in nausea and vomiting in pregnancy
Cyclizine	
Cyclobarbitone	
Cyclobenzaprine	
Cyclofenil	
Cyclomethycaine	
Cyclopentamine	
Cyclopenthiazide	
Cyclopentolate	
Cyclophosphamide	
Cyclopropane -	for inhalational use
Cycloserine	
Cyclosporin preparations	
Cyclothiazide	
Cycrimine	
Cyproheptadine	
Cyproterone Acetate	
Cyrcrimine	
Cytarabine	
Dabigatran	
Dacarbazine	

Llacti	omycin
Dacu	TOTH A CITT

Dalteparin

Danazol

Dantrolene

Dapagliflozin

Dapsone

Darifenacin

Dasatinib

Daunorubicin

Deanol

Debrisoquine

Deferasirox

Deferiprone

Dehydrocholic Acid

Dehydroemetine

Dehydroepiandrosterone

Delmadinone Acetate

Delorazepam

Demecarium Bromide

Demeclocycline

Denosumab

Deoxycortone

Deoxyribonuclease

Deptropine

Dequalinium Chloride

Deserpidine

Desferrioxamine

Desfluorotriamcinolone

Desipramine

Deslanoside

Desmopressin

Desogestrel

Desomorphine

Desonide

Desoximetasone, Desoxymethasone

 $De soxymethas one,\, De soximeta sone$

Dexamethasone

Dexamphetamine, Dextroamphetamine

Dexetimide

Dexlansoprazole

Dextranomer preparations -

for medicinal use

Dextroamphetamine,

Dexamphetamine

Dextromethorphan

Dextromoramide

Dextropropoxyphene

Dextrothyroxine

Diamorphine

Diampromide

Diazepam

Diazoxide

Dibenyline preparations

Dibenzepin

Dichloralphenazone

Dichlorophenarsine

Dichlorphenamide

Diclofenac Sodium

Dicloxacillin

Dicobalt Edetate

Dicyclomine, Dicloverine

Dicyloverine, Dicyclomine

Didanosine

Dienoestrol

Diethanolamine Fusidate

Diethyl Carbamazine Citrate

Diethylpropion

Diethylamide Ethyl Benzilate

Diethylamine Acetarsol

Diethylstilboestrol -

Diethylthiambutene

Difenoxin - (1-(3-cyano-3, 3-diphenylpropyl)-4-phenyl

and derivatives if for medicinal use

piperidine-4- carboxylic acid)

Diflorasone

Diflucortolone Valerate

Diflunisal

Digitalis Leaf

Digitalis prepared

Digitoxin

Digoxin

Dihydergot preparations

Dihydralazine

Dihydrocodeine

Dihydrocodeinone O-Carboxymethyloxime

Dihydroergocornine

Dihydroergocristine

Dihydroergocryptine

Dihydroergotamine

Dihydroergotoxine

Dihydromorphine

Dihydrostreptomycin

Di-iodohydroxquinoline

Diloxanide Furoate

Diltiazem

Dimenoxadole

Dimepheptanol

Dimepregnen

Dimercaprol

Dimethisoquin -

in preparations for local ophthalmic use

Dimethisterone Dimethothiazine

Dimethyl Sulphoxide

Dimethylthiambutene

Dimethytubocurarine

Dinitrodiphenylsulphonylethylenediamine

and derivatives if for medicinal use Dinitrophenol, 2,4--

Dinoprost

Dinoprostone

Dioxaphetyl Butyrate

Diphenhydramine for parenteral use

Diphenidol

Diphenoxylate

Diphetarsone

Diphylline

Dipipanone

Dipivefrin

Diprenorphine

Edogestrone Edoxaban

Diprophylline Dipropyltryptamine Dipyridamole Dipyrone Disodium Etidronate Disopyramide Distigmine Bromide Disulfiram Disulphamide Dobutamine Dolutegravir Domperidone Donepezil Hydrochloride Dopamine Dorzolamide Dothiepin Doxapram Doxazosin Doxepin Doxorubicin Doxycycline Doxycyline Calcium Chelate Dronabinol Dronedarone Droperidol Drostanolone Drotebanol Dulaglutide Duloxetine Dutasteride Dydrogesterone Dyflos Ecgonine any derivative of ecgonine which is convertible to ecgonine or to cocaine Econazole Ecothiopate Iodide Ectyl urea

Edrophonium Chloride

Efavirenz	
Eflornithine	
Eletriptan	
Eltrombopag	
Eluxadoline	
Embutramide	
Emepronium Bromide	
Emeside preparations	
Emetine	
Empagliflozin	
Emtricitabine	
Emylcamate	
Enalapril	
Enestebol	
Enflurane -	for inhalational use
Enoxaparin	
Entacapone	
Entecavir	
Ephedrine	
Ephedrine -	in inhalers
Epicillin	
Epinastine	
Epioestriol	
Epithiazide	
Epitiostanol	
Eplerenone	
Epoprostenol	
Ergometrine Maleate	
Ergot -	prepared
Ergotamine	
Ergotoxine	
Erlotinib	
Erythrityl Tetranitrate	
Erythromycin	
Escitalopram	
Esomeprazole	
Estazolam	
Estradiol	

Estramustine Phosphate

Estrogens, conjugated

Etafedrine

Etamiphylline

Etanercept

Ethacrynic Acid

Ethambutol

Ethamivan

Ethamsylate

Ethanolamine Oleate

Ethchlorvynol

Ethebenecid

Ether -

for inhalational use

Ethiazide Ethinamate

Ethinyloestradiol

Ethionamide

Ethisterone

Ethoglucid

Ethoheptazine Citrate

Ethopropazine

Ethosuximide

Ethotoin

Ethulose

Ethyl Acetanilide

Ethyl Alcohol for internal use 45%

Ethyl Biscoumacetate

Ethyl loflazepate

if for internal use Ethyl N-heptyloxyacetate -

Ethylmethylthiambutene

Ethylmorphine if for non-parenteral use and (a) in undivided

preparations with ms 2.5% (calculated as base); or(b) in single-dose preparations with ms per dosage unit 100mg (calculated as

base)

Ethyloestrenol

Ethylstibamine

Ethynodiol Diacetate

Etidronate Disodium

Etodolac

Etomidate Etonitazene Etonorgestrel Etoposide Etoricoxib Etorphine Etoxeridine Etravirine Etretinate Etymemazine Everolimus Evolocumab Exemestane Exenatide Ezetimibe Factor XIII Concentrate Factor VIII Famciclovir Famotidine Famprofazone Fazadinium Bromide Febuxostat Felodipine Fencamfamin Fenclofenac Fenethylline Fenfluramine (not in combination with Phentermine) Fenofibrate Fenoprofen Fenoterol Fenpipramide Fenpiprane Fentanyl Fenproporex Fentiazac Fentin Compounds

Ferrazone Ferrous Arsenate

Ferrous salts - for parenteral use

Fesoterodine

Fibrinolysin

Finasteride

Flavoxate

Flecainide

Floctafenine

Florantyrone

Floxapen preparations

Fluanisone

Fluclorolone Acetonide

Flucloxacillin

Fluconazole

Flucytosine

Fludarabine

Fludiazepam

Fludrocortisone Acetate

Flufenamic Acid

Flugestone

Flumedroxone Acetate

Flumethasone

Flumethiazide

Flunitrazepam

Flunixin

Fluocinolone Acetonide

Fluocinonide

Fluocortolone

Fluopromazine

Fluorometholone

Fluorouracil, 5-FU

Fluoxetine

Fluoxymesterone

Flupenthixol

Flupentixol

Fluperolene Acetate

Fluphenazine

Fluprednidene Acetate

Fluprednisolone

Fluprostenol

Glibornuride

Flurandrenolone	
Flurazepam	
Flurbiprofen	
Fluspirilene	
Flutamide	
Fluticasone	
Fluvastatin	
Fluvoxamine	
Folic Acid	- md greater than 1mg
Follicle stimulating hormone	
Formebolone	
Formocortal	
Formosulphathiazole	
Formoterol	
Fosfestrol Tetrasodium	
Fosinopril	
Framycetin Sulphate	
Frovatriptan	
Frusemide, Furosemide	
Fumagillin	
Furaltadone	
Furazolidone	
Furethidine	
Furoxone preparations	
Fusafungine	
Fusidic Acid	
Gabapentin	
Galantamine	
Gallamine Triethiodide	
Gefitinib	
Gelsemine	
Gelsemium	
Gemfibrozil	
Gentamicin	
Gestrenol	
Glafenine	
Glecaprevir	
Glibenclamide	

Gliclazide Glimepiride Glipizide Gliquidone Glutethimide Glyburide Glyceryl Trinitrate preparations, Nitroglycerin Glycopyrrolate Glycopyrronium Bromide Glymidine Glytona Gonadotraphon LH Goserelin Gramicidin Granisetron Gravigard Griseofulvin Growth hormone Guanethidine Guanfacine Guanoclor Guanoxan Hachimycin Halazepam Halcinonide Halobetasol Haloperidol Haloprogin Halopyramine Halothane Haloxazolam Halquinol Heparin Heptabarbitone Heptaminol Hetacillin

Hexachlorophane Hexamethonium

Hexamine

Hexobarbitone

Hexoestrol Histidine

Homatropine -

in preparations for local ophthalmic use

Homatropine Hydrobromide Homatropine Methylbromide

Hyaluronidase Hydralazine Hydrargaphen Hydrobromic Acid Hydrochlorothiazide

Hydrocodone
Hydrocortamate
Hydrocortisone
Hydroflumethiazide
Hydrogen cyanide
Hydromorphinol
Hydromorphone

Hydroquinone - ms 4% and above

Hydroxy-3-nitrophenylarsonic Acid, 4-

Hydroxychloroquine

Hydroxycholecalciferol, 1,a-Hydroxymethylgramicidin

Hydroxypethidine Hydroxyprogesterone

Hydroxyurea Hydroxyzine Hygromycine B

Hyoscine - in preparations for local ophthalmic use

Hyoscine Butylbromide - in inhalers
Hyoscine Hydrobromide - in inhalers
Hyoscine Methobromide - in inhalers
Hyoscyamine - in inhalers

Hypnomidate Concentrate

Ibandronate Ibogaine

Ibuprofen - md greater than 400mg

Idarubicin

Idoxuridine

Ifosfamide

Imatinib

Imipramine

Imiquimod

Immunoglobulins

Indapamide Hemihydrate

Indinavir

Indomethacin

Infliximab

Injectables - except insulins
Injections - except insulins

Inosine Pranobex

Intra-uterine contraceptive devices

Intravenous Fluids - all

Iodoxamic Acid

Iopanoic Acid

Ipratropium Bromide

Iprindole Iproniazid Irbesartan

Isoaminile Isocarboxazid

Isoconazole preparations

Isoetharine

Isoflurane - if for inhalational use

Isomethadone Isometheptene

Isoniazid Isoprenaline

Isopropamide Iodide

Isopropylaminophenazone

Isosorbide Dinitrate preparations

Isosorbide Mononitrate preparations

Isotretinoin

Isoxsuprine

Isradipine

Itraconazole

Levomoramide Levonorgestrel -

Levophenacylmorphan

Ivabradine Ivermectin Ixekizumab Jaborandi Kanamycin Sulphate Ketamine Ketazolam Ketobemidone Ketoconazole Ketoprofen Ketorolac Trometamol Ketotifen Khellin Labetolol Lacosamide Lamivudine Lamotrigine Lanatoside Lansoprazole Lanthanum Lapatinib Latamoxef Latanoprost in preparations for local ophthalmic use Lead and Opium Lotion BP 1959 Lead Arsenate Ledipasvir Lefetamine Leflunomide Letrozole Leuprolide Levallorphan Levetiracetam Levocetirizine Levodopa Levofloxacin Levomethorphan

except levonorgestrel 1.5mg

Maprotiline

Levorphanol Levothyroxine Lidoflazine Lignocaine in preparations for local ophthalmic use Linagliptin Linaglotide Lincomycin Linezolid Liothyronine Liraglutide Lisdexamphetamine Lisdexamfetamine, Lisdexamphetamine Lisinopril Lithium Carbonate Lithium Sulphate Lobeline Lodoxamide Lofentanil Lofepramine Lomustine, CCNU Loperamide Lopinavir Loprazolam Lorazepam Lorcaserin Lormetazepam Losartan Loteprednol Etabonate Loxapine Luteinising hormone Lynoestrenol Lypressin Mafenide Magnesium Bromide Magnesium Fluoride Magnesium Glutamate Mandragora Autumnalis Mannomustine

Maraviroc

Mazindol

Mebanazine

Mebeverine

Mebezonium Iodide

Mebhydrolin

Mebolazine

Mecamylamine

Mechlorethamine

Mecillinam

Meclizine, Meclozine -

Meclofenamic Acid

Meclofenoxate Mecloqualone

Meclozine -

Medazepam

Medicinal Opium -

Medigoxin Medrogestone

Medroxyprogesterone Acetate

Mefenamic Acid

Mefenorex

Mefloquine

Mefruside

Megestrol

Meglumine Diatrizoate

Melarsonyl Potassium

Melarsoprol

Melengestrol

Meloxicam

Melphalan

Memantine

if sold or recommended for the prevention of

nausea of pregnancy

if sold or recommended for the prevention of

nausea of pregnancy

if in preparations from which the opium cannot be readily recovered in amounts which constitute a risk to health and, also if

in liquid preparations with ms 0.2%

(calculated as anhydrous morphine base); in solid preparations with ms 0.2% (calculated

as anhydrous morphine base)

Menadiol if for parenteral route

Menotrophin Mepazine Mepenzolate Mephenesin Mephenoxolone Mephentermine Mepitiostane

Mepivacaine in preparations for local ophthalmic use

Meprobamate Meptazinol Mepyramine Mequitazine

Mercaptorpurine, 6-MP

Mercuderamide Mesabolone Mersalyl Acid Mesalamine Mescaline Mesna

Mesoridazine Mestanolone Mesterolone Mestranol

Metabutethamine in preparations for local ophthalmic use

Metaldehyde -

Metaraminol Metaxalone Metazocine Metformin Methacycline Methadone Methadyl Acetate Methallenoestril

Methandienone Methandriol Methaqualone Metharbitone Methazolamide

if for medicinal use

Methylphenobarbitone Methylprednisolone Methylsulphonal

Methdilazine Methenamine Methenolone Methicillin Methimazole Methionine all isomers Methisazone Methixene Methohexitone Methoin Methoserpidine Methotrexate Methotrimeprazine Methoxamine Methoxsalen Methoxyflurane for inhalational purposes Methoxyphenamine Methoxy Polyethylene Glycol-Epoetin Beta Methsuximide Methylaminorex Methyclothiazide Methyl benzoquate Methyl-3-Piperidylbenzilate, N-Methylacetanilide, N-Methylamphetamine Methyldesorphine Methyldihydromorphine Methyldihydromorphinone Methyldopa Methylephedrine Methylergometrine Methylergonovine Methylparafynol Methylpentynol Methylphenidate

Methyltestosterone

Methylthiouracil

Methyclothiazide

Methyprylone

Methysergide

Metiguanide Tablets

Metindizate

Metirosine

Metoclopramide

Metolazone

Metomidate

Metopon

Metopimazine

Metoprolol

Metribolone

Metronidazole

Metyrapone

Mexiletine

Mezlocillin

Mianserin

Mibolerone

Midazolam

Midodrine

Mifepristone

Minocycline

Minoxidil

Mirtazapine

Misoprostol

Mithramycin

Mitobronitol

Mitomycin C

Mitopodozide

Mitotane

Moclobemide

Modafinil

Moexipril

Molindone

Mometasone

Monensin

Monosulfiram for internal use

Montelukast Morazone Morpheridine

Morphine in liquid preparations with ms 0.2%

> (calculated as anhydrous morphine base); in solid preparations with ms 0.2% (calculated as anhydrous morphine base); in pentavalent

nitrogen derivatives

morphine N-Oxide and other pentavalent Morphine Methobromide -

nitrogen morphine derivatives

Moxifloxacin Mupirocin Mustine

Mycophenolate Mofetil

Myrophine

N-Ethylamphetamine

N-Ethyl-3-Piperidylbenzilate

Nabilone Nabiximols Nabumetone Nadolol Nafcillin

Naftidrofuryl Oxalate

Nalbuphine Nalidixic Acid Nalorphine Naloxone Naltrexone

Nandrolone

Naphazoline

Naproxen

Narasin

Naratriptan

Natamycin

Nateglinide

Nealbarbitone

Nedocromil

Nefopam

Noracymethadol Noradrenaline

Nelfinavir Neoarsphenamine Neocinchophen Neomycin Neostigmine Nepafenac in preparations for local ophthalmic use Nepenthe Oral Solution Netilmycin Nevirapine Nialamide Nicardipine Nicocodine Nicodicodine Nicodicodine, Nicotinoyldihydrocodeine Nicomorphine Nicotinaldehyde Thio-semicarbazone for human use (except in natural substances) Nicotine -Nicotinoyldihydrocodeine Nicodicodine Nicoumalone Nifedipine Nifenazone Niflumic Acid Nifuratel Nikethamide Nilotinib Nimetazepam Nimorazole Niridazole Nitrazepam Nitrofurantoin Nitrofurazone Nitroglycerin, Glyceryl Trinitrate Nitroprusside Sodium Nitroxoline Nizatidine Nomifensine

Norboletone

Norclostebol

Norcodeine

Nordazepam, Nordiazepam

Norethandrolone

Norethindrone

Norethisterone

Norethynodrel

Norfloxacin

Norgestrel

Norlevorphanol

Normethadone

Normorphine

Norpipanone

Nortriptyline

Novobiocin

Nux Vomica Seed

Nux Vomica Tincture BP

Nystatin except for topical use

Obeticholic Acid

Ocrelizumab

Octacosactrin

Oestradiol

Oestriol

Oestrogenic substances, conjugated

Oestrone

Ofloxacin

Olanzepine

Oleandomycin

Olmesartan

Olopatadine in preparations for local ophthalmic use

Omeprazole ms greater than 10mg

Ondansetron Opipramol

Opium, raw

Opium, Tincture BP

Oral contraceptives -

except for levonorgestrel 1.5mg

Orciprenaline

Orlistat - ms greater than 60mg

Orphenadrine

Orthocaine - in preparations for local ophthalmic use

Oseltamivir Ouabain Ovandrotone

Ovarian Gland, dried

Oxabolone
Oxacillin
Oxamniquine
Oxanamide
Oxandrolone
Oxantel Pamoate

Oxatomide Oxazepam Oxazolam Oxcarbazepine

Oxcarbazepine Oxedrine

Oxethazaine
Oxolinic Acid
Oxophenarsine
Oxprenolol

Oxtriphylline

Oxybuprocaine - except in preparations for local ophthalmic

use

Oxybutynin
Oxycodone
Oxymesterone
Oxymetholone
Oxymorphone
Oxypertine

Oxyphenbutazone Oxyphencyclimine

Oxyphenonium Bromide

Oxytetracycline

Oxytetracycline Dihydrate

Oxytocins - natural and synthetic

Palbociclib

Paliperidone	
Pancrelipase	
Pancreatin	
Pancuronium Bromide	
Pantoprazole	
Papaverine	
Papaverine -	in inhalers
Papaveroline	
Paradione Capsules	
Paraldehyde	
Paramethadione	
Paramethasone Acetate	
Parathyroid Gland	
Paregoric BP	
Pargyline	
Paromomycin	
Paroxetine	
Pavaveroline 2-sulphonic Acid	
Pazopanib	
Pecilocin	
Pembrolizumab	
Pemoline	
Pempidine	
Penamecillin	
Penbutolol	
Penethamate	
Penicillamine	
Penicillins -	all
Pentacosactride	
Pentaerythritol Tetranitrate	
Pentazocine	
Penthienate bromide	
Pentobarbitone	
Pentolinium Tartrate	
Pentosan Polysulfate Sodium	
Pentoxifylline	
Pentrium Tablets	

Peramivir Pergolide

Perhexiline
Pericyazine
Perindopril
Perphenazine
Pethidine
Phacetoperane

Phenacaine - except in preparations for local ophthalmic

use

Phenacemide Phenadoxone Phenaglycodol Phenampromide

Phenarsone Sulphoxylate

Phenazocine Phenazone

Phenazone and Caffeine Citrate

Phenazone Salicylate Phenbenicillin Potassium

Phenbutrazate
Phencyclidine
Phendimetrazine
Phenelzine Sulphate
Phenethicillin Potassium

Phenethylamine -

derivatives formed by substitution in the ring to any extentwith alkyl, alkoxy, alkylenedioxy

or halide substitutes, whether or not further substituted in the ring by one or more other univalent substituents with alkyl, alkoxy, alkylenedioxy or halide substitutes, whether or not further substituted in the ring by one

or more other univalent substituents

Pheneturide Phenglutarimide Phenindione Pheniprazine Phenmetrazine

n nemnetrazine

Phenobarbitone

Phenol - for parenteral use

Phenomorphan Phenoperidine

Phenoxybenzamine

Phenoxymethylpenicillin

Phenprocoumon

Phensuximide

Phentermine

Phentermine Resin Complex

Phentolamine

Phentoxate

Phenylaminosalicylate

Phenylbutazone

Phenylephrine -

Phenylindanedione -

Phenylmethylbarbituric Acid

Phenylpropanolamine

Phenytoin

Phenytoin Sodium

Pholcodine -

Phthalysulphacetamide

Phthalylsulfathiazole

Physostigmine

Phytomenadione, Phytonadione

Phytonadione, Phytomenadione

Pibrentasvir

Picrotoxin

Pilocarpine

Pimecrolimus

Piminodine

Pimozide

Pinazepam

Pindolol

Pioglitazone

Pipamazin

Pipenzolate Bromide

Piperacetazine

if for ophthalmic or nasal administration;

above 1%w/v

and its derivatives

if for non-parenteral use and in undivided preparations with ms 2.5% (calculated as base) if for non-parenteral use and in single-dose preparations with ms per dosage unit 100 mg (calculated as base)

Piperacillin

Piperazine Oestrone Sulphate

Piperidolate

Piperilate

Pipobroman

Pipothiazine

Pipradol

Piracetam

Pirbuterol

Pirenzepine

Piretanide

Piritramide

Piroxicam

Pituitary extract

Pituitary Gland (whole dried)-

if in inhalers e) - if in inhalers

all

Pituitary powdered (posterior lobe) -

Pivampicillin

Pivmecillinam

Pizotifen

Podophyllotoxin

Podophyllum

Podophyllum Indian

Podophyllum Resin

Poldine Methylsulphate

Polidexide

Poliovaccines -

Polymyxin B Sulphate - if for parenteral use

Polynoxylin

Polyoestradiol Phosphate

Polysaccharide Iron Complex

Polythiazide

Posaconazole

Potassium Aminosalicylate

Potassium Arsenite

Potassium Bromide

Potassium Chloride - ms greater than 99mg

Potassium Clorazepate

Potassium Gluconate

Potassium Hydroxyquinolone Potassium Perchlorate

Practolol Pralidoxime

Pramipexole

Prasterone

Pravastatin

Prazepam

Prazosin

Prednisolone

Prednisone

Pregabalin

Prenylamine Lactate

Prethcamide

Prilocaine except in preparations for local ophthalmic

use

Primaquine Phosphate

Primidone Probenecid Probucol Procainamide

Procaine except in preparations for local ophthalmic

Procaine Penicillin

Procarbazine

Prochlorperazine

Procyclidine

Prodilidine

Progesterone

Proguanil

Proheptazine

Prolactin

Proligestone

Prolintane

Promazine

Promethazine if for parenteral use

Propafenone

Propanidid

Propantheline Bromide

Proparacaine - in preparations for oral, parenteral and

ophthalmic use

Properidine Propetandrol Propicillin Propiomazine Propiram

Propiverine Hydrochloride'

Propranolol

Propylhexedrine - if in inhalers

Propyliodone
Propylthiouracil
Propyphenzone
Proquamezine
Prostaglandins

Prostaglandins - all

Protamine Proteline Prothionamide Prothipendyl Protirelin

Protoveratrines A and B

Protriptyline

Proxymetacaine - except in preparations for local ophthalmic

use

Proxyphylline Pseudoephedrine

Psilocybin Pyrazinamide

Pyridostigmine Bromide

Pyrimethamine Pyroglutamyl Pyrovalerone

Quetiapine Quinagolide Quinalbarbitone

Quinapril Quinbolone Quinestradol

Ristocetin

Quinestrol Quinethazone Quingestanol Quinidine Quinine Quinuronium Sulphate Rabeprazole Racemethorphan Racemoramide Racemorphan Racephedrine Ragwort Raloxifene Raltegravir Ramipril Ranibizumab Ranitidine Rasagiline Razoxane Repaglinide Reproterol Rescinnamine Reserpine Retinol for oral use in preparations containing more than 10,000 units per dosage unit if for parenteral use Ribavirin Rifamide Rifampicin Rifamycin Rifaximin Rilpivirine Riluzole Rimexolone Rimiterol Risedronate Risperidone

Ritodrine

Sirolimus Sissomicin

Ritonavir	
Rituximab	
Rivaroxaban	
Rivastigmine	
Rizatriptan	
Rolitetracycline Nitrate	
Ropinirole	
Rosiglitazone	
Rosuvastatin	
Rotigotine	
Roxibolone	
Rufinamide	
Rupatadine	
Sabadilla	
Salazosulphadimidine	
Salbutamol, Albuterol	
Salcatonin	
Salmefamol	
Salmeterol	
Salsalate	
Sandostatin	
Saquinavir	
Sarilumab	
Saxagliptin	
Secbutobarbitone	
Secukinumab	
Selegiline	
Sertraline	
Sevelamer Carbonate	
Sevelamer Hydrochloride	
Silandrone	
Sildenafil	
Silver Nitrate -	if for medicinal use
Silver Sulphadiazine	
Simvastatin	

Sitagliptin

Sodium Aminosalicylate

Sodium Antimonylgluconate

Sodium Apolate

Sodium Arsanilate

Sodium Arsenate

Sodium Arsenite

Sodium Aurothiomalate

Sodium Bromate

Sodium Bromide

Sodium Cacodylate

Sodium Cromoglycate

Sodium Ethacrynate

Sodium Fluoride

Sodium Fusidate

Sodium Iodide preparations -

Sodium Methylarsinate

Sodium Monofluorophosphate -

Sodium Nitroprusside

Sodium Stibogluconate

Sodium Tauroglycocholate

Sodium Tetradecyl Sulphate

Sodium Valproate

Sofosubir

Solapsone

Solifenacin

Somatotropin, Somatrophin

Somatrem

Sorafenib

Sotalol

Spectinomycin

Spiramycin

Spironolactone

Stannous Fluoride

Stanolone

Stanozolol

Stavudine

Stenbolone

Stibocaptate

for internal use

no restriction if in dentifrices and ms 1.14%

Stibophen

Stilboestrol

Streptodornase

Streptokinase

Streptomycin

Streptozocin

Strontium Bromide

Strophanthin-K

Strychnine

Styramate

Succinamide

Succinylsulphathiazole

Sucralfate

Sufentanil

Sulbutiamine

Sulfacytine

Sulfadicramide

Sulfadoxine

Sulfamethoxazole, Sulphamethoxazole

Sulfamethoxazole / Trimethoprim, Co-

trimoxazole

Sulfametopyrazine

Sulfamonomethoxine

Sulfapyrazole

Sulfasuxidine Tablets

Sulfonamide, Sulphonamide

Sulfoxone

Sulindac

Sulphabromomethazine

Sulphacetamide

Sulphachlorpyridazine

Sulphadiazine

Sulphadimethoxine

Sulphadimidine

Sulphaethidole

Sulphafurazole

Sulphafurazole Diethanolamine

Sulphaguanidine

Sulphaloxic Acid

Sulphamerazine

Sulphamethizole

Sulphamethoxazole, Sulfamethoxazole

Sulphamethoxydiazine

Sulphamethoxypyridazine

Sulphamethylphenazole

Sulphamezathine preparations

Sulphamoprine

Sulphamoxole

Sulphanilamide

Sulphanitran

Sulphaphenazole

Sulphapyridine

Sulphaquinoxaline

Sulphasalazine, Sulfasalazine

Sulphasomidine

Sulphathiazole

Sulphathiourea

Sulphatolamide

Sulphaurea

Sulphinpyrazone

Sulphomyxin

Sulphonal

Sulphonamide, Sulfonamide

Sulpiride

Sulthiame

Sumatriptan

Sunitinib

Suprofen

Sutilains -

Suxamethonium Bromide Suxamethonium Chloride

Suxethonium Bromide

Tacrine

Tacrolimus

Tadalafil

Talampicillin

when sold or recommended as a debriding agent

Tamoxifen

Tamsulosin

Tapentadol

Tazarotene

Tazobactam

Teclothiazide Potassium

Telithromycin

Telmisartan

Temazepam

Temozolomide

Tenofovir

Terazosin

Terbutaline

Terfenadine

Teriflunomide

Testosterone

Testosterone 17B Chloral Hemiacetal

Tetrabenazine

Tetracaine - if for parenteral or ophthalmic use

Tetracosactrin Tetracycline

Tetracycline Phosphate Complex

Tetrasodium Fostestrol

Tetrazepam

Thalidomide

Thallium Acetate

Thebacon - and its salts

Thebaine

Theobromine

Theophylline

Thiambutosine

Thiethylperazine

Thiocarlide

Thioguanine, Tioguanine

Thiomesterone

Thiopropazate

Thioproperazine

Thioridazine

Thiosinamine

Thiosinamine and Ethyl Iodide
Thiotepa
Thiothixene
Thiouracil
Thrombin preparations
Thymoxamine
Thyroid
Thyrotrophin
Thyrotrophin releasing hormone
Thyroxine Sodium
Tiagabine
Tianulin
Tiaprofenic Acid
Ticagrelor
Ticarcillin
Tigloidine
Tilidate
Timolol
Tinidazole
Tinzaparin
Tioguanine, Thioguanine
Tiotropium
Tipranavir
Tizanidine
Tobramycin
Tocainide
Tofacitinib
Tofenacin
Tolazamide
Tolazoline
Tolbutamide
Tolcapone
Tolmetin Sodium Dihydrate
Tolperisone
Tolterodine
Topiramate
Torasemide
Toremifene

Totaquine

Tramadol

Trandolapril

Tranexamic Acid

Tranylcypromine Sulphate

Travoprost

Trazodone

Tretamine

Tretinoin

Triacetyloleandomycin

Triamcinolone

Triamcinolone Acetonide

Triamterene

Triaziquone

Triazolam

Tribenoside

Tribromoethyl Alcohol

Trichloroethylene -

Triclofos Sodium

Tricyclamol Chloride

Tridione preparations

Trienbolone Acetate

Trifluoperazine

Trifluperidol

Triflupromazine

Trifluridine

Trihexphenidyl

Triiodothyronine Injection

Triiodothyroproprionic Acid

Trilostane

Trimeperidine

Trimeprazine

Trimetaphan

Trimetazidine

Trimethadione

Trimethoprim

Trimipramine

Trimustine

Trioxsalen

Trypsin

for inhalational purposes

Trometamol Tropicamide Trospium Troxidone Tryptamine -

Tryptamine or ring-hydroxy tryptamine derivatives formed by substitution at the nitrogen atom of the sidechain with one or more alkyl substituents; their salts; their esters and ethers; their salts (None of these derivatives specified above is thought to be commercially available)

Tryptophan, L-

Trypure

Tubocurarine Chloride

Tybamate Tylosin

Tylosin Phosphate Tylosin Tartrate Tyrothricin

Uramustine Umeclidinium

Urea -

Urea Stibamine

Uredofos Urethane

Uridine-5-triphosphoric Acid

Urokinase

Ursodeoxycholic Acid

Ustekinumab

Vaccines -

Valacyclovir

Valproic Acid Valsartan

vaisartan

Vancomycin

Vardenafil

Varenicline

Vedolizumab

Velpatasvir

if for medicinal use

all

Venlafaxine

Verapamil

Veratrine

Vernakalant

Vidarbine

Vigabatrin

Vilanterol

Viloxazine

Vinbarbitone

Vinblastine

Vincristine

Vindesine

Viomycin

Virginiamycin

Til i Dia

Vitamin B12 -

vitaliiii biz

Vitamin D -

Vitamin D

Voriconazole Vortioxetine

Voxilaprevir

Warfarin

Xantinol Nicotinate

Xipanide

Xylazine

Yohimbine

Zafirlukast

Zaleplon

Zeranol

Zidovudine

Zimelidine

Zipeprol

Zinc Sulphate -

Ziprasidone

Zolmitriptan

Zolpidem

Zonisamide

Zopiclone

with intrinsic Factor Concentrate above 50,000 I.U. per dosage unit

50,000 units and above

if for oral use with md greater than 200mg

- 1-Ethyl-3-piperidyl-alpha-cyclopentyl mandelate
- $1\hbox{-}Methyl\hbox{-}4\hbox{-}phenylpiperidine}\hbox{-}4\hbox{-}carboxylic acid}$
- 2-Methyl-3-morpholino-1,1-diphenylpropane-Levomethorphan carboxylic acid
- 4-Chloromethandienone
- 4-Cyano-1-methyl-4-Isomethadone phenylpiperidine
- 4-Cyano-2-dimethylamino-4,4-Hydromorphone diphenylbutane
- 4-Phenylpiperidine-4-carboxylic acid ethyl ester
- 5-FU, Fluorouracil
- 6-MP, Mercaptopurine
- α -Methylphenethylhydroxylamine
- 2 Any ester or ether or substance for the time being specified in paragraph 1.
- 3 Any salt of a substance for the time being specified in paragraph 1 or 2.

[Third Schedule substituted by 1989 : 56 ϵ] fective 15 January 1990; amended by BR 21 / 1992 ϵ] fective 8 May 1992; amended by BR 42 / 1998 ϵ] fective 15 May 1998; Third Schedule section reference amended by 2011 : 31 s. 5 ϵ] fective 10 August 2011; Third Schedule para. 1 amended by BR 35 / 2013 reg. 2 ϵ] fective 19 April 2013; amended by 2013 : 48 s. 26 ϵ] fective 24 December 2013; amended by 2014 : 36 s. 2 ϵ] fective 22 December 2014; Third Schedule repealed and replaced by BR 111 / 2017 para. 2 ϵ] fective 24 November 2017; Third Schedule amended by BR 69 / 2019 para. 2 ϵ] fective 7 June 2019

FOURTH SCHEDULE

(Sections 28(1); 28(2))

PART I

DRUGS OBTAINABLE ONLY AT REGISTERED PHARMACIES

Note: The following annotations used in this Schedule have the following meanings:					
md (maximum dose)		i.e. the maximum quantity of the substance contained in the amount of a medicinal product which is recommended to be taken or administered at any one time.			
mdd	(maximum daily dose)	i.e. the maximum quantity of the substance that is contained in the amount of a medicinal product which is recommended to be taken or administered in any period of 24 hours.			
mg	milligram				
ms	(maximum strength)	i.e. either or, if so specified, both of the following:			
external use	3	(a) the maximum quantity of the substance by weight or volume that is contained in the dosage unit of a medicinal product; or (b) the maximum percentage of the substance contained in a medicinal product calculated in terms of w/w, w/v, v/w, or v/v, as appropriate. means for application to the skin, teeth, mucosa of the mouth, throat, nose, eye, ear, vagina or anal canal when a local action only is necessary and extensive systemic absorption is unlikely to occur. Note: the following are not regarded as for external use: throat sprays, throat pastilles, throat lozenges, throat tablets, nasal drops, nasal sprays, nasal inhalations or teething preparations.			
parenteral use		means administration by breach of the skin or mucous membrane.			
1					
Acetomenapt Acetylcholine		in preparations for external use and ms 0.2% in preparations for external use (ms 1.3% of the crude drug)			
Aconite root	-	in preparations for external use and ms 0.02%			

Aconitine - Eye drops, neutral BP in preparations for external use

Acriflavine Adrenaline Albendazole

Alkaline Eye Drops BP

Allantoin Aloxiprin

Aluminium acetate - for medicinal use
Aluminium chloride - alcoholic solutions
Aluminium oxide - for human use

Alverine

Ambucetamide

Amethocaine - in all other preparations for non-parenteral use

Aminacrine - in preparations for non-parenteral use

Amylocaine

Antazoline - if for nasal or ophthalmic administration

Azatadine

Bamethan

Belladonna herb - in preparations for external use, in preparations for

internal use and mdd 1mg of the alkaloids

Belladonna root - in preparations for external use, in preparations for

internal use and mdd 1mg of the alkaloids

Benorylate

Benzamine lactate

Benzocaine - if in preparations for non-parenteral use with ms more

than 1%

Benzoyl peroxide - in concentrations of 10% or less

Benzydamine preparations Benzyl Benzoate preparations

Betaine Borax BP Boric Acid BP Bromelains

Bromodiphen hydramine

Brompheniramine

Buclizine Buclosamide

Buphenine - in preparations for internal use with md 6mg and mdd

18mg

Bupivacaine - in preparations for non-parenteral use

Butacaine - in preparations for non-parenteral use Butanilicaine - in preparations for non-parenteral use

Butethamide

Butoxyethyl nicotinate

Butylaminobenzoate - for topical use only
Calcium if for oral administration

Glucogalactogluconate -Calcium polystyrene

sulphonate

Calcium resonium

Cantharidin - in preparations for external use and ms 0.01%

Caramiphen - in liquid preparations and ms 0.1% (calculated as base),

in tablet preparation and ms 7.5mg (calculated as base)

Carbaryl preparations

Carbenoxolone - in gels and ms 2%, in pellets with md 5mg and mdd

25mg

Carbetapentane citrate

Carbinoxamine

Cetylpyridium chloride - if for internal use Charcoal - if for internal use

Chloral hydrate - in preparations for external use

Chlorcyclizine Chlordantoin

Chlorhexidine - if for administration into the nasal or oral cavities, for use

specifically as a bath additive, if impregnated onto gauze

dressing for direct application to a wound

Chlorpheniramine Chlorphenoxyethanol

Chlorprenaline Chlorprenaline

Chlorpyriline Citrate

Chlorxylenol - for application to the skin

Cholebrin tablets Choline magnesium

trisalicylate Choline salicylate Chymotrypsin

Cinchocaine - in preparations for non-parenteral use and ms 3%

(calculated as base)

Cineole Cinnarizine

Clioquinol - in preparations for external use, in preparations for

internal use for treatment of mouth ulcers with ms 35mg

and mdd 250mg

Clotrimazole - for topical use

Coal tar - in preparations Conium leaf in preparations for external

use and ms 7% of the crude drug

Creosote - if for medicinal use

Crotamiton

Cyclizine - if in preparations 1% and less Cyclomethacaine - if for nasal administration

Cyclopentamine - if for oral administration and maximum dose 15mg

Cyclopropane

Cyteal

Danthron

Deanol - in preparations for internal use and mdd 26 mg

Dequalinium - chloride in external paint preparations and ms 1% in throat lozenges or throat pastilles and ms 0.25mg

Desloratadine

Dexbrompheniramine Dexchlorpheniramine

Dextromethorphan - in preparations for internal use with md 15 mg

(calculated as base) and mdd 75 mg (calculated as base)

Di-iodohydroxyquinoline,

iodoquinol -

for topical use

Diabetic Diagnostic Reagents

and Tests

Diatrizoate sodium - for non-parenteral use Dibromopropamidine - for ophthalmic use

Dichlorophen

Diclofenac - for topical use

Dicophane

Dihydrotachysterol Dimenhydrinate Dimethindene

Dimethisoquin - in preparations for non-parenteral use

Dimethylaminoethanol tartrate

Dioctylsodium sulphosuccinate

Diphenhydramine Diphenylpyraline Dithranol preparation Docusate sodium

Domiphen Bromide -

if for oral use

Embramine -

Doxylamine

Emetine Ephedrine - in preparations for internal or external use and ms 1%

in nasal sprays or nasal drops and ms 2%, in

preparations for external use, in preparations for internal use (except nasal sprays or nasal drops) with md 30 mg

and mdd 60 mg

Ethyl alcohol -

for medicinal use

Famotidine in preparations for internal use with ms 10 mg

Ferrous salts for internal use where the ferrous salt is the sole active

ingredient

Fexofenadine Fluorescein Fluothane

Flurbiprofen oral lozenges Folic Acid ms 1 mg

Frangula preparations

Gamma Benzene hexachloride, Lindane

Gelsemine in preparations for internal or external use and ms 0.1% Gelsemium in preparations for internal use with md 25mg of the crude drug and mdd 75mg of the crude drug

Glutaraldehyde

Glycopyrronium bromide in preparations for internal use with md 1 mg and mdd 2

mg

Grindelia liquid extract

Guaiacol Guar gum Gynomin Heparin -

in preparations for external use

Heparinoid

Hexachlorophane if in preparations for external use in:

> (a) soaps with ms more than 0.1% but not more than 2% (b) products other than soaps or aerosols with ms more

than 0.1% but not more than 0.75%

Hexamidine isethionate

Histapyrrodine

Histidine if for use as an ingredient in dietary or nutritional

products as an aminoacid

if in preparations for internal use with md 0.2mg and Homatropine hydrobromide -

mdd 0.6mg

Hydrargaphen in preparations for local application to the skin

Hydroquinone ms 2%

Hydroxymethylgramicidin if in throat lozenges or throat pastilles

Hyoscine, Scopolaminein preparations for external use, in preparations for

internal use with ms 0.15%

in preparations for external use, in preparations for Hyoscine hydrobromide -

internal use with md 300 micrograms and mdd 900

micrograms

Hyoscine methobromide in preparations for external use, in preparations for

internal use with md 2.5 mg and mdd 7.5 mg

Hypromellose for ophthalmic use

Ibuprofen for topical use and md 400mg orally

Inositol nicotinate

Iocetamic acid if for oral administration

Iodinated glycerin

Iodoquinol, Di-

iodohydroxyquinoline -

Ipecacuanha

Isoconazole for topical use

Isopropamide iodide in preparations for internal use with md 2.5 mg (as

for topical use

isopropamide ion) and mdd 5 mg (as isopropamide ion)

Isothipendyl Ispagula husk

Itraconazole for topical use

Jaborandi in preparations for external use and ms more than

0.025% of the alkaloids in the medicinal product;

Kaolin Poultice BP

in oral preparations with ms 75mg, in preparations for Ketoprofen -

external use

Lachesine Eye Drops BP

Lactulose

Lead Subacetate Solution,

Dilute BP

Lead Subacetate Solution,

Strong BP Lignocaine -

in preparations for external use and ms 4% in

preparations for non-parenteral use

Lindane, Gamma Benzene

Hexachloride

Lobeline - in preparations for external use, in preparations for

internal use with md 3mg and mdd 9mg (calculated as

base)

Loratadine - in tablets with ms 10 mg in syrup with ms 5 mg/5 ml

Mafenide - in eye drops and ms 5%

Magnesium citrate Malathion preparations

Mebeverine - if in preparations for internal use with md 100mg and

mdd 300mg

Meclizine, Meclizine Meclozine, Meclizine

Medicinal opium - in liquid preparations with ms 0.02% (calculated as

anhydrous morphine base) and md 3mg (calculated as

anhydrous morphine base)

in solid preparations with ms 0.04% (calculated as

anhydrous morphine base) and md 3mg (calculated as

anhydrous morphine base)

Menadiol - for internal use excluding parenteral route

Mepenzolate bromide - in preparations for internal use with md 25mg and mdd

75mg

Mepivacaine - in preparations for non-parenteral use

Mepyramine - if for non-parenteral use Mercuric oxide if for human use

MetabutethamineB - in preparations for non-parenteral use

Methapyrilene

Methoxamine - in nasal sprays or nasal drops not containing liquid

paraffin as a vehicle and ms 0.25%

Methylephedrine - in preparations for internal use with md 30mg and mdd

60mg

Methylhydroxybenzoate

Miconazole - for topical use
Minoxidil topical use, ms 2%

Miristalkonium chloride

Monosulfiram - for external use

Naphazoline - in nasal sprays or nasal drops not containing liquid

paraffin as a vehicle and ms 0.05%

Naproxen Sodium - ms 220mg

if in eye drops and ms 0.25%

Natuderm Cream

Niclosamide

Nicotinic Acid - for internal use Nicotinyl alcohol - for internal use

Nizatidine - in preparations for internal use with ms 75 mg

Orthocaine - if in preparations for non-parenteral use

Oxolamine

Oxybuprocaine - if in preparations for non-parenteral use

Oxymetazoline

Oxyphenonium bromide - in preparations for internal use with md 5mg and mdd

15mg

Padimate Pancreatin

Papaverine - in preparations for internal use with md 50mg (calculated

as base) and mdd 150mg (calculated as base)

Penthienate methobromide - in preparations for internal use with md 5mg and mdd

15mg

Penthrane - if in preparations for non-parenteral use

Permethrin Phenacaine

Phenazone - in preparations for external use

Phenindamine Pheniramine

Phenol - for all medicinal use

Phenolphthalein

Phenylephrine - if for internal use (excluding parenteral route) with md

20mg and mdd 40mg

if for ophthalmic or nasal administration; with a

maximum strength of 1%w/v

Phenyltoloxamine

Pholcodine - 5mg/5ml Linctus BP

Phosphorylcolamine

Phytomenadione, if for non-parenteral use in preparations for internal use

Phytonadione- with md 5mg and mdd 15mg

Pipenzolate bromide - in preparations for internal use with md 5mg and mdd

15mg Piperazine

Piperazine

Piperidolate - if in preparations for internal use with md 50mg and mdd

150mg

Podophyllum resin - in preparations for external use and ms 20%

Poldine methylsulphate - in preparations for internal use with md 2mg and mdd

6mg Polvinyl alcohol if for ophthalmic use

Polyethylene glycol - for oral use

Polystyrene sulphonate resins

for use as an enema

Ponoxylan

Potassium arsenite - if in preparations for internal or external use and ms

0.0127%

Potassium citrate preparations Potassium guaicolsuphonate Povidone iodine preparations - all

Pramoxine

Prilocaine - if in preparations for non-parenteral use Procaine - if in preparations for non-parenteral use

Promethazine

Propantheline bromide - if in preparations for internal use with md 15 mg and

mdd 45mg

Propamidine

Proxamine

Proxymetacaine - if in preparations for non-parenteral use

Pseudoephedrine - if in preparations for internal use with md 60mg and mdd

180mg

Pumilio pine oil

Pyrantel

Pyrrobutamine phosphate

Quinine - in preparations for internal use with md 100mg and mdd

300mg (calculated as base)

Racephedrine - in nasal sprays or nasal drops and ms 2% in

preparations for external use

Ranitidine - ms 75mg

Resonium A - in preparations for internal use (except nasal sprays or

nasal drops) with md 30mg and mdd 60mg

Resorcinol preparations -

if for medicinal use

Retinol - in preparations containing 10,000 units or less

Rose Bengal - if for ophthalmic use

Salicylamide

Salicylic Acid - if for medicinal use

Scarlet Red Ointment

Scopolamine, Hyoscine - in preparations for external use, in preparations for

internal use with ms 0.15%

Selenium sulphide

Sodium alkylsulphoacetate - if for rectal administration

Sodium apolate - if in preparations for external use

Sodium arsenite - if in preparations for internal or external use and ms

0.013%

Sodium Cellulose phosphate - if for internal use

Sodium cromoglycate - if in preparations for use by being administered through

the nose

Sodium fluoride - in preparations for use in the prevention of dental caries,

other than dentifrices, in the form of: tablets or drops and mdd 2.2mg; or mouth rinses other than those for daily use and ms 0.2%; or mouth rinses for daily use and ms

0.05%

Sodium ipodate capsules

Sodium iron edetate

Sodium Perborate - in preparations for oral use

Sodium picosulphate Sodium pidolate

Squalane

Squill preparations - for human use

Sterculia preparations

Streptodornase - if in preparations for external use
Streptokinase - if in preparations for external use
Succinamide - in products for decontaminating water

Terbinafine - for external use only
Terpin hydrate - if for medicinal use

Tetracaine

Tetrahydrofurfuryl salicylate

Tetrahydrozoline Thiabendazole

Thimerosal, Thiomersal when used as a skin antiseptic
Thiomersal, Thimerosal - when used as a skin antiseptic

This properties for external uses

Tolazoline - if in preparations for external use

Totaquine - if in preparations for internal use with md 100mg and

mdd 300mg

Tramazoline
Tripelennamine
Triprolidine
Tripotassium
dicitratobismuthate

Trypsin - if for external use

Tryptophan, L- - if used as an ingredient in dietary or nutritional products

as an essential amino-acid; or in preparations for

external use

Turpentine oil - if for internal use

Tyrothricin - if in throat lozenges or throat pastilles

Urea - if for application to the skin

Urea hydrogen peroxide - if for aural use

Vanillylnonamide

Viprynium

Vitamin D - 1,000 - 49,999 IU per dosage unit

Xylometazoline

Zinc Sulphate - if for oral use

Zinc Sulphate and Adrenaline

Eye Drops

Zinc Sulphate Eye Drops BP

- 2 Any ester or ether or substance for the time being specified in paragraph 1.
- 3 Any salt of a substance for the time being specified in paragraph 1 or 2.

PART II

DRUGS OBTAINABLE ONLY FROM REGISTERED PHARMACISTS AT REGISTERED PHARMACIES

1

Acyclovir - in preparations for topical use and ms 5%

Adrenaline, Epinephrine

Ammonium Chloride and Morphine

Mixture BP Astemizole

Bacitracin - for topical use
Chloramphenicol - for ophthalmic use

Chloroform - except for inhalational use

Clemestine

Clotrimazole if in preparations for external or vaginal use for non-parenteral use and ms 8mg calculated as Codeine -

base

Cyproheptadine

Diclofenac in topical preparations

Econazole in cream, powder or solution for external use if in

ms 20mg

preparations for external vaginal use

Enflurane except for inhalational use

Epinephrine, Adrenaline

Esomeprazole -

Hydrogen cyanide -

except for inhalational use Ethyl alcohol for external Ether -

use

Ethyl alcohol for external use

Ethylmorphine in undivided preparations with ms 0.2% (calculated

> as base) and with md 7.5mg (calculated as base); or in single dose preparations with ms per dosage unit 0.2% (calculated as base) and 7.5mg (calculated as

base)

Fluconazole ms 150mg and mdd 150mg

if in preparations for internal use and md 500 Folic acid -

micrograms and mdd 1000 micrograms

Gramicidin in preparations for external use and ms 0.02% in

topical preparations for auricular or local ophthalmic

use

in preparations for external use Halothane except for Haloprogin -

inhalational use

Homatropine in preparations for external use, in preparations for

internal use with md 0.15mg and mdd 0.45mg

in preparations for internal use with md 2mg and Homatropine methylbromide -

mdd 6mg

for external use Hyaluronidase -

Hydrocortisone for external use and for ms 1%

in preparations for external use and ms 1%

in preparations for internal or external use and ms

0.1%

Hyoscine butylbromide in preparations for external use

in preparations for internal use (other than inhalers)

with md 10mg

Ibuprofen - if for use in rheumatic and muscular pain,

backache, neuralgia, migraine, headache, dental pain, dysmenorrhoea, feverishness, symptoms of colds and influenza and with md 400mg and mdd

1200mg

Injections - except insulin products

Insulin - all

Iodine, aqueous solution - for internal use

Isoconazole - if in preparations for external or vaginal use

Isoconazole preparations - if for application to the skin (excluding mucous

membranes)

Isoflurane - except for inhalational use

Itraconazole -if in preparations for external or vaginal useKetoconazole -if in preparations for external or vaginal useKetoprofen -in preparations for internal use with ms 75 mg

Lansoprazole ms 15mg

Levamisole

Levonorgestrel - ms 1.5mg if for use as an emergency contraception

Loperamide if for the treatment of acute diarrhoea

Mebendazole -

Miconazole - if in preparations for external or vaginal use

Minoxidil for topical use ms 5%

Minoxidil - in topical preparations with ms 2%

Morphine - in liquid preparations with ms 0.02% (calculated as

anhydrous morphine base) and md 3 mg (calculated as anhydrous morphine base) in solid preparations with ms 0.04% and 300 micrograms per dosage unit (calculated as anhydrous morphine base) with md 3mg (calculated as anhydrous morphine base)

Neomycin - for topical use only

Nicotine - if in oral preparations and md 2mg

in liquid form for inhalation via any electronic

delivery system with ms 21mg

Nicotine - in patches with ms 21 mg/24 hours

Nizatidine - in capsules with ms 75 mg
Nitroglycerin, Glyceryl Trinitrate - tablets and sublingual spray

Nystatin - for topical use only

Omeprazole - ms 10mg Orlistat - ms 60mg

Phenazopyridine

Phenylpropanolamine - in controlled release capsules with md 75 mg and

mdd 150mg

Polymyxin B sulphate

Ranitidine - ms 150mg
Ranitidine - with ms 75 mg

Silver Nitrate - in preparations for use on the skin

Sodium cromoglycate - Eye drops and ms 2% Eye ointment and ms 4%

Syringes - Insulin

Terconazole - for vaginal use

Terfenadine

Triamcinolone Acetonide - nasal spray ms 55 mcg/spray

Trichloroethylene - for other use

2 Any ester or ether or substance for the time being specified in paragraph 1.

3 Any salt of a substance for the time being specified in paragraph 1 or 2.

[Fourth Schedule substituted by 1989:56 ϵ] fective 15 January 1990; amended by BR 21/1992 ϵ] fective 8 May 1992; amended by BR 42/1998 ϵ] fective 15 May 1998; amended by 2013:48 s. 27 ϵ] fective 24 December 2013; amended by BR 69 / 2016 ϵ] fective 26 July 2016; Fourth Schedule repealed and replaced by BR 111 / 2017 para. 2 ϵ] fective 24 November 2017; Fourth Schedule amended by BR 113 / 2017 para. 2 ϵ] fective 1 December 2017; Fourth Schedule amended by BR 69 / 2019 para. 3 ϵ] fective 7 June 2019; Fourth Schedule Part II amended by BR 48 / 2022 para. 2 ϵ] fective 2 May 2022

FIFTH SCHEDULE

(Section 9)

PHARMACY PROFESSION COMPLAINTS COMMITTEE

- 1 The Committee shall consist of three members appointed by the Minister, as follows—
 - (a) one from a list of at least three registered pharmacists in good standing who is nominated by the Association;
 - (b) one from a list of at least three registered pharmacists in good standing nominated by the Council;
 - (c) one professionally qualified person who is not a registered pharmacist.
- 2 A person who is a member of the Council may not be appointed as a member of the Committee.
- 3 Appointment as a member under paragraph 1 shall be for a term not exceeding three years and a member is eligible for reappointment.
- 4 The Minister may appoint a second person to act as alternate to a member appointed under paragraph 1.
- 5 An alternate member shall be appointed in accordance with the requirements for the appointment of the member, and his term of appointment shall, if not sooner terminated, end at the expiration of the term of the member.
- 6 There shall be a Chairman of the Committee who shall be appointed annually by the Minister from among the members of the Committee to hold office until 31 December of the year for which he was appointed, and who shall be eligible for reappointment as Chairman.
- 7 If at any time the Chairman ceases to be a member of the Committee, or for any other reason ceases to be the Chairman, the Minister shall, as soon as may be, appoint from among the members of the Committee another person to be Chairman in his stead.
- 8 Three members of the Committee shall form a quorum at any meeting.
- 9 (1) Where any complaint is before the Committee, a member of the Committee shall advise the Chairman if he is personally acquainted with the facts of the case and may, with leave of the Chairman, withdraw on that ground or for any other reason which the Chairperson deems sufficient; and the Chairman may himself withdraw on any such ground.
- (2) Where a member has so withdrawn, the Chairman may request the Minister to appoint a member of equal standing as the withdrawn member to be a member of the Committee for the purpose of those proceedings, and the Minister may make such appointment, whereupon the person so appointed shall be deemed to be a member of the Committee for such purpose.
- 10 Fees shall be paid to members of the Committee in accordance with the Government Authorities Fees Act 1971.

- 11 The validity of any act or proceedings of the Committee shall not be affected by any vacancy among the members of the Committee or by any defect in the appointment of a member of the Committee or of the Chairperson.
- 12 The Committee shall, not later than such date as the Minister may determine after the end of each calendar year, submit a report on its activities for the preceding year to the Council.
- 13 Subject to this Act, the Committee shall regulate its own proceedings.

[Fifth Schedule repealed and replaced by 2013 : 48 s. 28 ϵ jfective 24 December 2013; Fifth Schedule amended by 2020 : 47 s. 114 ϵ jfective 11 December 2020]

SIXTH SCHEDULE

(Section 26B)

PROHIBITION ORDERS, PROHIBITION NOTICES AND NOTICES TO WARN

PART I PROHIBITION ORDERS

- 1 If the Minister proposes to make a prohibition order ("an order"), then, subject to paragraph 5, he shall before he makes the order—
 - (a) publish, in such manner as he thinks fit a notice stating—
 - (i) that he proposes to make the order and, in such terms as he thinks fit, the proposed effect of the order; and
 - (ii) that any person may make representations in writing to the Minister about the proposed order before a date specified in the notice (which must be after the expiration of the period of 28 days beginning with the date of the first publication of the notice); and
 - (b) consider any such representations made within that period.
- 2 The effect of an order must not be more restrictive, but may be less restrictive, than the proposed effect of it as stated in the notice.
- 3 Without prejudice to the power to make a further order and subject to paragraph 4, an order shall cease to have effect at the expiration of a period specified in the order which must not be longer than 12 months beginning with the date on which the order comes into force.
- An order may revoke a previous order or may vary it otherwise than providing for it to be in force after expiration of 12 months beginning with the date of the coming into force of the previous order.
- 5 Paragraphs 1 and 2 shall not apply to an order if the order contains a statement that in the opinion of the Minister the risk of danger connected with the drug or drug product to which the order relates is such that the order must be made without delay.

PART II

PROHIBITION NOTICES

Preliminary

6 In this Part—

"notice" means a prohibition notice;

- "notification" means a notification in writing;
- "the trader" in relation to a proposed notice or an actual notice means the person on whom the proposed notice is proposed to be served or on whom the actual notice has been served.
- A notice must specify the date on which it comes into force.

General Procedure

- 8 If the Minister proposes to serve a notice in respect of any drug or drug product, then, subject to paragraph 14, he shall before he serves the notice serve on the trader a notification—
 - (a) stating that the Minister proposes to serve on him a notice in respect of the drug or drug product; and
 - (b) specifying the drug or drug product in a manner sufficient to identify them and stating that, for the reasons set out in the notification, the Minister considers that the drug or drug products are not safe; and
 - (c) stating that the trader may make representations, in writing or both in writing and orally, for the purpose of satisfying the Minister that the drug or drug product is safe but that if the trader intends to make such representations he must, before the expiration of the period of 14 days beginning with the day when the notification is served on him, inform the Minister of his intention indicating whether the representations are to be in writing only or both in writing and oral.
- 9 Subject to paragraph 14, the Minister shall not serve a notice on the trader in respect of any drug or drug product before the expiration of the period of 14 days beginning with the day on which the Minister served on him a notification in pursuance of paragraph 8 relating to the drug or drug products; and if within that period the trader informs the Minister as mentioned in paragraph 8(c), then—
 - (a) the Minister shall not serve a notice on the trader in consequence of the notification before the expiration of the period of 28 days beginning with the day aforesaid; and
 - (b) if during that period the trader makes to the Minister such written representations as are mentioned in paragraph 8(c) the Minister shall not serve a notice on the trader in consequence of the notification before the Minister has considered the report of a person appointed in pursuance of paragraph 10 in consequence of the representations.
- Where, in consequence of the service on the trader of a notification in pursuance of paragraph 8, the trader informs the Minister as mentioned in paragraph 8(c) within the period so mentioned and makes to the Minister within that period or the fourteen days

beginning with the end of that period such written representations as are so mentioned, the Minister shall—

- (a) appoint any person to consider the written representations; and
- (b) if the trader informed the Minister in pursuance of paragraph 8(c) that the representations would be both written and oral, inform the trader of the place and time (which must not be before the expiration of the fourteen days and of seven days beginning with the day when the information is given to the trader) at which the oral representations may be made to the person appointed;

and the trader or his representative may at that place and time make to the person appointed oral representations for the purpose of satisfying the Minister that the drug or drug product in question is safe and may call and examine witnesses in connection with the representations.

- 11 The person appointed in pursuance of paragraph 10 to consider written representations with respect to any drug or drug product shall, after considering the representations, any oral representations made in pursuance of that paragraph with respect to the drug or drug product and any statements made by witnesses in connection with the oral representations, make a report (including recommendations) to the Minister about the representations and the proposed notice.
- If at any time after the Minister has served a notification on the trader in pursuance of paragraph 8 the Minister decides not to serve a notice on him in consequence of the notification, the Minister shall inform him of the decision; and after the Minister informs him of the decision the notification and anything done in consequence of it in pursuance of the preceding paragraphs shall be disregarded for the purposes of those paragraphs.
- Where a notification is served on the trader in respect of any drug or drug product in pursuance of paragraph 8, a notice served on him in consequence of the notification may relate to some only of those the drug or drug product.

Special Procedure

- Paragraphs 8 to 13 do not apply to a notice which contains a statement that the Minister considers that the risk of danger connected with the drug or drug product to which the notice relates is such that the notice must come into force without delay; and references to a notice in paragraphs 15 to 18 are to a notice containing such a statement.
- 15 A notice in respect of any drug or drug product must—
 - (a) state that, for the reasons set out in the notice, the Minister considers that the drug or drug product is not safe; and

- (b) state that the trader may, at such time as the trader thinks fit, make representations in writing to the Minister for the purpose of satisfying him that the drug or drug product is safe.
- 16 If representations in writing about a notice are made by the trader to the Minister, the Minister shall consider the representations and either revoke the notice and inform the trader that he has revoked it or—
 - (a) appoint a person to consider the representations; and
 - (b) serve on the trader a notification stating that he may make to the person appointed oral representations for the purpose mentioned in paragraph 15 and specifying the place and time (which, except with the agreement of the trader, must not be before the date of service of the notification) at which the oral representations may be made,

and the trader or his representative may at that place and time make to the person appointed oral representations and may call and examine witnesses in connection with the representations.

- 17 The person appointed in pursuance of paragraph 16 to consider written representations with respect to any drug or drug product shall, after considering the representations, any oral representations made in pursuance of that paragraph with respect to the goods and any statements made by witnesses in connection with the oral representations, make a report including recommendations to the Minister about the representations and the notice in question.
- Where the Minister has appointed a person in pursuance of paragraph 16 to consider any representations relating to a notice then, without prejudice to the operation of paragraphs 19 and 20, paragraphs 16 and 17 shall not apply to any subsequent representations in writing about the notice.

Other Representations

- 19 If at any time the trader on whom a notice has been served makes representations in writing to the Minister for the purpose of satisfying him that the drug or drug product to which the notice relates is safe and, by virtue of paragraph 18, paragraph 16 does not apply to the representations, the Minister shall consider the representations and serve on the trader, before the expiration of one month beginning with the day when the Minister receives the representations, a notification stating—
 - (a) that the Minister will revoke the notice or vary it or declines to do so; or
 - (b) that the Minister has appointed a person to consider the representations and that the trader may make to the person appointed, at a place specified in the notification and a time so specified (which, except with the agreement of the trader, must not be before the expiration of the period of twenty-one days beginning with the date of service of the notification), oral representations for the purpose,

and the trader or his representative may at that place and time make to the person appointed oral representations and may call and examine witnesses in connection with the representations.

20 The person appointed in pursuance of paragraph 19 to consider written representations with respect to any drug or drug product shall, after considering the representations, any oral representations made in pursuance of that paragraph with respect to the drug or drug product and any statements made by witnesses in connection with the oral representations, make a report including recommendations to the Minister about the representations and the notice in question.

Miscellaneous

- 21 The Minister may revoke or vary a notice by serving on the trader a notification stating that the notice is revoked or, as the case may be, is varied as specified in the notification; but the Minister shall not have power to vary a notice so as to make the effect of the notice more restrictive for the trader.
- The Minister shall consider any report made to him in pursuance of paragraph 17 or 20 and, after considering the report, inform the trader of his decision with respect to the notice in question.

PART III

NOTICES TO WARN

- 23 If the Minister proposes to serve on a person a notice to warn in respect of any drug or drug product, the Minister shall, before he serves the notice, serve on the person a notification in writing—
 - (a) containing a draft of the notice and stating that the Minister proposes to serve on the person such a notice in the form of the draft;
 - (b) stating that, for the reasons set out in the notification, the Minister considers that the drug or drug product specified in the draft is not safe; and
 - (c) stating that the person may make representations, in writing or both in writing and orally, for the purpose of satisfying the Minister that the drug or drug product is safe but that if the person intends to make such representations he must, before the expiration of the period of fourteen days beginning with the day when the notification is served on him, inform the Minister of his intentions indicating whether the representations are to be in writing only or both in writing and oral.
- Paragraphs 9 to 13 and 21 shall with the necessary modifications have effect in relation to a notice to warn as they have effect in relation to a prohibition notice but as if—

- (a) the reference to paragraph 14 in paragraph 9 were omitted;
- (b) for the references to paragraph 8 in paragraphs 9, 10, 12 and 13 there were substituted references to paragraph 23;
- (c) in paragraph 13 for the words from "relate" onwards there were substituted the words "be less onerous than the draft of the notice contained in the notification"; and
- (d) in paragraph 21 the words "or vary" and the words from "or, as" onwards were omitted.

[Sixth Schedule inserted by 2013: 48 s. 29 effective 24 December 2013]

SEVENTH SCHEDULE

(section 14A)

	FEES	
(1)	Applying for registration as a pharmacist under section 7	\$245
(2)	Applying for re-registration as a pharmacist under section 7	\$165
(3)	Fee for late re-registration as a pharmacist under section 7	\$65
(4)	Applying to re-register as a non-practising pharmacist under section $7A(1)$	\$50
(5)	Applying to re-register for a change of status from non-practising pharmacist to practising pharmacist within 1 year registration cycle	\$115
(6)	Requesting a certificate of professional standing regarding a pharmacist	\$25
(7)	Requesting a duplicate copy of registration certificate after issuance	\$25

[Seventh Schedule inserted by 2020 : 47 s. 115 ϵ] fective 11 December 2020]

[Assent Date: 23 July 1979]

[This Act was brought into operation on 1 January 1980]

```
[Amended by:
     BR 62 / 1980
     BR 63 / 1980
     BR 64 / 1980
     BR 16 / 1984
     BR 17 / 1984
     1984 : 46
     1989 : 56
     BR 21 / 1992
     BR 42 / 1998
     2008 : 20
     2011:31
     BR 35 / 2013
     2013 : 48
     2014 : 36
     BR 69 / 2016
     BR 111 / 2017
     BR 113 / 2017
     2018 : 58
     2018:66
```