BERMUDA

PHARMACY AND POISONS ACT 1979

1979 : 26

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[*preamble and words of enactment omitted*]

PART I

PRELIMINARY

Short title

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

Interpretation

2 In this Act, unless the context otherwise requires—

"Association" means the professional association representing pharmacists in Bermuda;

"certificate of competence" means a certificate of competence granted by the Council under regulations made under section 15(1)(b);

"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;

"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 the official for whose appointment section 7(1) provides;

"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 s.17 & Sch. 2 effective 9 July 2010; Section 2, "Schedule 3 drug" amended by 2011 : 31 s. 2 effective 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 s. 2 effective 24 December 2013]

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 after consulting with the Chief Medical Officer;

(b) one member, who shall be a practitioner, appointed by the Minister after consulting with the Chief Medical Officer; 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 effective 24 December 2013]

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 effective 24 December 2013]

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, who shall be appointed by the Minister.

(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 who is qualified for registration as a pharmacist under this Act applies in the required form to the Registrar and pays the appropriate fee, the Registrar shall 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 re-registration every two years after the first registration.

(4B) The Registrar 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 Registrar 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) The Registrar's decision to refuse to register or re-register, or failure to register or re-register, an applicant does not have effect until the expiration of the appeal period, or where an appeal is brought, until the appeal is decided or abandoned.

(8) "appropriate fee" in subsections (4) and (5A) means the relevant fee prescribed in the Government Fees Regulations 1976.

(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 effective 24 December 2013]

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) In subsection (1) "the appropriate fee" means the relevant fee prescribed in the Government Fees Regulations 1976.

[Section 7A inserted by 2013 : 48 s. 6 effective 24 December 2013]

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 by post 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.

(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 effective 24 December 2013]

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 effective 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 effective 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 Minister 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 Minister for the purpose and surrenders to him his certificate of registration.

[Section 11 amended by 2013 : 48 s. 9 effective 24 December 2013]

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 effective 24 December 2013]

Proof of registration

13 A certificate signed by the Permanent Secretary to the Minister 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.

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 effective 24 December 2013]

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 effective 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 effective 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 effective 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 3A of the Pharmacy and Poisons (Control of Prescriptions) Regulations 1979.

(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 effective 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 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 effective 10 August 2011]

Declaration relating to imported medicines

26 *[Repealed by 2011 : 31 s. 4]*

[Section 26 repealed by 2011 : 31 s. 4 effective 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 effective 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 or the European Union, or another jurisdiction that the United States, Canada 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 effective 24 December 2013]

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 effective 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 effective 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 effective 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 effective 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

40 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,—

(i) 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

46 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 effective 24 December 2013]

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 effective 24 December 2013; subsection (1)(g) deleted by 2014 : 36 s. 2 effective 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 effective 22 December 2014]

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

48B 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 effective 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 effective 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 effective 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 6, 23, 25, 27 to 30, 32, 37, 38, 40, 42 to 46, 49 and 50.

(3) 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 $5,000, or both such imprisonment and fine ;

(b) Punishment on conviction on indictment: imprisonment for 3 years or a fine of $15,000, or both such imprisonment and fine ;

(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.

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.

3 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.

4 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.

6 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.

7 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.

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 effective 24 December 2013; paragraph 10 deleted by 2014 : 36 s. 2 effective 22 December 2014]

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- subject to the restrictions and requirements under 8B(1) and (2) of the Nursing Act 1997

[Second Schedule repealed and replaced by 2013 : 48 s. 25 effective 24 December 2013]

THIRD SCHEDULE

(Sections 25(6); 27(1);48(1)(g))

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

Note: The following annotations used in this Schedule and the Fourth 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 BPC 1968
Aconite Root
Aconitine
Actinomycin C
Actinomycin D
Acyclovir
Adapalene
Adefovir
Adiciilin
Adiphenine
Admune Influenza Vaccine
Adrenaline
Adrenocortical Extract
Adriamycin
Adrosterone
Aerosoxacin
Aesculin
Agomelatine
Albamycin preparations
Albamycin T preparations
Albumin Human
Albumin Microspheres Human (3M)
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
Amidorpyrine	
Amikacin	
Amiloride	
Aminocaproic Acid	
Aminodarone	
Aminoglutethimide	
Aminophylline	
Aminopterin	
Aminosalicylic Acid	
Amiodarone	

Amiphenazole	
Amitriptyline	
Amlodipine	
Ammonium Bromide	
Ammonium Chloride	in inhalers
Amoxycillin	
Amoxycillin Trihydrate	
Amphetamine	
Amphomycin	
Amphotericin	
Ampicillin	
Ampicillin Trihydrate	
Amyl Nitrite Vitrellae BPC	
Amylobarbitone	
Amylocaine	in preparations for local ophthalmic use
Anaesthetics	all inhalational
Anagrelide	
Anastrozole	
Ancrod	
Aneurone	
Angiotensin Amide	
Anileridine	
Antazoline	
Anterior Pituitary Extract	
Anti-lymphocyte Immunoglobulin	
Antimony	
Apiol	
Apomorphine	
Apramycin	
Aprepitant	
Aprobarbitone	
Aprotinin	
Arecoline	
Areocoline-acetarsol	
Aripiprazole	
Arprinocid	
Arsanilic Acid	
Arsenic	
Arsphenamine	
Asparaginase	
Asparaginase, L-Atenolol	

Atazanavir	
Atenolol	
Atomoxetine	
Atorvastatin	
Atovaquone	
Atracurium Besylate	
Atropine Eye Drops B.P., Eye Ointment B.P.	in preparations for local opthalmic use
Atropine	in inhalers
Atropine Methobromide	in preparations for local ophthalmic use
Atropine Methobromide	in inhalers
Atropine Oxide	in preparations for local ophthalmic use
Atropine Oxide	in inhalers
Azacyclonol	
Azaperone	
Azapropazone	
Azaribine	
Azathioprine	
Azelaic Acid	
Azidocillin	
Azithromycin	
Bacampicillin	
Bacitracin Methylene Disalicylate	
Baclofen	
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	
Benethamine Penicillin	
Benoxaprofen	
Benperidol	
Benserazide	
Benzafibrate	
Benzathine Penicillin	
Benzbromarone	
Benzethidine	
Benzhexol	
Benzilonium Bromide	
Benzocaine [sic]	for local ophthalmic use
Benzoctamine	
Benzoestrol	
Benzoyl Peroxide	in concentrations greater than 10%
Benzoylsuphanilamide, N-	
Benzphetamine	
Benzquinamide	
Benzthiazide	
Benztrone Injections	
Benztropine Mesylate	
Benzylmorphine	
Benzylpenicillin	
Betacetylmethadol	
Betahistine	
Betameprodine	
Betamethadol	
Betamethasone	
Betaprodine	
Betaxolol	
Bethanechol Chloride	
Bethanidine	
Bexarotene	
Bezafibrate	
Bezitramide	
Bicalutamide	
Bimatoprost	
Biorphen Oral Solution	
Biperiden	
Bismuth Glycollylarsanilate	
Bisoprolol	

Bleomycin Sulphate	
Boldenone Undecylenate	
Bosentan	
Bretylium Tosylate	
Brimonidine	
Brinzolamide	
Bromazepam	
Bromhexine	
Bromocriptine	
Bromvaletone	
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
Butaperizine	
Butobarbitone	
Butorphanol	
Butriptyline	
Butylchloral Hydrate	
Cabergoline	
Cadexomer	
Cafadroxil	
Calcipotriol	
Calcitonin	
Calcitriol	
Calcium 5-allyl-5-N-Butylbarbiturate	
Calcium Acetate	
Calcium Aminosalicylate	
Calcium Amphomycin	
Calcium Benzamidosalicylate	
Calcium Bromide	
Calcium Bromidolactobionate	

Calcium Carbimide
Calcium Folinate
Calcium Leucovorin preparations
Calcium Sulphaloxate
Camphorated Opium tincture BP
Candesartan
Candicidin
Cannabinol and derivatives
Cannabis
Cannabis resin
Cantharadin
Capecitabine
Capriomycin Sulphate
Captodiamine
Captopril
Caramiphen
Carbachol
Carbamazepine
Carbenicililn [sic]
Carbenoxolone
Carbidopa
Carbidopa Monohydrate
Carbimazole
Carbocisteine
Carbon Tetrachloride
Carboxymethylcysteine
Carfecillin
Carisoprodol
Carmustine
Carperidine
Carphenazine
Carvedilol
CCNU Capsules
Cefaclor
Cefdinir
Cefixime
Cefotoxamine
Cefoxitin
Cefpodoxime Proxetil
Cefsulodin
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	
Chlordiazepoxide	
Chlorhexadol	
Chlorisondamine Chloride	
Chlormadinone Acetate	
Chlormerodrin	
Chlormethiazole	
Chlormezanone	
Chlorodyne BPC	
Chloroform	for inhalational use
Chloroform and Morphine Tincture BPC	
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	in preparations for local ophthalmic use
Cinchophen	
Cinoxacin	
Ciprofloxacin	
Cisplatin	
Citalopram	
Citrated Calcium Carbimide	
Clarithromycin	
Clavulanic Acid	
Clemizole	
Clenbuterol	
Clidinium Bromide	
Clindamycin	
Clioquinol	
Clobazam	
Clobetasol 17-propionate	
Clobetasone Butyrate	
Clofazimine	
Clofibrate	
Clomiphene Citrate	
Clomipramine	
Clomocycline	
Clonazepam	
Clonidine	
Clonitazene	

Clopamide	
Clopenthixol	
Clopidogrel	
Cloprosternol Sodium	
Clorazepate	
Clorexolone	
Clorprenaline	
Clostebol Acetate	
Clotrimazole	
Cloxacillin	
Clozapine	
Coca leaf	
Cocaine	
Cocculus Indicus	
Cocillana Compound Syrup BPC 1949	
Codeine	for non-parental use with ms greater than 8mg calculated as base
Co-dergocrine Mesylate	
Colchicine	
Colesevelam	
Colestipol	
Colistin	
Collagen preparations	if for implantation under the skin
Collagenase	when sold or recommended as a debriding agent
Colocynth and Jalap Compound Tablets BPC 1963	
Concentrate of poppy straw	
Coniine	
Conium Leaf	
Contraceptives	oral
Corticotrophin	
Cortisone	
Cortodoxome	
Cotarnine Chloride	
Co-Trifamole	
Co-trimoxazole	
Coumarin derivatives	
Cropropamide	
Crotamiton	
Crotethamide	
Croton Oil	

Croton Seed	
Cuemid	
Curare	
Cyano-1-methyl-4-phenylpiperidine, 4-	
Cyano-2-dimethylamino-4, 4-diphenylbutane, 4-	
Cyclandelate	in nausea and vomiting in pregnancy
Cyclizine	
Cyclobarbitone	
Cyclobenzaprine	
Cyclofenil	
Cyclomethacaine	
Cyclopentamine	
Cyclopenthiazide	
Cyclopentolate	
Cyclophosphamide	
Cyclopropane	for inhalational use
Cycloserine	
Cyclosporin preparations	
Cyclothiazide	
Cycrimine	
Cyproheptadine	
Cyproterone Acetate	
Cyrimine	
Cytarabine	
Dabigatran	
Dacarbazine	
Dactinomycin	
Danazol	
Dantrolene	
Dapsone	
Darifenacin	
Dasatinib	
Daunorubicin	
Deanol	
Debrisoquine	
Deferasirox	
Deferiprone	
Dehydrocholic Acid	
Dehydroemetine	
Dehydroepiandrosterone	
Delmadinone Acetate	

Demecarium Bromide
Demeclocycline
Deoxycortone
Deoxyribonuclease
Deptropine
Dequalinium Chloride
Deserpidine
Desferrioxamine
Desfluorotriamcinolone
Desipramine
Deslanoside
Desloratadine
Desmopressin
Desogestrel
Desomorphine
Desonide
Desoxymethasone
Dexamethasone
Dexamphetamine
Dexetimide
Dextranomer preparations — for medicinal use
Dextromethorphan
Dextromoramide
Dextropropoxyphene
Dextrothproxine
Diamorphine
Diampromide
Diazepam
Diazoxide
Dibenyline preparations
Dibenzepin
Dichloralphenazone
Dichlorophenarsine
Dichlorphenamide
Diclofenac Sodium
Dicloxacillin
Dicobalt Edetate
Dicyclomine
Didanosine
Dienoestrol
Diethanolamine Fusidate

Diethyl Carbamazine Citrate	
Diethyl Propion	
Diethylamide Ethyl Benzilate	
Diethylamine Acetarsol	
Diethylstilboestrol	and derivatives if for medicinal use
Diethylthiambutene	
Diethyltryptamine, N,N-	
Difenoxin	(1-(3-cyano-3, 3-diphenylpropyl)-4-phenyl piperidine-4- carboxylic acid)
Diflucortolone Valerate	
Diflunisal	
Diflurasone	
Digitalis Leaf	
Digitalis prepared	
Digitoxin	
Digoxin	
Dihydergot preparations	
Dihydrallazine Sulphate	
Dihydrocodeine	
Dihydrocodeinone O-Carboxymethyloxime	
Dihydroergocornine	
Dihydroergocristine	
Dihydroergocryptine	
Dihydroergotamine	
Dihydroergotoxine	
Dihydromorphine	
Dihydrostreptomycin	
Di-iodohydroxquinoline	
Diloxanide Furoate	
Diltiazam	
Dimenoxadole	
Dimepheptanol	
Dimepregnen	
Dimercaprol	
Dimethisoquin	in preparations for local ophthalmic use
Dimethisterone	
Dimethothiazine	
Dimethoxy-a, 4-dimethylphenethylamine, 2,5-	
Dimethyl Sulphoxide	
Dimethylthiambutene	
Dimethyltryptamine, N,N-	
Dimethytubocurarine	

Dinitrodiphenylsulphonylethylenediamine	
Dinitrophenol, 2,4-	and derivatives if for medicinal use
Dinoprost	
Dinoprostone	
Dioxaphetyl Butyrate	
Diphenhydramine	for parenteral use
Diphenidol	
Diphenoxylate	
Diphetarsone	
Diphylline	
Dipipanone	
Dipivefrin	
Diprenorphine	
Diprophylline	
Dipropyltryptamine	
Dipyridamole	
Dipyrone	
Disodium Etidronate	
Disopryamide	
Distigmine Bromide	
Disulfiram	
Disulphamide	
Dobutamine	
Domperidone	
Donepezil Hydrochloride	
Dopamine	
Dorzolamide	
Dothiepin	
Doxapram	
Doxazosin	
Doxepin	
Doxorubicin	
Doxycycline	
Doxycyline Calcium Chelate	
Dronabinol (Marinol)	
Dronedarone	
Droperidol	
Drostanolone	
Drotebanol	
Duloxetine	
Dutasteride	

Dydrogesterone	
Dyflos	
Ecgonine	any derivate of ecgonine which is convertible to ecgonine or to cocaine
Econazole	
Ecothiopate Iodide	
Ectyl urea	
Edogestrone	
Edrophonium Chloride	
Efavirenz	
Eflornithine	
Eletriptan	
Eltrombopag	
Embutramide	
Emepronium Bromide	
Emeside preparations	
Emetine	
Emtricitabine	
Emylcamate	
Enalapril	
Enflurane	for inhalational use
Entacapone	
Entecavir	
Ephedrine	
Ephedrine	in inhalers
Epicillin	
Epinastine	
Epioestriol	
Epithiazide	
Eplerenone	
Epoprostenol	
Ergometrine Maleate	
Ergot	prepared
Ergotamine	
Ergotoxine	
Erlotinib	
Erythrityl Tetranitrate	
Erythromycin	
Escitalopram	
Esomeprazole	
Estradiol	
Estramustine Phosphate	

Etafedrine	
Etamiphylline	
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 N-heptyloxyacetate	if for internal use
Ethyl-3-Piperidylbenzilate, N-	
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	
Etoposide	
Etorphine	
Etoxeridine	

Etravirine	
Etretinate	
Etymemazine	
Everolimus	
Exemestane	
Exenatide	
Ezetimibe	
Factor XIII Concentrate	
Factorate	
Famciclovir	
Famotidine	
Famprofazone	
Fazadinium Bromide	
Febuxostat	
Felodipine	
Fencamfamin	
Fenclofenac	
Fenfluramine	
Fenofibrate	
Fenoprofen	
Fenoterol	
Fenpipramide	
Fenpiprane	
Fentanyl	
Fentiazac	
Fentin Compounds	
Feprazone	
Ferrous Arsenate	
Ferrous salts	for parenteral use
Fesoterodine	
Fexofenadine	
Fibrinolysin	
Finasteride	
Flavoxate	
Flecainide	
Floctafenine	
Florantyrone	
Floxapen preparations	
Fluanisone	
Fluclorolone Acetonide	
Flucloxacillin	

Fluconazole
Flucytosine
Fludarabine
Fludrocortisone Acetate
Flufenamic Acid
Flugestone
Flumedroxone Acetate
Flumethasone
Flumethiazide
Flunitrazepam
Flunixin
Fluocinolone Acetonide
Fluocinonide
Fluocortolone
Fluopromazine
Fluorometholone
Fluorouracil
Fluoxetine
Fluoxymesterone
Flupenthixol
Flupentixol
Fluperolene Acetate
Fluphenazine
Fluprednidene Acetate
Fluprednisolone
Fluprostenol
Flurandrenolone
Flurazepam
Flurbiprofen
Fluspirilene
Flutamide
Fluticasone
Fluvastatin
Fluvoxamine
Folic Acid
Follicle stimulating hormone
Formocortal
Formosulphathiazole
Formoterol
Fosfestrol Tetrasodium
Fosinopril

Framycetin Sulphate
Frovatriptan
Frusemide
Fumagillin
Furaltadone
Furazolidone
Furethidine
Furoxone preparations
Fusafungine
Fusidic Acid
Gabapentin
Galantamine
Gallamine Triethiodide
Gefitinib
Gelsemine
Gelsemium
Gemfibrozil
Gentamicin
Gestronol
Glafenine
Glibenclamide
Glibornuride
Gliclazide
Glimepiride
Glipizide
Gliquidone
Glyburide
Glyceryl Trinitrate preparations
Glycopyrronium Bromide
Glymidine
Glyquidone
Glytona
Gonadotraphon LH
Goserelin
Gramicidin
Granisetron
Gravigard
Griseofulvin
Growth hormone
Guanethidine
Guanoclor

Guanoxan	
Hachimycin	
Halcinonide	
Halobetasol	
Haloperidol	
Haloprogin	
Halopyramine	
Halothane	
Halquinol	
Heparin	
Heptabarbitone	
Heptaminol	
Hetacillin	
Hexachlorophane	
Hexamethonium	
Hexamine	
Hexobarbitone	
Hexoestrol	
Histidine, L-	
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	
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	
Hyoscine Butylbromide	in inhalers
Hyoscine Hydrobromide	
Hyoscine Hydrobromide	in inhalers
Hyoscine Methobromide	
Hyoscine Methobromide	in inhalers
Hyoscyamine	
Hyoscyamine	in inhalers
Hypnomidate Concentrate	
Ibandronate	
Ibuprofen	
Idarubicin	
Idoxuridine	
Ifosfamide	
Imatinib	
Imipramine	
Imiquimod	
Immunoglobulins	
Indapamide Hemihydrate	
Indinavir	
Indomethacin	
Injectables	all
Injections	all preparations for human use
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
Isolysergamide	

Isomethadone	
Isometheptine	
Isoniazid	
Isoprenaline	
Isopropamide Iodide	
Isopropylaminophenazone	
Isosorbide Dinitrate preparations	
Isosorbide Mononitrate preparations	
Isotretinoin	
Isoxuprine	
Isradipine	
Itraconazole	
Ivabradine	
Jaborandi	
Kanamycin Sulphate	
Ketamine	
Ketazolam	
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 BPC 1959	
Lead Arsenate	
Leflunomide	
Letrozole	
Leuprolide	
Levallorphan	
Levetiracetam	
Levocetirizine	
Levodopa	

Levofloxacin	
Levomethorphan	
Levomoramide	
Levonorgestrel	
Levophenacylmorphan	
Levorphanol	
Levothyroxine	
Lidoflazine	
Lignocaine	in preparations for local ophthalmic use
Lincomycin	
Linezolid	
Liothyronine	
Lisinopril	
Lithium Carbonate	
Lithium Sulphate	
Lobeline	
Lodoxamide	
Lofepramine	
Lomustine	
Loperamide	
Lopinavir	
Loprazolam	
Lorazepam	
Lormetazepam	
Losartan	
Loteprednol Etabonate	
Loxapine	
Luteinising hormone	
Lynoestrenol	
Lypressin	
Lysergamide	
Lysergide	and other N-alkyl derivatives of lysergamide
Mafenide	
Magnesium Bromide	
Magnesium Fluoride	
Magnesium Glutamate	
Mandragora Autumnalis	
Mannomustine	
Maprotiline	
Maraviroc	
Mazindol	

Mebanazine	
Mebeverine	
Mebezonium Iodide	
Mebhydrolin	
Mecamylamine	
Mechlorethamine	
Mecillinam	
Meclofenamic Acid	
Meclofenoxate	
Meclozine	if sold or recommended for the prevention of nausea of pregnancy
Medazepam	
Medicinal Opium	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)
Medigoxin	
Medrogestone	
Medroxyprogesterone Acetate	
Mefenamic Acid	
Mefloquine	
Mefruside	
Megestrol	
Meglumine Diatrizoate	
Melarsonyl Potassium	
Melarsoprol	
Melengestrol	
Meloxicam	
Melphalan	
Memantine	
Menadiol	if for parenteral route
Menotrophin	
Mepazine	
Mepenzolate	
Mephenesin	
Mephenoxolone	
Mephentermine	
Mepivacaine	in preparations for local ophthalmic use
Meprobamate	

Meptazinol	
Mepyramine	
Mequitazine	
Mercaptorpurine	
Mercuderamide	
Mersalyl Acid	
Mesalamine	
Mescaline	
Mesna	
Mesoridazine	
Mestanolone	
Mesterolone	
Mestranol	
Metabutethamine	in preparations for local ophthalmic use
Metaldehyde	if for medicinal use
Metaraminol	
Metaxolone	
Metazocine	
Metformin	
Methacycline	
Methadone	
Methadyl Acetate	
Methallenoestril	
Methandienone	
Methandriol	
Methaqualone	
Metharbitone	
Methazolamide	
Methdilazine	
Methenamine	
Methenolone	
Methicillin	
Methimazole	
Methindizate	
Methionine	all isomers
Methisazone	
Methixene	
Methohexitone	
Methoin	
Methoserpidine	
Methotrexate	

Methotrimeprazine	
Methoxamine	
Methoxsalen	
Methoxyflurane	for inhalational purposes
Methoxyphenamine	
Methsuximide	
Methyclothiazide	
Methyl benzoquate	
Methyl-3-morpholino-1,1-diphenylpropane-carboxylic Acid, 2--	
Methyl-3-Piperidylbenzilate, N-	
Methyl-4-phenylpiperidine-4-carboxylic Acid, 1-	
Methylacetanilide, N-	
Methylamphetamine	
Methylchlorthiazide	
Methyldesorphine	
Methyldihydromorphine	
Methyldihydromorphinone	
Methyldopa	
Methylephedrine	
Methylergometrine	
Methylergonovine	
Methylparifynol	
Methylpentynol	
Methylphenidate	
Methylphenobarbitone	
Methylprednisolone	
Methylsulphonal	
Methyltestosterone	
Methylthiouracil	
Methyprylone	
Methysergide	
Metiguanide Tablets	
Metirosine	
Metoclopramide	
Metolazone	
Metomidate	
Metopon	
Metoprimazine	
Metoprolol	
Metronidazole	

Metyrapone	
Mexiletine	
Mezlocillin	
Mianserin	
Mibolerone	
Miconazole	
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 Methobromide	morphine N-Oxide and other pentavalent nitrogen morphine derivatives
Moxifloxacin	
Mupirocin	
Mustine	
Mycophenolate Mofetil	
Myrophine	
Nabilone	
Nabiximols (Sativex)	
Nabumetone	

Nadolol	
Nafcillin	
Naftidrofuryl Oxalate	
Nalbuphine	
Nalidixic Acid	
Nalorphine	
Naloxone	
Naltrexone	
Nandrolone	
Naphazoline	
Naproxen	
Narasin	
Naratriptan	
Natamycin	
Nateglinide	
Nealbarbitone	
Nedocromil	
Nefopam	
Nelfinavir	
Neoarsphenamine	
Neocinchophen	
Neomycin	
Neostigmine	
Nepafenac	in preparations for local ophthalmic use
Nepenthe Oral Solution	
Netilmycin	
Nevirapine	
Nialamide	
Nicardipine	
Nicodicodine	
Nicomorphine	
Nicotinaldehyde Thio-semicarbazone	
Nicotine	for human use (except in natural substances)
Nicoumalone	
Nifedipine	
Nifenazone	
Niflumic Acid	
Nifuratel	
Nikethamide	
Nilotinib	
Nimorazole	

Niridazole	
Nitrazepam	
Nitrofurantoin	
Nitrofurazone	
Nitroprusside Sodium	
Nitroxoline	
Nizatidine	
Nomifensine	
Noracymethadol	
Noradrenaline	
Norcodeine	
Norethandrolone	
Norethindrone	
Norethisterone	
Norethynodrel	
Norfloxacin	
Norgestrel (d-Norgestrel)	
Norlevorphanol	
Normethadone	
Normorphine	
Norpipanone	
Nortriptyline	
Novobiocin	
Nux Vomica Seed	
Nux Vomica Tincture BP	
Nystatin	
Octacosactrin	
Oestradiol	
Oestriol	
Oestrogenic substances, conjugated	
Oestrone	
Ofloxacin	
Olanzepine	
Oleandomycin	
Olmesartan	
Olopatadine	in preparations for local ophthalmic use
Omeprazole	
Ondansetron	
Opipramol	
Opium, raw	
Opium, Tincture BP	

Oral Contraceptives	all
Orciprenaline	
Orlistat	
Orphenadrine	
Orthocaine	in preparations for local ophthalmic use
Oseltamivir	
Ouabain	
Ovarian Gland, dried	
Oxacillin	
Oxamniquine	
Oxanamide	
Oxandrolone	
Oxantel Pamoate	
Oxatomide	
Oxazepam	
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
Paliperidone	
Pancrelipase	
Pancuronium Bromide	
Pantoprazole	
Papaverine	
Papaverine	in inhalers

Papaveroline	
Paradione Capsules	
Paraldehyde	
Paramethadione	
Paramethasone Acetate	
Paramomycin	
Parathyroid Gland	
Paregoric B.P.	
Pargyline	
Paromomycin	
Paroxetine	
Pavaveroline 2-sulphonic Acid [sic]	
Pazopanib	
Pecilocin	
Pemoline	
Pempidine	
Penamecillin	
Penbutolol	
Penethamate	
Penicillamine	
Penicillins	all
Pentacosactride	
Pentaerythritol Tetranitrate	
Pentazocine	
Penthienate Methobromide	
Pentobarbitone	
Pentolinium Tartrate	
Pentosan Polysulfate Sodium	
Pentoxifylline	
Pentrium Tablets	
Pergolide	
Perhexiline	
Pericyazine	
Perindopril	
Perphenazine	
Pethidine	
Phacetoperone	
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 of not further substituted in the ring by one or more other univalent substituentswith alkyl, alkoxy, alkylenedioxy or halide substitutes, whether of not further substituted in the ring by one or more other univalent substituents
Pheneturide	
Phenglutarimide	
Phenindione	
Pheniprazine	
Phenmetrazine	
Phenobarbitone	
Phenol	for parenteral use
Phenomorphan	
Phenoperidine	
Phenoxybenzamine	
Phenoxymethylpenicillin	
Phenprocoumon	
Phensuximide	
Phentermine	
Phentermine Resin Complex	
Phenthoxate	
Phentolamine	
Phenylaminosalicylate	
Phenylbutazone	
Phenylephrine	if for ophthalmic or nasal administration; above 1%w/v

Phenylindanedione	and its derivatives
Phenylmethylbarbituric Acid	
Phenylpiperidine-4 Carboxylic Acid Ethyl Ester, 4-	
Phenylpropanolamine	
Phenytoin	
Phenytoin Sodium	
Pholcodine	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)
Phthalysulphacetamide	
Phthalyysulphathiazole [sic]	
Physostigmine	
Phytomenadione	
Phytonadione	
Picrotoxin	
Pilocarpine	
Pimecrolimus	
Piminodine	
Pimozide	
Pindolol	
Pioglitazone	
Pipamazin	
Pipenzolate Bromide	
Piperacetazine	
Piperazine Oestrone Sulphate	
Piperidolate	
Piperilate	
Pipobroman	
Pipothiazine	
Pipradol	
Piracetam	
Pirbutolol	
Pirenzapine	
Piretanide	
Piritramide	
Piroxicam	
Pituitary extract	
Pituitary Gland (whole dried)	
Pituitary Gland (whole dried)	if in inhalers

Pituitary powdered (posterior lobe)	
Pituitary powdered (posterior lobe)	if in inhalers
Pivampicillin	
Pivmecillinam	
Pizotifen	
Podophyllotoxin	
Podophyllum	
Podophyllum Indian	
Podophyllum Resin	
Poldine Methylsulphate	
Polidexide	
Poliovaccines	all
Polymyxin B Sulphate	if for parenteral use
Polynoxylin	
Polyoestradiol Phosphate	
Polysaccharide Iron Complex	
Polythiazide	
Poppy capsules	
Posaconazole	
Potassium Aminosalicylate	
Potassium Arsenite	
Potassium Bromide	
Potassium Chloride	if for non-parenteral medicinal use
Potassium Clorazepate	
Potassium Gluconate	
Potassium Hydroxyquinolone	
Potassium Perchlorate	
Practolol	
Pralidoxime	
Pramipexole	
Pravastatin	
Prazepam	
Prazosin	
Prednisolone	
Prednisone	
Pregabalin	
Prenylamine Lactate	
Prethcamide	
Prilocaine	except in preparations for local ophthalmic use
Primaquine Phosphate	
Primidone	

Probenecid	
Probucol	
Procainamide	
Procainamide Durules	
Procaine	except in preparations for local ophthalmic use
Procaine Penicillin	
Procarbazine	
Prochlorperazine	
Procyclidine	
Prodiladine	
Progesterone	
Proguanil	
Proheptazine	
Prolactin	
Proligestone	
Prolintane	
Promazine	
Promethazine	if for parenteral use
Propafenone	
Propanidid	
Propantheline Bromide	
Properidine	
Propicillin	
Propiomazine	
Propiram	
Propracaine	in preparations for oral, parenteral and ophthalmic use
Propranolol	
Propylhexedrine	if in inhalers
Propyliodone	
Propylthiouracil	
Propyphenzone	
Proquamezine	
Prostaglandins	all
Protamine	
Prothionamide	
Prothipendyl	
Protirelin	
Protoveratrines A and B	
Protriptyline	
Protyline	

Proxymetacaine	except in preparations for local ophthalmic use
Proxyphylline	
Pseudoephedrine	
Psilocin	
Psilocybin	
Pyrantel	
Pyrazinamide	
Pyridostigmine Bromide	
Pyrimethamine	
Pyroglutamyl, L-histidyl-L-proline Amide, L	
Quetiapine	
Quinagolide	
Quinalbarbitone	
Quinapril	
Quinestradol	
Quinestrol	
Quinethazone	
Quingestanol	
Quinidine	
Quinine	
Quinine and Urea	
Quinuronium Sulphate	
Rabeprazole	
Racemethorphan	
Racemoramide	
Racemorphan	
Racephedrine	
Ragwot [sic]	
Raloxifene	
Raltegravir	
Ramipril	
Ranitidine	
Rasagiline	
Raufolfie (serpentine and vomitoria) [sic]	
Raw Opium	
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	
Riluzole	
Rimexolone	
Rimiterol	
Risedronate	
Risperidone	
Ristocetin	
Ritodrine	
Ritonavir	
Rivaroxaban	
Rivastigmine	
Rizatriptan	
Rolitetracycline Nitrate	
Ropinirole	
Rosiglitazone	
Rosuvastatin	
Rotigotine	
Rufinamide	
Sabadilla	
Salazosulphadimidine	
Salbutamol	
Salcatonin	
Salmefamol	
Salmeterol	
Salsalate	
Sandostatin	
Saquinavir	
Saxagliptin	
Secbutobarbitone	
Selegeline	
Sertraline	
Sevelamer Carbonate	
Sildenafil	
Silver Nitrate	if for medicinal use
Silver Sulphadiazine	
Simvastatin	

Sirolimus	
Sissomicin	
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	for internal use
Sodium Methylarsinate	
Sodium Monofluorophosphate	no restriction if in dentifrices and ms 1.14%
Sodium Nitroprusside	
Sodium Stibogluconate	
Sodium Tauroglycocholate	
Sodium Tetradecyl Sulphate	
Sodium Valproate	
Solapsone	
Solifenacin	
Somatotrophin	
Sorafenib	
Sotalol	
Spectinomycin	
Spiramycin	
Spironolactone	
Stannous Fluoride	
Stanolone	
Stanozolol	
Stavudine	
Stibocaptate	
Stibophen	
Stilboestrol	
Streptodornase	

Streptokinase
Streptomycin
Streptozocin
Strontium Bromide
Strophanthin-K
Strychnine
Styramate
Succinamide
Succinylsulphathiazole
Sucralfate
Sufentanil
Sulbutiamine
Sulfacytine
Sulfadicramide
Sulfadoxine
Sulfametopyrazine
Sulfamonomethoxine
Sulfapyrazole
Sulfasuxidine Tablets
Sulfoxone
Sulindac
Sulphabromomethazine
Sulphacetamide
Sulphachlorpyridazine
Sulphadiazine
Sulphadimethoxine
Sulphadimidine
Sulphaethidole
Sulphafurazole
Sulphafurazole Diethanolamine
Sulphaguanidine
Sulphaloxic Acid
Sulphamerazine
Sulphamethizole
Sulphamethoxazole
Sulphamethoxydiazine
Sulphamethoxypyridazine
Sulphamethylphenazole
Sulphamezathine preparations
Sulphamoprine
Sulphamoxole

Sulphanilamide	
Sulphanitran	
Sulphaphenazole	
Sulphapyridine	
Sulphaquinoxaline	
Sulphasalazine	
Sulphasomidine	
Sulphathiazole	
Sulphathiourea	
Sulphatolamide	
Sulphaurea	
Sulphinpyrazone	
Sulphomyxin	
Sulphonal	
Sulphonamides	all
Sulpiride	
Sulthiame	
Sumatriptan	
Sunitinib	
Suprofen	
Sutilains	when sold or recommended as a debriding agent
Suxamethonium Bromide	
Suxamethonium Chloride	
Suxethonium Bromide	
Tacrine	
Tacrolimus	
Tadalafil	
Talampicillin	
Tamoxifen	
Tamsulosin	
Tazarotene	
Teclothiazide Potassium	
Telithromycin	
Telmisartan	
Temazepam	
Temozolomide	
Tenofovir	
Terazosin	
Terbutaline	
Testosterone	
Testosterone 17B Chloral Hemiacetal	

Tetrabenazine	
Tetracaine	if for parenteral or ophthalmic use
Tetracosactrin	
Tetracycline	
Tetracycline Phosphate Complex	
Tetrasodium Fostestrol	
Thalidomide	
Thallium Acetate	
Thebacon	and its salts
Thebaine	
Theobromine	
Theophylline	
Thiambutosine	
Thiethylperazine	
Thiocarlide	
Thioguanine	
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	
Ticarcillin	
Tigloidine	
Tilidate	
Timolol	
Tinidazole	
Tioguanine/Thioguanine	
Tiotropium	
Tipranavir	

Tizanidine	
Tobramycin	
Tocainide	
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	for inhalational purposes
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	
Tripsin	if for internal use
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 drivatives specified above is thought to be commercially available)
Tryptophan, L-	
Trypure	
Tubocurarine Chloride	
Tybamate	
Tylosin	
Tylosin Phosphate	
Tylosin Tartrate	
Tyrothricin	
Uramustine	
Urea	if for medicinal use
Urea Stibamine	
Uredofos	
Urethane	
Uridine-5-triphosphoric Acid	
Urokinase	
Ursodeoxycholic Acid	
Vaccines	all
Valacyclovir	

Valerian preparations	
Valproic Acid	
Valsartan	
Vancomycin	
Vardenafil	
Varenicline	
Venlafaxine	
Verapamil	
Veratrine	
Veratrum (green and white)	
Vidarbine	
Vigabatrin	
Viloxazine	
Vinbarbitone	
Vinblastine	
Vincristine	
Vindesine	
Viomycin	
Virginiamycin	
Vitamin B12)	with intrinsic Factor Concentrate
Vitamin D)	above Vitamin D 50,000 I.U. per dosage unit [sic]
Voriconazole	
Warfarin	
Xantinol Nicotinate	
Xipanide	
Xylazine	
Yohimbine	
Zafirlukast	
Zaleplon	
Zeranol	
Zidovudine	
Zimelidine	
Zinc Sulphate	if for oral use with md greater than 200mg
Ziprasidone	
Zolmitriptan	
Zolpidem	
Zonisamide	
Zopiclone	

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 effective 15 January 1990; amended by BR 21 / 1992 effective 8 May 1992; amended by BR 42 / 1998 effective 15 May 1998; Third Schedule section reference amended by 2011 : 31 s. 5 effective 10 August 2011; Third Schedule para. 1 amended by BR 35 / 2013 reg. 2 effective 19 April 2013; amended by 2013 : 48 s. 26 effective 24 December 2013; amended by 2014 : 36 s. 2 effective 22 December 2014]

FOURTH SCHEDULE

(Sections 28(1); 48(1)(g))

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:

(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	
Acetomenapthone	
Acetylcholine	in preparations for external use and ms 0.2%
Aconite root	in preparations for external use (ms 1.3% of the crude drug)
Aconitine	in preparations for external use and ms 0.02%
Acriflavine	
Adrenaline	Eye drops, neutral BPC in preparations for external use

Albendazole	
Alkaline Eye Drops BPC	
Allantoin	
Aloxiprin	
Aluminium acetate	for medicinal use
Aluminium chloride	alcoholic solutions
Aluminium oxide	for human use
Alverine	
Ambucetamide	
Amethocaine	in all other preparation *[sic]* for non-parenteral use
Aminacrine	
Amylocaine	in preparations for non-parenteral use
Antazoline	if for nasal or ophthalmic administration
Aspirin	if enteric coated or formulated in any other way so as to delay absorption
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	
Bromodiphenhydramine	
Brompheniramine	
Buclizine	
Buclosemide	
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 glucogalactogluconate	if for oral administration
Calcium polystyrene sulphonate	
Calcium resonium	
Calcium with Vitamin D tablets BPC	
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	
Castor oil	if for ophthalmic use
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, if for use specifically as a bath additive, if impregnated onto gauze dressing for direct application to a wound
Chlorpheniramine	
Chlorphenoxyethanol	
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
Coal tar preparations	
Conium leaf	in preparations for external use and ms 7% of the crude drug
Creosote	if for medicinal use
Crotamiton	
Cyanocobalamin	if in a formulation in which it is the sole active ingredient and is for internal use
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
Dexbrompheniramine	
Dexchlorpheniramine	
Dextromethorphan	in preparations for internal use with md 15 mg (calculated as base) and mdd 75 mg (calculated as base)
Di-iodohydroxyquinoline	for topical preparations for the skin
Diabetic Diagnostic Reagents	all
Diabetic diagnostic tests	
Diatrizoate sodium	for non-parenteral use
Dibromopropamidine	for ophthalmic use
Dichlorophen	
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
Doxylamine	
Embramine	
Emetine	in preparations for internal or external use and ms 1%
Ephedrine	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
Fluorescein	
Fluothane	
Folic Acid	if in preparations for internal use and mdd 500 micrograms
Frangula preparations	
Gamma Benzene hexachloride	
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	
Halibut-Liver Oil Capsules	
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, L-	if for use as an ingredient in dietary or nutritional products as an aminoacid
Homatropine hydrobromide	if in preparations for internal use with md 0.2mg and mdd 0.6mg
Hydrargaphen	in preparations for local application to the skin
Hydroxymethylgramicidin	if in throat lozenges or throat pastilles
Hyoscine	in preparations for external use, in preparations for internal use with ms 0.15%

Hyoscine butylbromide in preparations for external use, in preparations for internal use (other than inhalers) with md 3mg and mdd 9mg; or

Hyoscine hydrobromide in preparations for external use, in preparations for 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

Inositol nicotinate

Iocetamic acid if for oral administration

Iodinated glycerin

Ipecacuanha

Isopropamide iodide in preparations for internal use with md 2.5 mg (as isopropamide ion) and mdd 5 mg (as isopropamide ion)

Isothipendyl

Ispagula husk

Jaborandi in preparations for external use and ms more than 0.025% of the alkaloids in the medicinal product;

Kaolin Poultice BPC

Lachesine Eye Drops BPC

Lactulose

Lead Subacetate Solution, Dilute BPC

Lead Subacetate Solution, Strong BPC

Lignocaine in preparations for external use and ms 0.7% in preparations for non-parenteral use

Lindane

Lithium carbonate in preparations for internal use with md 5mg (calculated as base) and mdd 15 mg (calculated as base)

Lithium sulphate in preparations for internal use with md 5mg (calculated as base) and mdd 15 mg (calculated as base)

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
Meclozine	
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
Metabutethamine	in preparations for nonparenteral 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	
Miristalkonium chloride	
Monosulfiram	for external use
Naphazoline	in nasal sprays or nasal drops not containing liquid paraffin as a vehicle and ms 0.05%
	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 nonparenteral use
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
Phenylpropanolamine	in nasal sprays or nasal drops and ms 2% in preparations for internal use (except controlled release capsules, nasal sprays or nasal drops) with md 50mg and mdd 150mg
Phenyltoloxamine	
Pholcodine	if for non-parenteral use and in undivided preparations with ms 1.5% (calculated as base) and md 20 mg (calculated as base)
	if for non-parenteral use and in single-dose preparations with ms per dosage unit 1.5% (calculated as base) and md 20 mg (calculated as base)
Phosphorylcolamine	
Phytomenadione	if for non-parenteral use in preparations
for internal use with md 5mg and mdd 15mg	
Pipenzolate bromide	in preparations for internal use with md 5mg and mdd 15mg
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
Polystyrene sulphonate resins	for use as an enema
Ponoxylin	
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
Propramidine	if for ophthalmic use
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	
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
	in preparations for internal use (except nasal sprays or nasal drops) with md 30mg and mdd 60mg
Resonium A	
Resorcinal 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	
Selenium sulphide	
Senna	
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
Terpin hydrate	if for medicinal use
Tetracaine	
Tetrahydrofurfuryl salicylate	
Tetrahydrozoline	

Thiabendazole	
Thiomersal	when used as a skin antiseptic
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
Tyloxapol	
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	1000-50,000 I.U. per dosage unit
Xylometazoline	
Zinc sulphate	if for oral use
Zinc sulphate and Adrenaline Eye Drops	
Zinc Sulphate Eye Drops BPC	

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 pargraph *[sic]* 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	
Ammonium chloride	and [*sic*] Morphine Mixture BPC
Astemizole	
Bacitracin	in topical preparations for auricular or local opthalmic use
Chloroform	except for inhalational use
Clemestine	
Clotrimazole	if in preparations for external or vaginal use
Cyproheptadine	
Diclofenac	in topical preparations
Econazole	in cream, powder or solution for external use
	if in preparations for external vaginal use
Enflurane	except for inhalational use
Ether	except for inhalational 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)
Folic acid	if in preparations for internal use and md 500 micrograms and mdd 1000 micrograms
Gramicidin	in preparations for external use and ms 0.02%
	in topical preparations for auricular or local ophthalmic use
Haloprogin	in preparations for external use
Halothane	except for inhalational use
Homatropine	in preparations for external use, in preparations for internal use with md 0.15mg and mdd 0.45mg
Homatropine methylbromide	in preparations for internal use with md 2mg and mdd 6mg
Hyaluronidase	if in preparations for external use
Hydrocortisone	in preparations for topical use ms 0.5%
	in preparations for external use and ms 1%
Hydrogen cyanide	in preparations for internal or external use and ms 0.1%

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 use
Ketoconazole	if in preparations for external or vaginal use
Ketoprofen	in preparations for internal use with ms 75 mg
Levamizole	
Loperamide	if for the treatment of acute diarrhoea
Mebendazole	
Miconazole	for external application to the skin, or for oral use or vaginal use
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 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 *[sic]*
Neomycin	in preparations for external use with ms 3.5 mg per gram
Nicotine	if in oral preparations and md 2mg
Nicotine	in liquid form for inhalation via any electronic delivery system with ms 21mg
Nicotine	in patches with ms 21 mg/24 hours
Nitroglycerin Solution BPC	
Nitroglycerin Tablets	
Nizatidine	in capsules with ms 75 mg
Phenazopyridine	
Phenylpropanolamine	in controlled release capsules with md 75 mg and mdd 150mg

Polymyxin B sulphate	
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
Terfenadine	
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 effective 15 January 1990; amended by BR 21/1992 effective 8 May 1992; and amended by BR 42/1998 effective 15 May 1998; amended by 2013 : 48 s. 27 effective 24 December 2013; amended by BR 69 / 2016 effective 26 July 2016]

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 31 January 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 effective 24 December 2013]

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.

4 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.

7 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.

10 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.

12 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.

13 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

14 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.

18 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.

22 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.

24 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]

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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]