

PHARMACY ACT

Act 60 of 1983 – 1 January 1985

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PHARMACY ACT

EDITORIAL NOTE: By the coming into operation of the Dangerous Drugs Act and the Dangerous Chemicals Act which repealed the Psychotropic Substances Act and Pesticides Control Act, respectively, a number of sections of the Pharmacy Act have become obsolete and/or require to be reviewed.

PART I – PRELIMINARY

1. Short title

This Act may be cited as the Pharmacy Act.

2. Interpretation

In this Act—

“authorised person” means a—

- (a) medical practitioner;
- (b) dental surgeon; or
- (c) veterinary surgeon,

in the exercise of his profession;

“Board” means the Pharmacy Board established under section 3;

“Chairperson” means the Chairperson of the Board;

“Committee” means the Education Committee, the Trade and Therapeutics Committee, the Poisons Committee or the Planning Committee;

“Council” means the Pharmacy Council established under section 3 of the Pharmacy Council Act;

“dangerous drug” has the same meaning as in the Dangerous Drugs Act;

“Director-General” means the Director-General of the Mauritius Revenue Authority established under the Mauritius Revenue Authority Act;

“drug” means a substance or ingredient intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in a human being or an animal;

“guidelines” means guidelines issued by the Permanent Secretary—

- (a) setting out the requirements, the applicable law and the procedure for an application for, or renewal of, a licence or permit;
- (b) available for consultation at the Ministry; and
- (c) posted on the website of the Ministry;

“inspector” means any public officer designated as such by the Minister;

“manufacture”, in relation to a pharmaceutical product, includes compound, formulate, fill, package and label or perform any other operation;

“manufacturer” means a person licensed under section 36;

“medicine” means a chemical product, preparation, biological product or other substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of any ailment, infirmity or injury affecting a human being or an animal or for dental treatment;

“Minister” means the Minister to whom responsibility for the subject of health is assigned;

“Permanent Secretary” means the Permanent Secretary of the Ministry;

“Pesticides Control Board” means the Pesticides Control Board established under section 3 of the Pesticides Control Act;

“pharmaceutical product” means a drug, medicine, preparation, poison or therapeutic substance;

“pharmacist” means a person registered as such under section 18 of the Pharmacy Council Act;

“pharmacy” means any premises where, subject to this Act, any pharmaceutical product may be stored, dispensed, sold, exposed or offered for sale;

“pharmacy technician” means a person registered as such under section 12 who is a dispenser of pharmaceutical products or assists a pharmacist in the dispensing of pharmaceutical products;

“Planning Committee” means the Planning Committee referred to in section 9;

“poison” —

- (a) means a substance specified in the First, Third, Fourth and Fifth Schedules; and
- (b) subject to paragraph (c), includes any poisonous substance or liquid; but
- (c) does not include—
 - (i) a substance which is an ingredient in adhesives, antifouling compositions, builders’ materials, ceramics, distempers, electrical valves, enamels, explosives, fillers, fireworks, fluorescent lamps, glazes, glue, inks, lacquer solvents, loading materials, machine spread plasters, matches, motor fuels and lubricants, paints other than pharmaceutical paints, photographic paper, pigments, plastics propellants, rubber, surgical dressings, varnishes or vascular plants and their seeds;

- (ii) a substance specified in the first column of the Second Schedule and constituted or used in the manner specified in the second column of that Schedule;
- (iii) an article containing barium carbonate or zinc phosphide which has been prepared for the destruction of rats or mice; or
- (iv) cannabis or a cannabis derivative when used as an ingredient in a corn paint;

“Poisons Committee” means the Poisons Committee referred to in section 8;

“preparation” means—

- (a) a solution or mixture, in any physical state, containing a medicine or a therapeutic substance; or
- (b) a medicine or a therapeutic substance in dosage form;

“prescription” means a written order for a pharmaceutical product issued by an authorised person;

“psychotropic substance” has the same meaning as in the Psychotropic Substances Act;

“purity”, in relation to a substance, means the degree to which other chemical or biological entities are present in the substance;

“quality control” means measures designed to ensure the conformity of raw materials, finished products and stocks with established specifications of identity, strength, purity and other characteristics;

“register” means the register specified in section 11 (b);

“Registrar” means the Registrar of the Board;

“shelf life”, in relation to a drug, means the period under which the potency of the drug has been maintained under such conditions of storage as may be specified on the label of the drug;

“specified standards” means such standards as are specified in the British, French, United States or European Pharmacopoeia;

“temporary absence” means a period of absence not exceeding 2 hours in a day;

“therapeutic substances”—

- (a) means a substance whose purity and potency cannot be adequately tested by chemical means; and
- (b) includes a preparation;

“Trade and Therapeutics Committee” means the Trade and Therapeutics Committee referred to in section 7;

“TradeNet” has the same meaning as in the Customs Act;

“wholesale pharmacy” means any premises used or intended to be used for the sale of pharmaceutical products by wholesale.

[S. 2 amended by s. 34 (a) of Act 27 of 2013 w.e.f. 1 July 2016; s. 46 (a) of Act 13 of 2015 w.e.f. 1 November 2017.]

PART II – BOARD AND COMMITTEES

3. Pharmacy Board

(1) There is established for the purposes of this Act a Pharmacy Board which shall consist of—

- (a) the Chief Medical Officer as Chairperson;
- (b) the Chief Government Pharmacist;
- (c) 5 pharmacists appointed by the Minister; and
- (d) a law officer designated by the Attorney-General.

(2) A Government Pharmacist designated by the Minister shall act as Registrar of the Board.

4. Functions of Board

(1) The Board may, subject to the approval of the Minister—

- (a) consider and, if satisfied, approve the qualifications of any person wishing to be registered as a pharmacy technician;
- (b) exercise control over the manufacture, importation, distribution, sale and possession of any drug, poison, dangerous drug and psychotropic substance;
- (c) on what appears to it to be good cause, take disciplinary action against any pharmacy technician;
- (d) remove from, or restore to, the register the name of any pharmacy technician;
- (e) exercise supervision and control over any inspector in the exercise of his functions under this Act;
- (f) —
- (g) grant a licence to any person who wishes to operate any pharmacy;
- (h) seek the advice of any committee in respect of any matter relating to this Act; and
- (i) take such measures as it thinks fit to ensure the implementation of this Act.

(2) The Board shall, as and when required, provide the Council with such assistance as may be necessary for it to discharge its functions most effectively under the Pharmacy Council Act.

[S. 4 amended by s. 46 (b) of Act 13 of 2015 w.e.f. 1 November 2017.]

5. Meetings of Board

(1) The quorum of the Board shall be 5.

(2) (a) The Chairperson or, in his absence, the Chief Government Pharmacist shall preside at all meetings of the Board.

(b) In the absence of both the Chairperson and the Chief Government Pharmacist from a meeting of the Board, the members present shall elect from among themselves a member to preside at that meeting and the member so elected shall, in relation to that meeting, exercise the functions and have all the powers of the Chairperson.

(3) Everything required or authorised to be done by the Board shall be decided by a simple majority of the members present and voting.

(4) At any meeting of the Board, each member shall have one vote on the matter in issue and, in the event of an equality of votes, the Chairperson shall have a casting vote.

(5) Subject to this section, the Board shall regulate its meetings in such manner as it thinks fit.

6. —

[S. 6 repealed by s. 46 (c) of Act 13 of 2015 w.e.f. 1 November 2017.]

7. Trade and Therapeutics Committee

(1) There shall be for the purposes of this Act a Trade and Therapeutics Committee which shall advise the Board on—

- (a) any matter relating to the manufacture and importation of pharmaceutical products;
- (b) the compilation and maintenance of a National Drugs Formulary;
- (c) any reported adverse effect caused by any drug and any measure required to be taken to protect public health;
- (d) any area which is in need of a pharmacy; and
- (e) any matter referred to it by the Board.

(2) The Committee shall consist of—

- (a) the Principal Medical Officer as Chairperson;
- (b) the Chief Government Pharmacist;

- (c) a representative of the Ministry responsible for the subject of trade;
- (d) 3 medical practitioners appointed by the Minister;
- (e) 2 pharmacists appointed by the Minister.

8. Poisons Committee

(1) There shall be for the purposes of this Act a Poisons Committee which shall advise the Board on any matter relating to poisons, dangerous drugs and psychotropic substances.

(2) The Committee shall consist of—

- (a) the Chief Government Pharmacist as Chairperson;
- (b) a representative of the Ministry responsible for the subject of agriculture;
- (c) a Government analyst or a Forensic Science Officer with experience in toxicology;
- (d) 3 pharmacists appointed by the Minister; and
- (e) a specialist in general medicine appointed by the Minister.

9. Planning Committee

(1) There shall be for the purposes of this Act a Planning Committee which shall advise the Board on any matter relating to the building of any factory which is intended to manufacture pharmaceutical products.

(2) The Committee shall consist of—

- (a) a Principal Medical Officer as Chairperson;
- (b) the Chief Government Pharmacist;
- (c) the Chief Government Analyst; and
- (d) a Principal Engineer designated by the Minister to whom responsibility for the subject of public infrastructure is assigned.

10. Appointed members of committees

(1) Every appointed member of a committee shall hold office on such terms and conditions as the Minister may determine.

(2) No appointed member of a committee shall be deemed to hold a public office solely by virtue of his appointment.

(3) Every committee shall regulate its meetings in such manner as it thinks fit.

PART III – REGISTRATION AND EXAMINATIONS

11. Registrar

The Registrar shall—

- (a) act as secretary to the Board;
- (b) keep a register in which he shall record the particulars of pharmacy technicians;
- (c) correct any entry in the register which, in the opinion of the Board, is incorrect; and
- (d) keep a record of every licence granted by the Board for operating a pharmacy or wholesale pharmacy.

[S. 11 amended by s. 46 (d) of Act 13 of 2015 w.e.f. 1 November 2017.]

12. Registration

(1) No person shall practise as a pharmacy technician unless he is registered.

(2) Any person who—

- (a) wishes to be registered under this section; and
- (b) holds the prescribed qualifications,

shall make a written application to the Registrar for registration.

(3) On receipt of an application under subsection (2), the Registrar shall—

- (a) on being satisfied that the applicant holds the prescribed qualifications; and
- (b) on payment of the prescribed fee by the applicant,

register the applicant, with the approval of the Board, and issue to him a certificate of registration.

(4) —

(5) (a) A pharmacy technician shall, on or before 15 January in each year, pay the prescribed fee to the Registrar for the retention of his name on the register.

(b) The Registrar shall remove from the register the name of any pharmacy technician who fails to pay the prescribed fee.

(c) A name removed from the register under paragraph (b) may be restored on payment of the prescribed fee together with a surcharge of 15 per cent of the prescribed fee.

[S. 12 amended by Act 16 of 1989; s. 46 (e) of Act 13 of 2015 w.e.f. 1 November 2017.]

13. —

[S. 13 repealed by s. 46 (f) of Act 13 of 2015 w.e.f. 1 November 2017.]

14. —

[S. 14 repealed by s. 46 (f) of Act 13 of 2015 w.e.f. 1 November 2017.]

15. —

[S. 15 repealed by s. 46 (f) of Act 13 of 2015 w.e.f. 1 November 2017.]

16. —

[S. 16 repealed by s. 46 (f) of Act 13 of 2015 w.e.f. 1 November 2017.]

PART IV – PHARMACEUTICAL TRADE

17. Sale of pharmaceutical products

(1) No person shall sell in a pharmacy any article other than—

- (a) a pharmaceutical product;
- (b) a surgical, medical, scientific, or hygienic appliance;
- (c) a toilet preparation; or
- (d) such other product as may be prescribed which is used, prepared or sold for a medical, scientific, hygienic or industrial purpose.

(2) Subject to subsections (3) and (4), no person shall sell by retail any medicine or drug in any place other than a pharmacy.

(3) A medical practitioner may sell any medicine or drug if he does not keep open shop and there is no pharmacy within a distance of 5 kilometres from the place where he attends a patient.

(4) The Minister may, after consultation with the Board, make regulations authorising the sale by retail, in any place other than a pharmacy, of such medicines or drugs as may be specified in those regulations.

[S. 17 amended by Act 26 of 1988.]

18. Operation of pharmacy

(1) No person shall operate a pharmacy unless—

- (a) he holds a licence; and
- (b) there is a pharmacist in charge of the pharmacy.

(2) Any person who wishes to obtain a licence under this section shall make an application to the Board on the prescribed form.

(3) The Board shall, on receipt of an application under subsection (2), require the Trade and Therapeutics Committee to inspect the premises of the applicant which are intended for use as a pharmacy and submit its recommendations.

(4) In considering an application under subsection (2), the Board shall take into account—

- (a) the number of pharmacies in the area in which the applicant intends to operate;

(b) the needs of the area for an additional pharmacy; and

(c) the recommendations of the Trade and Therapeutics Committee.

(5) The Board may grant the application on payment of the prescribed fee and on such conditions as it thinks fit or reject the application.

(6) Where the Board rejects an application under subsection (5), it shall notify the applicant of the reasons for its decision.

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(7) A licence which is granted under this section shall be valid for a period of one year as from the date specified in the licence and may be renewed annually on payment of the prescribed fee.

(8) Except with the written permission of the Board, no pharmacist shall be in charge of more than one pharmacy.

(9) (a) Subject to paragraph (b) and to section 19, no person in a pharmacy, other than a pharmacist, shall dispense a prescription, compound a medicine or sell a drug specified in the First or Sixth Schedule.

(b) A person in a pharmacy may perform any of the acts specified in paragraph (a)—

- (i) in the presence of the pharmacist in charge of the pharmacy; or
- (ii) where the pharmacist in charge is temporarily absent, in the presence of an assistant pharmacist.

(10) Every licensee shall—

- (a) affix a conspicuous sign board outside his pharmacy, bearing his name and that of the pharmacist in charge; and
- (b) display his licence in a conspicuous position in his pharmacy.

(11) Where the Board is satisfied that a licensee has contravened this Act or any condition attached to his licence, it may, by notice in writing, require the licensee within 15 days from the date of service of the notice to show cause why his licence ought not to be revoked and if the Board is satisfied that, having regard to all the circumstances of the case, it is expedient to do so, it may revoke his licence.

19. Death of pharmacist

On the death of any pharmacist who is in charge of a pharmacy—

- (a) the licensee, or where the pharmacist was himself the licensee, the spouse or heirs of the deceased pharmacist, may, with the approval of the Board—
 - (i) operate the pharmacy under the direct management of an assistant pharmacist for a period not exceeding 8 days; and
 - (ii) cause the pharmacy to be supervised by a pharmacist already in charge of another pharmacy for a further period not exceeding 3 months;
- (b) where there is no pharmacist or assistant pharmacist to take charge of the pharmacy—
 - (i) the licensee, or where the pharmacist was the sole licensee, the spouse or heirs of the deceased pharmacist, shall, subject to subparagraph (ii), sell the stock of the pharmacy to another pharmacy within such time as the Board may determine; and

- (ii) the stock of dangerous drugs shall be placed under seal by the Board and may be sold through the Board to another pharmacy.

20. Prescription Book

(1) Every pharmacist, or in his temporary absence or in the case provided for in section 19 (a) (i), an assistant pharmacist, shall keep a Prescription Book in which shall be entered all prescriptions which are dispensed.

(2) The Prescription Book shall be kept in the pharmacy for a period of 2 years from the date on which the last prescription is entered.

21. Prescriptions

(1) Subject to subsection (2), no pharmacist or assistant pharmacist shall refuse to dispense a prescription at a pharmacy to any person who offers to pay in cash for any pharmaceutical product prescribed.

(2) Where the pharmacist considers that an authorised person has made an evident error or overlooked any matter which may endanger the life or health of the patient, he shall delay the execution of the prescription and refer the matter immediately to such person for confirmation.

(3) Every prescription shall—

- (a) be handwritten, dated and signed by an authorised person;
- (b) state the address of the authorised person who signed it;
- (c) specify the name and address—
 - (i) of the patient for whose use it is given; or
 - (ii) where it is given by a veterinary surgeon, of the person to whom the medicine prescribed is to be delivered;
- (d) where it is given by—
 - (i) a dental surgeon, contain the words “For Dental Treatment Only”;
 - (ii) a veterinary surgeon, contain the words “For Animal Treatment Only”;
- (e) specify—
 - (i) the total amount of the pharmaceutical product to be supplied; or
 - (ii) where the pharmaceutical product is packed in ampoules, the total amount intended to be administered or injected; and
- (f) indicate—
 - (i) the dose to be taken; or
 - (ii) the amount intended to be administered or injected in each dose where the pharmaceutical product is packed in ampoules.

22. Dispensing prescriptions

(1) No person shall dispense a prescription unless—

- (a) the prescription complies with section 21 (2); and
- (b) he recognises the signature of the authorised person by whom the prescription purports to have been issued and is satisfied that the signature is genuine.

(2) Subject to subsection (3), no person shall supply a pharmaceutical product more than once.

(3) Where a prescription so directs, it may be dispensed on any number of occasions at the interval specified in the prescription.

(4) Every person dispensing a prescription shall—

- (a) at the time of dispensing, record on the prescription—
 - (i) the date on which it is dispensed; and
 - (ii) where it is a prescription which may be dispensed on more than one occasion, the dates on which it is dispensed;
- (b) deliver to the person for whose use the pharmaceutical product is supplied, or to his agent, a true copy of the prescription bearing—
 - (i) the serial number of the prescription;
 - (ii) the date on which the prescription is dispensed; and
 - (iii) the stamp of the pharmacy; and
- (c) place on the container of each drug dispensed a proper label indicating all instructions for the proper use of the drugs.

23. Wholesale pharmacy

(1) No person shall operate a wholesale pharmacy unless—

- (a) he holds a licence;
- (b) there is a pharmacist who is in charge of the wholesale pharmacy on full-time basis; and
- (c) the premises used for the wholesale pharmacy are distinctly separate from those of any other pharmacy.

(2) Any person who wishes to obtain a licence under this section shall make an application to the Board on the prescribed form.

(3) The Board may, on receipt of an application under subsection (2), grant the application on payment of the prescribed fee and on such conditions as it may determine or reject the application.

(4) A licence which is granted under this section shall be valid for a period of one year as from the date specified on the licence and may be renewed annually on payment of the prescribed fee.

(5) Where the Board rejects an application under subsection (3), it shall notify the applicant of the reasons for its decision.

(6) Where the Board is satisfied that a licensee has contravened this Act or any condition attached to his licence, it may, by notice in writing, require the licensee, within 15 days from the date of service of the notice, to show cause why his licence ought not to be revoked and if the Board is satisfied that, having regard to all the circumstances of the case, it is expedient to do so, it may revoke his licence.

24. Quality of pharmaceutical products

No person shall sell—

- (a) any pharmaceutical product which—
 - (i) is adulterated or impure; or
 - (ii) does not conform to a prescription or to specified standards;
- (b) any drug—
 - (i) which is not of good quality and in perfect state of preservation for medicinal use; or
 - (ii) whose shelf life has expired; or
- (c) any medicine with any ingredients which injuriously affect its quality.

25. Registration of pharmaceutical product

(1) (a) Subject to subsection (6), no person shall import a pharmaceutical product unless it is registered with the Board.

(b) No pharmacist in charge of a pharmacy shall, for himself or on behalf of another person, import a pharmaceutical product for sale by wholesale unless it is registered with the Board.

(2) (a) A person who wishes to register a pharmaceutical product shall make an application to the Board in the prescribed form.

(b) An application made under paragraph (a) shall be accompanied by such non-refundable processing fee as may be prescribed.

(3) On receipt of an application made under subsection (2), the Board shall refer the application to the Trade and Therapeutics Committee for its recommendations.

(4) After considering the recommendations of the Trade and Therapeutics Committee, the Board may approve or reject the application.

(5) Where the Board approves an application, it shall, on payment of the prescribed registration fee by the applicant, register the pharmaceutical product and issue to the applicant a certificate of registration in such form as may be prescribed and on such conditions as it may determine.

(6) The certificate of registration referred to in subsection (5) shall be valid for a period of one year as from the date specified on the certificate of registration and may be renewed annually on payment of the prescribed fee.

(7) The holder of a certificate of registration of a registered pharmaceutical product shall inform the Board and pay such prescribed fee for any change in the characteristics and extension in range of the registered pharmaceutical product.

(8) The Board may exempt any pharmaceutical product from registration.

[S. 25 repealed and replaced by s. 34 (b) of Act 27 of 2013 w.e.f. 1 April 2016.]

25A. Import of pharmaceutical product

(1) Subject to section 25, no person shall import a pharmaceutical product unless he has obtained a clearance issued by the Registrar.

(2) An application for a clearance under subsection (1) shall be—

(a) made either electronically through the TradeNet or, in exceptional or unforeseen circumstances, in such other manner as the Board may determine;

(b) in accordance with relevant guidelines.

(3) An application referred to in subsection (2) shall be accompanied by a scanned copy of the pro forma invoice and such other document or information as may be referred to in the guidelines.

(4) The Registrar may, as soon as is reasonably practicable before the import of the pharmaceutical product—

(a) grant the clearance by endorsing the pro forma invoice; or

(b) refuse an application, electronically through the TradeNet or, in exceptional or unforeseen circumstances, in such manner as the Board may determine.

(5) On arrival of the consignment of pharmaceutical product, the importer shall submit the final invoice—

(a) to the Board electronically through the TradeNet or, in exceptional or unforeseen circumstances, in such manner as the Board may determine; and

(b) in accordance with relevant guidelines.

(6) The Registrar may, as soon as practicable, give the clearance to the Director-General to allow the removal of the imported pharmaceutical product, through the TradeNet or in exceptional or unforeseen circumstances, in such manner as the Board may determine.

[S. 25A inserted by s. 34 (c) of Act 27 of 2013 w.e.f. 1 July 2016.]

PART V – POISONS

26. Import of poisons

(1) No person other than—

- (a) a manufacturer;
- (b) a licensee of a wholesale pharmacy;
- (c) an authorised person;
- (d) a pharmacist; or
- (e) a person who holds a licence under section 27 (1) (b),

shall import any poison.

(2) No person shall, unless he holds a permit, import a poison specified in Part II of the First Schedule.

(3) No person shall, unless he holds a permit issued by the Pesticides Control Board, import a poison specified in the Third Schedule.

(4) Any person who wishes to import a poison specified in Part II of the First Schedule shall—

- (a) make an application, in writing, to the Permanent Secretary; and
- (b) furnish, in support of his application, such information as the Permanent Secretary may require.

(5) The Permanent Secretary may, on receipt of an application under subsection (4), reject the application or accept it on such conditions as he may determine.

27. Sale of poisons

(1) Subject to section 28, no person, other than a pharmacist, shall sell—

- (a) a poison specified in Part I of the First Schedule; or
- (b) a poison specified in Part II of the First Schedule or in the Third or Fourth Schedule unless he holds a licence.

(2) No person shall sell—

- (a) a poison specified in the Third Schedule except to a person who is engaged in the business of agriculture or horticulture and for the purpose of that business;
- (b) a poison specified in the first column of the Fourth Schedule, otherwise than in the form specified in the second column of that Schedule, after obtaining a written declaration from the buyer regarding the use to which the poison will be put;
- (c) to a minor a poison specified in Part II of the First Schedule, in the Third Schedule or in the first column of the Fourth Schedule.

(3) No person who holds a licence under this section shall sell a poison specified in Part II of the First Schedule or in the Third or Fourth Schedule to any person other than a person who holds a permit to purchase the poison, issued by the Permanent Secretary.

(4) No person shall purchase a poison specified in Part II of the First Schedule or in the Third or Fourth Schedule unless he holds a permit issued by the Permanent Secretary.

(5) No person shall sell a poison specified in the Fifth Schedule unless the purchaser is—

- (a) certified by an authorised person in the prescribed form to be a person to whom the poison may properly be sold; or
- (b) known by the seller, or by a pharmacist in the employment of the seller at the premises where the sale is effected, to be a person to whom the poison may properly be sold.

(6) No person shall, except on a prescription, sell by retail any poison specified under this section.

(7) Any person who wishes to obtain a licence under this section shall make an application, in writing, to the Board.

(8) The Board shall, on receipt of an application under subsection (7), require the Poisons Committee to examine the application and submit its recommendations.

(9) Where the Board is satisfied, in the light of the recommendations of the Poisons Committee, that the sale of poisons will be effected—

- (a) under the supervision of a pharmacist; and
- (b) on premises registered with the Permanent Secretary,

it may, on payment of the prescribed fee, grant the licence on such conditions as it may determine.

(10) The licence referred to in subsection (9) shall be valid for a period of one year as from the date specified on the licence and may be renewed annually on payment of the prescribed fee.

(11) Where the Board is satisfied that a licensee has contravened this Act or any condition attached to his licence, he may, by notice in writing, require the licensee, within 15 days from the date of service of the notice, to show cause why his licence ought not to be revoked and if the Board is satisfied that, having regard to all the circumstances of the case, it is expedient to do so, it may revoke his licence.

[S. 27 amended by Act 15 of 1998.]

28. Exemption

Section 27 (1) shall not apply to the sale of a poison—

- (a) by wholesale;
- (b) to an authorised person;

- (c) for use in—
 - (i) a hospital, an infirmary or a dispensary maintained by any public authority; or
 - (ii) in a private clinic; or
- (d) to any person who proves to the satisfaction of the Board that he is engaged in scientific education or research and requires the poison for the purpose of scientific education or research.

29. Poisons Book

(1) Subject to subsection (2), every person who sells a poison specified in the First or Fifth Schedule shall—

- (a) keep a Poisons Book;
- (b) in the case of a poison—
 - (i) specified in the First Schedule, make an entry in the Poisons Book before the delivery of the poison to the purchaser;
 - (ii) specified in the Fifth Schedule, cause the purchaser to sign an entry in the Poisons Book before delivering the poison to him; and
- (c) keep the Poisons Book on his premises for a period of 2 years from the date on which the last entry is made.

(2) Any person who sells a poison specified in the Fifth Schedule may accept a signed order from the purchaser in lieu of a signature in the Poisons Book where—

- (a) the poison is sold to a person for the purpose of his trade, business or profession;
- (b) the seller has obtained a signed order before the completion of the sale;
- (c) the signed order contains—
 - (i) the signature, name, address and trade, business or profession of the purchaser;
 - (ii) the total quantity of the poison to be purchased or, in the case of a poison packed in ampoules, the total quantity intended to be administered or injected; and
 - (iii) the purpose for which the poison is required;
- (d) the seller is satisfied that—
 - (i) the signature on the signed order is genuine;
 - (ii) the person signing the order carries on the business, trade or profession stated; and
 - (iii) the poison will be used in that business, trade or profession; and

- (e) the seller inserts in the entry in the Poisons Book the words “signed order” and a reference number by which the order can be identified.

(3) Any person who makes a false statement for the purpose of obtaining delivery of any poison shall commit an offence.

PART VI – THERAPEUTIC SUBSTANCES

30. Import of therapeutic substances

(1) No person shall import any therapeutic substance other than that specified in the Sixth Schedule.

(2) No person shall, unless he holds a permit, import a therapeutic substance.

(3) No permit for the importation of a therapeutic substance shall be issued to any person other than—

- (a) a pharmacist;
- (b) an authorised person; or
- (c) a person who proves to the satisfaction of the Permanent Secretary that he requires the therapeutic substance for purposes of scientific education or research.

(4) Any person who wishes to obtain a permit under this section shall—

- (a) make an application to the Permanent Secretary, through the TradeNet or, in exceptional or unforeseen circumstances, in such manner as the Permanent Secretary may determine;
- (b) furnish, in support of his application, either electronically through the TradeNet or, in exceptional or unforeseen circumstances, in such other manner as the Permanent Secretary may determine, such information as the Permanent Secretary may require.

(5) The Permanent Secretary may, on receipt of an application under subsection (4), reject the application or grant it on such conditions as he may determine, either electronically through the TradeNet or, in exceptional or unforeseen circumstances, in such other manner as the Permanent Secretary may determine.

[S. 30 amended by s. 34 (d) of Act 27 of 2013 w.e.f. 1 July 2016.]

31. Standards of therapeutic substances

(1) Subject to section 32, no person shall manufacture or sell a therapeutic substance specified in the Sixth Schedule unless it conforms to the specified standards.

(2) The Permanent Secretary may order the forfeiture of any therapeutic substance which does not comply with subsection (1).

32. Sale of therapeutic substances

(1) Subject to subsection (2), no person shall, except on a prescription, sell by retail any therapeutic substance.

(2) Subsection (1) shall not apply to—

- (a) the supply of a therapeutic substance which is an antibiotic where it is made on production of a written requisition from one pharmacist to another; or
- (b) a therapeutic substance sold—
 - (i) by wholesale;
 - (ii) for export;
 - (iii) to an authorised person;
 - (iv) to the owner or master of a ship or aircraft for medical use on board;
 - (v) to any institution or business which proves to the satisfaction of the Board that it carries on scientific education or research;
 - (vi) to Government; or
 - (vii) to a person in charge of a hospital, clinic or nursing home, or any other institution which is approved by the Board and provides medical, dental, surgical or veterinary treatment.

33. Sale of antibiotics

(1) Every person who sells or supplies a therapeutic substance which is an antibiotic shall—

- (a) keep an Antibiotics Book; and
- (b) make a record of every sale or supply in the Antibiotics Book.

(2) The Antibiotics Book and every requisition produced under section 32 (2) (a) shall be kept by the seller on his premises for a period of 2 years from the date on which the last entry is made.

34. Treatment

No person shall administer a therapeutic substance by way of treatment unless—

- (a) he is, or is acting under the directions of, an authorised person; or
- (b) he is the master, or a person authorised by the master, of a ship or aircraft which does not include among its crew a medical practitioner.

PART VII – MANUFACTURE OF PHARMACEUTICAL PRODUCTS

35. Building of factory

(1) No person shall, unless he holds a licence, build a factory to manufacture pharmaceutical products.

(2) Any person who wishes to obtain a licence under this section shall—

- (a) make a written application to the Board; and
- (b) furnish, in support of his application—
 - (i) plans of all installations to be made;
 - (ii) details of the type of machinery to be used and the sources of energy;
 - (iii) details of the type of pharmaceutical product to be manufactured; and
 - (iv) such other information or documents as the Board may require.

(3) The Board shall, on receipt of an application under subsection (2), require the Planning Committee to examine the application and submit its recommendations.

(4) The Board may, in the light of the recommendations of the Planning Committee, grant the application on payment of the prescribed fee and subject to such conditions as it may determine or reject the application.

(5) Where the Board rejects an application under subsection (3), it shall notify the applicant of the reason for its decision.

(6) Where the Board is satisfied that a licensee has contravened this Act or any condition attached to his licence, it may, by notice in writing, require the licensee, within 15 days from the date of service of the notice, to show cause why his licence ought not to be revoked and if the Board is satisfied that, having regard to all the circumstances of the case, it is expedient to do so, it may revoke his licence.

36. Licence for manufacture

(1) No person shall, unless he holds a licence, manufacture any pharmaceutical product.

(2) Any person who wishes to obtain a licence under this section shall—

- (a) make a written application to the Board; and
- (b) furnish, in support of his application—
 - (i) the formula of each pharmaceutical product to be manufactured;
 - (ii) the technical description of the production process;

- (iii) details of all quality control; and
- (iv) such other information or documents as the Board may require.

(3) The Board may, on receipt of an application under subsection (2), grant the application on payment of the prescribed fee and on such conditions as it may determine or reject the application.

(4) Where the Board rejects an application under subsection (3), it shall notify the applicant of the reasons for its decision.

(5) No application for a licence to manufacture therapeutic substances shall be granted unless—

- (a) there are adequate facilities for manufacture of sterile preparations;
- (b) there is appropriate quality control of any therapeutic substance used and of the finished product; and
- (c) the manufacture takes place under the supervision of a pharmacist, a pharmacologist or a chemist who proves to the satisfaction of the Board that he has adequate experience in the manufacture of the therapeutic substances.

(6) Every licence issued under this section shall be valid for a period of one year as from the date specified in the licence and may be renewed every year on payment of the prescribed fee.

(7) Where the Board is satisfied that a licensee has contravened this Act or any condition attached to his licence, it may, by notice in writing, require the licensee, within 15 days from the date of service of the notice, to show cause why his licence ought not to be revoked and if the Board is satisfied that, having regard to all the circumstances of the case, it is expedient to do so, it may revoke his licence.

36A. Sale of manufactured pharmaceutical product

(1) Subject to section 36, no manufacturer shall sell a manufactured pharmaceutical product unless he is registered with the Board.

(2) (a) A manufacturer who wishes to register a manufactured pharmaceutical product shall make an application to the Board in the prescribed form.

(b) An application made under paragraph (a) shall be accompanied by such non-refundable processing fee as may be prescribed.

(3) On receipt of an application made under subsection (2), the Board shall refer the application to the Trade and Therapeutics Committee for its recommendations.

(4) After considering the recommendations of the Trade and Therapeutics Committee, the Board may approve or reject the application.

(5) Where the Board approves an application, it shall, on payment of the prescribed registration fee by the applicant, register the manufactured pharmaceutical product and issue to the applicant a certificate of registration in such form as may be prescribed and on such conditions as it may determine.

(6) A certificate of registration which is issued under this section shall be valid for a period of one year as from the date specified on the certificate of registration and may be renewed every year on payment of the prescribed fee.

(7) The holder of a certificate of registration of a manufactured pharmaceutical product shall inform the Board and pay such prescribed fee for any change in the characteristics and extension in range of the manufactured pharmaceutical product.

(8) The Board may exempt any manufactured pharmaceutical product from registration.

[S. 36A inserted by s. 34 (e) of Act 27 of 2013 w.e.f. 1 April 2016.]

37. Supervision of factory

No manufacturer shall operate a factory except under the supervision and control of a manager who—

- (a) has such degree in pharmacy or pharmacology as the Board may approve; and
- (b) satisfies the Board that he has adequate qualifications and at least 10 years' experience in the manufacture of pharmaceutical products.

38. Quality control

Every manufacturer shall—

- (a) provide on his premises adequate facilities for quality control of raw materials, finished products and stocks;
- (b) ensure that raw materials used in the manufacture of a pharmaceutical product are of the required degree of purity and fit for pharmaceutical use;
- (c) ensure that in pharmaceutical products requiring aseptic technique—
 - (i) the factors influencing their contamination are under control;
 - (ii) the aseptic precautions are fulfilled; and
 - (iii) the finished products comply with tests for pyrogens or for freedom from undue toxicity or for sterility.

39. Storage, records and samples

Every manufacturer shall—

- (a) provide facilities for storing his raw materials and products at the required temperature and relative degree of humidity to ensure that loss of potency and deterioration are reduced to a strict minimum;
- (b) keep at the factory, for a period of 3 years after the date of manufacture, a record of—
 - (i) all products manufactured;

- (ii) the date of manufacture and the expiry date of products manufactured;
 - (iii) the batch or lot number of raw materials and finished products;
 - (iv) the raw materials used in the manufacture of a product; and
 - (v) all analytical results in respect of each raw material and each finished product; and
- (c) keep at the factory, for a period of 5 years after the date of manufacture, representative samples of all raw materials and finished products.

PART VIII – MISCELLANEOUS

40. Illegal arrangements

(1) No manufacturer, licensee of a wholesale pharmacy or pharmacist shall enter into any arrangement with an authorised person under which the authorised person is to receive any gain or benefit in return for the custom he brings to the manufacturer, licensee of a wholesale pharmacy or pharmacist.

(2) No authorised person shall have any share, participation or other financial interest in the manufacture or sale, whether by wholesale or retail, of pharmaceutical products.

41. Advertising

No person shall advertise any pharmaceutical product intended for human or veterinary use except in such technical or professional publications as the Board may approve.

42. Inspectors

An inspector may, for the purpose of ensuring that this Act or any regulations made under this Act, is being complied with—

- (a) visit and inspect any premises registered or licensed under this Act;
- (b) examine any document required to be kept under this Act;
- (c) seize and, with the authority of the Board, destroy any pharmaceutical product which is, in his opinion, unwholesome or unfit for use; and
- (d) institute proceedings in respect of any offence under this Act or any subsidiary enactment made under this Act.

43. Samples

Where an inspector takes a sample for analysis, he shall—

- (a) divide the sample into 3 parts, each part to be marked, sealed and signed by him and by the person from whom it is taken;

- (b) deliver one part to the person from whom the sample has been taken;
- (c) retain one part for future comparison; and
- (d) forward one part to the appropriate laboratory for analysis.

44. Powers of Director-General

(1) The Director-General shall not allow the removal of any imported pharmaceutical product from the place where it is stored unless the relevant invoice has been endorsed by the Registrar to show that the importation of the pharmaceutical product is authorised under this Act.

(2) Where any pharmaceutical product is imported in contravention of this Act, the Director-General shall seize and remit it to the Permanent Secretary to be disposed of in such manner as the Permanent Secretary may determine.

44A. Power of Permanent Secretary to issue guidelines

The Permanent Secretary may, for the purposes of this Act, issue such guidelines as he may determine.

[S. 44A inserted by s. 34 (f) of Act 27 of 2013 w.e.f. 1 July 2016.]

45. Offences

(1) Any person who—

- (a) contravenes—
 - (i) this Act or any regulations made under this Act; or
 - (ii) any condition of a certificate of registration, licence or permit granted under this Act;
- (b) manufactures a pharmaceutical product which does not comply with the specified standards of purity, potency or quality; or
- (c) for the purposes of an application under section 25 or obtaining clearance under section 25A, wilfully—
 - (i) makes a false statement or a statement which he knows or ought to have known to be false in any material particular;
 - (ii) makes a false representation; or
 - (iii) fails to disclose a material fact,

shall commit an offence.

(2) Any person who commits an offence under subsection (1) shall, on conviction, be liable to a fine not exceeding 10,000 rupees and to imprisonment for a term not exceeding 2 years.

(3) The Court before which a person is convicted of an offence under subsection (1) may, in addition to any penalty imposed, order the cancellation or suspension of any certificate of registration, licence or permit in respect of which the offence was committed and the forfeiture of any pharmaceutical product which is the subject matter of the offence.

[S. 45 amended by Act 5 of 1999; s. 34 (g) of Act 27 of 2013 w.e.f. 1 April 2016.]

46. Application of Act

This Act shall not apply to—

- (a) any pharmaceutical product found in possession of a person in transit in Mauritius from a ship or aircraft who satisfies the Director-General or the Permanent Secretary that the pharmaceutical product is solely intended for his own use;
- (b) any pharmaceutical product based on the principles of ayurvedic or Chinese or homeopathic medicine and certified as such by the Board.

47. Regulations

(1) The Minister may make such regulations as he thinks fit for the purpose of this Act.

(2) Any regulations made under subsection (1) may—

- (a) provide for the taking of fees and the issue of licences; and
- (b) amend the Schedules.

48. – 51. —

FIRST SCHEDULE

[Sections 2, 27 and 29]

PART I

Acetanilide; alkyl acentanilides

Acetohexamide

Acetorphine; its salts; its esters and ethers; their salts

Acetylcarbromal

Acetyldihydrocodeine; its salts

Alcuronium

Alkali fluorides other than those specified in Part II

Alkaloids, their quarternary compounds; any salt, simple or complex, of any such substance

Aconite, alkaloids of

Atropine

Belladonna, alkaloids of

Brucine

Calabar bean, alkaloids of

Coca, alkaloids of

Coniine

Cotarnine

Curare, alkaloids of, curare bases

Ecgonine, its esters and ethers

Ephedra, alkaloids of

Ergot, alkaloids of, whether hydrogenated or not; their homologues

continued on page P8 – 25

FIRST SCHEDULE—continued

Gelsemium, alkaloids of
Homatropine
Hyoscyamine
Jaborandi, alkaloids of
Lobelia, alkaloids of
Morphine, its esters and ethers
Papaverine
Pomegranate, alkaloids of
Quebracho, alkaloids of, other than the alkaloids of red quebracho
Rauwolfia, alkaloids of, their derivatives
Sabadilla, alkaloids of
Solanaceous, alkaloids not otherwise included in this Schedule
Stavesacre, alkaloids of
Strychnine
Thebaine
Veratrum, alkaloids of
Yohimba, alkaloids of
Allylisopropylacetylurea
Allylprodine; its salts
Alphameprodine; its salts
Alphaprodine; its salts
Amino-alcohols esterified with benzoic acid, phenylacetic acid, phenylpropionic acid, cinnamic acid or the derivatives of these acids; their salts
P-Aminobenzenesulphonamide, its salts, derivatives of p-aminobenzene-sulphonamide having any of the hydrogen atoms of the p-amino group or of the sulphonamide group substituted by another radical; their salts
p-Aminobenzoic acid, esters of; their salts
Aminorex; its salts
Amitriptyline; its salts
Amyl nitrite
Androgenic, oestrogenic and progestational substances — Benzoestrol
Derivatives of stilbene, dibenzyl or naphthalene with oestrogenic activity, their esters
Steroid compounds with androgenic or oestrogenic or progestational activity; their esters
Anileridine; its salts
Anti-histamine substances, their salts; their molecular compounds—
 Antazonline
 Bromodiphehydramine

FIRST SCHEDULE—continued

Buclizine
Carbinoxamine
Chlorcyclizine
Chlorpheniramine
Cinnarizine
Clemizole
Cyclizine
Cyproheptadine
3-Di-n-butylaminomethyl-4, 5, 6-trihydroxyphthalide
Diphenhydramine
Diphenylpyraline
Doxylamine
Isothipendyl
Mebhydrolin
Meclozine
Phenindamine
Pheniramine
Phenyltoloxamine
Promethazine
Pyrrobutamine
Tetra-N-substituted derivatives of ethylenediamine or propylenediamine
Thenalidine
Tolpropamine
Triprolidine

Antimony, chlorides of; antinomates; antinomites; organic compounds of antimony

Apomorphine; its salts

Arsenical substances, other than those specified in Part II—

halides of arsenic; oxides of arsenic; arsenates; arsenites; organic compounds of arsenic

Azacyclonol; its salts

Barbituric acid; its salts; dervatives of barbituric acid; their salts; compounds of barbituric acid; its salts; its derivatives; their salts, with any other substance

Barium, salts of, other than barium sulphate and the salts of barium specified in Part II

Benactyzine; its salts

Benzethidine; its salts

Benzhexol; its salts

FIRST SCHEDULE—continued

Benxoylmorphine, its salts
Benztropine and its homologues; their salts
Benzylmorphine; its salts
Betameprodine; its salts
Betaprodine; its salts
Bexitramide; its salts
Bromvaletone
Busulphan; its salts
Butychloral hydrate
Cannabis (the dried flowering of fruting tops of Cannabis Sativa Linn); the resin of cannabis; extracts of cannabis; tinctures of cannabis; cannabin tannate
Cantharidin; cantharidates
Captodiamine; its salts
Caramiphen; its salts
Carbachol
Carbromal
Carisoprodol
Carperidine; its salts
Chloral; its addition and its condensation products; their molecular compound
Chlordiazepoxide; its salts
Chlormethiazole; its salts
Chloroform
Chloroquine
Chlorothiazide and other derivatives of benzo-1, 2, 4-thiadiazine-7-sulphonamide 1, 1-dioxide, whether hydrogenated or not
Chlorphenoxamine; its salts
Chlorphentermine; its salts
Chlorpropamide; its salts
Chlorprothizene and other derivatives of 9-methylenethizanthen; their salts
Chlorthalidone and other derivatives of co-chlorobenzene sulphonamide
Clioquinol
Clonitazene; its salts
Clorexolone
Clorprenaline; its salts
Corticitrophine, natural and synthetic
Creosote obtained from wood
Croton, oil of

FIRST SCHEDULE—continued

4-Cyano-2-dimethylamino-4, 4-diphenylbutane; its salts
4-Cyano-1-methyl-4-phenylpiperidine; its salts
Cyclarbamate
Cycrimine; its salts
Dehydroemetine; its salts
Demecarium bromide
Desipramine; its salts
Desomorphine; its salts; its esters and ethers; their salts
Dextromethorphan, its salts
Dextromoramide; its salts
Dextrorphan; its salts
Diacetylmorphine; its salts
Diacetylnalorphine; its salts
Diampromide; its salts
Diazepam and other compounds containing the chemical structure of dihydro-1
4-benzodiazepine substituted to any degree; their salts
Digitalis, glycosides of; other active principles of digitalis
Dihydrocodeine; its salts; its esters and ethers; their salts
Dihydrocodeinone O-carboxymethyloxime; its salts; its esters; their salts
Dihydromorphine; its salts; its esters and ethers; their salts
3- (3-4-Dihydroxyphenyl) alanine; its salts
Diennoxadole; its salts
Dimepheptanol; its salts; its esters and ethers; their salts
Dinitronaphthols; dinitrophenols; dinitrothymols
Dioxaphetyl butyrate; its salts
Diperodon; its salts
Diphenoxylate; its salts
Disulfiram/Dipipanone; its salts
Dithienylallylamines; dithienylalkylallylamines; their salts
Dothiepin; its salts
Dyflos
Ecothiopate iodine
Ectylurea
Elaterin
Embutramide
Emylcamate
Erythrityl tetranitrate
Ethacrynic acid; its salts

FIRST SCHEDULE—continued

Ethchlorvynol
Ethinamate
Ethionamide
Ethoheptazine; its salts
Ethylmorphine; its salts, its esters and ethers; their salts
Ethylnoradrenaline; its salts
Etonitazene; its salts
Etorphine; its salts; its esters and ethers; their salts
Etoxeridine; its salts
Fenfluramine; its salts
Fentanyl; its salts
Fluanisone
Flufenamic acid; its salts, its esters; their salts
Fluoroacetamide
Fluoracetanilide
Furethidine; its salts
Gallamine; its salts; its quaternary compounds
Glutethimide; its salts
Gyceryl trinitrate
Glymidine
Guanidines
di-p-anisyl-p-phenetylguanidine
polymethylene diguanidines
Haloperidol and other 4-substituted derivatives of N- (3-p-fluorobenzolypropyl)
Piperidine
Hexapropymate
Hydrazines, benzyl, phenetyl and phenoxyethyl; their methyl derivatives; acyl derivatives of any of those substances; salts of any compounds specified in this item
Hydrocyanic acid; cyanides, other than ferrocyanides and ferricyanides
Hydromorphinol; its salts, its esters and ethers; their salts
Hydroxycinchoninic acid; derivatives of; their salts; their esters
Hydroxy-N, N-dimethyltryptamines; their esters or ethers; any salt of other substance falling within this them
Hydroxypethidine; its esters and ethers; their salts
Hydroxyurea
Hydromysine; its salts
Imipramide; its salts

FIRST SCHEDULE—continued

Indomethacin; its salts
Insulin
Ipridole; its salts
Isoaminile; its salts
Isoetharine; its salts
Isomethadone (isoamidone); its salts
Isoprenaline; its salts
Ketobemidone; its salts; its esters and ethers; their salts
Laudexium; its salts
Lead acetates; compounds of lead with acids from fixed oils
Levomethorphan; its salts
Levophenacymorphan; its salts; its esters and ethers; their salts
Levorphanol; its salts; its esters and ethers; their salts
Lysergide; its salts, simple or complex; its quarternary compounds
Mannytyl hexanitrate
Mannomustine; its salts
Mebezonium iodine
Mebutamate
Meclofenoxate; its salts
Mefenamic acid; its salts; its esters; their salts
Mepacrine
Mephensin; its esters
Meprobamate
Mercaptopurine; its salts; derivatives of mercaptopurine; their salts
Mercury, oxide of; nitrates of mercury; meruric ammonium chlorides; potassiummercuric iodides; organic compounds of mercury which contain a methyl (CH) group directly linked to the mercury atom; mercuric osycyanides; mercuric thiocyanate
Mescaline and other derivatives of phenethylamine formed by substitution in the aromatic ring; their salts
Metaxalone
Metazocine; its salts; its esters and ethers; their salts
Metformin; its salts
Methadone (amidone); its salts
Methadyl acetate; its salts
Methaqualone; its salts
Methixene; its salts
Methocarbamol

FIRST SCHEDULE—continued

Methoxsalen

Methoxyphenamine; its salts

Methylaminoheptane; its salts

Methyl-desorphanine; its salts; its esters and ethers; their salts

Methyldihydromorphine; its salts; its esters and ethers; their salts

2-Methyl-3-morpholino-1, 1-diphenylpropanecarboxylic acid; its salts, its esters;

Methypentynol; its esters and other derivatives

&-Methylphenethylamine, B-methylphenethylamine and &-ethylphenethylamine, any synthetic compound structurally derived from any of those substances by substitution in the aliphatic part or by ring closure therein (or by both such substitution and such closure) or by substitution in the aromatic ring (with or without substitution at the nitrogen atom), except ephedrine, its optical isomers and N-substituted derivatives, fenfluramine, hydroxyamphetamine, methoxyphenamine, phenylpropanolamine, pholedrine and prenylamine; any salt of any substance falling within this item 1-Methyl-4-phenylpyridine-4-carboxylic acid; esters of; their salts

Methypyrone

Metoclopramide; its salts

Metopon; its salts, its esters and ethers; their salts

Mitopodizide; its salts

Monofluoroacetic acid; its salts

Morpheridine; its salts

Mustine and any other N-substituted derivatives of di-(2-chloroethyl) amine, their salts

Myrophine, its salts

Nalorphine; its salts

Nicocodine; its salts

m-Nitrophenol; o-nitrophenol; p-nitrophenol

Noracymethadol; its salts

Norcodeine; its salts; its esters and ethers; their salts

Norlevorphanol; its salts, its esters and ethers; their salts

Normethadone; its salts;

Normorphine; its salts; its esters and ethers; their salts

Norpipanone

Nortryptiline; its salts

Nux Vomica

Opium

Orciprenaline; its salts

Orphenadrine; its salts

FIRST SCHEDULE—continued

Orthocaine; its salts
Ouabain
Oxalic acid
Oxethazaine
Oxycodone; its salts; its ester and ethers, their salts
Oxymorphone, its salts, its esters and ethers; their salts
Oxyphebutazone
Oxytocins, natural and synthetic
p-chloro-a, a-dimethyl p-hemethyl-carbonate
Paraldehyde
Paramethadione
Pargyline; its salts
Pemoline; its salts
Pentazocine; its salts
Phenacemide
Phenadoxone; its salts
Phenaglycodol
Phenamipromide; its salts
Phenazocine; its salts; its esters and ethers; their salts
Phenbutrazate
Phenbucyclidine; its salts
Phenetidinphenacetin
Phenformin; its salts
Phenmetragine
Phenols (any member of the series of phenols of which the first member is phenol and of which the molecular composition varies from member to member by one atom of carbon and 2 atoms of hydrogen) except in substances containing less than 60 per cent, weight, of phenols; compounds of phenol with a metal, except in substances containing less than the equivalent of sixty per cent, weight in weight, of phenols
Phenomorphan; its salts; its esters and ethers; their salts
Phenoperidine; its salts; its esters and ethers; their salts
Phenothiazine, derivatives of; their salts; except dimethoxanate; its salts and promethazine; its salts and its molecular compounds
Phenylbutazone; its salts
2-Phenylcinchoninic acid; 2-salicylcinchonimic acid; their salts; their esters
5-Phenylhydantoin; its alkyl and aryl derivatives; their salts
4-Phenylpiperidine-4-carboxylic acid ethyl ester; its salts
Pholcodine; its salts; its esters and ethers; their salts

FIRST SCHEDULE—continued

Phosphorus, yellow
Picric acid
Picrotoxin
Piminodine; its salts
Pipradol
Piritramide; its salts
Pituitary gland, the active principles of
Podophyllum resin
Polymethylene bistrimethyl ammonium salts
Primaquine
Procainamide; its salts
Procarbazine; its salts
Procyclidine; its salts
Proguanil
Proheptazine; its salts
Promoxolan
Propoxphene; its salts
Propylhexedrine; its salts
Prothionamide
Prothipendyl; its salts
Pyrimethamine
Quinethazone
Quinine; its salts
Quinine; amodiaquine
Recemethorphan; its salts
Recemoramide; its salts
Recemorphan; its salts; its esters and ethers; their salts
Salbutamol; its salts
Savin, oil of
Sontonquine
Strophanthus; glycosides of strophanthus
Styramate
Sulphinphyrazone
Sulphonal; alkyl sulphonals
Suprarenal gland medulla, the active principles of; their salts
Syrosingopine
Tetrabenazine; its salts

FIRST SCHEDULE—continued

Thalidomide; its salts
Thallium, salts of
Thebacon; its salts
Thiocarlide; its salts
Thyroid gland, the active principles of; their salts
Tolbutamide
Totramine; its salts
Triaziquono
Tribromethyl alcohol
2,2,2-Trichloroethyl alcohol, esters of; their salts
Trimeperidine; its salts
Trimipramine; its salts
Troxidone
Tybamate
Vasopressina, natural and synthetic
Verapamil; its salts
Zoxazolamine; its salts

PART II

—
[First Sch. amended by s. 36 (2) (a) of Act 16 of 2004 w.e.f. 5 November 2004.]

—
SECOND – FOURTH SCHEDULES

—
[Second to Fourth Sch. repealed by s. 36 (2) (b) of Act 16 of 2004 w.e.f. 5 November 2004.]

FIFTH SCHEDULE

[Sections 2 and 29]

Acetorphine, its salts, its esters and ethers; their salts
Acetyldihydrocodeine; its salts
Alcuronium chloride
Alkaloids, their quarternary compounds; any salt, simple or complex, of any substance falling within the following—
Aconite, alkaloids of; except substances containing less than 0.02 per cent of the alkaloids of aconite Atropine; except substances containing less than 0.15 per cent of atropine or not more than 1.0 per cent of atropine methonitrate
Belladonna, alkaloids of; except substances containing less than 0.15 per cent of the alkaloids of belladonna calculated as hyoscyamine

FIFTH SCHEDULE—continued

Brucine, except substances containing less than 0.2 per cent of brucine Calabar bean, alkaloids of Coca, alkaloids of; except substances containing less than 0.1 per cent of the alkaloids of coca

Cocaine; except substances containing less than 0.1 per cent of cocaine

Codeine; its esters and ethers; except substances containing less than 1.5 per cent of codeine

Coniine except substances containing less than 0.1 per cent of coniine

Cotarnine; except substances containing less than 0.2 per cent of cotarnine

Curare, alkaloids of; curare bases

Ecgonine; its esters and ethers; except substances containing less than the equivalent of 0.1 per cent of ecgonine

Ephedrine; its optical isomers; except when contained in liquid preparations or preparations not intended for the internal treatment of human ailments and except solid preparations containing less than 10 per cent of ephedrine or its optical isomers otherwise than in an inert diluent

Gelsemium, alkaloids of; except substances containing less than 0.1 per cent of the alkaloids of gelsemium

Homatropine; except substances containing less than 0.15 per cent of homatropine

Hyoscine; except substances containing less than 0.15 per cent of hyoscine

Hyoscyamine; except substances containing less than 0.15 per cent of hyoscyamine

Jaborandi, alkaloids of; except substances containing less than 0.5 per cent of the alkaloids of jaborandi Lobelia, alkaloids of; except substances containing less than 0.5 per cent of the alkaloids of lobellia

Morphine; its esters and ethers; except substances containing less than 0.2 per cent of morphine calculated as anhydrous morphine

Nicotine

Papaverine; except substances containing less than 1.0 per cent of papaverine

Pomegranate, alkaloids of; except substances containing less than 0.5 per cent of the alkaloids of pomegranate

Quebracho, alkaloids of

Sabadilla, alkaloids of; except substances containing less than 1.0 per cent of the alkaloids of sabadilla

Salanaceous alkaloids, not otherwise included in this Schedule; except substances containing less than 0.15 per cent of solanaceous alkaloids calculated as hyoscyamine

Stavesacre, alkaloids of except substances containing less than 0.2 per cent of the alkaloids of stavesacre

Strychnine; except substances containing less than 0.2 per cent of strychnine

Thebaine; except substances containing less than 1.0 per cent of thebaine

FIFTH SCHEDULE—continued

Veratrum, alkaloids of; except substances containing less than 1.0 per cent of the alkaloids of veratrum

Yohimba; alkaloids of

Allylisopropylacetylurea

Allyprodine; its salts

Alphamelrodine; its salts

Alphaprodine; its salts

Amino-alcohols esterified with benzoic acid, phenylacetic acid, phenylpropionic acid, cinnamic acid or the derivatives of these acids; except substances containing less than 10 per cent of esterified amino-alcohols and except procaine when in a preparation containing a therapeutic substance prohibited by regulation

Anileridine; its salts

Antimonial poisons; except substances containing less than equivalent of 1.0 per cent of antimony trioxide

Apomorphine; its salts; except substances containing less than 0.2 per cent of apomorphine

Arsenical poisons; except substances containing less than the equivalent of 0.01 per cent of arsenic trioxide and except dentifrices containing less than 0.5 per cent of acetarsol

Barbituric acid; its salts; derivatives of barbituric acid; their salts; compounds of barbituric acid; its salts; its derivatives; their salts, with any other substance

Barium; salts of

Benzethidine; its salts

Benzoylmorphine; its salts

Benzylmorphine; its salts

Betameprodine; its salts

Betaprodine; its salts

Bezitramide; its salts

Busulphan; its salts

Cannabis; the resin of cannabis; extracts of cannabis; tinctures of cannabis; cannabis tannate

Canthaidin; except substances containing less than 0.01 per cent of cantharidin

Cantharidates; except substances containing less than equivalent of 0.01 per cent of cantharidin

Carbachol

Carperidine; its salts

Chloroform; except substances containing not more than 5 per cent of chloroform or when in preparations not intended for the internal treatment of human ailments

Clonitazene; its salts

FIFTH SCHEDULE—continued

- 4 Cyano-2-dimethylamino-4, 4-diphenylbutane; its salts
- Dehydroemetine; its salts
- Demecarium bromide
- Desomorphine; its salts; its esters and ethers; their salts
- Dextromethorphan; its salts except substances containing less than 1.5 per cent of dextromethorphan
- Dextromoramide; its salts
- Dextrorphan; its salts
- Diacetylmorphine; its salts
- Diampromide; its salts
- Digitalis, glucosides and other active principles of; except substances containing less than one unit of activity (as defined in the British Pharmacopoeia) in 2 grammes of the substances;
- Dihydrocodeine; its salts, its esters and ethers; their salts
- Dihydrocodeinone O-carboxymethyloxime; its salts; its esters; their salts
- Dihydromorphine; its salts, its esters and ethers; their salts
- Dimenoxadole; its salts
- Dimepheptanol; its salts; its esters and ethers; their salts
- Dinitroresols (DNOC); their compounds with a metal or base; except winter washes containing not more than the equivalent of 5.0 per cent of dinitroresols
- Dinitronaphthols; dinitrophenols; dinitrothymols
- Dinosam; its compounds with a metal or a base
- Dinoseb; its compounds with a metal or a base
- Dioxaphetyl butyrate; its salts
- Diphenoxylate—
- (a) pharmaceutical preparations in solid or liquid form containing not more than 0.0025 grammes of diphenoxylate calculated as base and not less than 25 microgrammes of atropine calculated as atropine sulphate per dosage unit and containing no substance to which the Dangerous Drugs Act applies; and
 - (b) liquid preparations containing not more than 0.5 milligrammes of diphenoxylate hydrochloride, 0.005 milligrammes atropine sulphate, 0.16 millilitres ethyl alcohol, 0.002 millilitres imitation cherry flavour, 0.45 millilitres glycerine, 0.4 millilitres sorbital solution (70 per cent) 0.01 milligrammes red dye colour index No. 14700 (F.D 4C. Red No. 4) and 0.0008 millilitres water
- Dipipanone; its salts
- Disulfiram
- Diothienylallylamines; dithienylallylamines; their salts
- Dyflos
- Ecothiopate iodine

FIFTH SCHEDULE—continued

Embutramide
Endosulfan
Endothal; its salts
Endrin
Ethylmorphine; its salts; its esters and ethers; their salts; except substances containing less than 0.2 per cent of ethylmorphine
Etonitazene; its salts
Etorphine; its salts; its esters and ethers; their salts
Etoxidine; its salts
Fentanyl; its salts
Fluanisone
Fluoroacetamide; fluoroacetanilide
Furethidine; its salts
Gallamine; its salts; its quaternary compounds
Guanidines, the following—
di-p-anisyl-p-phenethylguanide
polymethylene diguanidines
Hydrocyanic acid; except substances containing less than 0.15 per cent weight in weight, of hydrocyanic acid (HCN) cyanides, other than ferrocyanides and ferricyanides; except substances containing less than the equivalent of 0.1 per cent, weight in weight, of hydrocyanic acid (HCN)
Hydromorphanol; its esters and ethers; their salts
Hydromorphone; its salts; its esters and ethers; their salts
Hydrozincinonic acids; derivatives of; their salts; their esters; except substances containing less than 3.0 per cent of hydrozincinonic acid or a derivative thereof
Hydroxypethidine; its salts; its esters and ethers; their salts
Hydroxyurea
Isomethadone (isomidone); its salts
Ketobemidone; its salts; its esters and ethers; their salts
Laudexium; its salts
Lead, compounds of, with acids from fixed oils
Levomethorphan; its salts
Levomoramide; its salts
Levophenacymorphan; its salts; its esters and ethers; their salts
Levorphanol; its salts; its esters and ethers; their salts
Mannomustine; its salts
Mebezonium
Mercaptopurine; its salts; derivatives of mercaptopurine, their salts

FIFTH SCHEDULE—continued

Mercuric chloride; except substances containing less than 1.6 per cent of mercuric chloride; mercuric iodide; except substances containing less than 2.0 per cent of mercuric iodide; nitrates of mercury; except substances containing less than the equivalent of 3.0 per cent, weight in weight, of mercury (Hg); potassiummercuric iodide; organic compounds of mercury; except substances, not being aerosols, containing less than the equivalent of 0.2 per cent, weight in weight, of mercury (Hg)

Mescaline, and other derivatives of phenethylamine formed by substitution in the aromatic ring; their salts

Metazocine; its salts; its esters and ethers; their salts

Methadone (amidone); its salts

Methadyl acetate; its salts

Methyldesorphine; its salts; its esters and ethers; their salts

Methyldihydromorphine; its salts; its esters and ethers, their salts

2-Methyl-3-morpholino-1, 1-diphenylpropanecarboxylic acid; its salts; its esters; their salts

Monofluoroacetic acid; its salts

Morpheridine; its salts and any other N-substituted derivative of di-(2-chloroethyl) amine; their salts

Myrophine; its salts

Nalorphine; its salts

Nococodine; its salts

m-Nitrophenol; o-nitrophenol; p-nitrophenol

Norcodeine; its salts; its esters and ethers; their salts

Norlevorphanol; its salts; its esters and ethers; their salts

Normethadone; its salts

Normorphine; its salts; its esters and ethers; their salts

Norpipanone

Nux Vomica; except substances containing less than 0.2 per cent of strychnine

Opium; except substances containing less than 0.2 per cent of morphine calculated as anhydrous morphine

Organo-tin compounds; compounds of Fentin

Ouabain

Oxycodone; its salts; its esters and ethers; their salts

Oxymorphone; its salts, its esters and ethers; their salts

Phenacemide

Phenadoxone; its salts

Phenampromide; its salts

FIFTH SCHEDULE—continued

Phenazocine; its salts; its esters and ethers; their salts
Phencyclidine; its salts
Phenomorphane; its salts; its esters and ethers; their salts
Phenoperidine; its salts, its esters and ethers; their salts
2-Phenylcinchoninic acid; 2-salicylcinchonic acid; their salts; their esters
4-Phenylpiperidine - 4-carboxylic acid ethyl ester; its salts
Pholcodine; its salts; its esters and ethers; their salts; except substances containing less than 1.5 per cent of pholcodine
Phosphorous compounds—
 Amiton
 Azinphos-ethyl
 Azinphos-methyl
 Chlorfenvinphos except sheep dips containing not more than 10 per cent, weight in weight, of chlorfenvinphos
 Demeton-O
 Demeton-S
 Demeton-S-methyl
 Dichlorvos
 Diethyl 4-methyl-7-coumarinyl phosphorothionate
 Diethyl p-nitrophenyl phosphate
 Demefox
 Disulfoton
 Ethion
 Ethyl-p-nitrophenyl phenylphosphorothionate
 Mazidox
 Mecarbam
 Mevinphos
 Mipafox
 Oxydemeton-methyl
 Parathion
 Phenkapton
 Phorate
 Phosphamidon
 Schradan
 Sulfotep
 TEPP (HETP)
Thionazin

FIFTH SCHEDULE—continued

Triphosphoric pentadimethylamide
Vamidothion
Picrotoxin
Piminodine; its salts
Piritramide; its salts
Polymethylenebis(trimethylammonium) salts
Proheptazine; its salts
Propoxyphene; its salts
Racemethorphan; its salts
Racemorphan; its salts; its esters and ethers; their salts
Savin, oil of
Strophanthus, glycosides of
Thallium; salts of
Thebacon; its salts
Tretamine; its salts
Triaziquone
Trimeperidine; its salts
Zinc Phosphide

SIXTH SCHEDULE

[Section 30]

Vaccines, sera; toxins, antitoxins and antigens
Amikacin; its salts
Amphoterycin; its salts, its esters; their salts
Amphotericins; their salts
Arsphenamine and analogue substances used for the specific treatment of infective disease
Bacitracin
Campreomycin; its salts; its esters; their salts
Cephalosporins; their salts; their esters; their salts; esters of such salts
Cephameycins
Chloramphenicol; its esters
Chlortetracycline
Clindamycin; its salts; its esters
Colistin; its salts; its esters
Corticotrophin (Adrenocorticotrophichormone, ACTH)
Cortisone; its esters

SIXTH SCHEDULE—continued

Cycloserine; its salts

Dimethylchlortetracycline; its salts

Erythromycin; its esters

Framycetin; its salts

Fusidic acid; its salts; its esters; their salts

Gentamicin; its salts; its esters; their salts

Griseofulvin; its salts

Hydrocortisone; its esters

Isoniazid; its salts; its derivatives; their salts

Kanamycin; its salts

Lincomycins—

S-alkyl derivatives of 6, 8-dideoxy-6-trans- (4-alkyl-L-2-pyrrolidine-carboxamido)-l-thio-D-erythro- & -D-galacto-octo-pyranoside N-pyrrolidine analogues thereof; their esters; their salts

Nalidixic acid; its salts; its esters; their salts

Neomycin; its salts

Novobiocin; its salts

Nystatin; its salts

Oleandomycin; its salts; its esters; their salts

Organic substances having the specific biological action of curare on neuromuscular transmission; preparation of such substances

Oxytetracycline; its salts

Para-aminosalicylic acid; its salts

Paramomycin; its salts; its esters; their salts

Penicillins; their salts; their derivatives; their esters

Polymyxins; their salts

Prednisolone; its esters

Prednisone; its esters

Preparations of the specific antidiabetic principle of the pancreas known as insulin

Preparations of the posterior lobe of the pituitary body

Preparations of human blood

Rifamycins—

A group of related macrolactams, either produced by the growth of *Streptomyces mediterranei* or by modification of such products, and containing the chemical structure of 11,-acetoxy-7, 9, 15-trihydroxymethoxy-2, 6, 8, 10, 12-pentamethyl pentadeca-2, 4, 14-trienoic acid amide, attached by the nitrogen atom and by the oxygen atom in the 15-position respectively to the 7 and 2-position of a 5, 6, 9-tri-oxygenated 2, 4-dimethyl-1-oxonaphtho (2, 1-b) furan; their salts and esters

SIXTH SCHEDULE—*continued*

Salts of their esters

Ristocetins; their salts

Spectinomycin; its salts

Spiramycin; its salts

Streptomycin; its salts; its derivatives and salts of such derivatives

Tobramycin; its salts

Tetracyclines—

Antimicrobial substances containing the chemical structure – naphthacene-2-Carboxymide, hydrogenated to any extent, and having each of the position 1, 3, 10, 14 and 12 substituted by a hydroxyl or an oxogroup; their salts

Vancomycin; its salts

Viomycin; its salts

Virginiamycin; its salts

[Sixth Sch. amended by GN 42 of 1989.]
