

**PHARMACY ACT**

Act 60 of 1983 – 1 January 1985

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## PHARMACY ACT

**EDITORIAL NOTE:** With the repeal of the Pesticides Control Act and the Psychotropic Substances Act and the passing of Act 4 of 2001 and Act 16 of 2004, a number of sections of the Pharmacy Act have become obsolete and/or needs to be reviewed.

### PART I – PRELIMINARY

#### 1. Short title

This Act may be cited as the Pharmacy Act.

#### 2. Interpretation

In this Act—

“assistant pharmacist” means a person registered as such under section 12;

“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;

“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;

“Education Committee” means the Education Committee referred to in section 6;

“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 12;

“pharmacy” means any premises where, subject to this Act, any pharmaceutical product may be 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 or an assistant 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;
- (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;

“student” means a person registered as such under section 13;

“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;

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

## **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**

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 pharmacist, assistant pharmacist, pharmacy technician or student;
- (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 pharmacist, assistant pharmacist, pharmacy technician or student;
- (d) remove from, or restore to, the register the name of any pharmacist, assistant pharmacist, pharmacy technician or student;
- (e) exercise supervision and control over any inspector in the exercise of his functions under this Act;
- (f) conduct and appoint examiners for any examination in pharmacy and award diplomas to candidates who succeed at that examination;
- (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.

#### **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. Education Committee**

(1) There shall be for the purposes of this Act an Education Committee which shall advise the Board on the—

- (a) qualifications required in respect of persons applying for registration as students;
- (b) organisation of courses of instruction or students and assistant pharmacists;
- (c) preparation of the syllabus for any examination in pharmacy;
- (d) appointment of examiners for, and the conduct of, examinations in pharmacy.

(2) The Committee shall consist of—

- (a) the Chief Government Pharmacist as Chairperson;
- (b) a representative of the Ministry responsible for the subject of education;
- (c) a representative of the University of Mauritius; and
- (d) 2 pharmacists appointed by the Minister.

## **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 separately the particulars relating to pharmacists, assistant pharmacists, pharmacy technicians and students;

- (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.

## **12. Registration**

(1) No person shall practise as a pharmacist, assistant pharmacist or 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) No person shall be registered as a pharmacist unless he has obtained—

- (a) a diploma of pharmacist awarded by the Board; or
- (b) a diploma or degree in pharmacy acceptable to the Board and satisfies the Board that he reckons a full year's practical training—
  - (i) prior to obtaining the diploma or degree but after successful completion of the third year of studies; or
  - (ii) after obtaining the diploma or degree, in Mauritius or elsewhere.

(5) (a) A pharmacist, assistant pharmacist or 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 pharmacist, assistant pharmacist or 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.]



### **13. Students**

(1) No person shall serve as a student in a pharmacy unless he is registered.

(2) Any person who—

- (a) wishes to be registered as a student; 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 student and issue to him a certificate of registration.

### **14. Admission to examinations**

(1) Any student who has—

- (a) served a period of 2 years on a full-time basis in a pharmacy; and
- (b) followed a course of instruction arranged by the Board,

may apply to the Registrar for admission to the prescribed examination for an assistant pharmacist's diploma or a pharmacy technician's diploma.

(2) The applicant shall, on succeeding at the prescribed examination, be awarded an assistant's diploma or a pharmacy technician's diploma.

(3) Every pharmacist under whose supervision a student has served on a full-time basis in a pharmacy shall, on request, submit to the Board a written statement certifying the period of training served by the student under his supervision.

### **15. Pharmacist's diploma**

Any person who has—

- (a) been awarded the assistant pharmacist's diploma;
- (b) practised as an assistant pharmacist in a pharmacy for a period of 2 years; and
- (c) followed a course of instruction arranged by the Board,

may apply to the Registrar for admission to the prescribed examination for the pharmacist's diploma.

### **16. Examinations**

No person shall be admitted to any prescribed examination unless his application is accompanied by a certificate from the supervisor in charge of the course of instruction specified in section 14 or 15 to the effect that the applicant has attended the course regularly.

## **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.

(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 thinks fit 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. Import of drugs**

(1) No person shall, unless he holds a permit, import a drug other than a poison.

(2) Any person who wishes to obtain a permit shall make a written application to the Board.

(3) On receipt of an application under subsection (2), the Board may refer the application to the Trade and Therapeutics Committee and in the light of the recommendations of the Committee, shall decide whether or not to approve the application.

(4) Where the application is approved by the Board under subsection (3), the Permanent Secretary shall issue the permit on such conditions as he thinks fit.

(5) No pharmacist in charge of a pharmacy shall, for himself or on behalf of another person, import any drug for sale by wholesale.

### **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 a written application 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 thinks fit.

## **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 a written application 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 thinks fit.

(10) 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.

(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 the—

- (a) poison is sold to a person for the purpose of his trade, business or profession;
- (b) seller has obtained a signed order before the completion of the sale;
- (c) 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) 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) 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 a written application 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 grant it on such conditions as he thinks fit.

### **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 of 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 thinks fit 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 thinks fit 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 annually 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.

### **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 is approved by the Board; 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 may be approved by the Board.

### **42. Inspectors**

An inspector may, for the purpose of ensuring that this Act or any subsidiary enactment 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 article 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 thinks fit.

#### 45. Offences

(1) Any person who—

- (a) contravenes—
  - (i) this Act or any subsidiary enactment made under this Act; or
  - (ii) any condition of a certificate of registration, licence or permit granted under this Act; or
- (b) manufactures a pharmaceutical product which does not comply with the specified standards of purity, potency or quality,

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.]

#### 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. —**

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**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



**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  
Solanaeous, 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 esterfied 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  
Steriod 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  
Etoxidine; 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-phenethylguanidine  
polymethylene diguanidines  
Haloperidol and other 4-substituted derivatives of N- (3-p-fluorobenzoylpropyl)  
Piperidine  
Hexapropymate  
Hydrazines, benzyl, phenethyl 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  
Hydromorphanol; 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-desorphine; 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

&-Methylphene thylamine, 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, phenylpropanalamine pholedrine and prenylamine; any salt of any substance falling within this item 1-Methyl-4 phenylpyridine-4-carboxylic acid; esters of; their salts

Methyprylone

Metoclopramide; its salts

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

Mitopodozide; 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-methyl-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  
Hydrozycinchoninic acids; derivatives of; their salts; their esters; except substances containing less than 3.0 per cent of hydrozycinchoninic 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); potassio-mercuric 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-chloro-ethyl) 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

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**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.]

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