

THE PHARMACY ACT 1983

Act 60/1983

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ARRANGEMENT OF SECTIONS

PART I — PRELIMINARY

- 1 [Short title](#)
- 2 [Interpretation](#)

PART II- BOARD AND COMMITTEES

- 3 [Pharmacy Board](#)
- 4 [Functions of the Board](#)
- 5 [Meetings of the Board](#)
- 6 [Education Committee](#)
- 7 [Trade and Therapeutics Committee](#)
- 8 [Poisons Committee](#)
- 9 [Planning Committee](#)
- 10 [Appointed member of committee](#)

PART III — REGISTRATION AND EXAMINATIONS

- 11 [Registrar](#)
- 12 [Registration](#)
- 13 [Students](#)
- 14 [Admission to examinations](#)
- 15 [Pharmacist's diploma](#)
- 16 [Examinations](#)

PART IV - PHARMACEUTICAL TRADE

- 17 [Sale of pharmaceutical products](#)
- 18 [Operation of pharmacy](#)
- 19 [Death of pharmacist](#)
- 20 [Prescription book](#)
- 21 [Prescriptions](#)
- 22 [Dispensing prescriptions](#)
- 23 [Wholesale pharmacy](#)
- 24 [Quality of pharmaceutical products](#)
- 25 Registration of pharmaceutical product

PART V — POISONS

- 26 [Import of poisons](#)
- 27 [Sale of poisons](#)

- 28 [Exemption](#)
- 29 [Poisons book](#)

PART VI — THERAPEUTIC SUBSTANCES

- 30 [Import of therapeutic substances](#)
- 31 [Standards of therapeutic substances](#)
- 32 [Sale of therapeutic substances](#)
- 33 [Sale of antibiotics](#)
- 34 [Treatment](#)

PART VII- MANUFACTURE OF PHARMACEUTICAL PRODUCTS

- 35 [Building of factory](#)
- 36 [Licence for manufacture](#)
- 37 [Supervision of factory](#)
- 38 [Quality control](#)
- 39 [Storage, records and samples](#)

PART VIII — MISCELLANEOUS

- 40 [Illegal arrangements](#)
- 41 [Advertising](#)
- 42 [Inspectors](#)
- 43 [Samples](#)
- 44 [Comptroller's powers](#)
- 45 [Offences](#)
- 46 [Application of Act](#)
- 47 [Regulations](#)
- 48 [Repeal](#)
- 49 [Consequential amendment](#)
- 50 [Transitional provision](#)
- 51 [Commencement](#)
 - [First Schedule](#)
 - [Second Schedule](#)
 - [Third Schedule](#)
 - [Fourth Schedule](#)
 - [Fifth Schedule](#)
 - [Sixth Schedule](#)

PART I - PRELIMINARY

1 Short title

This Act may be cited as **the Pharmacy Act 1983**.

2 Interpretation

In this Act -

“authorised officer” means an officer designated by the Board to administer an application for –

- (a) a clearance under section 25A; or
- (b) a permit under sections 26 and 30,

as the case may be, and where applicable, the renewal thereof;

“authorised person” means -

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

in the exercise of his profession;

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

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

“Comptroller” means the Comptroller of Customs;

“Council” means the Pharmacy Council established under section 3 of the Pharmacy Council Act 2015;

"dangerous drug" has the same meaning as in the Dangerous Drugs 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;

“effective date”, in relation to an application, means the date by which all required documents, information or samples are submitted;

“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, clearance, a licence or permit;
- (b) available for consultation at the Ministry;
- (c) posted on the website of the Ministry;

- (d) listing every fee leviable under the regulations;
- (e) listing every pharmaceutical product registered for import with the Board, together with their corresponding importers;
- (f) listing every person eligible to import any poison; and
- (g) listing every licensee;

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

“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;

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

“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 any person registered as such under section 18 of the Pharmacy Council Act 2015;

“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 established under 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;
- (c) does not include -

- (i) a substance which is an ingredient in adhesives, anti fouling 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) any article containing barium carbonate or zinc phosphide which has been prepared for the destruction of rats or mice;
- (iv) cannabis or a cannabis derivative when used as an ingredient in a corn paint.

“Poisons Committee” means the Poisons Committee established under 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;

“professional misconduct or negligence”, in relation to a pharmacist, includes –

- (a) a breach of the Code of Practice;
- (b) a failure to exercise due professional skill or care which results in injury to, or loss of life of, a person;
- (c) a failure to exercise the proper and timely care expected from him;
- (d) the supply, or the dispensing, of a dangerous drug to any person otherwise than is properly required for the treatment of a person or an animal;

- (e) the supply, or the dispensing, of a dangerous drug to any person which is in excess of the amount that is properly required for the treatment of a person or an animal;
- (f) the supply, or the dispensing, of a dangerous drug on presentation of a prescription knowing the fictitious nature of any such prescription;
- (g) an act of fraud or dishonesty in the exercise of his calling;
- (h) an improper, a disgraceful, a dishonourable or an unworthy act, or any other conduct, act or omission, which brings the profession of pharmacists into disrepute;

"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;

"registers" 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 any period of absence not exceeding two 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 established under 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.

Amended by [\[Act No. 27 of 2013\]](#); [\[Act No. 13 of 2015\]](#); [\[Act No. 12 of 2019\]](#); [\[Act No. 14 of 2019\]](#)

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, Chairman;
 - (b) the Chief Government Pharmacist;
 - (c) 5 pharmacists appointed by the Minister;
 - (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 the 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) **Repealed by** [\[Act No. 13 of 2015\]](#)

(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;

(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 2015.

Amended by [\[Act No. 13 of 2015\]](#)

5 Meetings of the Board

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

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

(b) In the absence of both the Chairman 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 Chairman.

(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 Chairman shall have a casting vote.

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

6 Repealed by [\[Act No. 13 of 2015\]](#)

7 Trade and Therapeutics Committee

(1) There is established 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;
 - (e) any matter referred to it by the Board.
- (2) The Committee shall consist of -
- (a) the Principal Medical Officer, Chairman;
 - (b) the Chief Government Pharmacist;
 - (c) a representative of the Ministry of Trade and Shipping;
 - (d) 3 medical practitioners appointed by the Minister;
 - (e) 2 pharmacists appointed by the Minister.

8 Poisons Committee

- (1) There is established 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, Chairman;
 - (b) a representative of the Ministry of Agriculture, Fisheries and Natural Resources;
 - (c) a Government analyst or a Forensic Science Officer with experience in toxicology;
 - (d) 3 pharmacists appointed by the Minister;
 - (e) a specialist in general medicine appointed by the Minister.

9 Planning Committee

- (1) There is established 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, Chairman;
- (b) the Chief Government Pharmacist;
- (c) the Chief Government Analyst; and
- (d) a Principal Engineer designated by the Minister of Works.

10 Appointed member of Committee

- (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.

Amended by [\[Act No. 13 of 2015\]](#)

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

(4) **Repealed by** [\[Act No. 13 of 2015\]](#)

- (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.

Amended by [\[Act No. 16 of 1989\]](#); [\[Act No. 13 of 2015\]](#)

13 – 16 **Repealed by** [\[Act No. 13 of 2015\]](#)

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 subsection (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 3 miles 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.

Amended by [\[Act No. 26 of 1988\]](#)

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 and Sixth Schedules.
 - (b) A person in a pharmacy may perform any of the acts specified in paragraph (a) –

- (c) in the presence of the pharmacist in charge of the pharmacy; or
 - (d) 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;
 - (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;
 - (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 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 the authorised person has made an evident error or overlooked something 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 of -
 - (i) the patient for whose use it is given; or
 - (ii) where it is given by a veterinary surgeon, 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;
 - (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);
 - (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 occasion 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 a full-time basis;
 - (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;
 - (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;
- (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) 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 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.

Amended by [\[Act No. 27 of 2013\]](#)

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;
- (c) subject to the payment of the prescribed fees.

(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) (a) The importer shall, on arrival of the consignment of a pharmaceutical product, make an application for clearance.

- (b) An application under paragraph (a) shall –
 - (i) through the TradeNet or in such other manner as the Board may determine, be made in such application form as the Board may approve;

- (ii) be accompanied by such other document, including the original invoice, as may be required in the guidelines;
- (iii) be subject to the payment of such fees and such other conditions as may be set out in the guidelines.

c) The authorised officer shall, on receipt of the application, process the application and may grant or refuse to grant the clearance not later than 2 working days after the effective date of receipt of the application.

(d) For the purpose of paragraphs (c) and (d), the authorised officer shall notify his decision to grant or refuse to grant the clearance, to the Director-General and to the importer, through the TradeNet or in such other manner as the Board may determine.

(e) (i) Any fee payable under this section may be paid to the Director-General through the TradeNet or in such other manner as the Director-General may determine.

(ii) The Director-General shall, not later than 15 working days after the end of every month, remit the fees collected to the Board.

(6) Subject to subsection (5)(c), the Director-General shall release or clear the pharmaceutical product imported in accordance with section 25B of the Customs Act.

Amended by [\[Act No. 27 of 2013\]](#); [\[Act No. 14 of 2019\]](#)

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;
 - (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) For the purpose of an application for a permit under this section, the procedures set out in section 25A(5) and (6) of the Act shall apply with such modifications, adaptations and exceptions as may be necessary.
 - (5) **Repealed by [\[Act No. 14 of 2019\]](#)**

Amended by [\[Act No. 14 of 2019\]](#)

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;
 - (b) a poison specified in Part 11 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 -
 - (i) under the supervision of a pharmacist; and
 - (ii) 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.

Amended by [\[Act No. 15 of 1998\]](#)

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, infirmary, or dispensary maintained by any public authority;
or
 - (ii) in a private clinic;
- (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 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 book before delivering the poison to him;
 - (c) keep the 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 specified in the Sixth Schedule.
- (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) For the purpose of an application for a permit under this section, the procedures set out in section 25A(5) and (6) shall apply with such modifications, adaptations and exceptions as may be necessary.

(5) **Repealed by** [\[Act No. 14 of 2019\]](#)

Amended by [\[Act No. 27 of 2013\]](#); [\[Act No. 14 of 2019\]](#)

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 -
 - (a) to 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) to 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 Antibiotic Book; and
 - (b) make a record of every sale or supply in the book.

- (2) The book and every requisition produced under subsection 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;
- (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 to be manufactured; and
- (iv) such other information or documents as the Board may require.

(3) (a) The Board shall, on receipt of an application made under subsection (2), forthwith refer the application to the Planning Committee for its recommendations.

(b) The Planning Committee shall examine the application under paragraph (a) and shall submit its recommendations not later than 15 days after the application is referred to it.

- (4) The Board may, not later than 5 days after the Planning Committee submits its recommendations –
- (a) grant the application on payment of the prescribed fee and on such terms and conditions as it may determine; or
 - (b) 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.

Amended by [\[Act No. 1 of 2020\]](#)

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;
 - (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;
 - (iv) such other information or documents as the Board may require.
- (3) The Board may, not later than 15 working days from receipt of an application under subsection (2), grant the application on payment the prescribed fee and on such terms and conditions as it may determine.
- (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 licence 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.

Amended by [\[Act No. 1 of 2020\]](#)

36A. Sale of manufactured pharmaceutical product

- (1) Subject to section 36, no manufacturer shall sell a manufactured pharmaceutical product unless it 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 annually 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.

Added by [\[Act No. 27 of 2013\]](#)

36B. Sale of locally manufactured pharmaceutical products on local market

No person shall sell a locally manufactured pharmaceutical product on the local market unless –

- (a) he is licensed as a manufacturer under section 36; and
- (b) the pharmaceutical product is registered with the Board under section 36C.

36C. Registration of locally manufactured pharmaceutical products

(1) (a) A person who wishes to register a locally 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.

(2) The Board shall, on receipt of an application made under subsection (1), forthwith refer the application to the Trade and Therapeutics Committee for its recommendations.

(3) The Trade and Therapeutics Committee shall examine the application under subsection (1) and shall submit its recommendations not later than 21 days after the application is referred to it.

(4) The Board may, not later than 7 days after the Trade and Therapeutics Committee submits its recommendations grant or reject the application.

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

(7) The holder of a certificate of registration of a locally manufactured 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 locally manufactured pharmaceutical product from registration.

Added by [\[Act No. 1 of 2020\]](#)

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 ten 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;
- (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 manufacture, 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;
- (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 Comptroller's powers

- (1) The Comptroller 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 Register 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 Comptroller shall seize and remit it to the Permanent Secretary to be disposed of in such manner as the Permanent Secretary thinks fit.

44A. Power of Permanent Secretary to issue guidelines

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

Added by [\[Act No. 27 of 2013\]](#)

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;
 - (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.

Amended by [\[Act No. 5 of 1999\]](#); [\[Act No. 27 of 2013\]](#)

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 Comptroller 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;
- (b) amend the Schedule.

48 Repealed

The following enactments are repealed –

- (a) Pharmacy and Poisons Act;
- (b) Antibiotics (Control of Importation, Sale and Distribution) Regulations 1962;
- (c) Pharmacy and Poisons Regulations 1957.

49 Repealed

50 Transitional provision

- (1) Subject to subsections (2), (3) and (4), any pharmacist, assistant pharmacist or student who, at the commencement of this Act, is registered under the Pharmacy and Poisons Act shall be deemed to have been registered under this Act.
- (2) Every student registered under the Pharmacy and Poisons Act shall be allowed to take the Intermediate Examination to be held under the

Pharmacy and Poisons Act within a period not exceeding 15 months after the date of commencement of this Act.

- (3) Every student registered under the Pharmacy and Poisons Act who has passed the Intermediate Examination held under the Pharmacy and Poisons Act shall be allowed to take the Assistant Pharmacist's Examination to be held under the Pharmacy and Poisons Act, within a period not exceeding 6 years after the commencement of this Act.
- (4) Every assistant pharmacist registered on or before 31 December 1990 shall be allowed to take the Pharmacists' Examination to be held under the Pharmacy and Poisons Act within a period not exceeding 7 1/2 years after the commencement of this Act.
- (5) Every pharmacy which at the commencement of this Act is licensed under the Pharmacy and Poisons Act shall be deemed to have been licensed under this Act.
- (6) Subject to subsection (7), any registration, other than that specified in subsections (1) and (2), any licence, permit or authorisation relating to a pharmacy, a wholesale pharmacy or a factory, shall expire within 6 months from the date of commencement of this Act.
- (7) Any person who operates at the commencement of this Act, a wholesale pharmacy, shall comply with section 23 within one year from the date of commencement of this Act.

Amended by [\[Act No. 76 of 1989\]](#)

51 Commencement

Proclaimed by [\[Proclamation No. 24 of 1984\]](#) w. e. f. 1st January 1985

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 quaternary 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
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
Allyl isopropylacetylurea
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 sulpho-namide 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
Buclizine
Carbinoxamine
Chlorcyclizine
Chlorpheniramine
Cinnarizine

Clemizole
Cyclizine
Cyproheptadine
3-Di-n-butylami nomethyl-4, 5, 6-trihydroxyphthalide
Diphenhydramine
Diphenylpyraline
Doxylamine
Isothipendyl
Mebhydrolin
Meclozine
Phenindamine
Pheniramine
Phenyltoloxamine
Promethazine
Pyrrobutamine
Tetra-N-substituted derivatives of ethylenedi amine 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; derivatives 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
Benzoylmorphine, 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 fruiting tops of Cannabis Sativa Linn); the resin of cannabis; extractsof cannabis; tinctures of cannabis; cannabin tannate
Cantharidin; cantharidates
Captodiame; its salts
Caramiphen; its salts
Carbachol
Carbromal
Cansoprodol
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
Cblorthal idone and other derivatives of co-chlorobenzene sulphonamide
Clioquinol
Cionitazene; its salts
Clorexolone
Clorprenaline; its salts
Corticitrophine, natural and synthetic
Creosote obtained from wood
Croton, oil of
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
Dextrophan; 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 & other active principles of digitalis
Dihydrocodeine; its salts; its esters and ethers; their salts
Dihydrocodeinone O-carboxymethyl oxime; 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; dithienylallylamines; their salts
Dothiepin; its salts
Dyflos
Ecothiopate iodine
Ectylurea
Elaterin
Embutramide

Emylcamate
Erythrityl tetranitrate
Ethacrynic acid; its salts
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, benzyi, 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
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
Levometh9rphan; 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 quaternary compounds
Mannitol hexanitrate
Mannomustine; its salts
Mebezonium iodine
Mebutamate
Meclofenoxate; its salts
Mefenamic acid; its salts; its esters; their salts
Mepacrine
Mephensin; its esters
Mepropramate
Mercaptopurine; its salts; derivatives of mercaptopurine; their salts
Mercury, oxide of; nitrates of mercury; mercuric 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
Methoxsalen
Methoxyphenamine; its salts
Methylaminoheptane; 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;
Methypentynol; its esters and other derivatives
&-Methylphenethylamine, N-methylphenethylamine and N-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, phenylpropanamine 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; 0-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
Orthocaine; its salts
Ouabain
Oxalic acid
Oxethazaine
Oxycodone; its salts; its esters and ethers, their salts
Oxymorphone, its salts, its esters and ethers; their salts
Oxypehnbutazone.
Oxytocins, natural and synthetic
p-chloro-a, a-dimethy phemethyl-carbonate
Paraldehyde
Paramethadione
Pargyline; its salts
Pemoline; its salts
Pentazocine; its salts
Phenacemide
Phenadoxone; its salts
Phenaglycodol
Phenampramide; its salts
Phenazocine; its salts; its esters and ethers; their salts
Phenbutrazate
Phenbucyclidine; its salts
Phenetidylphenacetin
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 two atoms of hydrogen) except in substances containing less than sixty 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
Phenomorphin; 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

Phosphorus, yellow
Picric acid
Picrotoxin
Pimino-dine; its salts
Pipradol
Piritramide; its salts
Pituitary gland, the active principles of
Podophyllum resin
Polymethylenebis(trimethylammonium) salts
Primaquine
Procainamide; its salts
Procarbazine; its salts
Procyclidine; its salts
Proguanil
Proheptazine; its salts
Promoxolan
Propoxyphene; its salts
Propylhexedrine; its salts
Prothionamide
Prothipendyl; its salts
Pyrimethamine
Quinethazone
Quinine; its salts
Quinine; amodiaquine
Racemorphan; its salts
Racemoramide; its salts
Racemorphan; its salts; its esters and ethers; their salts
Salbutamol; its salts
Savin, oil of
Santonquin
Strophanthus; glycosides of strophanthus
Styramate
Sulphinpyrazone
Sulphonamide; alkyl sulphonamides
Suprarenal gland medulla, the active principles of; their salts
Syrosingopine
Tetrabenazine; its salts
Thalidomide; its salts
Thallium, salts of
Thebaine; its salts
Thiocarbonyl; its salts
Thyroid gland, the active principles of; their salts
Tolbutamide
Totramine; its salts
Triaziquone
Tribromethyl alcohol
2,2,2-Trichloroethyl alcohol, esters of; their salts
Trimeperidine; its salts
Trimipramine; its salts
Trolox
Tybamate

Vasopressina, natural and synthetic
Verapamil; its salts
Zoxazolamine; its salts

PART II

Repealed by [\[Act No. 16 of 2004\]](#)

SECOND SCHEDULE

Repealed by [\[Act No. 16 of 2004\]](#)

THIRD SCHEDULE

Repealed by [\[Act No. 16 of 2004\]](#)

FOURTH SCHEDULE

Repealed by [\[Act No. 16 of 2004\]](#)

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;
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 lobelia;

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, alkaloid~ of

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

Solanaceous 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;

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

Yohimbin, alkaloids of

Allylisopropylacetylurea

Allyloprodine; 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 the 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
 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 two grammes of the substances;
 Dihydrocodeine; its salts, its esters and ethers; their salts
 Dihydrocodeinone 0-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
 Dinitrocresols (DNOC); their compounds with a metal or base; except winter washes containing
 not more than the equivalent of 5.0 per cent of dinitrocresols
 Dinitronaphthols; dinitrophenols; di nitrothymols
 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; dithienylalkylallylamines; their salts
Dyflos
Ecothiopate iodine
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
Hydroxyethidine; 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
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
Metopon; its salts; its esters and ethers, 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
Phenampramide; its salts
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-Phenylkinochinonic 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
Triphosphoric pentadimethylamide
Vamidothion
Picrotoxin
Piminodine; its salts
Piritramide; its salts
Polymethylenebistrimethylammonium 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
Amphotericin; 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
Cephamycins
Chloramphenicol; its esters
Chlortetracycline
Clindamycin; its salts; its esters
Colistin; its salts; its esters
Corticotrophin (Adrenocorticotrophichormone, ACTH)
Cortisone; its esters
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-allyl-L-2-pyrrolidone-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 neuro-muscular 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, -acetoxyl-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-trioxygenated 2, 4-dimethyl-1-methylnaphtho (2, 1-b) furan; their salts and esters
 Salts of their esters
 Ristocetin; 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-carboxamide, 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

Amended by [\[GN No. 42 of 1989\]](#)