CHAPTER 198

THE NATIONAL DRUG POLICY AND AUTHORITY ACT

Arrangement of Sections

Section

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THE NATIONAL DRUG POLICY AND AUTHORITY ACT

Commencement: 3 December, 1993

An Act to provide for the establishment of the National Drug Policy and the National Drug Authority to ensure the availability, at all times, of essential, efficacious and cost-effective drugs to the entire population of Uganda, as a means of providing satisfactory health care and safeguarding the appropriate use of drugs.

PART I—INTERPRETATION

Interpretation

In this Act, unless the context otherwise requires—

"advertisement" includes any notice, circular, label, wrapper or other document, and any announcement made orally or by means of producing or transmitting light or sound;

"approved institution" includes gazetted hospitals, health centres, dispensaries, aid posts, registered medical clinics and nursing homes;

"authorised person" means a person authorised under this Act;

"authorised pharmacopoeia" means the current edition for the time being of any of the following, namely, the International Pharmacopoeia, the British Pharmacopoeia, the British Pharmaceutical Codex, the European Pharmacopoeia, the United States Pharmacopoeia and the British Veterinary Codex;

"Class A drug", "Class B drug" and "Class C drug" shall be construed in accordance with section 12;

"classified drug" means a Class A, B or C drug;

"Commission" means the National Drug Authority Commission;

"currency point" has the value assigned to it in Schedule 1 to this Act;

"descriptive matter" means any statement, whether written or oral, which purports to describe the composition or effect of any drug; and references to the publication of descriptive matter shall be references to its publication by way of advertisement, or on or

with the container in which the drug is supplied or in any other manner;

"disease" includes injury and bodily or mental deficiency or abnormality;

"dispense", in relation to a medicine or poison, means to supply a medicine or poison on and in accordance with a prescription duly given by a duly qualified medical practitioner, dentist or veterinary surgeon;

"drug" means any substance or preparation used or intended to be used for internal or external application to the human or animal body either in the treatment or prevention of disease or for improving physiological functions, or for agricultural or industrial purposes;

"Drug Authority" means the National Drug Authority established by section 3;

"duly qualified", used in relation to a medical practitioner, dentist or veterinary surgeon, means a person recognised by law to practise medicine, surgery, dentistry and midwifery or, as the case may be, veterinary surgery;

"generic name" means the International Non-proprietary Name (INN) established by a body of the World Health Organisation;

"Indian hemp" includes the dried flowering or fruiting tops of the pistillate plant known as cannabis sativa or cannabis indica from which the resin has not been extracted, by whatever name the tops are called, and resins obtained from those tops, all preparations of which those resins form the base and all extracts or tinctures obtained from those tops;

"inspecting officer" means a person empowered under Part VI of this Act to enter any premises;

"international control" means the international conventions on the control of narcotic drugs and psychotropic substances;

"International Non-proprietary Name (INN)" means the official name of a drug, regardless of the manufacturer;

"licensed person" means a person licensed under section 14;

"licensed seller" means a person licensed under section 15;

"manufacture" includes any treatment of a plant, mineral or other substance for the purpose of extracting a drug;

"Minister" means the Minister responsible for health;

"narcotic drug" means a Class A drug or preparation;

"pharmacist" means a pharmacist under the Pharmacy and Drugs Act;

smoked, and also includes any opium, for whatever purpose prepared, which is capable of being smoked;

"proprietary drug" means a drug distributed for sale by retail under a brand name or other proprietary description and in a form ready for use;

"register" means the register of specialties maintained under the Drug Authority;

"restricted drug" means a classified drug or any other drug which is not an exempted drug;

"substance" includes a preparation;

"supply", with its grammatical variations and cognate expressions, includes, in relation to a drug, the administration of any such drug.

PART II—NATIONAL DRUG POLICY AND NATIONAL DRUG AUTHORITY

National Drug Policy

(1) The National Drug Policy shall be—

(a) to ensure that essential, safe, efficacious and cost-effective drugs are made available to the entire population of Uganda to provide satisfactory health care;

(b) to make a continuous review of the needs, knowledge and resources of essential drugs;

(c) to promote the rational use of drugs both in the public and private sector;

(d) to improve Government regulation and control on manufacture, production, importation, exportation, marketing and use of drugs;

(e) to provide systematic public information and professional training and retraining of health workers;

(f) to improve the registration of drugs and licensing of pharmaceutical premises;

(g) to intensify research in all types of drugs, including traditional medicines;

(h) to comply with the international regulations on drugs, including the conventions on narcotic drugs and psychotropic substances under international control; and

(i) to fight against drug and substance abuse.

(2) The National Drug Policy shall relate to the regulation of the importation, production, distribution, marketing, exportation and use of pharmaceuticals in the public as well as in the private sector and to any matter related to the above.

3. Establishment of National Drug Authority

(1) There is established an authority known as the National Drug Authority which shall be a body corporate with perpetual succession and a common seal and may sue or be sued in its corporate name.

(2) The Drug Authority shall consist of the Chairperson and the following persons—

(a) the Director of Medical Services;
(b) the Commissioner for Veterinary Services;
(c) the Commissioner for Trade;
(d) the director of the criminal investigation department;
(e) the chief of medical services, Ministry of Defence;
(f) the chief of pharmaceuticals and health supplies;
(g) the head of the Natural Chemotherapeutics Laboratory;
(h) the director of Mulago National Referral Hospital;
(i) a representative of each of the following—
    (i) the National Medical Stores;
    (ii) the Uganda Medical Association;
    (iii) the Pharmaceutical Society of Uganda;
    (iv) the Uganda Veterinary Association;
    (v) the head of the School of Pharmacy, Makerere University;
    (vi) the Uganda herbalists;
    (vii) the Uganda Dental Association; and
    (viii) the Joint Medical Stores;
(j) the Director General of the Uganda AIDS Commission; and
(k) two persons appointed from the public.

(3) The Chairperson and the members appointed under subsection (2)(k) shall be appointed by the Minister.

4. Application of seal

(1) The common seal of the Drug Authority shall be as the Drug Authority may determine and shall be kept by the Secretary.

(2) The common seal shall, when affixed into any document, be authenticated by any two signatures of the Chairperson, the Secretary and any other member of the Commission as may be authorised by the Drug Authority.

(3) A contract or instrument which if entered into or executed by a person not being a body corporate would not be required to be under seal may be entered into or executed without seal on behalf of the Drug Authority by the Secretary or any other person authorised by the Drug Authority.

(4) Every document purporting to be—

(a) an instrument issued by the Drug Authority and sealed with the common seal of the Drug Authority and authenticated in the manner prescribed in subsection (2); or

(b) a contract or instrument entered into or executed by the Drug Authority,

shall be received in evidence without further proof as that instrument duly issued or a contract duly entered into or executed unless the contrary is proved.

Functions of Drug Authority

The Drug Authority shall be charged with the implementation of the National Drug Policy and, in particular, but without derogation of the foregoing, all—

(a) deal with the development and regulation of the pharmacies and drugs in the country;

(b) approve the national list of essential drugs and supervise the revisions of the list in a manner provided by the Minister;

(c) estimate drug needs to ensure that the needs are met as economically as possible;

(d) control the importation, exportation and sale of pharmaceuticals;

(e) control the quality of drugs;

(f) promote and control local production of essential drugs;

(g) encourage research and development of herbal medicines;

(h) promote rational use of drugs through appropriate professional training;
(i) establish and revise professional guidelines and disseminate information to health professionals and the public;
(j) provide advice and guidance to the Minister and bodies concerned with drugs on the implementation of the National Drug Policy; and
(k) perform any other function that is connected with the above or that may be accorded to it by law.

6. Commission and other bodies of Drug Authority

(1) There shall be a National Drug Authority Commission which shall consist of the Chairperson and four other members appointed by the Drug Authority from among themselves.

(2) The Chairperson of the Drug Authority shall be the Chairperson of the Commission.

(3) The functions of the Commission shall be—
(a) to exercise the functions of the Drug Authority which may require exercising when the Drug Authority is not sitting;
(b) to monitor and supervise the implementation of the decisions of the Drug Authority;
(c) to establish and revise the working procedure of the Drug Authority; and
(d) to perform any other function relating to the functions of the Drug Authority as the Authority may direct.

(4) There shall be the following committees of the Drug Authority—
(a) the committee on essential drugs; and
(b) the committee on the national formulary.

(5) The membership of the committee on essential drugs shall be as follows—
(a) a Chairperson appointed by the Drug Authority;
(b) the Commissioner of Curative Services of the Ministry of Health;
(c) the Chief of Pharmaceuticals and Health Supplies;
(d) the Chief of Medical Services, Ministry of Defence;

(f) a representative of each of the following specialities—
  (i) physician;
  (ii) paediatrician;
  (iii) gynaecologist/obstetrician;
  (iv) surgeon;
  (v) psychiatrist;
(g) a member from the Private Medical Practitioners Association; and
(h) a non-government organisation pharmacist from the Joint Medical Stores.

(6) The committee on essential drugs shall have power to co-opt members deemed necessary.

(7) The membership of the committee on the national formulary shall be as follows—
(a) a chairperson appointed by the Drug Authority on the recommendation of the appropriate professional bodies;
(b) a member of the faculty of medicine of the universities in Uganda;
(c) a member of the faculty of veterinary sciences;
(d) a member from the school of pharmacy;
(e) a member from the Pharmaceutical Society of Uganda;
(f) a member from the Private Medical Practitioners Association;
(g) a member from the Uganda Medical Association;
(h) the Executive Director of the Uganda National Bureau of Standards; and
(i) a representative of each of the following specialities—
  (i) physician;
  (ii) surgeon;
  (iii) paediatrician;
  (iv) gynaecologist/obstetrician;
  (v) psychiatrist.

Meetings of Drug Authority

(1) The Drug Authority shall meet for the discharge of its functions ɛast six times a year.

(2) The National Drug Authority Commission shall establish the king procedure for the Drug Authority.

PART III—CONTROL OF DRUG SUPPLY

8. National list of essential drugs

(1) There shall be a national list of essential drugs which shall be revised from time to time.

(2) There shall be a national formulary made of the national list of essential drugs and such other drugs as the Authority may approve.

(3) A person shall not import or sell any drug unless it appears on the national formulary.

(4) Notwithstanding subsection (3), a drug not appearing on the national formulary may be imported and sold after authorisation by the Drug Authority to meet emergency or extraordinary circumstances.

9. Selection of drug items

The Drug Authority shall receive from the committee on essential drugs the proposals of the revised list which shall be made in accordance with the available resources and existing diagnostic and therapeutic capacity.

10. Estimation of drug needs

(1) The Commission shall ensure regular assessment and estimation of the national drug needs both in the public and private sectors.

(2) Estimates of the national drug needs shall be expressed both in unit (quantity) and financial cost.

(3) For the purposes of providing accurate estimates of drug needs, the Commission shall promote and encourage investigations, including studies of current morbidity patterns, drug utilisation and available diagnostic and therapeutic resources.

11. Drug nomenclature

such name has been allocated and no satisfactory non-proprietary alternative exists.

12. Restricted drugs

(1) For the purpose of this Act and subject to this section—
(a) the drugs specified in Schedules 2, 3 and 4 to this Act shall be classified drugs;
(b) the drugs and articles specified in Schedule 5 to this Act shall be exempted drugs and articles; and
(c) any classified drug or any other drug which is not exempted shall be deemed to be a restricted drug.

(2) Subject to subsection (3), where a preparation contains any quantity of a drug which is included in Schedule 2, 3 or 4 to this Act, the preparation shall be deemed to be a classified or restricted drug of the same Class as the drug which it contains.

(3) Where an entry in Schedule 2, 3 or 4 to this Act defines the proportions of a drug which bring a preparation containing it within the list of restricted drugs, subsection (2) shall not apply to that preparation.

(4) Where, apart from this subsection, a preparation would fall to be treated as a Class A drug and also as a Class B or Class C drug or both, it shall be treated as a Class A drug only.

(5) Where, apart from this subsection, a preparation would fall to be treated as a drug of both Class B and Class C, it shall be treated as a Class C drug only.

13. Supply and dispensing of restricted drugs

(1) Subject to this section, no person shall mix, compound, prepare, supply or dispense any restricted drug unless that person is a registered pharmacist, medical practitioner, dentist or veterinary surgeon or a licensed person.

(2) Subsection (1) shall not prevent—
(a) the supply of any drug, other than a drug of Class A or B, by a licensed seller;

(b) the mixing, compounding or preparing of a drug under the immediate supervision of a registered pharmacist;

(c) the supply or dispensing of a restricted drug by a member of the staff of a hospital, dispensary or similar institution which has been authorised to do so by a general or special order of the Drug Authority; and

(d) the supply of restricted drugs subject to regulations made by the Minister after consultation with the Drug Authority, by a representative of a person engaged in the sale and supply of pharmaceutical goods for the purposes of giving free samples of the drugs to persons who may lawfully possess restricted drugs.

(3) A person registered or enrolled under the Nurses and Midwives Act or any other authorised person may supply or dispense restricted drugs in accordance with regulations made by the Minister in that behalf.

(4) The supply or dispensing of restricted drugs under subsections (2) and (3) shall be subject to the following—

(a) the restricted drug shall be distinctly labelled with the name and address of the person by whom it is supplied or dispensed;

(b) the following particulars shall, within twenty-four hours after the restricted drug has been supplied or dispensed, be entered in a book used regularly for the purpose, which shall be known as the Prescription Book

(i) the date on which the restricted drug was supplied or dispensed;

(ii) the ingredients and quantity supplied;

(iii) the name and address of the person to whom the restricted drug was supplied;

(iv) the name and address of the person by whom the prescription was given,

except that paragraph (a) shall not apply in any case where any restricted drug is administered by a medical practitioner, dentist, veterinary surgeon or midwife, or under his or her direct supervision and in his or her presence.

(5) Any record kept under this section shall be open to inspection by an inspector of drugs.

14. Licensed persons

(1) If, on application made in the prescribed form by any person, the Drug Authority is satisfied—

(a) that the applicant is fit to carry on a business of mixing, compounding and preparing and supplying restricted drugs by retail;

(b) that the business, so far as concerns the restricted drugs, will be carried on under the immediate supervision of a pharmacist in each set of premises where the business is to be carried on;

(c) in the case of a body corporate, that at least one of the directors is a pharmacist resident in Uganda; and

(d) in the case of a partnership, that at least one of the partners is a pharmacist resident in Uganda,

the Drug Authority may, on payment of a prescribed fee, issue a licence to the applicant to carry on the business required at the premises and on conditions specified in the licence.

(2) A licence issued under this section shall be valid for a period specified in the licence, but the Drug Authority may revoke the licence if, at any time, it is satisfied that the licensed person has contravened any provision of this Act or any condition specified in the licence, or has ceased to be fit to carry on the business.

(3) Any person who carries on the business of a pharmacist without a licence issued under this section commits an offence and is liable, on conviction, to a fine not exceeding fifty currency points or to imprisonment for a term not exceeding five years, or both.

15. Licensed sellers

(1) If, on application made in the prescribed form by a person other than a pharmacist or a licensed person, the Drug Authority is satisfied—

(a) that the applicant is fit to carry on a business of supplying by retail restricted drugs, other than drugs of Class A or B;

(b) that the area in which the applicant proposes to carry on that business is not sufficiently served by existing facilities for the retail supply of the drugs; and

(c) that the applicant is an authorised person,

the Drug Authority may issue to the applicant a licence authorising him or her, subject to any conditions specified in the licence, to carry on the business required from the premises specified in the licence.

(2) A licence issued under this section shall be valid for a period specified in the licence, but the Drug Authority may revoke the licence if, at any time, it is satisfied that the holder of the licence has contravened any provision of this Act or any condition specified in the licence, or has ceased to be fit to carry on the business.

16. Places from which restricted drugs may be supplied

(1) No person shall carry on the business of supplying restricted drugs from any premises—

(a) if restricted drugs including drugs of Class A or B are supplied, unless either a general or a limited certificate is issued under this Act for the purpose;

(b) if restricted drugs not including drugs of Class A or B are supplied, unless either a general or a limited certificate issued under this Act is in force.

(2) No person shall supply any drug by means of an automatic machine.

17. Certificate of suitability of premises

(1) If on application made in the prescribed form for a certificate in relation to any premises, the Drug Authority is satisfied that the accommodation, fixtures, equipment and other physical attributes of those premises render those premises suitable for the supply of restricted drugs or for the supply of restricted drugs excluding drugs of Classes A and B, it may issue in respect of those premises either a general or limited certificate.

(2) Every person carrying on the business of supplying restricted drugs from the premises in respect of which a certificate issued under this section is in force shall notify the Drug Authority of any alteration in the physical attributes of the premises, or if no alteration occurs in any calendar year, shall notify the Drug Authority of that fact before the end of January in

(3) A certificate issued under this section shall remain in force until a date specified in the certificate, but the Drug Authority may revoke the certificate if, at any time, it is satisfied, on the recommendation of the inspector of drugs, that, owing to an alteration or deterioration in the physical attributes of the premises, the premises have ceased to be suitable for the supply of the restricted drugs, or of restricted drugs other than drugs of Classes A and B, as the case may be.

(4) The Drug Authority shall keep a register in the prescribed form of the premises in respect of which a certificate is issued under this section.

18. Loss of Class A or B drugs

(1) Any person entitled under this Act to supply or dispense a Class A or B drug shall, upon the loss of that drug in his or her possession or control or of any records kept under this Act in relation to that drug, report that loss to the inspector of drugs, within seven days of the loss, giving particulars of the ingredients and quantities of the drug or the particulars of the records lost.

(2) Any person who contravenes any provision of this section ommits an offence and is liable, on conviction, to a fine not exceeding fifty ırrency points or to imprisonment for a term not exceeding five years, or ɔth.

PART IV—SPECIAL PROVISIONS RELATING TO CLASSIFIED DRUGS

Classified drugs

ɜ Minister may, by statutory instrument, on the advice of the Drug hority, declare a drug to be a classified drug.

Need for prescription for classified drugs

(1) A pharmacist or licensed person shall not supply a Class A or ɜ B Group I drug unless it is under prescription reasonably believed by erson supplying the drug to be valid.

(2) A prescription shall be valid only if—

(a) it is in indelible writing, dated and signed with the usual signature of a registered medical practitioner, dentist or veterinary surgeon;

(b) it states the name, qualification and address of the person signing it;

(c) it states the name and address of the person for whose treatment it is given or, if signed by a veterinary surgeon, of the person in charge of the animal to which the drug is to be administered;

(d) it is signed by a dentist, and bears the words "for dental treatment only" or, if signed by a veterinary surgeon, and bears the words "for animal treatment only";

(e) it indicates the total amount of the drug to be supplied and the dose to be taken or the manner of its application or use; and

(f) it has not previously been fully dispensed.

(3) A prescription shall be fully dispensed if the drug prescribed has been supplied once, unless it clearly states—

(a) the number of times it may be dispensed; and

(b) the intervals at which it may be dispensed, and shall in that case, be fully dispensed if the drug prescribed has been supplied the stated number of times.

(4) This section shall not apply—

(a) if the drug is supplied, whether personally or on a signed order, to a medical practitioner, dentist, veterinary surgeon, pharmacist or licensed pharmacy for the purpose of being subsequently dispensed or supplied or used for purposes of scientific education or research; or

(b) if the drug is supplied from the dispensing department of an approved institution in accordance with regulations made by the Minister in that behalf.

21. Action to be taken in relation to prescription

Where a classified drug is supplied under a prescription—

(a) the person supplying the drug shall enter on the prescription in indelible writing the date on which it is supplied and the name and address of the supplier;

(b) if the prescription is fully dispensed, it shall be retained by the supplier and, for two years thereafter, shall be kept on the premises at which it was dispensed in such a manner as to be

22. Classified drugs to be supplied to responsible persons

A pharmacist or licensed pharmacy shall not supply a Class A or B drug to a person who is not reasonably believed by the supplier to be a person to whom the drug may properly be supplied.

23. Supply to conform to prescription

No person shall supply any classified drug which does not conform to the prescription or order under which it is supplied.

24. Classified Drugs Book

(1) Every person who supplies Class A, B or C Group II drugs shall keep in all premises from which the drugs are supplied by him or her a book of the prescribed description to be known as the Classified Drugs Book.

(2) Subject to subsection (3), before any person supplies Class A, B or C Group II drugs, he or she shall enter or cause to be entered in the Classified Drugs Book the following particulars—

(a) the name and quantity of the drug to be supplied;
(b) the name and address of the person who requires the drug;
(c) the purpose for which the drug is stated to be required;
(d) the signature of the person to whom the drug is delivered; and
(e) the date of the delivery.

(3) Where any classified drug is sold in the presence of an agent or rvant of the person by whom it is to be used or where sale is effected by st, the following provisions shall apply

(a) before the sale is completed, the seller shall obtain an order in writing, signed by the purchaser showing—
    (i) the purchaser's name, address and occupation;
    (ii) the name and the quantity of drug to be purchased; and
    (iii) the purpose for which it is required,
    but where a person represents that he or she urgently requires a classified drug for the purpose of his or her trade, business or profession, and satisfies the seller that, by reason of some emergency, he or she is unable before delivery to furnish the order in writing, the seller may deliver the drug to the purchaser

who shall, within twenty-four hours of the sale, furnish the seller with a written order;

(b) before the sale is completed, the seller shall satisfy himself or herself that the signature on the order is that of the person by whom it is supposed to be signed and that that person carries on the occupation stated in that order, being an occupation for which the drug is properly required;

(c) the requirements of subsection (2) as to the making of entries in the Classified Drugs Book shall be complied with except that in place of the signature of the person to whom the drug is delivered, it shall be sufficient to record "signed order" giving a reference by which the particular signed order may be readily identified;

(d) all signed orders and prescribed records of transactions to which this subsection applies shall be retained on the premises where the sales were made for two years.

(4) Any person who contravenes any of the provisions of this section commits an offence and is liable, on conviction, to a fine not exceeding one hundred currency points or to imprisonment for a term not exceeding five years, or both.

25. Containers and labels

No person shall supply any classified or restricted drug unless—

(a) the drug is in a container of the prescribed description; and

(b) the container bears a label giving the prescribed particulars of its contents.

26. Further restrictions on the supply of narcotics

(1) The Minister may, by statutory instrument, make regulations further restricting the persons who may supply narcotic drugs, and otherwise controlling the supply of those drugs.

(2) No person shall supply any narcotic drugs under international control other than for medical, dental or veterinary purposes.

27. Possession of classified drugs

(1) The following persons may be in possession of classified drugs, but to the extent only and subject to the limitations prescribed below—

(a) any person specified in section 14 for the purposes of that section;

(b) a licensed person or seller of classified drugs, on premises registered under this Act;

(c) a wholesale dealer licensed under this Act for the purposes of the licence and on the premises so licensed;

(d) any person, institution or department to whom a classified drug has been lawfully sold in accordance with this Act, for the purpose for which the sale was made;

(e) any person for whom the classified drug has been lawfully supplied or dispensed by a duly qualified medical practitioner, dentist or veterinary surgeon or by an approved institution.

(2) Any person who is in possession of a classified drug otherwise than in accordance with this section commits an offence and is liable, on conviction, to a fine not exceeding one hundred currency points or to imprisonment for a term not exceeding five years, or both.

28. Withdrawal of authority

(1) Where any person authorised to obtain or supply narcotics under this Act is convicted of any offence under this Act, if the Minister is of the opinion that that person ought not to be allowed to obtain, possess or supply drugs, he or she may, acting in accordance with the recommendation of the Drug Authority, by notice in the *Gazette*, withdraw the authority of that person.

(2) Where the person whose authority is withdrawn under subsection (1) is a registered or licensed medical practitioner or dentist or a duly qualified veterinary surgeon, the Minister may, by notice in the *Gazette*, direct that it shall not be lawful for that person to give prescriptions or orders for the purposes of this Act.

29. Drug addicts

(1) Every medical practitioner or dentist shall keep a record in the prescribed form of all persons who are addicted to any drug specified in

Schedule 2 or 3 to this Act and shall at least every year make a report to the Minister specifying the names of those persons and the drugs to which they are addicted.

(2) Notwithstanding any other provision of this Act, no person may prescribe or supply any drug specified in Schedule 2 or 3 to this Act for the use of a person whom he or she knows or has reason to believe is addicted to any such drug, unless he or she is authorised in writing to do so by the Minister and in a manner and subject to conditions that may be prescribed.

Drugs generally

30. Impure drugs not to be supplied

Any person who—

(a) sells any drug, medical appliance or similar article which is not of the nature, substance and quality demanded or which, unless otherwise agreed at the time of demand, does not conform to the standards laid down in the authorised pharmacopoeia; or

(b) supplies any drug which is unwholesome or adulterated or which does not conform to the prescription under which it is supplied,

commits an offence and is liable, on conviction, to a fine not exceeding two hundred fifty currency points or to imprisonment for a term not exceeding ten years, or both.

31. Power to call for information as to proprietary drugs

(1) Where the Drug Authority has reason to believe that any person is proposing to sell any proprietary drug by retail or to procure, whether directly or indirectly, its sale by retail, the Drug Authority may require that person to furnish to it—

(a) details of the composition of the drug;

(b) copies of any descriptive matter published or proposed to be published in relation to the drug; and

(c) any other information that the Drug Authority may require.

(2) No disclosure of information furnished under this section shall be made without the consent of the person by whom it was furnished.

32. Power to prohibit retail sale of proprietary drugs

The Drug Authority may prohibit the sale by retail of a proprietary drug if, in the opinion of the Drug Authority—

(a) claims are made for the drug, whether or not in a statement furnished under section 31, which are unjustified;

(b) the use of the drug may endanger the health of the user or there may be other undesirable effects in the use of the drug;

(c) details of the composition of the drug furnished under section 31 differ substantially from those disclosed on an analysis of samples of the drug obtained from retail suppliers; or

(d) descriptive matter published in relation to the drug differs substantially from that, whether or not in the same language, contained in copies furnished to the Drug Authority in relation to the drug under section 31.

33. Control of publication of descriptive matter

(1) Subject to this section, no person shall, by way of advertisement, publish, in whatever manner, in relation to any drug, descriptive matter calculated to lead to the use of that drug—

(a) for prevention or treatment of any disease specified in Schedule 6 to this Act;

(b) for the purpose of termination or influencing the course of human pregnancy; or

(c) for any purpose relating to enhancing human potency.

(2) Subject to this section, the Drug Authority may, with the approval f the Minister, serve on any person a notice prohibiting him or her from ıblishing in relation to any drug descriptive matter referred to in the notice.

(3) This section shall not apply to the publication of descriptive atter(a) by direction of the Minister;

(b) in a document intended for persons whose profession or employment calls for a knowledge either of drugs generally or of drugs of the description to which the matter in question relates; or

(c) for the purposes of an application for the grant of a patent.

34. Return of details of pharmacy business

(1) Every person carrying on a pharmacy business on any premises shall, within twenty-one days after the commencement by him or her of that business on those premises and annually in the month of January thereafter, send to the Drug Authority returns in the prescribed manner, stating—

(a) the location and postal address of the premises;
(b) the name and principal postal address of the person carrying on the business; and
(c) the name of the pharmacist supervising the sale of drugs at those premises.

(2) If any alteration occurs in the particulars stated in the last return made, the person carrying on the business shall, within twenty-one days of the alteration, send notice in writing to the Drug Authority.

35. Drug regulation and registration of specialities

(1) The Drug Authority—
(a) may scientifically examine any drug for the purposes of ascertaining efficacy, safety and quality of that drug;
(b) shall institute a system for the approval of drugs or drug combinations not included in the national list of essential drugs.

(2) The Drug Authority shall keep a register of specialities in the prescribed form.

(3) If, on application made in the prescribed manner and on payment of the prescribed fee, the Drug Authority is satisfied—

(a) that the drug or preparation in respect of which the application is made has not previously been registered; and
(b) that the use of the drug or preparation is likely to prove beneficial,

the Drug Authority shall register the name and description of that drug or preparation.

(4) Where, on application so made, the Drug Authority is not satisfied as aforesaid, it shall notify the applicant that the application is dismissed on the grounds which shall be specified

(5) The Drug Authority may direct at any time for the deletion of any drug or preparation from the register.

(6) The register shall, at all reasonable times, be open for public inspection on payment of such fee as may be prescribed.

36. Drug quality

(1) The Drug Authority shall advise the Minister on measures to be taken to ensure the quality of drugs imported into or held in stock in the country.

(2) The execution of the measures prescribed shall be entrusted to bodies charged with the importation and distribution of drugs.

(3) The inspection of drugs and measures prescribed may be delegated to the chief of pharmaceuticals and health supplies or any other person properly qualified in pharmaceuticals and health supplies.

Wholesale trade

37. Licence required for wholesale supply of restricted drugs

(1) No person shall carry on a business of supplying restricted drugs by wholesale unless he or she is authorised to carry on that business by a licence granted under this section.

(2) The Drug Authority may, on application made in the prescribed form and upon payment of the prescribed fee, grant a licence for the carrying out of a business of supplying restricted drugs by wholesale, if the Drug Authority is satisfied—

(a) that the applicant is a person to whom the licence can properly be granted;

(b) that the business will be carried on in separate premises apart from any other business;

(c) that the business will be carried on in premises under the immediate supervision of a pharmacist;

(d) in the case of a company, that at least one of the directors is a pharmacist resident in Uganda; and

(e) in the case of a partnership, that at least one of the partners is a pharmacist resident in Uganda.

(3) A licence granted under this section may include a condition prohibiting or limiting the supply of restricted drugs of a description specified in the condition, and shall be deemed to include a condition prohibiting the supply of any prepared opium or Indian hemp which is prepared for smoking.

(4) A licence granted under this section shall be valid for a period specified in the licence; but the Drug Authority may revoke the licence if, at any time, it is satisfied that the holder of the licence has contravened any provision of this Act or any condition contained in the licence or has ceased to be fit to carry on the business.

Control of manufacture and storage of drugs

38. Restrictions on manufacture of classified drugs

(1) No person shall manufacture any drug or preparation which is not included on the national formulary unless the drug or preparation is approved by the Drug Authority.

(2) No person shall, unless approved by the Drug Authority in that behalf, manufacture a speciality.

(3) No person shall manufacture any classified drug unless the processes of manufacture are carried out or supervised by a pharmacist.

(4) Subsection (3) shall not apply to the manufacture of preparations mentioned in Schedule 7 to this Act if the processes of manufacture are carried out or supervised by a medical practitioner.

39. Further restrictions on manufacture of drugs

(1) The Minister may, by statutory instrument, make regulations further limiting the persons who may manufacture any drug or preparation and the premises in which they may be manufactured, and otherwise controlling their m

(2) No person shall manufacture any narcotic drug or psychotropic substances under international control for purposes other than for medical, dental or veterinary use.

40. Clinical trials

(1) The Drug Authority may issue a certificate to any person for the purpose of carrying out clinical trials in respect of a drug that may be specified in the certificate.

(2) No person may carry out any clinical trial in respect of any drug unless that person is in possession of a certificate issued under subsection (1).

41. Local research and production

(1) The Drug Authority shall encourage research by persons carrying on research and development in herbal and other medicines and where appropriate take such medicines into production as a component of the drug supply.

(2) Where the Drug Authority considers it economically advantageous nd it is in the interest of the development of a national drug industry, it shall ncourage and develop national production of essential drugs.

2. Storage

(1) Where restricted or classified drugs are kept on any premises, ey shall be kept in accordance with Schedule 8 to this Act, but that Schedule all not apply to drugs supplied to an individual for the treatment of himself herself or another individual residing with him or her or an animal in his her possession or control.

(2) If an act is done on any premises in contravention of the above section then—

(a) in a case where the act constitutes a breach of a duty imposed by or under the terms of his or her employment upon a person employed on the premises, that person shall be deemed to have committed an offence;

(b) in any other case, the occupier of the premises shall be deemed to have committed an offence.

(3) Nothing contained in subsection (2) shall prevent any person who wilfully removes or alters the label on any container, or does any other act, as opposed to an omission, in respect of a restricted drug, from being treated as having committed an offence under subsection (1).

PART V—CONTROL OF TRANSPORT, IMPORT AND EXPORT OF DRUGS

43. Transportation of drugs

(1) The consignment and transportation of classified drugs shall be in accordance with Schedule 9 to this Act.

(2) Notwithstanding subsection (1), the Minister may, on the advice of the Drug Authority, make regulations for the control of the transportation of any drug or class of drugs.

44. Importation of pharmaceuticals

(1) No person or body shall import any drugs into Uganda without a licence in relation to their import from the Drug Authority.

(2) The licence shall be valid for one year and shall state the range of preparations to be imported during that period.

45. Exportation of drugs

(1) No person or body shall export any drug or preparation without a licence in relation to that export from the Drug Authority.

(2) The licence shall be valid for one year and shall specify the drug to be exported.

(3) A person who exports any classified drugs shall keep a record in the prescribed form of all exports.

Import and export licences

(a) an application for the permit is made in the prescribed form and the applicant pays the prescribed fee; and

(b) the Drug Authority is satisfied that the applicant is a person to whom the permit can properly be granted.

(2) No permit shall be granted for the import or export of any narcotic drugs or psychotropic substances under international control, other than for medical, dental or veterinary use.

(3) A permit granted under this section may be granted generally for :he import or export of classified drugs or limited to specified drugs.

PART VI—POWERS OF ENTRY AND INVESTIGATION

7. Powers of entry

(1) An inspector or assistant inspector of drugs may enter—

(a) at all reasonable times, any premises in respect of which a certificate issued under this Act is in force or on which any person is required to carry out any functions imposed under this Act;

(b) at any time, any premises on or in relation to which he or she has reasonable cause to suspect that an offence under this Act has been or is being committed;

(c) at any reasonable time, any premises on which a business relating to the manufacture or supply of narcotic drugs is carried on;

(d) at any time, any vehicle or vessel which he or she reasonably suspects is being or is about to be used in the commission of an offence under this Act.

(2) Any police officer not below the rank of assistant superintendent enter, at any reasonable time, any premises or detain and enter any :le or vessel on or in relation to which he or she has reasonable cause to :ct that an offence under this Act has been or is being committed.

Powers of investigation

(1) A drug inspector, assistant inspector of drugs or police officer of ık of assistant superintendent empowered under this Act to enter any es, vehicle or any other means of transport may—

(a) inspect the premises, vehicle or vessel and any articles found in the premises, vehicle or vessel;

(b) require any person on or in the premises, vehicle or vessel to furnish any information in his or her possession as to the activities carried on or in the premises and the person by whom they are carried on or the purposes for which the vehicle or vessel is being used;

(c) take away any drug or records and other documents found on or in the premises, vehicle or vessel.

(2) Where a drug is taken away pursuant to this section, reasonable payment thereof shall be tendered by the inspecting officer, but—

(a) no payment need be tendered in respect of a drug if the inspecting officer reasonably suspects that the drug is unfit for its purpose by reason of deterioration, impurity, adulteration or other defect; but if the drug is later found on analysis not to be so unfit, reasonable payment shall be tendered by the inspecting officer in respect of the drug which is not returned to its owner in good condition;

(b) no payment shall be made in respect of a drug if the inspecting officer anticipates that proceedings for an offence under this Act will be brought in respect of the drug; but if the proceedings are not commenced within six months, reasonable payment shall be tendered by the inspecting officer in respect of the drug which is not returned to its owner in good condition.

49. Authority to be shown

An inspecting officer exercising any powers conferred by this Act shall produce, on demand, a duly authenticated document showing that he or she is entitled to exercise those powers.

50. Obstruction

No person shall obstruct an inspecting officer exercising powers under this Part or fail to comply with a requirement made by him or her in exercise of those powers.

PART VII—SECRETARIAT AND FINANCIAL PROVISIONS

51. Secretariat

(1) The Drug Authority shall have a Secretariat which shall be responsible for the day-to-day operations of the Drug Authority.

(2) The Secretariat shall be headed by the Secretary to the Drug Authority who shall be appointed by the Drug Authority on terms and conditions that the Drug Authority may determine.

(3) In addition to any other functions that may be conferred upon ıim or her by the Drug Authority, the Secretary shall—

(a) have custody of the seal of the Drug Authority;

(b) be responsible for taking the minutes of the Drug Authority and the Commission and for keeping the records of the transactions of the Drug Authority.

(4) There shall be other officers and employees of the Drug Authority the Drug Authority may determine.

(5) An employee of the Drug Authority shall not, in his or her rsonal capacity, be liable to any civil or criminal proceedings in respect of / act done or omission made in good faith in the performance of his or her ies under this Act.

Funds of Drug Authority

(1) The funds of the Drug Authority shall consist of—

(a) grants from the Government;

(b) grants and loans from any body, organisation or person;

(c) interest on savings made by the Drug Authority;

(d) money that may accrue to the Drug Authority in the discharge of its functions; and

(e) money from any other source as may be approved by the Minister.

(2) The Drug Authority shall possess a bank account in a bank ved by it.

53. Estimates

(1) The Drug Authority shall, within three months before the commencement of each financial year, prepare and submit to the Minister, estimates and expenditure for the Drug Authority for the next ensuing year; and any time before the end of a financial year, the Drug Authority may prepare and submit to the Minister for approval any estimates supplementary to the estimates of a current year.

(2) The Minister shall notify the Drug Authority of his or her decision on the estimates submitted to him or her within one month of the submission of the estimates.

(3) No expenditure shall be made out of the funds of the Drug Authority unless that expenditure is part of the expenditure approved by the Minister under the estimates for the financial year in which the expenditure is to be incurred or in supplementary estimates for that year.

54. Accounts

(1) The Drug Authority shall keep proper books of accounts of all its income and expenditure and proper records in relation to those accounts.

(2) Subject to any direction given by the Minister responsible for finance, the Drug Authority shall cause to be prepared in respect of each financial year, a statement of account which shall include—

(a) a balance sheet, a statement of income and expenditure and a statement of surplus and deficit; and

(b) any other information in respect of the financial affairs of the Drug Authority as the Minister responsible for finance may require.

55. Audits

(1) The accounts of the Drug Authority shall, in respect of each financial year, be audited by the Auditor General or an auditor appointed by him or her.

(2) The Drug Authority shall ensure that within four months after the end of the financial year a statement of account is submitted to the Auditor General for auditing.

(3) The Auditor General and any auditor appointed by him or her shall have access to all books of accounts, vouchers and other financial records of the Drug Authority and be entitled to have any information and explanation required by him or her in relation to those records.

(4) The Auditor General shall, within two months after receipt of statements of accounts under this section, audit the accounts and deliver to the Drug Authority and the Minister a copy of the audited accounts and his or her report on those accounts.

PART VIII—MISCELLANEOUS

56. Rational use of drugs

(1) The Drug Authority shall, in the interest of public health and the economical use of resources, and in consultation with the bodies concerned, promote the rational use of drugs both in the private and public sector.

(2) In the implementation of subsection (1), the Drug Authority may adopt methods and materials which have proved effective in other countries and shall, among other methods, do the following—

(a) develop basic and postgraduate training in the health sector;

(b) promote public awareness and knowledge of the proper use of drugs; and

(c) disseminate information on the purposes and progress of the National Drug Policy.

Offences and penalties

(1) A person contravening a provision of this Act commits an offence and, where no punishment is provided, is liable—

(a) to a fine not exceeding fifty currency points;

(b) to a withdrawal of the licence or permit for a period not exceeding five years;

(c) to cause the items in contravention to be impounded, forfeited, destroyed or disposed of in a manner prescribed by the Minister;

(d) to imprisonment not exceeding one year; or

(e) to any two of the above punishments,

and for any subsequent offence under this Act, a person is liable to a fine not exceeding one hundred currency points or to a term of imprisonment not exceeding five years, or both.

(2) Any person who commits an offence under this Act and no other punishment is provided is liable—

(a) where the offence relates to Class A drugs, to a fine not exceeding one hundred currency points or to imprisonment for a term not exceeding five years, or both;

(b) where the offence relates to narcotic drugs or psychotropic substances under international control and is a second or more subsequent offence, to a term of life imprisonment;

(c) where the offence relates to manufacturing, smoking or having possession of any narcotic drug or psychotropic substance under international control and is a second or more subsequent offence, to a term not exceeding ten years.

(3) Where no case is proved in respect of any drug or article taken from an accused person, the court shall order reasonable payment to the owner in respect of the drug or article which is not returned to him or her in good condition.

(4) No proceedings shall be instituted for an offence under section 35 without the consent of the Director of Public Prosecutions.

58. Vicarious criminal responsibility

(1) Any act or omission which if done by an individual would be an offence under this Act or any regulations made under it shall, if done by a body corporate, be deemed to be an offence committed by every director, secretary and manager of the body corporate, unless the director, secretary or manager proves that the offence was committed without his or her consent or connivance and that he or she exercised all such diligence to prevent the commission of the offence as he or she ought to have exercised, having regard to the nature of his or her functions in that capacity and to all the circumstances of the case.

(2) If an offence under this Act or any regulations made under it is committed by a partner in a firm, every person who at the time of the commission of the offence was a partner in that firm, or was purporting to act in that office, shall be deemed to have committed the like offence unless he or she proves that the offence was committed without his or her consent or connivance and that he or she exercised all such diligence to prevent the commission of the offence as he or she ought to have exercised, having regard to the nature of his or her functions in that capacity and to all the circumstances of the case.

). Evidence

(1) In any proceedings under this Act—
(a) any licence, permit or certificate purporting to have been issued under this Act; or
(b) any document purporting to state the results of an analysis carried out on behalf of the Drug Authority for the purposes of this Act,

ll be *prima facie* evidence of the facts stated in it.

(2) Where, in any proceedings under this Act, a person is charged

(a) the unlawful possession, sale or supply of any restricted drug and the drug is in a container; or
(b) any other offence where the contents of a container are in issue in the proceedings,

e container appears to the court to be intact and in its original state of ıg by its manufacturer, the contents of the container shall be deemed, the contrary is proved, to be of the description specified on the label container.

rugs Bureau

) There shall be established a Drugs Bureau under the Office of ector of Drugs.

The Drugs Bureau shall—
keep and maintain a register in which shall be entered details of the composition of all drugs registered under section 35;
keep and maintain a list of all toxic substances, their composition, toxicity and antidotes;

(c) supply such information to medical practitioners, dentists or veterinary surgeons in respect of drugs as may be in its possession in emergency cases of poisoning.

(3) In order to discharge its functions under this section, the Drugs Bureau may require any person to give any information in his or her possession or control regarding any drug, and that person shall furnish the information within such period as may be specified by the Drugs Bureau.

(4) Subject to subsection (2)(c), any information furnished to the Drugs Bureau under subsection (3) shall be kept confidential and shall not be published without the consent of the person furnishing the information.

61. Regulations

The Minister may, by statutory instrument, on the advice of the Drug Authority, make regulations generally for better carrying into effect the provisions of this Act—

(a) including the period within which all drugs imported—
  (i) should be labelled and prescribed by their International Non-proprietary Names (INN) or generic names; and
  (ii) but not appearing on the national list of essential drugs or the national formulary may be off the market;
(b) prescribing the procedure to be followed at meetings, inquiries and other proceedings of the Drug Authority and its committees;
(c) prescribing conditions to be inserted in licences or permits granted under this Act, and otherwise prescribing things to be done in relation to such licences or permits;
(d) laying down conditions in respect of supplies and issues of drugs by hospitals and the storage of drugs by hospitals and the records to be kept;
(e) use of drugs in first-aid boxes notwithstanding any other enactment;
(f) prohibiting, regulating or restricting the manufacture, sale or advertising of drugs, pharmaceutical preparations and therapeutic substances;
(g) regulating, restricting or prohibiting the importation, sale or advertising of surgical instruments and appliances;
(h) regulating and restricting the use of classified drugs for

the measures to be taken to protect the persons using such classified drugs, including the types and standards of protective clothing which shall be worn;

(i) requiring the registration and treatment of persons addicted to drugs;

(j) the registration and operation of authorised persons; and

(k) prescribing anything which under this Act may be prescribed.

62. Power to amend Schedules

(1) The Minister responsible for finance may, by statutory instrument, with the approval of Cabinet, amend Schedule 1 to this Act.

(2) The Minister may, after consulting the Drug Authority, by statutory order, amend Schedules 2, 3, 4, 5, 6, 7, 8 and 9 to this Act.

SCHEDULES

Schedule 1

Sections 1, 62(1)

Currency Point

A currency point is equivalent to twenty thousand shillings.

Schedule 2

Sections 12, 29, 62(2)

Class A Drugs or Narcotics

The drugs included in this class may only be imported, or exported, manufactured or used, under authority. They may be sold by retail only on the prescription of a duly qualified medical practitioner, dentist, and veterinary surgeon but only for medical, dental or veterinary purposes and may be supplied only by a licensed person.

3-Methylfentanyl
3-Methylthiofentanyl Acetorphine
Acetyl-Alpha-Methylfentanyl
Acetyldihydrocodeine, except as specified in group II of class B
Acetylmethadol
Alfentanil
Alphacetylmethadol
Alphameprodine Alphamethadol
Alpha-Methylfentanyl
Alpha-Methylthiofentanyl
Alphaprodine
Anileridine
Benzylmorphine
Betacetylmethadol
Beta-Hydroxy-3-Methylfentanyl
Beta-Hydroxyfentanyl
Betameprodine
etaprodine
Bezitramide
Buprenorphine
Cannabis (the flowering and fruiting tops of the Cannabis plant)
Cannabis Resin, Extracts and Tinctures of Cannabis
Carfentanil
Cocaine
Codeine, except as specified in group II of class B
Codoxime
Concentrate of Poppy Straw
Cyprenorphine hydrochloride
Desomorphine
Dextromoramide
Dextropropoxyphene Diampromide
Diethylthiambutene
Difenoxin

Dihydrocodeine, except as specified in group II of class B Dihydroetorphine V
Dimenoxadol
Dimepheptanol Dimethylthiambutene
Dioxaphetyl Butyrate
Diphenoxin

Diphenoxylate
Dipipanone

Diprenorphine
Drotebanol

cgonine
mbutramide V
:hylmethylthiambutene

hylmorphine orphine V
ntanyl and its salts

rethidine morphine
(Heroin)

drocodone
dromorphinol
lromorphone

lroxypethidine
ıethadone

bemidone
methorphan

moramide
phenacylmorphan

rphanol
ridine and its intermediates

:ocine
ıdone, its salts, intermediates

l derivatives ldesorphine
ldihydromorphine

on
eridine
ne
ne Methobromide

Morphine-N-Oxide
Myrophine
Nicocodine
Nicodicodine
Nicomorphine
Noracymethadol
Norcodeine, except as specified in class B, group II Norlevorphanol
Normethadone
Normorphine
Opium (all preparations made direct from opium are considered to be opium)
Oxycodone
Oxymorphone
Para-Fluorofentanyl
Pepap (1-phenethyl-4-phenyl-4-piperidinol acetate (ester)) Pethidine, its salts, intermediates and derivatives
Phenadoxone
Phenazocine
Phenomorphan
Phenoperidine
Pholcodine, except as specified in class B group II or in class C Piritramide
Propiram
Racemethorphan
Racemoramide
Racemorphan
Remifentanil
Sufentanil
Tapendatol
Thebacon
Thebaine
Thiofentanyl
Tilidine
Trimeperidine

All substances referred to in this Schedule include, unless expressly excluded or unless listed in another Schedule, the following—

(a) the isomers of such substances, where the existence of such isomers is possible within the specific chemical designation;

(b) the esters and ethers of such substances and of the isomers referred to in paragraph (a), as well as the isomers of such esters and ethers, where the existence of such esters, ethers and isomers is possible;

(c) the salts of such substances and of the isomers referred to in paragraph (a), as well as the salts of the esters, ethers and isomers referred to in paragraph (b), where the existence of such salts is possible;

(d) the isomers of any of the salts referred to in paragraph (c), where the existence of such isomers is possible; and

(e) all preparations and mixtures of any of the above.

Schedule 3

Sections 12, 29, 60(2)

Class B Drugs or Controlled Drugs

GROUP I

The following drugs may be supplied by retail, by a licensed person only on the prescription of a duly qualified medical practitioner, dentist or veterinary surgeon, but only for medical, dental or animal treatment respectively.

4-Aminosalicylic acid (p-aminosalicylic acid) and its salts
5-Fluorouracil its salts derivatives and metabolites
5-Aminosalicylic acid (Mesalazine or Mesalamine)
5-Phenylhydantoin; its alkyl and aryl derivatives; their salts
6-Mercaptopurine and its derivatives, except if listed in another schedule
Abamectin V
Abciximab
Acamprosate, and its salts
Acarbose, and its salts
Acebutolol, and its salts
Aceclofenac
Acepromazine, and its salts V
Acetahexamide
Acetanilide; alkyl acetanilides (except as provided in Group II of this class)
Acetazolamide and its salts
Acetylcarbromal
Acocanthera, glycosides of
Adenium, glycosides of
Alcuronium chloride
Allylisopropyl-acetylurea
Amidopyrine, its salts; amidopyrine sulphonates, their
salts Acetylcholine, when intended for ophthalmic use
Acetylcysteine except as specified in group II of this class
Acetylpromazine maleate V
Acetylsalicylic acid except as specified in group II of this class and class C Acipimox
Acitrelin, its salts and derivatives
Aconiazide, and its salts
Acyclovir, and its salts, except when intended for topical application
Adalimumab

Adapalene, its salts and derivatives
Adefovir, its salts and derivatives
Adenosine and its salts (for parenteral use)
Agalsidase alfa
Agalsidase beta
Agomelatine
Aklomide V
Albendazole injection V
Albumin
Alefacept
Alemtuzumab
Alendronic acid, and its salts
Alfacalcidol
Alfadolone V
Alfaprostol V
Alfuzosin, and its salts
Aliskiren, and its salts
Allobarbital
Allopurinol
Allylisopropyl-acetylurea
Almotriptan and its salts
Alpha-chloralose V
Alphadolone and its salts
Alpha-galactosidase
Alphaxalone
Alteplase, its salts and derivatives
Altrenogest V
Altretamine
Alverine, and its salts (for parenteral use)
Amantadine, and its salts
Ambenonium chloride
Ambrisentan
Amfepramone
Amfetamine
Amicarbalide V
Amidapril
Amifostine, and its salts
Amikacin, its salts and derivatives
Amiloride, and its salts
Amino acids, in preparations intended for parenteral use

Aminocaproic acid
Aminoglutethimide
Aminometradine
Aminophylline
Aminopromazine (proquamezine) and its salts
Aminopterin, and its salts
Aminopyrine and its derivatives V
Amiodarone and its salts
Amisulpride
Amitriptyline, and its salts
Amlexanox, its salts and derivatives
Amlodipine, and its salts
Ammonium bromide
Ammonium chloride, in preparations intended for parenteral use
Ammonium molybdate V
Ammonium tetrathiomolybdate V
Amodiaquine, except as specified in group II of this class
Amonolevulinic acid, its salts and derivatives
Amoxapine
Amphomycin, and its salts, its esters and salts of such esters
Amphotericin, its salts and derivatives
Amprolium, its salts and derivatives
Amsacrine, and its salts
Amyl nitrite
Anagrelide, and its salts
Anakinra, its salts and derivatives
Anastrazole
Androgenic, oestrogenic and progestational substances and their derivatives, with either hormonal, prohormonal or anti-hormonal activity (except as specified elsewhere in the schedules) such as:
Anzoestral
Bicalutamide
Bromiphene and its alts
Bisogestrel
Bonogest
Canspirenone
Chlorogesterone
Clostadiol
Cyamustin
Cyclo gen

Estrone
Ethinylestradiol
Ethynodiol
Etonogestrel
Flugestone
Flutamide
Hydroxyprogesterone hexanoate
Levonorgestrel
Megestrol
Mesterolone
Methyltestosterone
Mifepristone
Norelgestromin
Norethandrolone
Norethindrone
Norethisterone
Norgestimate
Norgestrel
Progesterone
Proligestone V
Stanozolol
Stilbenes such as Diethylstibesterol (Stilbesrol)
Tamoxifen
Testosterone
Toremifene
Ulipristal acetate
Anethole
Anthrax vaccine
Apomorphine
Apramycin, and its salts
Aprepitant and its derivatives
Aprotinin
Arecoline, and its salts
Argatroban, its salts and derivatives
Aripiprazole
Arsenic and its compounds, including Arsenic trioxide, except as specified in class C
Arteether (beta-alfa)
Artemisinin

Arterolane, and its salts
Artesunate, except as specified in group II of this class and in class C
Asiaticoside
Asparaginase
Astemizole, and its salts
Atenolol, and its salts
Atipamezole, and its salts V
Atomoxetine, and its salts
Atorvastatin, and its salts
Atovaquone and its salts, except as specified in group II of this class
Atracurium, and its salts
Atropine, and its salts, preparations intended for parenteral use
Auranofin
Aurothioglucose
Avian coccidiosis vaccine V
Avian Infectious bronchitis vaccine V
Avilamycin V
Azacyclonol acid, and its salts
Azaperone injection V
Azaribine
Azatadine, and its salts
Azathioprine, and its salts
Azelaic acid
Azithromycin, its salts and derivatives
Azlocillin, its salts and dervatives
Aztreonam, its salts and derivatives
Bacaplermin
Bacillus Calmette–Guérin (BCG) vaccine V
Bacitracin, its salts and derivatives except as specified in group II of this class
Baclofen and its salts
Barbituric acid, its salts; derivatives of barbituric acid; their salts; compounds of barbituric acid; their salts; their derivatives, such as:
Amobarbital
Aprobarbital
Butabarbital
Butalbital
Cyclobarbital
Methohexital
Methylphenobarbital (Mephobarbital)

Pentobarbital
Phenobarbital
Primidone
Secbutabarbital
Secobarbital
Thiamylal (Surital)
Thiopental
Vinylbital
Balsalazide
Bambermycin V
Bambuterol, and its salts
Baquiloprim V
Barium sulphate
Basiliximab
Beclomethasone, except as specified in group II of this class
Bedaquiline
Bemegride
Bemiprarin
Benactyzine, and its salts
Benazepril, and its salts
Bendazac and its salts
Bendrofluazide (Bendroflumethiazide)
Benoxaprofen, and its salts
Benserazide, and its salts
Benzafibrate
Benzfetamine
Benzhexol (Trihexyphenidyl) and its salts
Benzocaine and its salts; except as specified in group II of this class and in class C
Benzodiazepines, and salts or derivatives thereof (except as listed elsewhere in the schedules), such as:
Alprazolam
Bromazepam
Brotizolam
Camazepam
Chlordiazepoxide
Clobazam
Clonazepam
Clorazepate

Cloxazolam
Delorazepam
Diazepam
Estazolam
Ethyl loflazepate
Fludiazepam
Flunitrazepam

Flurazepam
Halazepam
Haloxazolam
Ketazolam
Oprazolam
Orazepam ormet
azepam
edazepam

dazolam
netazepam
razepam
dazepam
zepam
zolam
arbazepine a
zepam
epam

pam
zepam
epam
lam
pam
yl Peroxide except as specified in group II of this class
iazide
pine, its homologues; their salts nt

ol and its derivatives
ine, and its salts
l
chol
mab
ycin
ycin

Bimatoprost
Bisoprolol
Bismuth and its salts, except as specified in group II of this class and in class C Bivalirudin
Bleomycin
Blood, its components and products derived from blood
Boldenone undecylenate
Bonsetan, its salts and derivatives
Bordetella bronchiseptica (Infectious tracheobronchitis) vaccine V
Boric acid in preparations intended for parentral use
Bovine ephemeral fever vaccine V
Bovine mastitis vaccine V
Bovine Tuberculin vaccine V
Bretylium,
Brinzolamide
Brolamfetamine
Bromocriptine, and its salts
Brucellosis vaccine
Bumetanide
Bunamidine
Buparvaquone, for parenteral use V
Bupivacaine, and its salts (for parenteral use)
Buquinolate
Buserelin injection
Buspirone, and its salts
Busulphan, and its salts
ButamisoleV
Butenafine hydrochloride
Cabergoline and its salts.
Caffeine, except as specified in group II of this class or in class C
Calcitonin
Calcitriol
Calcium acetate
Calcium borogluconate V
Calcium disodium edetate
Calcium dobesilate
Calcium gluconate in injectable form for parenteral use.
Cambendazole V
Candesartan, its salts and [illegible]

Canine distemper virus vaccine V
Canine parvovirus vaccine V
Capecitabine
Capreomycin and its salts, deravatives, its esters and salts of such esters
Captodiamine and its salts
Captopril and its salts
Caramiphen; its salts
Carbachol, its ophthalmic preparations when intended for glaucoma
Carbadox, V
Carbamazepine
Carbetocin
Carbidopa, and its salts
Carbimazole
Carbomycin
Carboplatin
Carboplost
Carbromal
Carisoprodal
Carnitine
Carprofen, its salts and derivatives V
Carvedilol, and its salts
Chine
Chinone
chemokine receptor type 5 (CCR5) antagonists such as maraviroc
Cprolol
Cephalosporins, their derivatives and salts (except as specified in group II of this class), such as:
Cefetrile
Cefor

Cefoperazone
Cefotaxime
Cefpirome
Cefpodoxime proxetil.
Cefprozil, its salts and derivatives
Cefquinome
Cefradine
Ceftazidime
Ceftiofur
Ceftriaxone
Cefuroxime
Cephaloridine
Cephalosporin C
Cerebrolysin
Cetrorelix
Chlamydophiliosis vaccineV
Chloral hydrate
Chlorambucil, its salts and derivatives
Chloramphenicol, its salts and derivatives except as specified in class C
Chlordiazepoxide and its salts
Chlormethiazole
Chloroprocaine
Chloroquine and its salts, except as specified in group II of this class
Chlorpheniramine, and its salts, in preparations intended for injection
Chlorphenoxmine, and its salts
Chlorphentermine; and its salts
Chlorothiazide and other derivatives of Benzol 2:4-thiadiazine
-7-sulphonamide 1:1-dioxide, whether hydrogenated or not
Chlorpromazine, and its salts
Chlorpropamide, and its salts
Chlorprothixene, and other derivatives of 9-methylenethiazane-ther, their salts
Chlorthalidone, and other derivatives of o-chlorobenzene sulphonamide
Cholera vaccine
Choline theophyllinate
Cidofovir
Cilastatin and its salts
Cimetidine, and its salts

Cisapride and its salts
Cisatracurium and its salts
Cisplatin
Citalopram and its salts
Clarithromycin
Clavulanic acid, except as specified in group II of this class
Clazuril V
Clemizole penicillin
Clenbuterol and its salts V
Clindamycin, its salts and derivatives.
Clofazimine

Clofibrate
Clomethiazole
Clomipramine and its salts
Clonidine and its salts.
lopidogrel and its salts
loprostenol, its salts and derivatives, V
lorexolone, its salts
orsulon V
osantel and its salts V
ostridial infections vaccineV
ostridium botulinum toxins type A & B
zapine, and its salts
icistat
chicine
ecalciferol
sevelam
stipol
styramine

tin (Polymyxin E), its salts and derivatives
vaptan
igious Caprine Pleuropneumonia vaccine V
er salts, when intended for injection for parenteral nutrition, V

Corticosteroids; their salts and derivatives; whether natural or synthetic, (except as specified elsewhere in the schedules); such as:

ethasone
onide
onide

Cortisol
Cortisone
Desonide
Desoximetasone
Desoxycorticosterone PivalateV
Dexamethasone
Diflucortolone
Difluprednate
Fludrocortisone acetate,
Fludroxycortide
Flumethasone
Flunisolide
Fluocinolone
Fluticasone
Hydrocortisone
Methylprednisolone
Mometasone
Prednicarbate
Prednisolone
Prednisone
Triamcinolone
Coumarin and its derivatives, such as:
4-Hydroxycoumarol
Acenocoumarol
Dicoumarol
Esculoside (Esculin)
Warfarin
Cromoglycic acid and its salts; except as specified in group II of this class
Crofelemer
Cuprimyxin
Cyclandelate
Cyclizine, except as specified in group II of this class
Cyclopenthiazide
Cyclopentolate and its salts in preparations for parenteral use
Cyclophosphamide
Cycloserine and its salts
Cyclosporin A
Cycrimine, and its salts
Cytarabine and its salts,
Cythioate V

Dabigatran, its salts and derivatives
Dacarbazine
Daclatasvir
Daclizumab
Dactinomycin
Dalteparin and its salts.
Danaparoid, its salts and derivatives
Danazol
Dantrolene and its salts
Dapagliflozin
Dapiprazole and its salts
Dapoxetine, and its salts
Daptomycin
Darifenacin
Daunorubicin and its salts.
Debrisoquine and its salts
Decamethoxin
DecoquinateV
Deferasirox
Deferoxamine and its salts.
Delavirdine
Demacarium bromide
Desferrioxamine mesilate
Desflurane
Desimipramine and its salts
Desipramine; its salts
DeslorelinV
Despramine, and its salts
Detomidine and its salts V
Dexamfetamine
Dextran
Dextrose in solutions for parenteral use
Diacerin
Diaminazene and its salts V
Dimenhydrinate and its salts except as specified in group II of this class
Diatrizoate
Diaveridine V
Diazoxide and its salts
Dichloracetic acid
Dichlorophen V

Dichlorvos V in preparations intended for oral use
Diclazuril V
Diclofenac, and its salts; except as specified in group II of this class
Dictyocaulus viviparus vaccine
Dicycloverine (Dicyclomine) except as specified in group II of this class.
Diethylcarbamazine and its salts
Diflunisal and its salts
Digitalis, its glycosides, derivatives and their salts
Dihydrochlorothiazide
Dihydrostreptomycin, its salts and derivatives
Diidohydroxyquin
Diiodohydroxyquinoline (Iodoquinol)
Diloxanide furoate
Diltiazem and its salts,
Dimercaprol
Dimethicone and its salts, except as specified in group II of this class
Dimethindene
Dimethyl Sulfoxide
Dimethylglycine
Dimetridazole injection V
Diminazene and its salts V
Dinitolmide, V except as specified in class C
Dinoprost
Dinoprostone
Diphenidol and its salts
Diprophylline
Dipyridamole
Dirithromycin
Disodium hydrogen citrate
Disopyramide and its salts
Disulfiram
Dithiazanine iodide V
DiuredosanV
Divalproex
Dobutamine and its salts
Docetaxel and its salts
Domperidone
Donepezil
Dopamine
Dopexamine

Doramectin, V
Dornase alpha (rhDNase)
Dorzolamide and its salts
Dosulepin
Doxapram
Doxazosin and its salts
Doxepin and its salts
Doxercalciferol and its derivatives
Doxorubicin (Adriamycin) and its salts
Dronabinol
Dronedarone
Droperidol and its salts
Drotaverine
Duloxetine and its salts
Dutasteride
Dyflos (Isoflurophate)
East Coast Fever vaccineV
Echinocandins, their salts and derivatives, such as Caspofungin, Anidulafungin and Micafungin
Econazole and its salts
Ecothiophate and its salts V
Ectylurea and its salts
Eculizumab
Edrophonium
Efalizumab
Efavirenz
Eflornithine, its salts and derivatives
Electrolyte solutions for parenteral use
Eletriptan and its salts
Emedastine and its salts
Emepronium
Emtricitabine
Emylcamate
Enalapril, its salts and derivatives
Enflurane
Enfuvirtide
Enilconazole except when intended for application to the skin
Enoxaparin and its salts
Enoximone
Enramycin V

Entacapone
Entecavir
Enteric red mouth disease vaccine V
Ephedrine and its salts, except as specified in group II of this class
Epinephrine (adrenaline) and its salts
Epirubicinesc and its salts
Eplerenone
Epoprostenol and its salts
Eprinomectin V
Eprosartan, its salts and derivatives
Epsiprantel V
Eptifibatide and its salts
Equine anti-human thymocyte globulin
Equine chorionic gonadotrophin, V
Equine gamma globulin;
Equine herpesvirus vaccine V
Equine influenza virus vaccine V
Erdosteine
Ergot, alkaloids of, whether hydrogenated or not; their homologues; any salt of any substance falling within this item (except as provided in Group II of this class) such as Ergotamine, Ergometrine, Cabergoline, Nicergoline
Erlotinib and its salts
Ertapenem and its salts
Erythrityl tetranitrate
Erythropoietin
Escitalopram and its salts
Esmolol and its salts
Esomeprazole and its salts, except as specified in group II of this class
Etamiphylline, its salts and derivatives
Etamsylate
Etanercept
Ethacrycin acid, its salts
Ethambutol, and its salts.
Ethchlorvynol
Ethinamate
Ethionamide, and its salts
Ethoheptazine, and its salts
Ethopropazine hydrochloride (profenamine), and its salts
Ethosuximide

Ethotoin and its salts
Etilamfetamine
Etilefrine
Etiproston V
Etodolac, its salts and derivatives
Etomidate
Etoposide and its derivatives
Etoricoxib
Etravirine
Etymemazine and its salts
Everolimus
Exemestane
Ezetimibe
Famciclovir and its salts.
Famotidine, except as specified in group II of this class Fampridine
Febantel V
Febuxostat
Feline Chlamydial vaccine V
Feline leukaemia vaccine V
Feline panleucopenia vaccine V
Feline viral respiratory disease complex vaccine V
Feline viral rhinotracheitis vaccine V
Felodipine and its salts
Fencamfamin
Fenetylline
Fenfluramine and its salts
Fenofibrate
Fenoprofen, except as specified in group II of this class
Fenoterol
Fenproporex
Fenticonzole
Fertirelin V
Fexofenadine and its salts
Filgrastim
Finasteride
Fipronil V, when used in preparations intended for cutaneous spray
Flavoxate
Flecainide and its salts
Florfenicol and its derivatives

Fluanisone
Flubendazole
Fluconazole, except as specified in group II of this class
Flucytosine
Fludarabine, its salts and derivatives
Flufenamic acid
Flumazenil
Flumequin V
Flunarizine and its salts
Flunixin, its salts and derivatives V
Fluorescein, except when intended for ophthalmic use by the topical route only
Fluoxetine and its salts
Flupentixol, its salts and derivatives.
Fluphenazine and its salts.
Fluprostenol
Flurbiprofen, except as specified in group II of this class
Fluvastatin, its salts and derivatives
Fluvoxamine and its salts
Folinate (Folinic acid)
Fondaparinux sodium
Formoterol, and its salts
Fortimycin V
Fosaprepitant
Foscarnet sodium
Fosfomycin and its salts
Fosphenytoin and its salts
Fowl pox vaccine V
Framycetin and its salts
Furadantin
Furaltadone and its salts V
Furazolidone and its salts
Furazolium chloride
Furosemide
Fusidic acid and its salts, its esters and salts of such esters
Fusion inhibitors and their salts such as enfurvitide
Gabapentin, its salts and derivatives
Gadopentetic acid
Galantamine, its salts and derivatives
Gallamine; its salts, derivatives and quaternary compounds

Gallium and its salts
Gamithromycin V
Gamma-aminobutyric acid, its derivatives and salts there of
Ganciclovir and its salts and derivatives
Gemcitabine and its salts and derivatives
Gemfibrozil and its salts
Gemifloxacin, its salts and derivatives
Gemtuzumab
Gentamycin and its salts, its esters and salts of such esters
Glafenine
Gleptoferron
Glibenclamide
Gliclazide
Glimepiride
Glipizide
Glucosamine, substances, preparations and mixtures when intended for the treatment of primary and secondary osteoarthritis, osteochondrosis and spondylosis
Glutethimide, and its salts.
Glyburide, and its salts and derivatives.
Glyceryl trinitrate (Nitroglycerin)
Glycopyrrolate and its salts
Glycopyrronium and its salts
Goat pox virus vaccine V
Goserelin and its salts
Gramicidin, except as specified in group II of this class
Granisetron and its salts
Grepafloxacin, its salts and derivatives
Guanabenz
Guanethidine, and its salts
Halofantrine and its salts
Halofenate
Halofuginone V
Haloperidol and its salts
Halothane
Haloxon V
Heparin and its salts
Hepatitis A vaccine
Hepatitis B immunoglobulin
Heptaminol

Hexapropymate
Hexoprenaline
Histrelin and its salts
Homatropine and its salts, except as specified in group II of this class
Homidium bromide (ethidium bromide) V
Human anti-D immunoglobulin
Human anti-thymocyte rabbit immunoglobulin
Human menopausal gonadotrophin (Menotrophin)
Human normal immunoglobulins
Hyaluronic acid and its salts, except as specified in group II of this class and class C
Hyaluronidase
Hydralazine and its salts
Hydrochlorothiazide
Hydroflumethiazide
Hydroxycarbamide (Hydroxyurea)
Hydroxychloroquin and its salts
Hydroxyethyl starch, and its derivates intended for parentral use
Hydroxyzine, and its salts
Hyoscine and its salts, except as provided in group II of this class
Hyoscyamine, except as provided in class C
Ibalizumab
Ibandronic acid and its salts
Ibuprofen, except as specified in group II of this class and in class C
Idarubicin and its salts
Idoxuridine, except when intended for application to the skin
Ifosfamide
Iloprost
Imidacloprid V
Imidocarb, and its salts V
Imipenem, its salts and derivatives
Imipramine, and its salts
Indacaterol
Indapamide, and its salts
Indomethacin, and its salts, except as specified in group II of this class
Indoramin
Infectious Bovine Rhinotracheitis (IBR) vaccines V
Infectious bursal disease (Gumboro) vaccine V
Infectious canine hepatitis vaccine V
Infectious Coryza vaccine V

Infectious tracheobronchitis vaccine V
Infliximab
Inosine pranobex
Inositol
Insulin
Integrase inihibitors, and their salts such as;
Bictegravir
Dolutegravir
Elvitegravir
Raltegravir
Interferons, such as Interferon-alpha, Interferon-beta, Interferon-gamma, Interferon-omega and their corresponding subtypes.
Intra uterine devices; whether hormonal or copper based
Iohexol
Iopanoic acid
Iopromide
Iopamidol
Ipratropium, and its salts
Iprindole, and its salts
Isoniazid, and its salts, derivatives and their salts
Irbesartan
Irinotecan and its salts
Isetharine, and its salts
Isocarboxazid and its salts
Isoconazole and its salts
Isoflurane
Isometamidium and its salts V
Isoprenaline
Isopropamide and its salts
Isopyrin
Isosorbide, its salts and derivatives
Isotretinoin, its salts and derivatives
Isoxsuprine and its salts
Isradipine and its salts
Itraconazole and its salts
Ivabradine
Ivermectin
Josamycin
Kanamycin and its salts
Lincomycins, their salts, their esters and salts of such esters

Ketamine and its salts
Ketoconazole and its salts, except as specified in group II of this class and class C
Ketoprofen and its salts, except as specified in group II of this class
Ketorolac and its salts
Ketotifen and its salts
Kitasamycin
Labetalol and its salts
Laci di pine
Lacosamide
Ladepasvir
Lamotrigine and its salts
Lanatoside
Lanreotide and its salts
Lansoprazole except as specified in group II of this class
Lasalocid V
Latanoprost
Laudexium, its salts
Ledipasvir
Lefetamine
Leflunomide
Lepirudin
Leptospirosis vaccine V
Lercanidipine
Letrozole
Leuprolide
Levamfetamine
Levamisole and its salts, for injection V
Levetiracetam
Levocabastine, except as specified in group II of this class
Levodopa and its salts
Levomepromazine
Levosalbutamol, except as specified in group II of this class lidocaine, except as specified in group II of this class and class C
Lincomycin, and its salts and derivatives
Linezolid and its salts
Lisinopril, and its salts
Lithium, and its salts except as specified in group II of this class
Lodoxamide
Lofepramine

Lornoxicam (Chlortenoxicam)
Losartan and its salts
Lovastatin
Loxapine, and its salts
Lumefantrine except as specified in class C
Lumiracoxib
Lungworm disease vaccine V
Luprostol V
Lutropin alfa
Macrogol (polyethylene glycol), when used for faecal impaction, or for the purposes of bowel cleansing prior to surgery or diagnostic procedures, except when intended for the treatment of constipation.
Maduramycin V
Mafenide
Magnesium glutamate hydrobromide
Malathion V
Mandelic acid
Mannitol
Mannomustine, and its salts
Mebezonium, and its salts V
Mebutamate
Meclofenokate, and its salts
Marek's disease vaccine V
Maropitant V
Mazindol
Mebezonium and its salts V
Mebutamate
Meclofenamic acid, and its salts
Meclofenokate, and its salts
Mecloqualone
Medetomidine injection V
Medical gases, such as:
Carbondioxide
Medical air
Nitrogen
Nitrous oxide
Oxygen
Mefenamic acid, its salts and derivatives, except as specified in group II of this class. Mefenorex

Mefloquine, its salts and derivatives; in oral preparations intended for treatment of malaria infection
Melarsomine V
Melarsoprol
Melatonin, except as specified as specified in group II of this class
Meloxicam, its salts and derivatives except as specified in group II of this class.
Melphalan and its derivatives
Memantine
Meningococcal vaccine
Mepacrine
Mepenzolate bromide
Mephenesin, and its derivatives
Mepirizole
Mepivacaine and its salts, in preparations intended for parenteral use
Meprobamate
Meropenem, its salts and derivatives
Mesna
Mesocarb
Metamfetamine Racemate
Metaproterenol (Orciprenaline) when intended for the prevention or delay of labour and its preparations for injection, or when contained in respirator solutions
Metaraminol, and its salts
Metaxalone, and its salts
Metchlorothiazide
Metformin, its salts and derivatives
Methacholine
Methaqualone, and its salts
Methenamine (Hexamine)
Methimazole
Methisazone
Methixene; and its salts
Methocarbamol
Methohexital and its salts
Methotrexate, and its salts
Methoxyflurane
Methoxysalen
Methsuximide
Methy sulphonyl methane

Methyldopa and its salts
Methylene blue (Methylthioninium chloride), when used for treatment of methemoglobinemia
Methylone
Methylpentynol; its esters and other derivatives
Methylphenidate
Methyprylon
Metoclopramide and its salts
Metolazone and its salts
Metomidate and its salts
Metronidazole except as specified in group II of this class
Metoprolol and its salts
Mianserin
Mibefradil.
Miconazole, and its salts except as specified in group II of this class.
Milbemycin and its derivatives V
Miloxacin V
Milrinone and its salts
Mineral salts either alone or in combination,
(a) in preparations intended for parenteral use
(b) except as listed elsewhere in the schedules; when intended for correction of pH of body fluids or correction of electrolyte imbalances; except as specified in group II of this class and class C.
Minoxidil, except as specified in group II of this class
Mirosamycin V
Mirtazapine and its salts
Misoprostol
Mitomycin and its salts
Mitopodozide, its salts
Moclobemide
Modafinil
Monensin V except as specified in class C
Montelukast and its salts
Moracizine
Morantel V
Moxidectin V
Moxonidine
Mupirocin, except as specified in group II of this class
Mustine and any other N-substituted derivatives of di-(2-chloroethyl) amine; their salts

Mycophenolate mofetil, its derivatives and salts there of Nabilone
Nabumetone
Nadolol
Nadroparin
Naftidrofuryl oxalate
Nalorphine
Nalorphine, and its salts
Naloxone and its salts
Naltrexone
Nandrolone decanoate
Naphthalene-1-yl (1-Pentyl-1h-Indol-3-yl) Methanone
Naproxen, and its salts, except as specified in group II of this class.
Narasin V
Naratriptan
Natalizumab
Natamycin
Nateglinide, its salts and derivatives.
N-Benzylpiperazine
Nebivolol and its salts
Nedocromil
Neomycin and its salts; except as specified in group II of this class
Neostigmine and its salts
Nepafenac
Netilmicin
Netobimin V
Niacin (Nicotinic acid) when intended for hypercholesterolaemia
Nicarbazin V
Nicardipine
Niclosamide
Nicorandil
Nicotine, except as specified in group II of this class.
Nifedipine
Niflumic acid
Nifuroxazide
Nifurtimox
Nilotinib and its salts
Nimesulide
Nimodipine
Nimorazole

Nimotuzumab
Nitarsone
Nitazoxanide
Nitrofurazone (Nitrofural)
Nitroscanate V
Nitroxynil and its salts V
Nizatidine
Non-Nucleoside Reverse Transcriptase Inihibitors, and their salts such as;
- Delavirdine
- Doravirine
- Efavirenz
- Etravine
- Nevirapine
- Rilpirivine

Norepinephrine (Noradrenaline)
Nortryptyline; and its salts
Noscapine
Nosiheptide
Novobiocin and its salts
Nucleoside and Nucleotide Reverse Transcriptase Inihibitors, and their salts such as;
- Abacavir
- Didanosine
- Emtricitabine
- Lamivudine
- Stavudine
- Tenofovir
- Zalcitabine
- Zidovudine

Obidoxime
Octreotide and its salts
Olanzapine
Olaquindox V
Oleandomycin and its salts; its esters and their salts
Olmesartan, and its salts
Olsalazine
Omalizumab
Omeprazole and its salts, except as specified in group II of this class.
Ondansetron and its salts
Orf (Contagious ecthyma) vaccine V

Orlistat, except as specified in group II of this class
Ormetoprim, and its salts V
Ornidazole
Orphenadrine
Oxaliplatin
Oxantel V
Oxaprozin, its salts and derivatives.
Oxcarbazepine
Oxethazaine (oxetacaine) except as specified in group II of this class
Oxfendazole V
Oxibendazole V
Oxiconazole
Oxolinic acid V
Oxprenolol
Oxybuprocaine, and its salts
Oxybutynin
Oxyclozanide V
Oxyphenbutazone
Paclitaxel, and its derivatives
Paliperidone, its salts and derivatives
Palivisumab
Palonosetron
Pancreatic enzymes such as amylase, lipase and proteases
Pancuronium and its salts
Pantoprazole and its salts
Pantothenate injection
Papaverine, except as specified in group II of this class
Paracetamol, except as specified in group II of this class and class C
Paraldehyde
Paramethadione
Paromomycin and its salts, its esters and salts of such esters
Pargyline; and its salts
Paroxetine, and its salts
Parvaquone V
Pemoline, and its salts
Penbutolol
Penciclovir and its salts, except as specified in group II of this class.
Penicillamine
Penicillin antibiotics, their salts and derivatives (except as specified elsewhere in the schedules), such as:

Amoxicillin
Ampicillin
Azlocillin
Benethamine penicillin V
Benzathine penicillin
Benzylpenicillin
Carbenicillin
Cloxacillin
Dicloxacillin
Flucloxacillin
Hetacillin V
Mecillinam
Methicillin
Mezlocillin
Nafcillin
Oxacillin
Penethamate (hydroiodide) V
Penicllin G
Phenethicillin
Phenoxymethylpenicillin
Piperacillin
Procaine fortified penicillin
Temocillin
Ticarcillin
Tobicillin
Pentamidine, and its salts
Pentazocine, and its salts
Pentolinium
Pentoxifylline and its salts
Pepsin
Pericyazine and its salts
Perindopril
Peritoneal and haemoldialysis preparations
Perphenazine and its salts
Pestes des petits ruminants virus vaccine V
Phenacemide
Phenaglycodol
Phenamidine V
Phenazopyridine
Phenbutrazate

Phendimetrazine
Phenelzine and its salts
Phenindione
Phenmetrazine
Phenoxybenzamine
Phentermine
Phentolamine and its salts
Phenylbutazone and its salts
Phenylephrine, except as specified in group II of this class and class C
Phenylpropanolamine (norephedrine), except as specified in group II of this class
Phenytoin, and its salts
Pholedrine
Physostigmine, its salts and derivatives
Pilocarpine
Pimobendan
Pimozine.
Pindolol
Pioglitazone and its salts
Piperacetazine and its salts
Piperazine and its salts
Piperonyl V
Pipotiazine
Pipradrol
Piracetam
Pirbuterol
Pirlimycin and its salts V
Piroxicam, its salts and derivatives except as specified in group II of this class
Pituitary gland, the active principles of, whether natural or synthetic, such as:
Adrenocorticotrophic hormone
Anti-diuretic hormone
Chorionic Gonadotropin
Follicle-stimulating hormone
Follitropin alfa
Gonadorelin (Gonadotropin Releasing Hormone)
Growth hormone
Luteinising hormone
Melanocyte-stimulating hormone
Oxytocin

Prolactin
Thyroid-stimulating hormone
Poloxalene V
Polygeline
Polymyxin B, and its salts
Polysulfated glycosaminoglycan V
Polythiazide
Porcine parvovirus (PPV) Vaccine V
Porcine pneumonia Vaccine V
Potassium bromide
Potassium Iodide
Pralidoxime and its salts
Prasugrel
Pravastatin and its salts
Praziquantel
Prazosin and its salts
Pregabalin, its salts and derivatives
Pregnant Mare's Serum Gonadotropin V
Primaquine and its salts
Probenecid and its salts
Procainamide and its salts
Procarbazine, and its salts
Procaterol
Prochlorperazine
Procyclidine and its salts
Proguanil and its salts, except as specified in group II of this class
Promethazine, and its salts; except as specified in group II of this class
Propafenone, and its salts
Propentofylline
Propionylpromazine
Propofol
Propranolol, and its salts
Propylhexedrine; its salts
Protamine sulfate
Protease inihibitors, and their salts such as;
Amprenavir
Atazanavir
Darunavir
Fosamprenavir
Indinavir

Lopinavir
Nelfinavir
Pipranavir
Ritonavir
Saquinavir
Prothionamide
Prothipendyl, and its salts
Proxymetacaine, and its salts
Pseudoephedrine, except as specified in group II of this class and class C
Psilocybine
Purines, their salts and derivatives, whether natural or synthetic (except as specified elsewhere in the schedules)
Pyrantel, its salts and derivatives
Pyrazinamide
Pyridostigmine Pyrimethamine
Pyrimidines, their salts and derivatives, whether natural or synthetic (except as specified elsewhere in the schedules)
Pyronaridine and its salts
Pyrovalerone
Quetiapine, its salts and derivatives
Quinacrine
Quinapril
Quinapyramine V, its salts derivatives
Quinethazone
Quinidine and its salts
Quinine and its salts
Quinolones and fluoroquinoles, and their salts such as;
Ciprofloxacin
Danofloxacin V
Difloxacin V
Enrofloxacin V
Eprofloxacin V
Flumequine V
Flumequine V
Gatifloxacin
Levofloxacin
Lomefloxacin
Morbofloxacin V
Moxifloxacin
Nadifloxacin

Naldixic acid
Norfloxacin
Ofloxacin
Orbifloxacin V
Pefloxacin
Pradofloxacin V
Sarafloxacin V
Sparfloxacin
Rabeprazole and its salts
Rabies immunoglobulin
Racecadotril (acetorphan)
Radiopharmaceuticals, being radio compounds and radio-active labelled compounds, when used for diagnostic or therapeutic purposes, unless listed elsewhere in the schedules
Rafoxanide V
Raloxifene and its salts
Ramipril, its salts and derivatives
Ranibizumab
Ranitidine, and its salts except as specified in group II of this class
Ranolazine
Raubasine and its salts
Rauwolfia alkaloids, salts and derivatives
Remoxipride and its salts
Repaglinide, its salts and derivatives
Reproterol
Reserpine
Ribavirin
Ricobendazole V
Rifamycins, their salts, their esters and salts of such esters, including:
Rifabutin
Rifampicin
Rifapentine
Rifaximin
Rimiterol
Risedronate sodium
Risperidone and its salts
Ritodrine and its salts
Rituximab
Rivaroxaban
Rizatriptan

Robenacoxib V
Robenidine V
Rocuronium and its salts
Roflumilast
Romifidine, and its salts V
Ronidazole, its salts and derivatives V
Ropinirole
Rose Bengal
Rosiglitazone and its salts
Rosuvastatin and its salts
Roxarsone V
Roxatidine
Roxithromycin
Ruxolitinib
Salbutamol, except as specified in group II of this class and in class C
Salinomycin V
Salmeterol and its salts
Salmonellosis/Fowl Typhoid vaccine V
Saxagliptin
Scorpion anti-venom
Secnidazole
Sedecamycin V
Selamectin V
Selegiline and its salts
Semduramicin V
Sertaconazole and its salts
Sertindole
Sertraline and its salts
Sevelamer hydrochloride
Sevoflurane
Sheep pox virus vaccine V
Sildenafil and its salts
Simethicone, except as specified in group II of this class
Simvastatin
Sirolimus
Sitagliptin
Sitaxentan and its salts
Snake anti-venom
Sofosbuvir
Sodium chloride when formulated alone in preparations intended for parenteral

or oral use
Sodium iodide
Sodium nitroprusside and its salts
Sodium oxybate
Sodium stibogluconate
Sodium thiosulphate
Sodium valproate
Sofosbuvir
Solifenacin
Solutions for parentral nutrition (glucose, protein hydrolysates, aminoacids or lipid/fat emulsions)
Solutions of carbohydrates or proteins, synthetic or natural substances used for injection as plasma volume expanders
Sorbitol, in preparations intended for parenteral administration
Sotalol and its salts
Spectinomycin, its salts and derivatives
Spiramycin and its salts
Streptomycin, its salts, its derivatives and their salts
Fosfomycin (Sulphomycin), its derivatives and their salts
Spironolactone
Streptogramins their salts, derivatives and their salts; including:
Dalfopristin
Pristinamycin
Quinupristin
Virginiamycin
Streptokinase
Streptozocin
Strontium and its salts, when indicated for oral use for the treatment of osteoporosis in adults
Strychnine V
Styramate
Substances commonly known as vaccines, sera, toxins, anti-toxins and antigens; if not listed anywhere in the schedules
Sucralfate
Sulbactam
Sulconazole and its salts
Sulfonamide antibiotics, their salts, derivaties and salts thereof; (except as specified elsewhere in the schedules) such as:
Phthalylsulfathiazole V
Succinylsulfathiazole

Sulfacetamide
Sulfachlorpyridazine
Sulfadiazine
Sulfadimerazin V
Sulfadimethoxine
Sulfadimidine
Sulfadoxine
Sulfafurazole V
Sulfaguanidine
Sulfamerazine
Sulfamerazine V
Sulfamethazine
Sulfamethazine V
Sulfamethoxazole
Sulfamethoxine
Sulfamethoxypyridazine
Sulfamonomethoxine
Sulfanilamide
Sulfapyridine
Sulfaquinoxaline
Sulfasalazine
Sulfathiazole
Sulfisoxazole
Sulindac and its salts.
Sulphinpyrazone and its salts
Sulphones; their salts and derivatives such as Dapsone
Sulpiride
Sumatriptan and its salts
Suramin
Suxamethonium and its salts
Sylimarin
Syrosingopine, and its salts
Tacrolimus and its salts
Tadalafil and its salts
Tafluprost
Tamsulosin and its salts
Tasonermin
Taurolidine
Tazarotene
Tazobactam

Teflubenzuron
Tegaserod and its salts
Teicoplanin
Telbivudine
Telithromycin, its salts and derivatives and salts thereof
Telmisartan, its salts and derivatives and salts thereof
Temozolomide
Temsirolimus
Tenecteplase
Teniposide
Tenocyclidin
Tenoxicam, and its salts
Terazosin and its salts
Terbinafine, except as specified in group II of this class
Terbutaline, and its salts except as specified in group II of this class
Terconazole and its salts
Terdecamycin V Terfenadine and its salts Teriparatide and its salts. Tetanus immunoglobulin
Tetrabenazine, and its salts
Tetracaine (Amethocaine), and its salts, except as specified in group II of this class and class C
Tetracyclines, their salts, derivatives and their salts, (except as listed anywhere else in the schedules), including:
Chlortetracycline
Demeclocycline (Demethylchlortetracycline)
Doxycycline
Lymecycline
Methacycline
Minocycline
Oxytetracycline Rolitetracycline
Tetracycline
Tigecycline
Tetramisole V
Thalidomide, and its salts
Theophylline, and its salts
Thiabendazole V
Thiacetazone, its salts; its derivatives and salts thereof
Thiamphenicol
Thiocarlide, and its salts
Thioctic acid (thioctacid)

Thioguanine
Thiopropazate and its salts
Thioproperazine and its salts
Thyroid gland; its active principles, their salts and derivatives thereof; whether natural or synthetic, such as:
Desiccated thyroid
Levothyroxine sodium
Liothyronine
Thyroglobulin
Thyroid extract
Thyrotropin
Thyrotropin alfa
Thyroxin
Tri-iodothyronine
Tiamulin V
Tiaprofenic acid and its salts
Tibolone
Tildipirosin V
Tiletamine
Tilmicosin
Timepidium, except as specified in group II of this class
Timolol and its salts
Tinidazole
Tinzaparin and its salts
Tioconazole, except as specified in group II of this class
Tiotropium bromide
Tirofiban, its salts and derivatives
Tizanidine and its salts
Tobramycin, its salts and derivatives
Tolazamide
Tolazoline and its salts
Tolbutamide
Tolfenamic acid, its salts and derivatives
Tolmetin and its salt
Tolperisone and its salts
Toltrazuril V
Tolvaptan
Topiramate
Topotecan
Meprobamate

Mercaptopurine, and its salts, derivatives of mercaptopurine, their salts
Mescaline, and other derivatives of phenethylamine formed by substitution in the aromatic ring, their salts
Torasemide (torsemide) and its salts
Tramadol hydrochloride
Trandolapril, its salts and derivatives
Tranexamic acid
Trastuzumab
Travoprost
Trazodone and its salts
Tretamine, and its salts
Tretinoin, its salts and derivatives
Triamterene, and its salts
Triaziquone; its salts
Tricaine and its salts
Trichlormethiazide
Triclabendazole V
Trifluoperazine and its salts
Triflupromazine, and its salts
Trifluridine
Trilostane V
Trimeprazine (Alimemazine) its salts and derivatives V
Trimethadione (Troxidone)
Trimethoprim
Trimipramine and its salts
Tryptan blue solution for opthalamic use
Vasopressin, its analogues, whether natural or synthetic; such as Desmopressin and Terlipressin
Tuberculin
Tubocurarine
Tulathromycin V
Tulobuterol
Tybamate
Tylosin V
Tylvalosin V
Typhoid vaccine
Tyrothricin, except as specified in group II of this class.
Viomycin and its salts
Ulinastatin
Unoprostone, its salts and derivatives

Uracil, salts of, when sold for treatment of cancer
Urokinase
Ursodeoxycholic acid and its salts
Valacyclovir and its salts
Valdecoxib and its salts
Valganciclovir, its salts and derivatives
Valnemulin V
Valrubicin and its derivatives
Valsartan, its salts and derivatives
Vancomycin, its salts and derivatives
Vardenafil and its salts
Varicella immunoglobulin
Varicella–zoster virus vaccine
Vasoactive intestinal polypeptide
Vecuronium
Vedaprofen, its salts and derivatives
Velpatasvir
Venlafaxine and its salts
Verapamil (Iproveratril) and its salts
Vildagliptin
Vinca alkaloids, their salts and derivatives; such as:
Vinblastine and its salts
Vincamine
Vincristine and its salts
Vindesine
Vinorelbine
Vinpocetine
Viomycin, its salts and derivatives
Viral neuraminidase enzyme inhibitors, the following—
    Laninamivir, and its salts and derivatives
    Oseltamivir, and its salts and derivatives
    Peramivir, and its salts and derivatives
    Zanamivir, and its salts and derivaties
Vitamins either alone or in combination, in preparations intended for injection
Xanthinol nicotinate
Xipamide
Xylazine and its salts
Yersinia ruckeri vaccine V
Zafirlukast and its salts
Zaleplon

Zeranol
Zinc sulphate in preparations intended for ophthalmic use
Zipeprol
Zofenopril
Zoledronic acid and its salts
Zolpidem
Zopiclone and its salts
Zuclopenthixol and its salts
Any drugs derived from any of the drugs referred to in this schedule, unless expressly excluded or unless listed in another schedule.
Any drug or preparation not listed in the schedules.
Herbal drugs, including plant parts, crude extracts, tinctures, mixtures, decoctions, concoctions; and processed or semi-processed derivatives thereof; (unless expressly excluded or unless listed in another schedule) in preparations intended for parenteral administration.

GROUP II

The following drugs and preparations containing such drugs may be supplied by retail only by a licensed person.
Acetylcysteine, in preparations intended for oral use when labelled with a recommended daily dose not exceeding 1000 milligrams.
Acetyldihydrocodeine - oral solid preparations, in combination with one or more therapeutically active substances, and containing 20 milligrams or less of acetyldihydrocodiene (calculated as base) per dosage unit; and liquid oral preparations and mixtures, in combination with one or more therapeutically active substances, and containing 0.4 percent w/v of acetyldihydrocodeine (calculated as base).
Acetylsalicylic acid and its salts, in preparations intended for rectal application in strengths of more than 150 milligrams per dosage unit, but not exceeding 600 milligrams per dosage unit Acrivastine
Alginic acid and its salts
Alverin
Ambroxol Hydrochloride
Amidines acaricides V such as Amitraz and Cymiazole
Amino acids, in preparations intended for oral use, in concentrations exceeding the recommended dietary allowances
Aminopentamide V
Amodiaquine, when contained in preparations intended for oral use

Amoxicillin and its salts, when combined with Clavulanic acid and its salts; in preparations intended for oral use, for a treatment period not below 5 days and not exceeding 7 days
Amylocaine and its salts, in preparations intended for topical use
Antazoline and its salts
Artesunate, in preparations intended for oral administration
Atovaquone and its salts, in oral preparations intended for use in malaria prophylaxis
Atropine; except as specified in group I of this class
Attapulgite
Azatadine
Azelastine

Bacitracin and its salts and derivatives, in preparations intended for application to the skin
Bamipine
Beclomethasone dipropionate, when intended for nasal administration as an aqueous spray for use in adults and children over 12 years of age, subject to—
(a) maximum dose of 100 micrograms per nostril and a maximum daily dose of 200 micrograms of beclomethasone per nostril; and
(b) a maximum pack size of 200 doses
Benfotiamine and its salts
Benproperine V
Benzocaine and its salts, when intended for topical application
Benzoyl peroxide, when intended for topical application
Benzydamine, and its salts
Betamethasone valerate either alone or in combination with one or more drugs listed in this group or in class C, in concentrations not exceeding 0.5 percent w/w in preparations intended for topical administration
Beta-sitosterol in preparations intended for topical application
Bifonazole, when intended for application to the skin
Bisacodyl and its salts
Bismuth subgallate
Bitolterol
Bromhexine and its salts
Bromodiphenhydramine
Brompheniramine
Buclizine

Bufexamac, in preparations intended for topical use
Butinoline
Butoconazole in preparations intended for topical administration

Caffeine—

(a) in combination with one or more other drugs listed in this group; in concentrations not exceeding 65 milligrams per dosage unit.

(b) in combination with one or more other drugs listed in class C; in concentrations exceeding 65 milligrams per dosage unit.

Cantharidin and its derivatives
Carbachol
Carbinoxamine and its salts
Carbocisteine
Casanthranol
Cefalexin, in preparations intended for oral use, for a maximum treatment duration of 7 days.
Celecoxib and its salts
Cepae fluid extract
Clioquinol, in preparations intended for ophthalamic and topical administration
Chlorcyclizine and its salts
Chlorfenvinphos V
Chloroquine, in oral preparations intended for malaria prophylaxis
Chlorpheniramine, and its salts in preparations intended for oral or topical use
Chlorzoxazone
Choline Salicylate
Chondroitin and its salts
Cinchocaine when contained in preparations intended for rectal administration
Cinnarizine
Clemastine
Clemizole
Clidinium bromide
Clobetasol and its salts, either alone or in combination with one or more drugs listed in this group or in class C; in concentrations not exceeding 0.05 percent w/w in preparations intended for application to the skin
Clobetasone and its salts, either alone or in combination with one or more drugs listed in this group or in class C; in concentrations not exceeding 0.05 percent w/w in preparations intended for application to the skin
Codeine (methylmorphine):

(a) in oral solid preparations, in combination with one or more drugs listed in this group or in class C, in concentrations not exceeding 10 milligrams (calculated as base) per dosage unit; in pack sizes not exceeding 10 dosage units.

(b) In liquid oral preparations and mixtures, in combination with one or more drugs listed in this group or in class C, in concentrations not exceeding 0.2 percent w/w, in pack sizes not exceeding 100 millilitres.

Cromoglycic acid and its salts in solutions of sodium cromoglycate in concentrations not exceeding 2 percent w/v or less, for ophthalmic or intranasal use

Cyclizine, in preparations intended for oral use

Cyproheptadine and its salts

Dehydroemetine; its salts

Demeton-S-methyl

Desloratadine and its salts

Dexamethasone,

(a) either alone or in combination with one or more drugs listed in this group or in class C, in concentrations not exceeding 1 percent w/w in preparations intended for topical or ophthalmic use or in concentrations not exceeding 0.01 percent w/v in preparations intended for oral use

(b) as the only active therapeutic substance when contained in oral solid dosage forms not exceeding 0.5 milligrams per dosage unit

Dexchlorpheniramine

Dextroketoprofen

Dextromethorphan, and its salts except as specified in class C

Dextrorphan, and its salts

Diastase

Dichlorvos

Diclofenac when contained in:

(a) preparations intended for topical use in concentrations exceeding 1.16 percent w/w

(b) preparations intended for rectal administration

(c) oral solid dosage, immediate release preparations containing not more than 50 milligrams per dosage unit, in pack sizes not exceeding 10 dosage units.

(d) oral solid dosage, modified release preparations containing not more than 100 milligrams per dosage unit, in pack sizes not exceeding 10 dosage

units.
Dicyclanil V
Dicycloverine (Dicyclomine) and its salts, intended for topical use Dihydroartemisinin
Dihydrocodeine—

(a) oral solid preparations, in combination with one or more drugs listed in this group or in class C, in concentrations not exceeding 20 milligrams (calculated as base) per dosage unit; or
(b) liquid oral preparations and mixtures, in combination with one or more drugs listed in this group or in class C, in concentrations not exceeding 0.4 percent w/w (calculated as base).

Dimenhydrinate and its salts for oral use
Dimethicone, its salts and derivatives when contained in oral liquid, oral solid or topical preparations
Dimethoxanate
Diosmectite
Diphenhydramine and its salts
Diphenylpyraline
Docusate
Doxylamine melilotus officinalis extract

Ebastine
Emedastine
Ephedrine, and its salts in:

(a) concentrations not exceeding 1 percent w/v in preparations intended for nasal administration for a maximum treatment period of 5 days.
(b) concentrations not exceeding 0.15 percent w/v in liquid preparations intended for oral use, with daily doses not exceeding 50 milligrams.

Epinastine
Ergotamine tartarate, in oral preparations in concentrations not exceeding 2 milligrams per dosage unit, with a maximum daily dose of 6 milligrams and no more than 10 milligrams per week
Esomeprazole and its salts, in oral preparations in concentrations not exceeding 20 milligrams per dosage unit when intended for a treatment period not exceeding 10 days
Etofenamate
Euphorbia prostata extract

Famotidine, in oral solid dosage forms in concentrations not exceeding 20 milligrams per dosage unit, in packs containing not more than 30 dosage units.

Fenchlorphos V

Fexofenadine in preparations intended for oral use

Fluconazole in single dose oral preparations containing 150 milligrams or less of Fluconazole for the treatment of vaginal candidiasis

Flurbiprofen:

(a) in preparations intended for topical use

(b) when intended for oral use in concentrations not exceeding 100 milligrams per dosage unit, and a maximum daily dose not exceeding 300 milligrams for a maximum treatment period of 5 days

Fluticasone propionate, when intended for nasal administration as an aqueous spray for use in adults and children over 12 years, subject to a maximum daily dose of 100 micrograms per nostril and a maximum pack size of 120 dosage units.

Gentamycin sulphate in concentrations not exceeding 0.1 percent w/w in preparations intended for application to the skin and in concentrations not exceeding 0.3 percent w/v in preparations intended for application to the eye

Ginkgo biloba extract

Glycerine (Glycerol)

Gramicidin, its salts and derivatives in preparations intended for application to the skin

Griseofulvin, in preparations intended for oral or topical use

Heparin and its salts, when intended for topical use

Homatropine and its salts when intended for oral use in concentrations not exceeding 2 milligrams per dosage unit

Hormones (natural or synthetic, including recombinant forms), with either hormonal, prohormonal or anti-hormonal action:

(a) as Levonorgestrel in concentrations of 1.5 milligrams or less per oral dosage unit, intended for emergency postcoital contraception, in pack sizes containing not more than 1.5 milligrams of levonorgestrel

(b) in oral preparations, either alone or in combination; when intended for emergency postcoital contraception

(c) when intended for oral contraception, except as specified in class C

Hyaluronic acid and its salts when intended for ophthalmic use ın concentrations not exceeding 0.1 percent w/v

Hydroquinone; preparations and mixtures containing 2 percent or less thereof, when intended for application to the skin, and indicated for management of melanin hyperpigmentation.

Hydroxyethylcellulose, in preparations intended for ophthalmic use Hydroxyethyl starch, and its derivates in preparations intended for ophthalamic use

Hydroxypropylmethylcellulose (Hypromellose), in preparations intended for ophthalmic use

Hyoscine and its salts; when contained in transdermal preparations or oral preparations

Ibuprofen when contained in oral medicinal preparations in combination with one or more drugs listed in this group or in class C, in packs not exceeding 100 millilitres in volume or in solid preparations in packs not exceeding 10 dosage units, where the recommended daily dose of ibuprofen in the case of adults and children over 12 years does not exceed 1200 milligrams and in children from the age of 6 months up to 12 years does not exceed 20 milligrams per kilogramme of body weight.

Indomethacin, when intended for topical or rectal application

Ipecacuanha tincture

Ispaghula husk

Isoaminile, and its salts

Isothipendyl

Ketoconazole, in preparations intended for application on the skin ın concentrations not exceeding 2 percent w/w

Ketoprofen:

(a) in preparations intended for topical use

(b) when intended for oral use in concentrations not exceeding 25 milligrams per dosage unit, in pack sizes not exceeding 30 dosage units.

Lactulose

Lansoprazole and its salts, in oral solid dosage forms in concentrations not exceeding 30 miligrams per dosage unit, in packs containing not more than 10 dsage units.

Levocabastine, in preparations intended for ophthalmic application or nasal administration
Levocetirizine and its salts
Levosalbutamol when contained in pressurized aerosol preparations in concentrations not exceeding 50 micrograms per dosage unit, in pack sizes not exceeding 200 metered doses
Lidocaine in preparations for topical use other than eye drops
Lithium salts, when intended for application to the skin
Loratadine and its salts

Macrogol (polyethylene glycol), when contained in preparations intended for oral or vaginal administration.
Magnesium citrate, intended for oral use as a purgative
Magnesium salicylate
Magnesium sulphate, in preparations intended for oral use, use as a laxative
Mebeverine
Mebhydrolin
Meclizine (Meclozine) and its salts
Mecysteine
Mefenamic acid as the only therapeutically active substance in oral formulations, when intended for use in adults and children over the age of 12 years, subject to a maximum daily dose of 1500 millligrams and a maximum treatment period of 5 days.
Mefloquine, its salts and derivatives; in oral preparations intended for prophylaxis against Malaria infection
Melatonin, when used for the treatment of desyncronosis (jet-lag) in doses not exceeding 6 milligrams daily
Meloxicam, its salts and derivatives, in preparations intended for oral use, for a maximum treatment period of 5 days in adults and children aged 12 years and above, where the maximum daily dose does not exceed 15 milligrams.
Mepivacaine and its salts when intended for topical use
Mequitazine
Mercury, preparations and mixtures that contain mercury metal and that are intended for external use in concentrations not exceeding 0.5 percent of mercury
Metamizole (Dipyrone)
Metaproterenol (orciprenaline), except as specified in group 1 of this class. Metronidazole when contained in preparations:
(a) intended for topical application

(b) intended for oral administration as solid dosage forms, in concentrations not exceeding 400 milligrams per dosage unit, and supplied for a treatment duration not exceeding 7 days

(c) intended for oral administration as liquid dosage forms, in concentrations not exceeding 4 percent w/v, in pack sizes not exceeding 100 millilitres.

Methylprednisolone and its salts, in concentrations not exceeding 0.25 percent w/w when contained in preparations intended for application to the skin

Miconazole, when contained in preparations:

(a) intended for application to the skin; and

(b) intended for human vaginal use, specifically for the treatment of vaginal candidiasis; and

(c) intended for human use in preparations containing 2 per cent or less of miconazole, when intended for the topical treatment of fungal infections of the mouth (oral candidiasis).

Mineral salts except as listed elsewhere in the schedules, either alone or in combination with vitamins, amino acids or other micronutrients as specified in this group, in preparations intended for oral use in concentrations above the recommended dietary allowances

Minoxidil, when contained in topical preparations, in concentrations not exceeding 5 percent w/v

Mizolastine

Mometasone furoate, when intended for nasal administration as an aqueous spray for use in adults and children above the age of 2 years, subject to:

(a) a maximum dose of 200 micrograms per nostril in adults and 50 micrograms per nostril in children; and

(b) a maximum pack size of 200 doses.

Mupirocin, in preparations intended for application to the skin

Naphazoline except as specified in class C

Naproxen:

(a) in preparations intended for application to the skin

(b) in oral solid dosage forms, in concentrations not exceeding 500 milligrams per dosage unit, and in packs containing not more than 20 dosage units.

Neomycin and its salts, in concentrations not exceeding 0.5 percent w/w in preparations intended for topical or opthalamic administration.

Nialamide, its salts

Nicotine when intended for human medicinal use as an aid to smoking

cessation, and presented:

(a) as nicotine gum or lozenges containing not more than 4 milligrams of Nicotine per piece,

(b) as metered sprays containing 1 milligram per dose or less, as nicotine transdermal patches for continuous application to the skin in strengths not exceeding 25 milligrams per 24 hours,

(c) as oral solid dosage forms containing 2 milligrams or less, or

(d) as inhalers containing 10 milligrams or less per cartridge.

Nitrofurantoin

Nonoxynol-9

Norcodeine-oral solid preparations, in combination with one or more therapeutically active substances, and containing 20 milligrams or less of Norcodeine (calculated as base) per dosage unit; or liquid oral preparations and mixtures, in combination with one or more therapeutically active substances, and containing 0.4 percent w/v or less of norcodeine (calculated as base).

Octatropine methylbromide Olopatadine and its salts omeprazole and its salts, in oral solid dosage forms in concentrations not exceeding 20 milligrams per dosage unit, in packs containing not more than 10 dosage units.

Orlistat, in oral preparations containing not more than 60 milligrams per doage unit, and indicated for weight loss in overweight adults with a body mass index greater or equal to 28 kilogrammes per square meter, in doses not exceeding 180 milligrams per day.

Orphenadrine citrate

Orthocaine; its salts

Otilonium bromide

Ouabain

Oxatomide

Oxethazaine when contained in antiacid or antihemorroidal preparations

Oxymetazoline and its salts, in preparations intended for nasal administration

Oxyphencyclimine

Oxyphenonium

Papain (Papaya proteinase 1)

Papaverine; substances, preparations and its mixtures for oral use

Paracetamol:

(a) as the only active therapeutic substance in immediate release oral or rectal formulations containing more than 500 milligrams per

dosage unit, where the recommended cumulative daily dose does not exceed 4000 milligrams

(b) as the only active therapeutic substance in modified release formulations

(c) in combination with one or more drugs listed in this group or in class C, in a solid dosage form contained in packs not exceeding 10 dosage units, for use in adults and children over 12 years of age where the cumulative daily dose of Paracetamol does not exceed 3250 milligrams.

(d) in combination with one or more drugs listed in this group or in class C in oral liquid preparations containing Paracetamol in a strength of not more than 5 percent w/v, in packs not exceeding 100 millilitres, intended for use in children aged 3 months and above.

Penciclovir and its salts, in preparations intended for topical use for the treatment of herpes simplex virus infections of the lips and face (Herpes labialis) in adults and children over 12 years of age.

Pentoxyfylline

Peppermint (Mentha piperita) including leaf and oil when intended for oral or topical use

Phenazone (antipyrine).

Phenazopyridine

Phenindamine

Pheniramine

Phenylephrine, either alone or in combination with any other drug listed in this schedule or in class C; when contained in:

(a) preparations for topical or rectal application

(b) solid preparations intended for oral use, in concentrations not exceeding 20 milligrams per dosage unit

(c) when contained in oral liquid preparations not exceeding 0.4 percent w/v

Phenylpropanolamine (norephedrine), preparations and mixtures where the recommended daily dose for adults does not exceed 100 milligrams and for children 6 to 12 years does not exceed 50 milligrams, when intended for the symptomatic relief of nasal and sinus congestion

Phenyltoloxamine and its salts

Pholcodine, either alone or in combination with one or more drugs listed in this schedule or in class C in oral preparations in concentrations not exceeding 20 milligrams per dosage unit or 0.4 percent w/v.

Pimethixene, preparations and mixtures thereof when used solely as an antihistamine

Pinaverium

Pipenzolate

Piperaquine and its salts

Pipoxolan

Piroxicam, its salts and derivatives in oral dosage forms in concentrations not exceeding 20 milligrams per dosage unit, in pack sizes not exceeding 10 dosage units.

Pizotifen, preparations and mixtures, when intended for prophylaxis of migraine

Podophyllum resin, preparations and mixtures containing 20 percent or less.

Potassium permanganate

Povidone iodine, for ophthalmic use

Prifinium bromide

Probiotics, containing microrganisms such as; Lactobacillus acidophilus, Bifidobacterium infantis, enterococcus faecium and Saccharomyces boulardii

Proglumide

Proguanil, in oral preparations intended for malaria prophylaxis

Promethazine, when intended for use:

(a) in preparations for application to the skin

(b) in preparations for oral use containing not more than 25 milligrams per dosage unit for solid formulations, and not more than 0.1 percent w/v for liquid formulations.

Propantheline bromide

Propyphenazone

Pseudoephedrine, either alone or in combination with one or more drugs listed in this group or in class C, when contained in:

(a) oral solid dosage forms in concentrations not exceeding 120 milligrams per dosage unit

(b) oral liquid dosage forms in concentrations not exceeding 1.2 percent w/v.

Pyrethrins V, their salts and derivaties such as;

Alphacypermethri

n Cyhalothrin

Cypermethrin

Deltamethrin

Flumethrin

Permethrin

Pyrethrin
Pyrrobutamine

Ranitidine and its salts, when contained in oral solid dosage forms at a concentration not exceeding 150 milligrams per dosage unit in pack sizes containing not more than 30 dosage units.
Retapamulin, when intended for topical application to the skin, nares and external ear
Rupatadine and its salts

Salbutamol:
(a) when contained in pressurized aerosol preparations in concentrations not exceeding 200 micrograms per dosage unit, in pack sizes not exceeding 200 metered doses
(b) either alone or in combination with any drug listed in this group or in class C, in oral liquid preparations in concentrations not exceeding 0.04 percent w/v
Serratiopeptidase
Silver nitrate, when intended for topical application
Silymarin
Simethicone, its salts and derivatives when contained in oral liquid, oral solid or topical preparations
Sodium bisphosphate when contained in oral and rectal preparations, and intended for use as a purgative
Sodium chlorate
Sodium chloride when formulated at a concentration on 0.9 percent w/v, in preparations intended for ocular irrigation
Sodium phosphate when contained in oral and rectal preparations, and intended for use as a purgative
Sorbitol, except as specified in group II of this class
Sulfotep

Terbinafine and its salts, in preparations intended for topical administration
Terbutaline, either alone or in combination with any drug listed in this group or in class C, in oral liquid preparations in concentrations not exceeding 0.05 percent w/v
Tetracaine when contained in preparations intended for oral, rectal or topical application to the skin
Tetracycline and its salts, in preparations intended for topical administration
Tetrahydrozoline for ophthalamic use

Thiethylperazine, in oral preparations for relief of nausea and vomiting
Tiaprofenic acid, in concentrations not exceeding 300 milligrams per dosage unit when intended for a maximum treatment period of 5 days
Timepidium in preparations intended for oral use
Tioconazole and its salts in preparations intended for application to the skin and in preparations intended for intra-vaginal use
Tolpropamine
Triamcinolone acetonide when contained in nasal spray formulations delivering not more than 55 micrograms per spray, intended for use by adults and children over the age of 12 years.
Tribenoside when contained in preparations intended for rectal administration
Tricholine
Trichloroacetic acid.
Trimebutine
Tripelennamine
Triprolidine, except as specified in class C
Trospium
Tyrothricin, when used in oral preparations for symptomatic relief of soar throat

Urea when contained in preparations intended for application on the skin

Vaccines, sera, toxins, antitoxins and antigens for human use; except as specified elsewhere in the schedules; the following:
Diphtheria toxoid vaccine
Haemophilus influenza vaccine
Hepatitis B vaccine
Human papillomavirus vaccine
Influenza virus vaccine
Mumps vaccine
Pertussis toxoid vaccine
Pneumococcal vaccine, conjugated Pneumococcal vaccine, polysaccharide
Polio vaccine
Rabies antisera
Rabies vaccine
Rota virus vaccine
Rotavirus, live attenuated vaccine
Rubella vaccine
Tetanus toxoid vaccine

Tuberculosis (Bacillus Calmette--Guérin) vaccine
Yellow fever vaccine
Vaccines, sera, toxins, antitoxins and antigens for veterinary use; except as specified elsewhere in the schedules; the following:
Bovine Contagious Pleuropneumonia vaccine V
Foot and Mouth disease vaccines V
Lumpy Skin disease vaccine V
Newcastle disease vaccine V
Rinderpest vaccine V
Rabies vaccine V
Vitamin B1 (Thiamine), and its derivatives; in preparations intended for oral use
Vitamin B2 (Riboflavin), and its derivatives; in preparations intended for oral use
Vitamin B3 (Niacin), and its derivatives; in preparations intended for oral use
Vitamin B5 (Pantothenic acid), and its derivatives; in preparations intended for oral use
Vitamin B6 (Pyridoxine), and its derivatives; in preparations intended for oral use
Vitamin B12 (Cobalamin), and its derivatives; in preparations intended for oral use
Vitamins (except as specified elsewhere in the schedules), either alone or in combination, in preparations intended for oral use, ın concentrations above the recommended dietary allowances.

Water for injection
Water for irrigation

Xylometazoline; in preparations intended for nasal administration

Yohimbe, alkaloids of, such as Yohimbine
Zinc pyrithione, in preparations intended for topical use
Herbal drugs, including plant parts, crude extracts, tinctures, mixtures, decoctions, concoctions; and processed or semi-processed derivatives thereof; (unless expressly excluded or unless listed in another schedule) in preparations intended for topical or oral use; except as specified in class C. Any substances derived from any of the medicines referred to in this schedule, unless expressly excluded.

Schedule 4

Sections 12, 60(2)

Class C Drugs

The following drugs, except such as are in a form suitable for administration by injection are the drugs included in this Schedule. They may be sold by retail only by a person or company operating as a licensed person or a licensed seller, but in the case of the latter only in accordance with the terms of his or her license.

GROUP I

Acetylsalicylic acid and its salts:

(a) in preparations intended for application on the skin

(b) either alone or in combination with one or more drugs listed in this class, intended for oral use in concentrations ranging from 300 milligrams to 600 milligrams per dosage unit subject to a maximum daily dose of 2400 milligrams subject to a maximum treatment period of 5 days.

Acriflavine
Activated charcoal
Acyclovir and its salts, in preparations intended for topical use
Albendazole in preparations intended for oral use
Alexidine
Allantoin
Ammonium chloride, except as specified in group I of this class
Amoxicillin, its salts; in preparations intended for oral use
Amylmetacresol
Antacid preparations containing compounds such as;
Aluminium hydroxide
Bismuth salts
Calcium carbonate
Magaldrate
Magnesium carbonate
Magnesium hydroxide
Magnesium sulphate
Magnesium trisilicate
Sodium alignate
Sodium bicarbonate
Sodium carbonate

Anti histamines as listed in class B group II but only when contained in preparations for external application only other than for the eyes or nose and in preparations containing not less than 1 percent

Antibiotics, when contained in preparations or concentrates for animal feedstuffs

Arsenic, in preparations containing less than the equivalent of 0.01 percentof arsenic trioxide, and dentifrices containing less than 0.5 percent of acetarsol

Artemether in combination with Lumefantrine, in oral preparations for parasitologically diagnosed uncomplicated malaria

Artesunate, in preparations intended for rectal administration

Benzalkonium, and its salts

Benzocaine, when contained in lozenge preparations

Benzoic acid

Benzyl Alcohol

Benzyl benzoate for topical use

Boric acid for topical use

Brucine, when contained in surgical spirit containing not more than 0.2 percent of brucine

Caffeine, in combination with one or more other drugs listed in this class; in concentrations not exceeding 65 milligrams per dosage unit.

Calamine lotion

Camphor oils in preparations intended for topical use

Candicidin

Castor oil

Cetalkonium, and its salts

Cetirizine and its salts

Cetrimide

Cetylpyridinium chloride

Chlorhexidine and its salts

Chloramphenicol in preparations formulated as eye/ear drops

Chloroform, in preparations containing not more than 0.5 percent w/v of chloroform

Citric acid

Clotrimazole

Coal tar

Crotamiton

Dexpanthenol in preparations intended for topical use
Dextromethorphan when contained in oral preparations in concentrations not exceeding 10 milligrams per dosage unit or 0.2 percent w/v
2, 4 dichlorobenzyl alcohol
Diazepam, in preparations intended for rectal administration Dichlorophen
Diclofenac when contained in preparations intended for topical use ın concentrations not exceeding 1.16 percent w/w
Didecyl dimethyl ammonium chloride
Dinitolmide V
Dioctyl dimethyl ammonium chloride enilconazole, for topical use

Erythromycin and its salts, in preparations intended for oral use
Ethanol, in concentrations exceeding 70 percent w/v in preparations intended for oral or topical use
Ethinyl estradiol when used in combination with levonorgestrel in oral preparations intended for contraception
Ethylenediamine dihydroiodide V

Fenbendazole V
Ferric and ferrous salts, and their combinations when contained in preparations for oral use
Fipronil V when used in spot-on solutions for topical use in concentrations not exceeding 10 percent w/v
Folic acid

Gentian Violet
Glutaraldehyde, when contained in topical preparations in concentrations not exceeding 10 percent w/w Guaifenesin (Glyceryl guaiacolate)

Hyaluronic acid and its salts, when contained in topical preparations
Hydrocortisone either alone or in combination with one or more drugs in this class, in concentrations not exceeding 1 percent w/w in preparations intended for application to the skin.
Hydrogen peroxide solution for topical use
Hyoscyamine, in preparations containing less than 0.15 percent of hyoscyamine in preparations intended for topical use
Ibuprofen:

(a) when contained in preparations intended for application to the skin

(b) as the only active therapeutic substance, in a solid dose form contained in packs not exceeding 20 dosage units for use in adults and children over 12 years of age where the recommended daily dose of ibuprofen does not exceed 1200 milligrams

(c) when contained in oral liquid preparations as the only active therapeutic substance in packs not exceeding 100 millilitres in volume when intended for children over the age of 1 year but not exceeding 12 years; where the recommended daily dose of ibuprofen does not exceed 20 milligrams per kilogramme of body weight

(d) in combination with one or more drugs listed in this Schedule, in a solid dose form contained in packs not exceeding 10 dosage units, for use in adults and children over 12 years of age where the recommended daily dose of ibuprofen does not exceed 1200 milligrams

Idoxuridine, when intended for application to the skin
Iodine tincture, for topical use
Isopropanol

Kaolin
Ketoconazole, in preparations for topical use as shampoos in concentrations not exceeding 2 percent w/v
Lanolin
Levamisole and its salts for oral use
Levomenthol
Lidocaine when contained in oral lozenges
Lindane for topical use liquid Paraffin
Liquorice root extact (Glycyrrhiza glabra) in preparations intended for use in the relief of the symptoms of mucus coughs and colds
Loperamide 2 milligrams oral formulations intended for short–term relief of non-infectious diarrhea.
Lozenges for common cold and cough
Lufenuron V
Lugol's iodine

Malathion for topical use
Mebendazole

Medroxyprogesterone acetate
Menthol
Mepyramine
Metacresol sulphonic acid for topical use
Methyl nicotinate for topical use
Methy salicylate in preparations for topical use
Methylated spirit (Denatured alcohol)
Metriphonate V
Monensin V
Moxidectin for topical use V
Multivitamin preparations intended for oral use, containing a combination of two or more of the following vitamins or their derivatives;
Vitamin A
Vitamin B
Vitamin C
Vitamin D
Vitamin E

Naphazoline for nasal
use Nystatin:

(a) when intended for vaginal application in the initial treatment of vaginal candidiasis
(b) when intended for application to the skin, nares, and external ear
(c) when contained in preparations intended for oral administration Octyl 2- cyanoacrylate, when used as a wound barrier and closure adhesive.

Oral Rehydration Salt

Paracetamol in preparations intended for oral or rectal use:

(a) as the only active substance in immediate release formulations containing not more than 500 milligrams per dosage unit, in pack sizes not exceeding 20 dosage units or in liquid preparations containing not more than 5 percent w/v in pack sizes not exceeding 100 millilitres
(b) in combination with one or more drugs listed in this Schedule, in a solid dosage form contained in packs not exceeding 10 dosage units, for use in adults and children over 12 years of age where the cumulative daily dose of Paracetamol does not exceed 2000 milligrams

Parathion V
P-chlorocresol

Pectin

Phenylephrine, either alone or in combination with any other drug listed in this Schedule:

(a) when contained in solid preparations intended for oral use, in concentrations not exceeding 10 milligrams per dosage unit

(b) when contained in oral liquid preparations not exceeding 0.2 percent w/v

Pholcodine in preparations containing not more than 1 percent w/v of pholcodine

Piperazine and its salts

Povidone iodine, in topical preparations

Pseudoephedrine, either alone or in combination with one or more drugs listed in this Schedule, when contained in:

(a) oral solid dosage forms in concentrations not exceeding 60 milligrams per dosage unit

(b) oral liquid dosage forms in concentrations not exceeding 0.6 percent w/v

Salbutamol;

(a) as the only active therapeutic substance contained in oral liquid preparations in concentrations not exceeding 0.04 percent w/v when used for relief of bronchospasm in bronchial asthma

(b) when contained in oral solid preparations in concentrations not exceeding 4 milligrams per unit dose, when used for relief of bronchospasm in bronchial asthma

Salicylic acid, in preparations for topical application

Schradan

Selenium Sulphide in topical preparations in concentrations not exceeding 2.5 percent w/v

Senna and its preparations

Sodium borate (Borax)

Sodium citrate when contained in oral cough preparations as a mucolytic agent

Sodium chloride when formulated alone in preparations intended for nasal administration

Sulfadiazine silver when intended for application to the skin in the shortterm treatment of minor burns, subject to a maximum pack size of 30 grams

Sulphur contained in preparations for topical administration

Syzygium aromaticum (clove oil) in preparations intended for topical use

Tartaric acid
Tetracaine when contained in lozenges in concentrations not exceeding 0.2 milligrams per dosage unit
Tolnaftate
Tetracycline ointment for ophthalmic use, in adults and children above 12 years of age
Tibezonium and its salts in preparations for topical use
Thymol
Tolnaftate, intended for topical application
Triprolidine, either alone or in combination with any other drug listed in this Schedule when contained in:

(a) oral solid dosage forms in concentrations not exceeding 2.5 milligrams per dosage unit
(b) oral liquid dosage forms in concentrations not exceeding 0.025 percent w/v

Turpentine oils in preparations intended for application on the skin undecyclenic acid for topical application.
Vitamin A, in preparations for oral use
Vitamin C, in preparations intended for oral use
Wintergreen oil in preparations intended for topical use.

Zinc oxide
Zinc sulphate in preparations intended for oral administration

Herbal drugs, including plant parts, crude extracts, tinctures, mixtures, decoctions, concoctions; and processed or semi-processed derivatives thereof; (except as specifically listed in the schedules) in preparations intended for—

(a) topical application, where not indicated or otherwise associated with the management of any condition specified in Schedule 6 of this Act;
(b) oral administration specifically intended for relief of mild to moderate coughs, flu, colds, pains and fever; and where not indicated or otherwise associated with the management of any condition specified in Schedule 6 of this Act.

Schedule 5

Sections 12, 60(2)

Exempted Drugs and Articles

The following drugs and articles are known as exempted drugs and articles.

Adhesives
Ammonia, substances containing less than five percent of ammonia, refrigerators.
Antifouling compositions
Antimony, chlorides of, when contained in polishes
Batteries and accumulators
Builders' materials
Ceramics
Chemicals not included in Class A, B or C when packed and labelled for culinary and cooking purposes
Creasote, obtained from coal tar
Dentrifrices
Distempers
Dressings on seeds or bulbs
Electrical valves
Enamels
Explosives
Fireworks
Fitters, fire extinguishers
Fluorescent lamps
Formaldehyde, when in photographic glasing or hardening solution Glazes
Glue
Inks
Lacquer solvents
Laundry materials; blue, bleaches and starch
Loading materials
Matches
Medicated soap
Motor fuels and lubricants
Nitrobenzene, when contained in polishes
Oxalic acid and metallic ozalates when contained in polishes and cleaning powders
Paints (other thin pharmaceutical paints)
Phenylmercuric salts, when used in a concentration not exceeding 0.01 per

cent in toilet and cosmetic preparations as a preservative or in textiles or antiseptic dressings as a bacteriostat or fungicide

Photographic paper
Pigments
Plastics
Propellants
Rubber
Tar (coal or wood)
Tobacco
Varnishes

Schedule 6

Sections 33, 60(2)

Diseases as to which Publication of Descriptive Matter is Restricted or Prohibited

1. Syphilis, gonorrhoea, soft chancre and any form of genitourinary disease or other diseases connected with the human reproductive functions.

2. Any of the following—

Amenorrhoea
Arteriosclerosis
Bladder stones
Blindness
Brights' disease
Cancer
Cataract
Deafness
Diabetes
Diphtheria
Dropsy Epilepsy
or fits Erysipelas
Gallstones
Glaucoma Goitre
Heart disease
Hernia or rupture
Kidney stones
Leprosy
Locomotorataxy
Lupus
Nephritis or Brights' disease
Paralysis
Pleurisy
Pneumonia
Poliomyelitis
Scarlet fever
Schistosomiasis
Septicaemia
Smallpox
Tetanus or lockjaw
Trachoma
Tuberculosis or consumption
Any structural organic ailment of the auditory system

Schedule 7

Sections 38(4), 60(2)

Preparations that May be Manufactured by, or Under the Supervision of, a Duly Qualified Medical Practitioner

1. Preparations containing extracts of pituitary, suprarenal, thyroid, liver, pancreas or parathyroid glands, or stomach.

2. Preparations containing the active principles of any of the aforesaid glands or the salts of the active principles of any of those glands.

Schedule 8

Sections 42, 60(2)

Requirements as to the Storage of Classified Drugs

1. All Class B and Class C (Group II) drugs and preparations except when in use shall be kept—
   (a) under secure lock and key—
      (i) in a separate room or compartment specially reserved for keeping these drugs and partitioned off from the rest of the premises; or
      (ii) in a suitable cupboard, box or other receptacle specifically reserved for keeping drugs, and kept in a place apart from anything containing food or drink; and
   (b) the drugs shall be kept in a place ordinarily accessible only to the person in charge of the drugs, or to some person under his or her immediate supervision and control; and

the key of the room, compartment, cupboard, box or other receptacle in which these drugs are kept shall be retained under the control of the person in charge of the drugs.

2. All Class A drugs and preparations shall, except when in use, be stored in a separate store or cupboard apart from all other drugs, in accordance with the requirements of paragraph 1 above, except that if stored in a cupboard or similar receptacle the cupboard or other receptacle shall be so fixed in position as to be immovable.

3. No Class A, Class B (Group I) or Class C (Group II) drugs shall be kept in a part of any premises to which members of the general public normally have access.

4. All drugs and preparations for external use shall be kept separate from drugs and preparations intended for internal use.

Schedule 9

Sections 43(1), 60(2)

Consignment and Transportation of Classified Drugs

1. No person shall consign for transport any drug specified in this Schedule, unless the outside of the package is labelled conspicuously with the name or description of the drug and a notice indicating that it is to be kept separate from food and from empty food containers.

2. No person shall, knowingly, transport any drug specified in this Schedule in any vehicle in which food is being transported, unless the food is carried in a part of the vehicle effectively separated from that containing the drug, or is otherwise adequately protected from the risk of contamination.

Aldrin
Aluminium phosphide
Arsenical preparations
Barium, salts of
Dieldrin
Dinitrocresols (DNOC), their compounds with a metal or base when contained in preparations for use in agriculture or horticulture
Dinosam, its compounds with a metal or base when contained in preparations for use in agriculture or horticulture
Dinoset, its compounds with a metal or base when contained in preparations for use in agriculture or horticulture
Endosulfan
Endothal, its salts
Endrin
Ethylene dibromide; ethylene dichloride
Fluoroacetamide, fluoroacetanilide

Hydrocyanic acid, cyanides

Mercury, its halides when contained ın preparations for use ın agriculture or horticulture

Methyl bromide

Monofluoroacetic acid; its salts

Nicotine; its salts

Organo tin compounds, the following compounds of gentin

Phosphorous compounds, the following—

Amiton, azinphos-ethyl, azinphos-methyl; chlorgenrinphos; demeton-O-methyl; demeton-O; demeton-S; demeton-S-methyl, diazinon, dichlorvos, diethyl 4-methyl-7-coumarinyl phosphorothianate, diethyl-p-nitrophenyl phosphate; dimefox; disulfotam ointment; disulfoton; ethion; ethyl-pitrophenyl, phenylphosphonothionate; mazidox, mecarbam, mevinphos, mipafox, oxydematon-methyl; parathon, phenkapton, photate, phosphamidon schradon, sulfetep, TEPP, HEPP, thionazin, triphosphoric pentadimethylamide; vamidothion

Selenium; its compounds when contained in preparations for use in agriculture or horticulture

Strychnine

Thallium, salts of

Hydrocyanic acid, cyanides

Mercury, its halides when contained ın preparations for use ın agriculture or horticulture

Methyl bromide

Monofluoroacetic acid; its salts

Nicotine; its salts

Organo tin compounds, the following compounds of gentin

Phosphorous compounds, the following

Amiton, azinphos-ethyl, azinphos-methyl; chlorgenrinphos; demeton-O-methyl; demeton-O; demeton-S; demeton-S-methyl, diazinon, dichlorvos, diethyl 4-methyl-7-coumarinyl phosphorothianate, diethyl-p-nitrophenyl phosphate; dimefox; disulfotam ointment; disulfoton; ethion; ethyl-pitrophenyl, phenylphosphonothionate; mazidox, mecarbam, mevinphos, mipafox, oxydematon-methyl; parathon, phenkapton, photate, phosphamidon schradon, sulfetep, TEPP, HEPP, thionazin, triphosphoric pentadimethylamide; vamidothion

Selenium; its compounds when contained in preparations for use in agriculture or horticulture

Strychnine

Thallium, salts of

Act **History:** Statute 13/1993; S.I. 31/1999; Cap. 206 (Revised Edition, 2000); S.I. 76/2019; S.I. 10/2021; Act 17/2023; Act 2/2024

Cross References

Nurses and Midwives Act, Cap. 301
Pharmacy and Drugs Act, Cap. 309