Republic of Botswana

DRUGS AND RELATED SUBSTANCES

ACT NO. 18 OF 1992

Price P8,00

Printed by the Government Printer, Gaborone, Botswana

An Act to provide for the control over and regulation of drugs, including habit-forming drugs, and related substances and for matters connected therewith.

Date of Assent: 8th September, 1992.

Date of Commencement: 18th September, 1992.

ENACTED by the Parliament of Botswana

PART I — *Preliminary*

Short tide, application and commence-ment

1. (1) This Actmay be cited as the Drugs andRelated Substances Act, 1992, and shall apply to all drugs and related substances-, including habit-forming drugs.

(2) This Act shall come into operation on such date *or* dates as the Minister may, by notice in the Gazette, appoint.

Interpretation

2. (1) In this Act, unless the context otherwise requires —

"advertisement", in relation to a drug, means any written, pictorial, visual or other descriptive matter or verbal statement or reference—

(a) appearing in any newspaper, magazine, pamphlet or other publication; or

(b) distributed to members of the public; or

(c) brought to the attention of the public in any manner whatsoever, which is intended or has the effect of promoting the sale of that drug, and "advertise" shall have a corresponding meaning;

"drug"means any substance ormixture of substances used orpurporting to be suitable for use, or manufactured or sold for use in the diagnosis, treatment, alleviation, modification or prevention of disease, illness, abnormal physical or organic condition or the symptoms thereof, or restoring, correcting or modifying any somatic or psychic or organic condition, and shall include a related substance and, to the extent that it complies with the aboye definition, a habit-forming drug;

"habit-forming drug" means any drag, plant, preparation or substance, or mixture of substances, whether or not otherwise complying with the definition of drag, which is prescribed by the Minister to be a habit-forming drag, and in so prescribing the Minister may prescribe different categories of habit-forming drugs and any special conditions relating thereto;

'"label" when used as a verb means to brand, mark or otherwise designate " or describe, and when used as a noun means any brand or mark or any written, printed or graphic matter on the immediate container, or the outside container or wrapper, or attached to or packed with and referring to the contents of the container;

"manufacture" includes all operations involved in the production, processing, compounding, formulation, filling, packaging, re-pacJdng and labelling of a drug, related substance or a habit-forming drug;

"pharmacist" means a person registered as a pharmacist under the Medical, Dental and Pharmacy Act;

"pharmacy" means premises approved by the Director for the storing, dispensing and selling of drugs and which is under the control of a pharmacist;

"related substance"means any substance or mixture of substances which the Minister, by notice in the Gazette, declares to be a substance to which the provisions of this Act shall apply.

PART II — *Control over Drugs*

Registration

3. (1) No drug shall be imported into or exported from Botswana, or manufactured, distributed or sold unless such drug has been and is registered by the Director of Health Services, hereinafter referred to as "the Director":

Provided that the Minister may, in such special circumstances as he considers constitute justification for such action, by notice in the Gazette —

(a) exempt any drug from the requirements of this section; or

(b) declare any drug to be a banned drug, in which case it shall not be registered or registrable, or if already registered such registration shall be forthwith null and void.

(2) The Director shall keep and maintain, or cause to be kept and maintained, a register in which shall be recorded all drugs registered by him under this section.

(3) The register shall be open for inspection by the public at such times and places and on such terms as may be determined by the Director.

(4) Application for the registration of a drug shall be made to the Director in such form and accompanied by such further information as may be prescribed.

(5) The registration of a drug shall cease to be valid if any significant change has been made in the composition of the product, the dosage form or the conditions of its manufacture without the prior approval of the Director to such change.

Suspension or revocation of registration

4. If, in the opinion of the Director, information not previously available indicates that a registered drug may not be safe and effective when used in the manner and for the purposes approved at the time of its registration, he may —

(a) require such revisions in the composition of the drug, its packaging, labelling or advertising as he may consider necessary or desirable to ensure safety and efficacy;

(b) suspend the registration for a specified period or pending compliance with any revisions required under paragraph *(a);* or

(c) revoke the registration.

Advisory Board

5. (1) The Minister may establish a Drugs Advisory Board, the function of which shall be to advise the Director as to whether a drug should be registered or not, or as to the conditions subject to which it should be registered, or whether those conditions should be revised in accordance with section *4(a),* or whether registration should be suspended or revoked.

(2) In establishing the Drugs Advisory Board, the Minister shall determine its composition and its terms of reference and make all necessary appointments thereto by notice published in the Gazette.

(3) Members of the Drugs Advisory Board shall hold office for three years but shall be eligible for re-appointment.

Manufacture of drugs

6. (1) The manufacture of drugs may only be, undertaken in an establishment licensed therefor under the Industrial Development Act, 1988, and with the written approval of the Director.

(2) A person wishing to manufacture drugs shall make application therefor to the Director in such form as may be prescribed, and shall supply such further information as the Director may require to satisfy himself that the premises to be used are satisfactory for the purpose, and will be operated in accordance with standards of good practice in the manufacture and quality control of drugs.

(3) The manufacture of drugs shall be under the control of a registered pharmacist.

(4) Where the Director is satisfied that the conditions of any licence, or of any approval by him, are not being observed, or that the manufacture is not being carried out in accordance with the provisions of this Act and in a satisfactory manner, he may withdraw his approval and give notice thereof to the manufacturer, whereupon any further such manufacture shall, unless or until the Director resumes his approval, constitute an offence under this Act.

Export, import and distribution of drugs

7. (1) Drugs shall not be exported or imported, except by the Central Medical Stores or by a person duly licensed therefor in accordance with any written law requiring such licence, and with the written approval of the Director for such export or import.

(2) A person wishing to export or import drugs shall make application for approval therefor to the Director, in such form as may be prescribed, and accompanied by such information as the Director may require to satisfy himself that the applicant has satisfactory premises and that the business will be operated in accordance with good professional standards.

(3) The business of exporting or importing drugs shall be under the control of a technical manager with such qualifications as the Director may approve.

(4) The distribution of drugs may only be made by establishments or persons approved by the Director for the sale or distribution of such drugs.

(5) Where the Director is satisfied that drugs are being exported, imported or distributed otherwise than in accordance with Lhe conditions of any licence or any other authority required under any other written law, or any approval given by the Director, or the provisions of this Act, or that the business is not being operated in accordance with good professional standards, he may by written notice to the exporter, importer or distributor concerned withdraw his approval for the continued operation of the business, either absolutely or pending compliance with such directions as he considers necessary or desirable.

8. Where drugs are to be imported into Botswana in the course of transit to another country, the importer shall, before such importation, notify the Director in writing, stating —

{a) the type and quantity of the drugs;

(b) the expected time of arrival and departure of the drugs;

(c) the expected method and place of arrival and departure of the drugs; and

(d) the ultimate destination of the drugs, and shall, in writing, notify the Director as soon as possible, and in any event within 48 hours, when such drugs have left Botswana.

9. (1) Drugs shall be classified according to the following classifications and descriptions —

(a) Schedule 1 drug—a drug which is or contains a prescribed habit-forming drug, and must be kept in a pharmacy under the control of a registered pharmacist; such drugs shall be further classified as follows —

Schedule 1A drug — which is highly liable to abuse and which may be dispensed only on written prescription, which prescription must be kept by the dispensing pharmacist for a minimum of three years;

Schedule IB drug — which is also liable to abuse though not as highly liable as a Schedule 1A Drug, and which may be dispensed only on written prescription;

Schedule 1C drug — which, though widely used therapeutically, is liable to some, but relatively minor, abuse in comparison with a Schedule 1A or a IB drug, and may be dispensed only on prescription;

Schedule ID drug— which is unlikely to produce dependence or cause harm if misused, and may be dispensed without prescription;

(b) Schedule 2 drag — a drug, not being or containing a habit-forming drug, which may be dispensed only on written prescription, and which must otherwise be kept in a pharmacy under the control of a registered pharmacist;

(c) Schedule 3 drug — a drug which may be sold from a pharmacy without prescription, but which must otherwise be kept in a pharmacy;

(d) Schedule 4 drug — a drug which may be sold over the counter by any licensed trader.

(2) Registered medical practitioners and dentists may prescribe all drugs, including Schedule 1 and Schedule 2 drugs, in the exercise of their professions, and the Director may in suitable circumstances authorize limited powers of prescription of any such drugs to pharmacists, registered nurses and other health personnel.

(3) The dispensing of Schedule 1 A, B and C drugs, and Schedule 2 and 3 drugs shall be by pharmacists through pharmacies, or through institutions approved by the Director, but regulations made by the Minister may provide for medical practitioners, dentists, pharmacy technicians or other health personnel to dispense such drugs to such extent or in such circumstances as may be specified in such regulations.

(4) Regulations made by the Minister may provide for the keeping of registers with regard to the prescription, dispensing or sale of Schedule 1A and B drugs, and such other drugs as he may consider necessary or desirable.

10. (1) The retailing of drugs, other than Schedule 4 drugs, shall, except as may be otherwise provided in this Act, be through a pharmacy duly licensed as such under the Trade and Liquor Act, and approved for the purpose by the Director, and shall be under the control of a pharmacist.

(2) If the Director is of the opinion that a pharmacy is being operated in an unsatisfactory manner, or not in accordance with good professional standards, he may, in writing to the pharmacy, withdraw his approval, either absolutely or pending compliance with such directions as he considers necessary or desirable.

11- (l)The advertising of any drug shall not, by word or by illustration, give any false, misleading or deceptive information concerning the properties of the drug, or which is likely to encourage wrong or excessive use of the drug.

(2) The advertising of drugs which may be sold on prescription only shall be disseminated solely through professional journals and magazines or only to persons authorized to dispense, prescribe or administer such drugs.

(3) The advertising of drugs which may be dispensed without prescription may be addressed to the public but shall not include promises of unfailing results or expressions or illustrations of a nature likely to offend or intimidate members of the public, or make reference to symptoms in a manner likely to induce members of the public to make wrong diagnoses.

12. (1) All premises where drags are stored, handled, dispensed, manufactured or sold shall be subject to periodical inspection by persons authorized by the Director in writing for the purpose, and such persons shall be given unhindered access to such premises with the right to take samples, without payment, of any drugs on the premises, and to carry out any investigations that he considers necessary or desirable.

(2) The licence holder of any such premises as are referred to in subsection (1), or the person in charge thereof, shall on demand by the person so authorized by the Director, provide any economic or statistical information required of him, and provide all other necessary assistance required by she authorized person for the performance of his duties.

13. The Director may, by writing under his hand, delegate to the Assistant Director of Technical Support Services or to the Chief Pharmacist, any of his powers under this Act.

14. Any person aggrieved by any decision of the Director, the Appeals Assistant Director of Technical Support Services or the Chief Pharmacist under this Act may appeal to the Minister against such decision.

15. (1) Any person who contravenes or fails to comply with any of the provisions Of this Act, Or who —

(a) manufactures, imports, exports, distributes or sells drugs without first obtaining the Director's approval in respect of such drugs;

(b) prescribes any Schedule 1 or Schedule 2 drug without being authorized thereto by this Act or by the Director;

(c) dispenses any Schedule 1 A, B or C drug or any Schedule 2 or 3 drug otherwise than in accordance with the provisions of section 9(3);

(a) advertises any drug otherwise than in accordance with the provisions of section 11; or

(e) obstructs or fails to comply with any reasonable request or demand made by the Director, in the exercise of his powers and the performance of his duties under this Act, shall be guilty of an offence and without prejudice to his liability in accordance with the provisions of subsection (2) or of section 16, shall be liable to a fine of P10 000 and to imprisonment for two years.

(2) Any person who manufactures, imports, exports, distributes, sells, prescribes, dispenses or advertises any drug banned in accordance with a notice by the Minister under section 3(i),or any drug or other substance falsely purporting to be, or intended to or likely to induce anyone to a mistaken belief that it is, a registered drag shall be guilty of an offence and without prejudice to his liability in accordance with the provisions of section 16, shall be liable to a fine of P20 000 and to imprisonment for 5 years.

(3) With regard to any matter in respect of which the Director has delegated his powers to the Assistant Director of Technical Support Services or to the Chief Pharmacist, subsection (1) and section 9(3) shall be read as though for "Director" were substituted the words "Assistant Director of Technical Support Services" or "Chief Pharmacist" respectively.

(4) Where any person is convicted of an offence against this Act or any regulations made thereunder the court may, at the request of the Director, order any drag or other substance in respect of which the offence was committed to be seized and disposed of as the Director may require, and the Director may at the same time withdraw any approval or authorization previously given by him to that person.

PART III — *Habit-Forming Drugs*

16. (1) Except to the extent and as may be otherwise provided in Part II of this Act, no person —

(a) shall deal in any habit-forming drug or any plant from which any habit-forming drug can be manufactured; or

(b) shall possess or use any such drug or plant.

(2) Any person who contravenes the provisions of subsection (l)(a), shall be guilty of an offence and shall be sentenced to all of the following punishments, namely, to imprisonment, without the option of a fine, and without the suspension of any part thereof, for not less than 10 years or more than 15 years, and to a fine of not less than P15 000 or in default thereof to an additional term of imprisonment of not less than three years or more than five years:

Provided that, in connection with an offence under this subsection relating to cannabis, the punishment shall be imprisonment, without the option of a fine, and without the suspension of any part thereof, for not less than 5 years or more than 10 years, and to a fine of not less than P7 000, or in default thereof to an additional term of imprisonment of not less than one year or more than two years.

(3) Any person who contravenes the provisions of subsection (l)(b), shall be guilty of an offence and, except in connection with an offence relating to the possession of less than 60 grams of cannabis, shall be liable to imprisonment for not less than one year or more than five years, and to a fine of not less than PI 500 or more than P5 000, or in default of payment thereof to imprisonment for not less than one year or more than five years:

Provided that where the offence or offences relate to the possession of—

(a) such habit-forming drags as the Minister may prescribe for the purposes of this proviso; or

(b) 100 or more tablets, capsules or pills, each consisting of or containing any habit-forming drug; or

© any preparation containing 40 grams or more of any habit-forming drug, other than cannabis,

the punishment thereof shall be the same as for an offence under subsection (2).

(4) Any person who contravenes the provisions of subsection (l)(b) in relation to the possession of less than 60 grams of cannabis shall be guilty of an offence and liable to a fine of PI 000 and to imprisonment for three years.

(5) Where, upon the trial of a person for an offence in terms of subsection (2), the court considers that the offence has not been proved, but is satisfied that the person is guilty of an offence in terms of subsection (3), the court shall find him guilty of such latter offence and convict and sentence him accordingly.

(6) For the purposes of this section —

"*cannabis*" includes dagga, Indian hemp, intsangu or motokwane, under what ever name it maybe described, sold, supplied or otherwise referred to or dealt with, and whether or not referring to the whole or any portion of the plant, or any extract, tincture, preparation or admixture thereof (other than cannabis indica plasters);

"deal in", in relation to any habit-forming drug or any plant from which such a drug can be manufactured, includes performing any act in connexion with the collection, importation, supply, trans-shipment, administration, exportation, cultivation, manufacture, transmission or prescription thereof;

"possess" includes keep, store or have in custody or under control or supervision.

17. (1) If any police officer has reasonable grounds for believing that any person has committed an offence under this Part or any regulations made under this Act in relation to this Part he may —

(a) enter without a search warrant upon any land, and there require any such person to produce for his inspection any habit-forming drug in his possession, or any permit or licence or other authorization issued to him or required to be kept by him under the provisions of this Act or any regulations made there under;

(b) without a search warrant search such person or any animal in the possession of such person, and enter and search any land, building, vehicle, aircraft or boat in the possession or use of such person, and open and search any receptacle or thing in the possession of or under the control of such person:

Provided that whenever a woman is searched the search shall be conducted by a woman with strict regard for decency, and if there is no female member of the Botswana Police Force avail able, the search may be conducted by any woman specially named for the purpose by a peace officer;

(c) seize any habit-forming drug or any article or substance which he suspects to be a habit forming drug, or any plant from which any such drug can be derived, extracted, produced or manufactured, or any pipe, receptacle or material for smoking opium, or cannabis, in the possession of such person, and any vehicle, aircraft, boat, receptacle, animal or thing in or upon which such habit-forming drug, article, substance, plant, pipe, receptacle or material was found, and unless he is satisfied that such person will appear and answer any charge which may be preferred against him, arrest him without warrant and detain him;

(d) undertake any inspection which he may deem necessary to determine whether the provisions of this Act and any regulations made thereunder in respect of habit-forming drags are being complied with.

(2) Every person who is detained and everything seized under the provisions of subsection (1) shall be taken as soon as is reasonably possible before a court to be dealt with according to law.

Special jurisdiction in respect of offences under this Part

18. (1) Notwithstanding anything to the contrary in any written law, any Magistrate Grade I, Senior Magistrate or Principal Magistrate shall have special jurisdiction to impose any penalties provided in this Act for any contravention of the provisions of this Part, or any regulations made under this Act relating to this Part, or to exercise any of the powers provided therein in respect of such contraventions.

(2) Where any person is found guilty of any contravention of the provisions of this Part or any regulations made under this Act relating to this Part, the court shall order any habit-forming drug, plant, pipe, receptacle or material in respect of which the offence was committed to be forfeited to the State.

(3) Where any person is found guilty of any contravention of the provisions of this Part or any regulations made under this Act relating to this Part, the court shall order that any vehicle, aircraft, boat, animal, receptacle or thing in or upon which such habit-forming drug, plant, pipe, receptacle or material was found to be detained for a period of 28 days, . and, if within such period no successful application is made under subsection (4), it shall be thereafter forfeited to the State.

(4) If, upon application being made to it within 28 days of the date of the order made under subsection (3) by a person claiming ownership, the court is satisfied that —

(a) such vehicle, aircraft, boat, animal, receptacle or thing is not the property of the person convicted; and

(b) the claimant is the owner; and

(c) that he did not know that it was being used for an illegal purpose, or was not able to prevent its use by the person convicted,

it may, if it considers it to be equitable and expedient to do so, order the return thereof to the claimant.

(5) If the convicted person used any motor vehicle to carry or convey the drug, plant, pipe, receptacle or material in respect of which the offence was committed, the court may suspend any driver's licence issued to that person, and disqualify him from driving for a period not exceeding five years, and may cancel any licence issued in respect of that vehicle in terms of the Road Traffic Act, and may order that such vehicle should not be relicensed for a period not exceeding five years.

(6) If the convicted person is the holder of any licence issued under the provisions of any written law relating to the issue of trading licences, and it is proved to the satisfaction of the court that he used the licence to conceal or assist him in concealing the offence, the court may cancel the licence, and may declare that person to be disqualified from obtaining another such licence for a period not exceeding five years.

(7) For the avoidance of doubt, it is hereby declared that the provisions of subsections (2), (3), (5) and (6) shall be in addition to and not in derogation of any other penalties imposed under this Act.

(8) Anything forfeited to the State under the provisions of this section shall be disposed of as the Minister may direct.

19. (1) Any duly registered medical practitioner, dentist or pharmacist vicarious shall be deemed guilty of and shall be liable to the penalties prescribed liability for contraventions of this Part in respect of habit-forming drugs where the act or default constituting an offence was that of a partner, manager, clerk, drags agent, apprentice or servant associated with or employed by him, unless he satisfies the court/that such act or default was committed without his knowledge and was not due to his negligence in the supervision or direction of such partner, manager, clerk, agent, apprentice or servant.

(2) Every director and manager of a company, who is resident in Botswana, shall be liable for and subject to the penalties prescribed for any contravention of the provisions of this Part in relation to habit-forming drags by such company.

20. (1) If in any charge under this Part it is alleged that cannabis, as defined in section 16, was being cultivated, evidence that such cannabis was found in cultivated land shall be sufficient proof that it was being cultivated with the knowledge of the owner or occupier of such land, unless the contrary is proved.

(2) Any person who is upon or in charge of or who accompanies any vehicle, aircraft or animal in or upon which there is any habit-forming drug, or any plant or portion of a plant from which any such drug can be extracted, derived, produced or manufactured shall, until or unless the contrary *is* proved, be deemed for the purposes of this Part, to be the possessor of such drug, plant or portion of a plant.

(3) The burden of proving any fact which would be a defence to a charge of contravening any provision of this Part shall lie upon the person charged.

(4) Every person required by this Part to be in possession of a permit, licence, prescription, approval or any other authority shall be deemed to be without such permit, licence, prescription, approval or authority unless he produces or gives satisfactory proof of possessing the same.

(5) In any indictment, summons or other form of charge under this Part, it shall be sufficient to set forth the offence charged in the words of this Part or in similar words, without negativing any exception, exemption or qualification.

PART IV — *Miscellaneous*

21.(1) The Minister may make regulations for the better carrying out of the provisions and purposes of this Act, and without prejudice to the generality of the foregoing, such regulations may provide for —

(a) any matter to be prescribed under this Act;

(b) the procedure for the registration of drugs, and the cancellation or suspension of such registration;

© the procedure for obtaining the approval of the Director in any matter where the approval of the Director is required under this Act, and for the withdrawal or suspension of such approval;

(d) the control and regulation of the manufacture, import, export, distribution and sale of drugs;

(e) the labelling and advertising of drugs;

(f) forms to be used and fees to be paid in respect of applications under this Act;

(g) the inspection of premises under this Act;

(h) the control, conduct and regulation of clinical trials of any drug, or any scientific or medical experiments in relation to habit-forming drugs.

(2) Regulations under this Act may provide penalties for breaches thereof of fines up to a maximum of P2 000 and imprisonment for not more than one year.

22. The Drags Act, 1991 and the Habit-Forming Drugs Act are hereby repealed.

PASSED by the National Assembly this 3rd day of August, 1992.

CG. M0K0BI,

***Clerk of the National Assembly*.**

Statutory Instrument No. 46 of 1993

DRUGS AND RELATED SUBSTANCES ACT, 1992

(Act No. 18 of 1992)

DRUGS AND RELATED SUBSTANCES REGULATIONS, 1993

(Published on 16th April, 1993)

ARRANGEMENT OF REGULATIONS

IN EXERCISE of the powers conferred by section 21 of the Drugs and Related Substances Act, 1992, the Minister of Health hereby makes the following Regulations —

1. These Regulations may be cited as the Drugs and Related Substances Regulations, 1993.

2. (1) In accordance with the provisions of section 5 of the Drugs and Related Substances Act, 1992, there is hereby established a Drugs Advisory Board, hereinafter referred to as "the Board", for the purposes specified in that section.

(2) The Board shall consist, of the following persons or their alternates appointed by the Minister —

(a) a hospital pharmacist;
(b) a physician in the service of the Government;
© a district medical officer;
(d) a quality control pharmacist in the service of the Government;
(e) a duly registered medical practitioner from the private sector;
(f) a registered pharmacist from the private retail sector;
(g) a pharmacist from the Drugs Regulatory Unit; and
(h) such other members as the Minister may determine.
(3) Members of the Board shall hold office for a period of three years, but shall be eligible for re-appointment, and the Minister may at any time revoke the appointment of any member, or may grant leave of absence to any member, if he thinks it desirable or expedient to do so.
(4) The appointment, resignation or the revocation of the appointment of any member of the Board shall be notified by the Minister by notice in the Gazette.
(5) The Minister shall appoint a public officer to be the Secretary of the Board.
(6) The Board shall elect from amongst its members a Chairman to preside over meetings of the Board, and a Deputy Chairman to act as Chairman whenever the substantive holder of the post is unable to attend.
(7) The Board shall meet at such times, and as often as may be necessary or expedient for the proper carrying out of its duties under the provisions of the Act:

Provided that intervals between meetings of the Board shall never be greater than three months.
(8) The Board may co-opt one or more persons qualified or able to assist it or advise it in its functions under the Act, to attend any meeting or meetings of the Board, but such person or persons may not vote on any matter before the Board.
(9) The members of the Board and any expert assisting the Board shall observe and preserve the confidentiality of all matters coming before the Board, and such professional discretion shall subsist even after the termination of their terms of office or of their expert mandates .
(10) The Secretary shall keep minutes of each meeting of the Board, which shall be submitted for acceptance at the next meeting of the Board.
Except as is otherwise provided in this regulation, the Board shall be responsible for regulating its own proceedings.
3. (1) An application to register a drug, or for the renewal of such registration shall be made to the Director in Form 1 in the Schedule hereto and shall be accompanied by a fee of P800 for a drug which is imported, P400 for a drug which is partially locally manufactured and P200 for a drug which is totally locally manufactured.
(2) The Director shall submit any such application to the Board, together with his own recommendations and any relevant comments, for consideration by the Board, and he shall abide by any advice tendered by the Board.
(3) Where a drug is approved for registration, or for renewal of registration, the Director shall issue to the applicant a certificate of registration in Form 2 in the Schedule, and if the drug is not approved for registration or renewal of registration, he shall so inform the applicant, giving the reasons for such disapproval, at the same time informing the applicant of his right to appeal against such disapproval.

(4) Where a drug is approved for registration, or re-registration, subject to conditions, the applicant shall be informed of such conditions and shall comply therewith.

(5) A certificate of registration shall be valid for five years or such lesser period as the Director may, in any particular case specify, and provided that an application for the renewal of registration is made at least six months before the date of expiry, such validity shall extend until a decision is made and communicated to the applicant.

(6) When a drug is registered, the following information shall be recorded in the drug register kept by the Director in accordance with section 3(2) of the Act —

(a) the name of the drug approved;

(b) the registration number allocated to the drug;

(c) the approved chemical name or international non-proprietary name (INN) of each active ingredient of the drug, and the quantity thereof contained in a dosage unit or per suitable mass or volume or unit of the drug;

(d) the dosage form of the drug;

(e) the conditions of registration of the drug;

(f) the name of the applicant; and

(g) the date of registration of the drug.

4. (1) The following drugs shall be exempted from registration —

(a) any drug manufactured or imported by the Central Medical S tores for specific therapeutic use;

(b) any drug imported through the Central Medical S tores as a donation to the Government or to a Government hospital or to a hospital run by a Mission for use in that hospital;

(c) any drug imported under the authority of the Director, or any person authorized by him, for experimental use in hospitals or for specific therapeutic use or scientific research or tests;

(d) any drug prepared extemporaneously by a pharmacist for use as prescribed by a medical practitioner;

(e) any non-scheduled herb used for traditional medicine and exempted by the Director;

(f) any preparation not containing active ingredients in excess of one millionth part of the preparation's own weight.

. (2) The prior approval by the Director shall be sought in the circumstances specified in paragraphs *(a)* and *(b)* of subregulation (1), but where this is not practical such approval shall be sought as soon as is, in the circumstances, reasonably possible thereafter.

(3) The Director shall make records of exempted drugs imported or manufactured under the provisions of paragraphs *{a), (b)* and (c) of sub-regulation (1), the quantity imported and the name and address of the person or organization who imported or manufactured any such drug.

5. (1) Any person wishing to manufacture, import, export, distribute or sell drugs shall apply to the Director for approval in Form 3 in the Schedule, accompanied by a fee of P50, and the approval of the Director, if given, shall be in Form 4 in the Schedule.

(2) If an application is not approved, the Director shall so inform the applicant, giving the reasons for such refusal.

(3) Any approval shall be valid for a period of five years, or such lesser period as may, in any particular case, be specified by the Director, and provided that an application for the renewal of approval is made at least two months before the date of expiry of such approval, the validity thereof shall extend until a decision is made and communicated to the applicant.

6. (1) A manufacturer of drugs shall keep and maintain and hold readily available for inspection, comprehensive records containing details of—

(a) all steps taken in the storage and testing of raw materials;

(b) all steps taken in the manufacture of each batch of drugs;

(c) all tests carried out on representative samples; and

(d) the sale and distribution of each batch of drugs.

(2) The records required to be kept in accordance with sub-regulation (1) shall be retained for at least 5 years from the date of manufacture, or for one year from the date of expiry of the relevant batch of drugs, whichever is the longer.

(3) The manufacturer shall, without any undue delay, report in writing to the Director any intention.—

(a) to change the process of manufacture, or the method of testing any drug; or

(b) to alter materially the establishment, where such alteration will or is likely to affect the conditions under which approval for the manufacture of drugs was given.

7. (1) Importers, exporters and distributors of drugs (and for the purpose of this regulation "distributor" includes wholesaler and retailer, and "distribution" shall be construed accordingly) shall keep and maintain records containing all details of the importation, wholesale and distribution of drugs by them, and such records shall be retained and kept available for inspection by a police officer, or by any person so authorized therefor by the Director for a period of at least five years from the date of each relevant entry.

(2) Any person wishing to import or export a Schedule 1A, IB or 1C drug shall —

(a) in the case of import, apply for the approval of the Director therefor on Form HFD 1 in the Schedule, and any such approval shall be in given on Form HFD 2 in the Schedule specifying such quantities of the drug as may be so imported, and any such approval shall be valid for three months, or such lesser period as may be specified therein; or

(b) n the case of export, apply for the approval of the Director on Form HFD 3 in the Schedule, and any such approval shall be given on Form HFD 4 in the Schedule specifying such quantities of the drug as may be exported out of Botswana, and any such approval shall be valid for three months, or such lesser period as may be specified therein.

(3) The export, import and distribution of all drugs other than Schedule 4 drugs shall be —

(a) in a private pharmacy, a referral or district hospital pharmacy, a private hospital pharmacy or in any other place authorized by the Director to sell such drugs, under the control of a pharmacist;

(b) in a private medical practice or surgery or in a Government primary hospital, under the control of a pharmacy technician under the supervision of the medical practitioner concerned or of a medical officer, as the case may be;

(c) in a private dental surgery or practice, under the control of the dentist in charge; or

(d) in a clinic or health post, under the control of a registered or enrolled nurse approved by the Director.

8. (1) The container of every drug imported, manufactured, processed or packed in Botswana shall bear a label written in English, with the following information clearly indicated thereon —

(a) either the approved name of the drug as used in official pharmacopoe ias or formularies, or the international non-proprietary name;
(b) the brand name, if any;
(c) the contents of the container;
(d) the quantity of active ingredients per dosage unit;
(e) the name of the manufacturer;
(f) the batch identification;
(g) the expiry date;
(h) any special storage conditions that may be necessary or desirable;
(i) any warnings or precautions that may be necessary or desirable.
(j) any directions for use if sold without prescription; and
(k) any appropriate statutory or restrictive direction or label in the Schedule that may be necessary.

(2) In any special circumstances the Director may, where he considers it desirable, exempt any particular consignment of drugs from the requirements of sub-regulation (1).

(3) The container of every drug dispensed to a patient shall have a label bearing the following information —

(a) the full name of the patient;
(b) the date of dispensing;
(c) the name of the pharmacy or other health facility dispensing it;
(d) all information required for the purposes of sub-regulation (1) with the exception of paragraphs *(b),* (e) and *(f)* thereof.

(4) The container of any drug exempted from registration shall as far as possible bear the information required under sub-regulation (1).

_ (5) In respect of those drugs listed in regulation 21, against which a label and a number in parenthesis is indicated, any such drug shall bear a label giving information or instructions in accordance with the following —

Label number	*Word Content*
(1)	"Contains aspirin" (unless name of product includes word "aspirin"); plus "If symptoms persist, consult your doctor"; plus the recommended dosage; plus "Do not use on children under 12 years except on medical advice."
(2)	"Contains an aspirin derivate"; plus "If symptoms persist, consult your doctor"; plus the recommended dosage.
(3)	"Contains paracetamol" (unless the name of the product in- cludes the word "paracetamol"); plus "If the symptoms persist, consult your doctor"; plus "Do not exceed the stated dose"; plus the recommended dosage.
(4)	"Warning. Asthmatics should consult their doctor before using this product."

(5) "Warning. May cause drowsiness. If affected do not drive or operate machinery. Avoid alcoholic drink."

(6) "Not to be used for babies" or "Not to be administered, except on medical advice, to a child under two years."

(7) "Oral Rehydration Therapy is recommended in all forms of diarrhoea."

(8) "For external use only." This cautionary wording should be used if a product is an embrocation, liniment, lotion, liquid antiseptic or other liquid preparation or gel for external application.

(9) "Warning. Do not exceed the stated dose." This cautionary wording should be used on pharmacy drugs (P) exempted from POD requirements by reason of the proportion or level in such product of any substance, and which are not for external use.

9. Whenever the Director finds that any portion of any batch of drugs does not conform to the standards of identity, strength, quality and purity, or any other requirement specified in the documentation for registration, he may instruct the licensee to discontinue the sale of the remainder of the batch and, so far as is practicable, to recall any portion of the batch already sold.

10. (1) Prescriptions of drugs shall be written in generic or approved international non-proprietary names (INN) except when a particular brand of drug is preferred and clinically acceptable reasons for such preference are communicated to the dispenser.

(2) Where a prescription is written using a generic or approved international non-proprietary name the least expensive drug of that description in the pharmacy shall be sold or dispensed for that prescription.

(3) In granting limited powers of prescription of Schedule 1, 2 and 3 drugs under section 9(2) of the Act, the Director may grant to —

(a) registered nurses in hospitals or Government clinics specializing in medical fields such as ophthalmology, psychiatry, midwifery, or as a registered family nurse practitioner, power to prescribe only those drugs specific to their speciality or training and, where applicable, which are specified for them in the Botswana National Drug Formulary;

(b) registered nurses and enrolled nurses in Government clinics and health posts, power to prescribe only those drags which are specified for them in the Botswana National Drug Formulary;

(c) dental therapists, power to prescribe only those drugs specified for them in the Botswana National Drug Formulary; and

(d) registered pharmacists power to prescribe drugs only in the circumstances referred to in regulation 12.

11. (1) Schedule 1A and IB drugs may only be dispensed or sold by a pharmacist upon a written prescription, by a medical practitioner or dentist, presented for dispensing within thirty days of the date of its issue, and for the supply of a quantity not greater than is indicated on the prescription, which shall not in any case exceed thirty days supply, and any such prescription shall be retained in the pharmacy for a period of three years after the date of dispensing.

(2) The dispenser or seller of a Schedule 1A or 1B drug shall enter a record of such sale or dispensing, as the case maybe, in an appropriate register, which register shall be kept for a period of five years after the last relevant entry therein.

(3) Separate registers shall be kept for Schedule 1A drugs and for Schedule IB drugs.

(4) Except when being administered to a patient, every Schedule 1A and Schedule IB drug shall be kept under safe custody in a lockable cabinet or in a safe.

(5) The destruction of any Schedule 1A or Schedule IB drug, in part or whole, shall be reported in writing to the Director, and, except where the destruction is accidental, shall be supervised by a pharmacist and witnessed by a police officer.

12. Schedule 1C drugs may only be dispensed or sold by a pharmacist upon a written prescription of a medical practitioner or dentist presented for dispensing within thirty days from the date of issue thereof, and for the supply of a quantity of the drug not in excess of that indicated on the prescription, and in any case not exceeding thirty days supply, and any such prescription shall be retained in the pharmacy for a period of not less than three years from the date of the last sale or dispensing:

Provided that where the prescribing medical practitioner or dentist is personally known to the dispensing pharmacist and is confirmed as being a medical practitioner or dentist, and the pharmacist is satisfied that it is impossible or impracticable to obtain a written prescription within a time that is reasonable in all the circumstances, he may dispense a prescription made by telephone or fascimile, in quantities not exceeding those stated above, on condition that a written prescription will be provided within 48 hours.

13. Schedule 2 drugs may be dispensed —

(a) in referral hospitals, district hospitals, mission hospitals, mine hospitals or private hospitals by a pharmacist or an intern pharmacist, or by a pharmacy technician under the supervision of a pharmacist, and upon a written prescription issued by a medical practitioner or a dentist;

(b) in a retail pharmacy by a pharmacist, or by a pharmacy technician under the supervision of a pharmacist, and upon a written prescription issued by a medical practitioner or a dentist; or

(c) in a private medical practice or surgery or a Government primary hospital, by a pharmacy technician upon a written prescription issued by a medical practitioner or a medical officer.

14. Notwithstanding regulations 11, 12 and 13, registered and enrolled nurses in referral, district, primary, mine, mission and private hospitals, clinics, health posts and mobile clinics, may, in the exercise of their duties, dispense Schedule 1 A, IB, 1C, 2 and 3 drugs to patients, upon written prescription by a medical practitioner or a dentist.

15. (1) The dispenser of any drug shall not dispense a quantity thereof greater than the amount stated in the prescription.

(2) A prescription may be repeated without further prescription if it so endorsed by the prescriber.

(3) Except as is otherwise provided in these Regulations or where a shorter period is endorsed thereon, a prescription shall be valid for dispensing for a period not exceeding twelve months from the date of issue.

(4) The dispenser of a drug shall endorse on the prescription the date when it is dispensed, the quantity dispensed, and shall append his signature thereto.

16. (1) In an emergency a Schedule 2 drug can be supplied or dispensed as provided in regulation 13, but without a prescription if—

(a) there is an immediate need for the drug requested to be supplied and it is impracticable in the circumstances to obtain a prescription; or

(b) the treatment with the drug has on a previous occasion been prescribed for the person requesting it.

(2) The quantity of the drug to be supplied in accordance with subregulation (1) shall not exceed five days' treatment:

Provided that —

(a) where the drug in question is an ointment, a cream or an aerosol for the relief of asthma, which has been made up for sale in a container elsewhere than at the place of supply, the dispenser may supply the smallest pack available;

(b) where the drug in question is an oral contraceptive, the dispenser may supply a sufficient quantity for a full cycle; or

(c) where the drug required is in such apackage that itis impractical to split the package, the whole package may be supplied.

17. (1) Separate registers shall be kept for Schedule 1A and Schedule IB drugs.

(2) Registers to be kept by the manufacturer, seller, importer, exporter or distributor of such drugs shall contain the following information, as appropriate —

(a) the approved name and quantity of the drug concerned;

(b) the name and business address of the supplier;

(c) the date on which the drug was received;

(d) the import permit number in the case of imports;

(e) the export permit number in the case of exports;

(f) the name and business address of the purchaser;

(g) the date of sale of the drug;

Qi) the invoice or reference number of such sale.

(3) Registers to be kept by the dispenser of such drugs in accordance with regulation 11(2) shall contain the following information, as appropriate —

(a) the approved name and quantity of the drug concerned;

(b) the name and business address of the supplier;

(c) the date on which the drug was received;

(d) the import permit number in the case of imports;

(e) the name and address of the person to whom the drug was dispensed;

(j) the prescription number or reference number upon which the drug was dispensed;

(g) the date of such dispensing;

(A) the name and address of the prescriber.

(4) All invoices for the purchase or supply of Schedule 1 A, IB and 1C drugs shall be kept for a minimum of five years.

(5) All registers or records required to be kept under this regulation must be retained for a period of five years after the date of the last relevant entry, and shall be kept available for inspection by authorized officers.

(6) All registers and records required to be kept under these Regulations shall be balanced at the end of every calender month.

18. (1) Clinical trials of drugs means studies in humans or animals in order to systematically generate new or verify existing information about their efficacy and their side effects, and also studies relating to their absorption in, metabolism and excretion from the human or animal body.

(2) Any person wishing to conduct a clinical trial of a drug shall submit to the Director an application signed by the applicant, and if the Director approves he shall issue a written authorization permitting the applicant to conduct such trial, with or without such conditions or directions as he may specify.

(3) To ensure protection of the general public against any risk or adverse effects from the clinical trial of any drug the Director shall monitor the trial from the beginning to the end so as to satisfy himself that all specific and general conditions or directions subject to which the trial was authorized are being strictly observed by the person conducting the trial, and that to all intents and purposes the trial will achieve its aims and objectives.

(4) If at any stage during the clinical trial of any drug the Director is satisfied that, having due regard to the initial risks, discomforts or other adverse effects caused to persons taking part in the trial, it is in the public interest immediately to stop or suspend the trial, he may, in writing, so notify the person conducting the trial, who shall immediately comply with such notice.

(5) Where a clinical trial is to be conducted in a hospital or other medical institution, the application therefor shall be countersigned by the medical superintendent, or by a senior medical officer of comparable, rank of such hospital or medical institution.

(6) Any person who is aggrieved, by a decision of the Director not to grant approval for the conduct of a clinical trial may appeal against such decision to the Minister.

19. Any appeal lodged in accordance with the provisions of section 14 of the Act or regulation 18(6) shall be lodged within thirty days after the date when the decision appealed against is communicated to the applicant.

20. For the purposes of the Act and these Regulatons drugs shall be classified in accordance with the lists set out in the First Schedule.

21. For the purposes of the definition of "habit forming drug", section 3(l)(b) and Part III of the Act the drugs listed in the Second Schedule are declared to be banned habit forming drugs.

22. The forms to be used for the purposes of the Act shall be in accordance with the forms set out in the Third Schedule.

FIRST SCHEDULE (reg. 20)

(1) SCHEDULE 1 DRUGS

	Category
Acetorphine; its salts; its esters and ethers; their salts	1A
Acetorphine hydrochloride	1A
Acetyldihydrocodeine; its salts but if for non-paxenteral use and:	1A
(a) in undivided preparations with ms 2.5% (calculated as base: Schedule 2)	ID
(b) in single-dose preparations with ms per dosage unit lOOmg (calculated as base: Schedule 2)	ID
Acetyl-methadol see Methadyl acetate	
Alfentanil	1A
Allobarbital	1C
Allyprodine; its salts	1A
Alphacetylmethadol; its salts; its esters and ethers; their salts	1A
AJphameprodine; its salts	1A
Alphaprodine; and its salts	1A
Amferpramone	IB
Amidone see Methadone	
Alpharaethadol; its salts, its esters and ethers; their salts	1A
Amphetamine; its salts	1A
Amphetamine phosphate	1A
Amphetamine sulphate	1A
Amylobarbitone	IB
Amylorbarbitone sodium	IB
Anileridine; its salts	1A
Barbitone	1C
Barbitone sodium	1C
Benzethidine; its salts	1A
Benzphetamine; its salts	IB
Bezphetamine hydrochloride	IB
Benzylmorphine; its salts; its esters and ethers; their salts	1A
Benzylmorphine hydrochloride	1A
Betacetylmethadol; its salts	1A
Betameprodine; its salts	1A
Betamethadol; its salts; its esters and ethers; their salts	1A
Betaminoisopropylbenzene see amphetamine	
Betaprodine; its salts	1A
Bezitramide; its salts	1A
Bromazepam	1C
Buprenorphine	IB
Buprenorphine hydrochloride	IB
Butalbital	IB
Butobarbitone	1C
Butorbabitone sodium	1C
Camazepam	1C
Carfentanil; its stereoisomers, its salts; its esters and ethers, their salts	1A
Cathine; its salts; its stereoisomers not being phenylpropanolamine; their salts	IB
Chlordiazepoxide	1C
Chlordiazepoxíde hydrochioride	1C

Chiorphentermine; its salts	IB
Chlorphentermine hydrocMoríde	IB
Clobazam	1C
Clonazepam	1C
Clonitazene; its salts	1A
Clorazepate	1C
Clotiazepam	1C
Cloxazolam	1C
Codeine; its salts but if for non-parenteral use and:	1A
(a) in undivided preparations with ms 2.5% (calculated as base: Schedule 2)	ID
(b) in undivided preparations with ms 1.5% (calculated as base: and not more than 200ml: Schedule 3)	ID
(c) in single-dose preparations with ms per dosage unit lOOmg (calculated as base: Schedule 2)	ID
(d) in single-dose preparations with ms per dosage unit 1.5% (calculated as base, and md lOmg: or calculated as base, and not more than 30 tablets: Schedule 3)	ID
Codeine hydrochloride see Codeine	
Codeine phosphate see Codeine	
Codeine sulphate see Codeine	
Codoxime see Dihydrocodeinone O-carboxymethyloxime	
4-cyano-2-dimethylamino-4,4-diphenylbutane; its salts	IA
4-cyano-1 -methyl-4-phenylpiperidine; its salts	1A
Cyclobarbitone	IB
Delorazepam	1C
Delta-9-tetrahydrocannabinol see Dronabinol	
Desomorphine; its salts; its esters and ethers; their salts	1A
Desoxyephedrine see Methylamphetamine	
Desoxynorephedrine see Amphetamine	
Dexamphetamine; its salts	IA
Dexamphetamine phosphate	1A
Dexamphetamine sulphate	IA
Dextrodiphenopyradine see Dextromoramide	
Dextromoramide; its salts	lA^
Dextromoramide tarírate	1A
Dextropropoxyphene; its salt; its esters and ethers; their salts but in a preparation for oral use containing not more than 135mg of dextropropoxyphene (calculated as base, per dosage unit, or with a total concentration of not more than 2.5% calculated as base, in undivided preparations: Schedule 2)	1A ID
Diampromide; its salts	IA
Diazepam	1C
Diethylpropion hydrochloride	IB
Diethylthiambutene; its salts	IA,
Diethylthiarnbutene hydrochloride	1A
Difenoxin (1 -(3-cyano-3,3-diphenyl-propyl)-4-phenylpiperidine-4-carboxyiic acid) ' (but if in preparation containing, per dosage unit, not more than 0.5mg of difenoxin and a quantity of atropine sulphate equivalent to at least 5% of the dose of difenoxin: Schedule 2)	IA ID

Dihydrocodeine; its salts	_ 1A
but if for non-parenteral use and:	
(a) in undivided preparations with ms 2.5% (calculated as base: Schedule 2)	ID
(b) in undivided preparations with ms 1.5% (calculated as base) and md lOmg (calculated as base: Schedule 3)	ID
(c) in single-dose preparations with ms per dosage unit lOOmg (calculated as base: Schedule 2)	ID
(d) in single-dose preparations with ms per dosage unit 1.5% (calculated as base) and md lOmg (calculated as base: Schedule 3)	ID
Dihydrocodeine phosphate; see dihydrocodeine	
Dihydrocodeine tartrate; see dihydrocodeine	
Dihydrocodeinone see hydrocodone	
Dihydrocodeinone enol acetate see Thebacon	
Dihydrocodeinone O-carboxymethyl-oxime; its salts; its esters and ethers; their salts	1A
Dihydrodeoxymorphine see Desomorphine	
Dihydrohydroxycodeinone; see Oxycodone	
Dihydrohydroxymorphinone; see Oxymorphine	
Dihydromorphine; its salts; its esters and ethers; their salts	1A
Dihydromorphinone see hydromorphone	
Dimenoxadole; its salts	1A
Dimepheptanol; its salts; its esters and ethers; their salts	1A
Dimethylthiambutene; its salts	1Â
Dioxaphetyl butyrate; its salts	1A
Diphenoxylate; its salts	1A
but if in preparation with *ms* per dosage unit 2.5mg of diphenoxylate (calculated as base, and quantity of atropine sulphate equivalent to at least 1% of the dose of diphenoxylate: Schedule 2)	ID
Diphenoxylate hydrochloride; see diphenoxylate	
Dipipanone; its salts	1A
Dipipanone hydrochloride	1A
Dronabinol	1A
Drotebanol; its salts; its esters and ethers; their salts	1A
Estozolam	1C
Ethchlorvynol	1C
Ethinimate	1C
Ethyl loflazepate	1C
N-Ethylamphetamine; its salts; its stereoisomers; their salts	1C
Ethylmethylthiambutene; its salts	1A
Ethylmorphine; its salts	1A
but if for non-parenteral use and;	
(a) in undivided preparations with ms 2.5% (calculated as base: Schedule 2)	ID
(b) in single dose preparations with ms per dosage unit lOOmg (calculated as base: Schedule 2)	ID
Ethylmorphine hydrochloride see Ethyl morphine	
Etonitazine; its salts	1A
Etorphine; its salts; its esters and ethers; their salts	1A

Etorphine hydrochloride	1A
Etoxeridine; its salts; its esters and ethers; their salts	1A
Fencamfamin; its salts; its stereoisomers; their salts	IC
Fenethylline; its salts; its stereoisomers; their salts	1A
Fenproporex; its salts; its stereoisomers; their salts	IB
Fentanyl; its salts	1A
Fludiazepam	IC
Flunitrazepam	IC
Flurazepam hydrochloride; its salts	IC
Flurazepam monohydrochloride	IC
Furethidine; its salts	1A
Glutethimide; its salts; its stereoisomers; their salts	1A
Halazepam	IC
Haloxazolam	IC
Heptabarbitone	IC
Hexobarbitone	IC
Hexobarbitone sodium	IC
Hydrocodone; its salts	1A
Hydrocodone bitartrate	1A
Hydromorphinol; its salts; its esters and ethers; their salts	1A
Hydromorphone; its salts; its esters and ethers; their salts	1A
Hydroxypethidine; its salts; its esters and ethers; their salts	1A
Isomethadone	1A
Ketazolam	IC
Ketobemidone; its salts; its esters and ethers; their salts	1A
Lefetamine(SPA)	- IB
Levamfetamine	1A
Levomethamphetamine	1A
Levomethorphane; its salts	1A
Levomoramide; its salts	1A
Levophenacylmorphan; its salts; its esters and ethers; their salts	1A
Levorphanol tartrate	1A
Lofentanil; its stereoisomers; its salts its esters and ethers; their salts	1A
Loprazolam mesylate	IC
Lorazepam	IC
Lormetazepam	IC
Mazindol	IB
Mecloqualone	1A
Medazepam	IC
Mefenorex; its salts; its stereoisomers; their salts	IB
Meperedine see Pethidine	
Mephentermine; its salts	IB
Mephen termine sulphate	IB
Meprobamate	IC
Metazocine; its salts; its esters and ethers; their salts	1A
Methadone; its salts	1A
Methadone hydrochloride	1A
Methadyl acetate; its salts	1A
Methamphetamine see Methylamphetamine	
Methylamphetamine; its salts	1A
Methylamphetamine hydrochloride	1A

Methyldesorphine; its salts; its esters and ethers; their salts	1A
Methyldihydromorphine; its salts; its esters and ethers; their salts	1A
Methyldihydroraorphinone see Metopon	
2-Methyl-3-moipholino-l,l-diphenyl-propanecarboxylic acid; its salts; its esters and ethers; their salts	1A
alpha-methylphenethyiamine see Amphetamine	
N- (2-(N-methylphenethylamino)propyl)propionaniIide see Diampromide	
Methylphenidate; its salts	1A
Methylphenidate hydrochloride	1A
Methylphenobarbitone	1C
l-methyl-4-phenylpiperidine-4-carboxylic acid; its salts; its esters and ethers; their salts	1A
Methyprylone	1C
Metopon; its salts; its esters and ethers; their salts	1A
Midazolam	1C
Morpheridine; its salts	1A
Morphine; its salts; its esters and ethers; their salts; its pentavalent nitrogen derivatives; their esters and ethers	1A
Morphine acetate see Morphine	
Morphine hydrochloride see Morphine	
Morphine methobromide; its esters and ethers	1A
Morphine-N-oxide; its esters and ethers	1A
Morphine sulphate see Morphine	
Morphine tartrate see Morphine	
Morpholinoethylnorpethidine see Morpheridine	
Myrophine; its salts	1A
Nicocodine; its salts	1A
but if for non parenteral use and:	
{a) in undivided preparations with ms 2.5% (calculated as base: Schedule 2)	ID
(b) in single dose preparations with ms per dosage unit lOOmg (calculated as base: Schedule 2)	ID
Nicodicodine; its salts	1A
but if for non-parenteral use and:	
(a) in undevided preparations with ms 2.5% (calculated as base: Schedule 2)	ID
(b) in single dose preparations with ms per dosage unit lOOmg (calculated as base: Schedule 2)	ID
Nicomorphine; its salts	*1A*
Nimetazepam	1C
Nitrazepam	1C
Noracymethadol; *its* salts	1A
Nordazepam	1C
Norcodeine; its salts	1A
but^if for non-parenteral use and:	
(a) in undivided preparations with ms 2.5% (calculated as base: Schedule 2)	ID
(b) in single dose preparations with ms per dosage unit lOOmg (calculated a£ base: Schedule 2)	ID
Norlèvorphanol; its salts; its esters and ethers; their salts	1A
Norme,thadone; its salts	1A
Normorphine; its salts; its esters and ethers; their salts	1A
Norpipanone; its salts	1A
Opium, medicinal	1A

Oxazepam	1C
Oxazolam	1C
Oxycodone; its salts; its esters and ethers; their salts	1A
Oxymorphone; its salts; its esters and ethers; their salts	1A
Papaveretum see Opium, medicinal	
Pemoline	IB
Pentazbcine hydrochloride	IB
Pentazocine lactate	IB
Pentobarbitone	IB
Pentobarbitone sodium	IB
Pethidine; its salts	1A
Pethidine hydrochloride	1A
Phenadone see Methadone	
Phenadoxone; its salts	1A
Phenampromide; its salts	1A
Phenazocine; its salts; its esters and ethers; their salts	1A
Phenazocine hydrobromide	1A
Phendimetrazine; its salts -	IB
Phendimetrazine tartrate	IB
Phenmetrazine; its salts	1A
Phenmetrazine hydrochloride	1A
Phenmetrazine theoclate	1A
Phenobarbitone	1C
Phenobarbitone sodium	1C
Phenomorphan; its salts; its esters and ethers; their salts	1A
Phenoperidine; its salts; its esters and ethers; their salts	1A
Phentermine	IB
Phenylmethylbarbituric acid	IB
4-Phenylpiperidine-4-carboxylic acid ethyl ester; its salts	1A
Pholcodine; its salts	1A
but if for non-parenteral use and	
(a) in undivided preparations with ms 2.5% (calculated as base: Schedule 2)	ID
(b) in undivided preparations with ms 1.5% (calculated as base) and md 20mg (calculated as base: Schedule 3)	ID
(c) in single-dose preparations with ms per dosage unit lOOmg (calculated as base: Schedule 2)	ID
(d) in single-dose preparations with ms per dosage unit 1.5% (calculated as base) and md 20mg (calculated as base: Schedule 3)	ID
Pholcodine citrate see Pholcodine	
Pholcodine tartrate see Pholcodine	
Piminodine; its. salts	1A
Pinazepam	1C
Pipradroi; its salts	IB
Pipradrol hydrochloride	IB
Piritramide; its salts	1A
Potassium clorazepate	1C
Prazepam	1C
Proheptazine; its sails	1A
Properidine; its salts	1A
Propiram; its salts	1A

but if in preparations containing, per dosage unit, not more than lOOmg propiram (calculated as base, and compounded with at least same amount of methylcellulose: Schedule 2)	ID
Propylhexedrine; its salts; its stereoisomers; their salts	1C
Pyrovalerone; its salts; its stereoisomers; their salts	1C
Quinalbarbitone	1A
Quinalbarbitone sodium	1A
Racemethorphan; its salts	1A
Racemoramide; its salts	1A
Racemorphan; its salts; its esters and ethers; their salts	1A
Secbutobarbitone	1C
Secbutobarbitone sodium	1C
Secobarbitone see Quinalbarbitone	
Sufentanil; its salts; its esters and ethers; their salts	1A
Temazepam	1C
Thebacon; its salts	1A
Thebaine; its salts	1A
Tilidate; its salts; its esters and ethers; their salts	1A
Triazolam	1C
Trimeperidine; its salts	1A
Vinylbital	1C

(2) SCHEDULE 2 DRUGS

Acebutolol
Acepromazine
Acepromazine maleate
Acetanilide
Acetarsol
Acetazolamide
Acetazolamide sodium
Acetohexamide
AcetylcarbromaJ
Acetylcholine chloride
Acetylcysteine
Acetyldigitoxin
Acetylsalicylic acid label *(1)*
Acetylstrophanthidin
Acetylsulphafurazole
Acetylsulphamethoxypyridazine
Aconite
Acros oxacin
Actinomycin C
Actinomycin D
Acyclovir
Adicillin
Adiphenine hydrochloride
Adrenaline
Adrenaline acid tartrate
Adreneline hydrochloride
Alkomide
Albumin human (immuno)
Alclofenac
Alclometasone diproprionate
Alcuronium chloride
Aldosterone
Alfacalcidol
Algestone acetonide
Algestone acetophenide
Allopurinol
Allyloestrenol
AlphadolOne acetate
Alphaxalone
Alprenolol
Alprenolol hydrochloride
Alprostadil
Alseroxylon
Altizide
Amantadine hydrochloride
Ambenonium chloride
Ambuside
Ambutonium bromide
Amcinonide
Ametazole hydrochloride
Amethocaine
Amethocaine gentisate
Amethocaine hydrochloride
Amidopyridone
Amikacin sulphate
Amiloride hydrochloride
Aminocaproic acid
Aminodarone hydrochloride
Aminoglutethemide
Aminophylline
Aminopterin sodium
Aminosalicylic acid
Amiphenazole hydrochloride
Amitriptyline
Amitriptyline embonate
Amitriptyline hydrochloride
Ammonium bromide
Amodiaquine hydrochloride
Amoxapine
Amoxycillin
Amoxycillin trihydrate
Amphomycin
Amphotericin
Ampicillin
Ampicillin sodium
Ampicillin trihydrate
Amsacrine
Amylocaine hydrochloride
Ancrod
Androsterone
Angiotensin amide
Anterior pituitary extract
Antimony barium tartrate
Antimony dimercaptosuccinate
Antimony lithium thiomalate
Antimony pentasulphide
Antimony potassium tartrate
Antimony sodium tartrate
Antimony sodium thioglycollate
Antimony sulphate _
Antimony trichloride
Antimony trioxide
Antimony trisulphide
Apiol
Apomorphine
Apomorphine hydrochloride
Apramycin
Apramycin sulphate

Aprotinin
Arecoline
Arecoline-acetarsol
Arecoline hydrobromide
Arsanilic acid
Arsenic
Arsenic triiodide
Arsenic trioxide
Arsphenamine
Aspirin see acetylsalicylic acid
Astemizole
Atenolol
Atracurium besylate
Atropine
Atropine methobromide
Atropine methonitrate
Atropine oxide hydrochloride
Atropine sulphate
Azacyclonol
Azacyclonol hydrochloride
Azaperone
Azapropazone
Azothioprine
Azothioprine sodium
Azidocillin potassium
Bacampicillin hydrochloride
Bacitracin
Bacitracin methylene disalicylate
Bacitracin zinc
Baclofen
Barium carbomate
Barium chloride
Barium sulphide .
Beclamide
Beclomethasone
Beclomethasone dipropionate
Belladonna herb
Belladonna root
Bemegride
Benactyzine hydrochloride
Benapryzine hydrochloride
Bendrofluazide
Benethamine penicillin
Benoxaprofen
Benperidol
Benserazide
Benza thine penicillin
Benzbromarone
Benzhexol hydrochloride
Benzilonium bromide
Benzocaine
Benzoctamine hydrochloride
Benzoyl peroxide
N-Benzoyl sulphanilamide
Benzquinamide
Benzquinamide hydrochloride
Benzthiazide
Benztropine mesylate
Benzyl penicillin
Benzyl penicillin calcium
Betahistine hydrochloride
Betamethasone
Betamethasone adamantoate
Betamethasone benzoate
Betamethasone dipropiomate
Betamethasone sodium phosphate
Betamethasone valerate
Betaxolol hydrochloride
Bethanecol chloride
Bethanidine sulphate
Biperidine hydrochloride
Biperidine lactate
Bismuth glucollylarsanilate
Bleomycin sulphate
Boldenone undecylenate
Bretylium tosylate
Bromhexine hydrochloride
Bromocriptine mesylate
Bromperidol
Bromvaletone
Budesonide
Bumetadine
Buphenine hydrochloride
Bupivacaine
Bupivacaine hydrochloride
Buspirone hydrochloride
Busulphan
Butacaine sulphate
Butanilicaine phosphate
Butriptyline hydrochioride
Butylchloral hydrate
Calcitonin
Calcitriol
Calcium aminosalicylate
Calcium amphomycin
Calcium benzamidosalicylate
Calcium bromide
Calcium bromidoiactobionate
Calcium carbimide
Calcium folinate
Calcium metrizoate
Calcium suiphaloxate

Candicidin
Canrenoic acid
Cantharidin
Capreomycin sulphate
Capiopril
Caramiphen hydrochloride
Caramiphen edisyiate
Carbachol
Carbamazepine
Carbenicillin sodium
Carbenoxolone sodium
Carbidopa
Carbidopa monohydrate
Carbimazole
Carbocisieine
Carbon tetrachloride
Carboprost trometamol
Carbuterol hydrochloride
Carbromal
Carindacillin sodium
Carisoprodol
Carmustine
Cefaclor
Cefazedone sodium
Gefoxitin sodium
Ceftazidime
Ceftizoxine sodium
Cefuroxime sodium
Cephalexin
Cephalexin sodium
Cephaloridine
Cephalosporin C
Cephalosporin E
Cephalosporin N
Cephalothin sodium
Cephamandole nafate
Cephazolin sodium
Cephradine
Cerium oxalate
Cetirizine
Chenodeoxycholic acid
Chloral antipyrine
Chloral beiaine
Chloral formamide
Chloral glycerolate
Chloral hydrate
Chloralose
Chloral urethene
Chlorambucil
Chloramphenicol
Chloramphenicol cinnamate
Chloramphenicol palmitate
Chloramphenicol sodium succinate
Chlorisondamine chloride
Chlormadinone acetate
Chlormerodrin
Chlormethiazole
Chormethiazole edisyiate
Chlormezanone
Chloroform
Chloroquine phosphate
Chloroquine sulphate
Chlorothiazide
Chlorotrianisene
Chlorphenoxamine hydrochloride
Chlorpromazine
Chlorpromazine embonate
Chlorpromazine hydrochloride
Chlorpropamide
Chlorprothixene
Chlorprothixene hydrochloride
Chlortetracycline
Chlortetracycline hydrochloride
Chlorthalidone
Chloroxazone
Cholestyramine
Chorionic gonadotrophin
Ciclacillin
Ciclobendazole
Cimetidine
Cimetidine hydrochloride
Cinchocaine
Cinchocaine hydrochloride
Cinchophen
Cinnarizine
Cinoxacin
Ciprofloxacin
Ciproiloxacin hydrochloride
Clavulanic acid
Clenbuterol hydrochloride
Clindinium bromide
Clindamycin
Clindamycin hydrochloride hydrate
Clindamycin palmitate hydrochloride
Clindamycin phosphate
Clioquinol
Clobetasol 17-propionate
Clobetasone butyrate
Clofazimine
Clofibrate
Clomiphene citrate
Clomipramine

Clomipramine hydrochloride
Clomocycline
Clomocycline sodium
Clonidine
Clonidine hydrochloride
Clopenthixol decanoate
Clopenthixol hydrochloride
Cloprostenol sodium
Clorexolone
Clorprenaline hydrochloride
Clostebol acetate
Clotrimazole
Cloxacillin benzathine
Cloxacillin sodium
Cocculus indicus
Co-dergocrine myselate
Colchicine
Colestipol hydrochloride
Colistin sulphate
Colistin sulphomethate
Colistin sulphomethate sodium
Conium leaf
Corticotrophin
Cortisone
Cortisone acetate
Cotarnine chloride
Co-tetroxazine
Co-trimoxazole
Cropropamide
Crotethamide
Croton oil
Croton seed
Curare
Cyclopenthiazide
Cyclopentolate hydrochloride
Cyclophosphamide
Cyclosporin
Cyclothiazide
Cyproterone acetate
Cytarabine
Cytarabine hydrochloride
Dacarbazine
Danazol
Dantrolene sodium
Dapsone
Dapsone ethane ortho sulphonate
Daunorubicin hydrochloride
Deanol salts and esters
Debrisoquine sulphate
Dehydroemetine hydrochloride
Delmadinone acetate
Demecarium bromide
Demeclocycline
Demeclocycline calcium
Demeclocycline hydrochloride
Deoxycortone acetate
Deoxycortone pivalate
Deptropine citrate
Dequalinium chloride
Deserpidine
Desferroxamine mesylate
Desfluorotriamcinolone
Desipramine hydrochloride
Deslânoside
Desmopressin
Desonide
Desoxymethasone
Dexamethasone
Dexamethasone 21-isonicotinate
Dexamethasone phenylpropionate
Dexamethasone pivalate
Dexamethasone sodium phosphate
Dexamethasone sodium m-sulphobenzoate
Dexamethasone trioxaundecanoate
Dextromethorphan hydrobromide
Dextrothyroxine sodium
Diazoxide
Dibenzepin hydrochloride
Dichloralphenazone
Dichlorophernasine hydrochloride
Dichlorphenamide
Diclofenac sodium
Dicyclomine hydrochloride
Dienoestrol
Diethanolamine fusidate
Diethylamine acetarsol
Diflucortolone valerate
Diflunisal
Digitalis leaf
Digi toxin
Digoxin
Dihydrallazine sulphate
Dihydroergotamine mesylate
Dihydrostreptomycin sulphate
Diltiazem hydrochloride
Dimercaprol
Dimethisoquin hydrochloride
Dimethisterone
Dimethothiazine mesylate
Dimethyl sulphoxide
Dimethyltubocurarine bromide
Dimethyltubocurarine chloride

Dimethyltubocurarine iodide
Dinitrodiphenylsulphonylethylenediamine
Dinoprost
Dinoprostone
Diphetarsone
Dipivefrin hydrochloride
Diprenorphine hydrochloride
Dipyridamole
Dipyrone
Disodium etidronate
Disopyramide
Disopyramide phosphate
Distigmine bromide
Disulfiram
Disulphamide
Dithranol
Dobutamine hydrochloride
Dompridone
Dopamine hydrochloride
Dothiepin
Dothiepin hydrochloride
Doxapram hydrochloride
Doxepin hydrochloride
Doxycycline
Doxycycline calcium chelate
Doxycycline hydrochloride
Droperidol
Ddrostanolone
Drostanolone propionate
Dyaxide
Dydrogesterone
Econazole
Econazole nitrate
Ecthiopate iodide
Edrophonium
Emepromium bromide
Emetine
Emetine bismuth iodide
Emetine hydrochloride
Enalapril maleate
Ephedrine
Ephedrine hydrochloride
Ephedrine sulphate
Epicillin
Epirubicin
Epithiazide
Epoprostenol sodium
Ergometrine maleafe
Ergometrine tartrate
Ergotamine tartrate
Ergotoxine esylate
Erythromycin
Erythromycin estolate
Erythromycin ethyl carbonate
Erythromycin ethyl succinate
Erythromycin lactobionate
Erythromycin phosphate
Erythromycin stearate
Erythromycin thiocyanate
Estramustine phosphate
Etafedrine hydrochloride
Ethacrynic acid
Ethamsylate
Ethchlorvynol
Ethebenecid
Ethiazide
Ethinyloestradiol
Ethionamide
Ethisterone
Ethoheptazine citrate
Ethopropazine hydrochloride
Ethosuximide
Ethotoin
Ethulose
Ethyl acetanilide
Ethyl biscoumacetate
Ethyloestrenol
Ethynodiol diacetate
Etidronate disodium
Etomidate
Factor XIII concentrate
Fazadinium bromide
Fenbufen
Fenfluramine hydrochloride
Fenoprofen
Fenoprofen calcium
Fenoterol hydrobromide
Fenpipramide hydrochloride
Fenpiprane hydrochloride
Ferrous arsenate
Flavoxate hydrochloride
Flecainide
Fluanisone
Fluclorolone acetonide
Flucloxacillin sodium
Flucytosine
Fludrocortisone acetate
Flufenamic acid
Flugestone
Flugestone acetate
Flumedroxone acetate
Flumethasone

Flumethasone pivalate
Fiunisolide
Fluocinolone acetonide
Fluocinonide
Fíuocoríolone
Fluocortolone hexanoate
Fluocortolone pivalate
Fluopromazine hydrochloride
Fluorouracil
Fluorouracil trometamol
Fluoxymesterone
Flupenthixol decanoaie
Flupenthixol dihydrochloride
Fluperolone acetate
Fluphenazine deconoate
Fluphenazine enanthate
Fluphenazine hydrochloride
Fluprednidene acetate
Fluprednisolone
Fluprostenol sodium salt
Flurandrenolone
Flurbiprofen
Fluspirilene
Folic acid
Follicle stimulating hormone
Formosulphathiazole
Fosfestrol tetrasodium
Framycetin sulphate
Frusemide
Fumagillin
Fumagillin bicyclohexylamine
Furazolidone
Fusidic acid
Gallamine triethiodide
Gelsemine
Gelsemium
Gemfibrozil
Gentamicin
Gentamicin sulphate
Gestronoi
Gestronol hexanoate
Glibenclamide
Glibornuride
Gliclazide
Glipizide
Glucagon
Giyceryl trinitrate
Glycopyrronium bromide
Glymide
Gonadorelin
Gramicidin
Griseofulvin
Growth hormone
Guanethidine monosulphate
Guanoclor sulphate
Guanoxan sulphate
Hachimycin
Halcinonide
Haloperidol
Heparin
Heparin calcium
Heptaminol hydrochloride
Hexachlorophene
Hexamine phenylcinchoninate
Hexoestrol
Hexoestrol dipropionate
L-Histidine hydrochloride
Homatropine
Homatropine hydrobromide
Homatropine methylbromide
Hydralazine hydrochloride
Hydrargaphen
Hydrobromic acid
Hydrochlorothiazide
Hydrocortamate hydrochloride
Hydrocortisone
Hydrocortisone acetate
Hydrocortisone 17-butyrate
Hydrocortisone caprylate
Hydrocortisone hydrogen succinate
Hydrocortisone sodium phosphate
Hydrocortisone sodium succinate
Hydroflumethiazide
Hydroquinone
Hydroxychloroquine sulphate
1 alpha-Hydroxycalciferol
Hydroxymethylgramicidin
4-Hydroxy-3-nitrophenylarsonic acid
Hydroxyprogesterone
Hydroxyprogesterone enanthate
Hydroxyprogesterone hexanoate
Hydroxyurea
Hydroxyzine embonate
Hydroxyzine hydrochloride
Hyoscine
Hyoscine butylbromide
Hyoscine hydrobromide
Hyoscine methobromide
Hyoscine methonitrate
Hyoscyamine
Hyoscyamine hydrobromide
Hyoscyamine sulphate

Ibuprofen
Idoxuridine
Ignatius bean
Imipramine
Imipramine hydrochloride
Imipramine ion exchange resin bound salt or complex
Indapamide hemihydrate
Indomethacin
Indoramin hydrochloride
Insulins
Iodamide
Iodamide meglumine
Iodamide sodium
Ipecacuanha see emetine
Iptratropium bromide
Iprindole hydrochloride
Iproniazid phosphate
Iron; its salts
Isoaminile
Isoaminile citrate
Isocarboxazid
Isoconazole nitrate
Isoetharine
Isoetharine hydrochloride
Isoetharine mesylate
Isoniazid
Isoprenaline hydrochloride
Isoprenaline sulphate
Isopropamide iodide
Jabprondi.
Kanamycin sulphate
Ketamine hydrochloride
Ketoconazole
Ketoprofen
Ketotifen
Labetolol hydrochloride
Lactogernic hormone
Lanatoside C
Lanatoside complex A,B and C
Latamoxef disodium
Lead arsenate
Levallorphan tartrate
Levodopa
Lidoflazine
Lignocaine
Lignocaine hydrochloride
Lncomycin
Lincomycin hydrochloride
Liothyronine sodium
Lithium carbonate
Lithium sulphate
Lobeliiie; its salts
Lofepramine
Lofepramine hydrochloride
Lomustine
Loperamide hydrochloride
Loratadine
Loxapine succinate
Luteinising hormone
Lymecycline
Lynoestrenol
Mafenide acetate
Mafenide hydrochloride
Mafenite propionate
Magnesium bromide
Magnesiun fluoride
Magnesium metrizoate
Mandragora autumnalis
Mannomustine hydrochloride
Maprotiline hydrochloride
Mcbeverine hydrochloride
Mebhydrolin napadisylate
Mecamylamine hydrochloride
Meclofenoxate hydrochloride
Medroges trone
Medroxyprogesterone acetate
Mefenamic acid
Mefruside
Megestrol
Megestrol acetate
Meglumine iodoxamate
Meglumine ioglycamate
Meglumine iotraxate
Meglumine ioxaglate
Melarsonyl potassium
Mclengestrol
Melengestrol acetate
Melphalan
Melphalan hydrochloride
Mepenzolate bromide
Mephenesin
Mephenesin carbamate
Mepivacaine hydrochloride
Meptazinol hydrochloride
Mequitazine
Mercaptopurine
Mercuderamide
Mersalyl
Mersalyl acid
Mesterolone
Metabutethamine hydrochloride

Metaraminol tartrate
Metformin hydrochloride
Methacycline
Methacycline calcium
Methacycline hydrochloride
Methallenoestril
Methandienone
Methandriol
Methdilazine hydrochloride
Methenolone acetate
Methenolone enanthate
Methicillin sodium
Methimazole
Methindizate hydrochloride
Methixene
Methixene hydrochloride
Methohexitone sodium
Methoserpidine
Methotrexate
Methotrexate sodium
Methotrimeprazine
Methotrimeprazine hydochloride
Methoxamine hydrochloride
Methylclothiazide
N-Methyl acetanilide
Methyldopa
Methyldopate hydrochloride
Methylephedrine hydrochloride
Methylergotamine maleate
Methylpentynol
Methylpetynol carbamate
Methylprednisolone
Methylprednisolone acetate
Methylprednisolone sodium succinate
Methyltestosterone
Methylyhiouracil
Methysergide maleate
Metoclopramide hydrochloride
Metolazone
Metomidate hydroehloride
Metoprolol tartrate
Metronidazole
Metronidazole benzoate
Mexiletine hydrochloride
Mezlocillin sodium
Mianserin hydrochloride
Miconazole
Miconazole nitrate
Minocycline
Minocycline hydrochloride
Minoxidil
Mithramycin
Mitomycin C
Mitopodozide
Mitozantrone hydrochloride
Molindone hydrochloride
Mustine hydrochloride
Nadolol
Naftidofuryl oxalate
Nalbuphine hydrochloride
Nalidixic acid
Naiorphine hydrobromide
Naloxone hydrochloride
Nandrolone decanoate
Nandrolone laurate
Nandrolone phenylpropionate
Naphazoline hydrochloride
Naphazoline nitrate
Naproxen
Naproxen sodium
Natamycin
Nedocromil sodium
Nefopam hydrochloride
Neoarsephenamine
Neomycin
Neomycin palmitate
Neomycin sulphate
Neomycin undecanoate
Neostigmine bromide
Neostigmine methylsulphate
Netilmicin sulphate
Nialamide
Nicotinaldemyde thio-semicarbazone
Nicoumalone
Nifedipine
Nikethamide
Niridazole
Nitrofurantoin
Nitrofurazone
NNitroxoline
Nomifensine hydrogen maleate
Noradrenaline
Noradrenaline acid tartrate
Norethandrolone
Norethisterone
Northisterone acetate
Northisterone heptanoate
Norethynodrel
Norgestrel
d-Norgestrel
Nortriptyline hydrochloride
Novobiocin calcium

Novobiocin sodium
Nystatin
Oestradiol
Oestradiol benzanoate
Oestradiol cypaionate
Oestradiol dipropionate
Oestradiol diundecanoate
Oestradiol enanthate
Oestradiol phenylpropionate
Oestrdiol undecanoate
Oestradiol vaierate
Oestriol
Oestriol di-hemisuccinate
Oestrogenic substances, congugated
Oes trone
Oleandomycin phosphate
Opipramol hydrochloride
Orciprenaline sulphate
Orphenadrine citrate
Orphanedrine hydrochloride
Orthocaine
Ouabain
Ovarin gland, dried
Oxamniquine
Oxandrolone
Oxantel pamoate
Oxatomide
Oxedrine tartrate
Oxolinic acid
Oxophernasine hydrochloride
Oxophernasine tartrate
Oxpentifyline
Oxprenolol hydrochioride
Oxbuprocaine hydrochloride
Oxymeterone
Oxymetholone
Oxypertine
Oxypertine hydrochloride
Oxyphenbutazone
Oxyphencyclamine hydrochloride
Oxyphenonium bromide
Oxytetracycline
Oxytetracycline calcium
Oxytetracycline dihydrate
Oxytetracycline hydrochloride
Oxytocins, natural and synthetic
Pancuronium bromide
Papaverine
Papaverine hydrochloride
Papaveroline
Papaveroline 2-sulphonic acid
Paraldehyde
Parameihadione
Paramethasone acetate
Parathyroid gland
Pargyline hydrochloride
Paromycin sulphate
Pecilocin
Pempidine tartrate
Penbutolol sulphate
Penethamate
Penicillamine
Penicillamine hydrochloride
Penicillin V
Pentamidine
Pentolinium tartrate
Perhexiline hydrogen maleate
Pericyazine
Perphenazine
Phenacaine
Phenacemide
Phernasone suiphoxylate
Phenazone
Phenazone salicylate
Phenbenicillin potassium
Phebutrazate hydrochloride
Phenelzine sulphate
Phenethicillin potassium
Pheneturide
Phenformine hydrochloride
Phenglutarimide hydrochloride
Phenindone
Phenoxybenzamine hydrochloride
Phenoxymethylpenicillin
Phenoxymethylpenicillin calcium
Phenoxymetliylpenicillin potassium
Pheprocoumon
Phensuximide
Phentolamine hydrochloride
Phentolamine mesylate
Phenyl aminosalicylate
Phenylbutazone
Phenylbutazone sodium
Phenylephrine hydrochioride
Phenylpropanolamine hydrochloride
Phenytoin
Phenytoin sodium
Phthalylsulphacetamide
Phthalylsulphathiazole
Physostigmine
Physostigmine aminoxide salicylate
Physostigmine salicylate

Physostigmine sulphate
Piloearpine
Pilocarpine hydrochloride
Piloearpine nitrate
Pimozide
Pindoíol
Pipenzolate bromide
Piperacillin sodium
Piperazine oestrone sulphate
Piperidolate hydrochloride
Pipothiazine palmitate
Piracetam
Pirbuterol acetate
Pirbuterol hydrochloride
Pírenzepine hydrochloride
Pixentanide
Piroxicam
Pituitaíry gland (whole dried)
Pituitary powdered (posterior globe)
Pivampicillin hydrochloride
Pivmeciilinam
Pivmecillinam hydrochloride
Pizotifen
Pizotifen hydrogen maleate
Plicamycin
Podophyllum indian
Podophyllum resin
Poldine methylsulphate
Polidexide
Polidexide hydrochloride
Polidexide sulphate
Polymyxin B sulphate
Polyoestradiol phosphate
Polythiazide
Potassium aminosalicylate
Potassium arsenite
Potassium bromide
Potassium cancrenoate
Potassium chloride
Potassium citrate
Potassium elavulanate
Potassium perchlorate
Pralidoxime chloride
Pralidoxime iodide
Praiidoxime mesylate
Prazosin hydrochloride
Prednisolone
Prednisolone acetate
Prednisolone butylacetate
Prednisolone hexanoate
Prednisolone pivalate
Prednisolone sodium phosphate
Prednisolone sodium m-sulphoben.zoate
Prednisolone 21-steaglate
Prednisolone m-sulphobenzoate
Prednisone
Prednisone acetate
Prenalterol hydrochloride
Prenylamine lactate
Prilocaine hydrcchloride
Primaquine phosphate
Primodine
Probenecid
Prooucol
Procainamide hydrochloride
Procaine hydrochloride
Procaine penicillin
Procarbazine hydrochloride
Prochlorperazine edisylate
Prochlorperazine maleate
Prochlorperazine mesylate
Procyclidine hydrochloride
Progesterone
Proguanil hydrochloride
Prolintane hydrochloride
Promazine embonate
Promazine hydrochloride
Propanidid
Propantheline bromide
Propicillin potassium
Propiomazine hydrogen maieate
Propranolol hydrochloride
Propylthiouracil
Propylphenazone
Proquamezine fumarate
Proquazone
Prostaglandin F2 alpha tromethamine
Protamine sulphate
Prothionamide
Prothipendyl hydrochloride
Protriptyline hydrochloride
Proxymetacaine hydrochloride
Pseudoephrine hydrochloride
Pseudoephrine sulphate
Pyrantel embonate
Pyrantel tartrate
Pyrazin amide
Pyridostigmine bromide
Pyrimethamine
L-Pyroglutamyl-L-histidyl-L-proline amide
Quines tradiol
Quincstrol

Quinethazone
Quingestanol
Quinidine
Quinidine bisulphate
Quinidine phnylethylbarbiturate
Quinidine polygalacturonate
Quinidine sulphate
Quinine; its salts
Quinuronium sulphate
Racephedrine hydrochloride
Ranitidine hydrochloride
Rawolfia (serpetina and vomitória)
Reproterol hydrochloride
Rescinnamide
Reserpine
Rfamide
Rifampicin
Rifamycin
Rimiterol hydrobromide
Ritodrine hydrochloride
Rolitetracycline nitrate
Salazosulphadimidine
Salbutamol
Salbutamol sulphate
Selegiline hydrochloride
Sera and antisera
Serum gonadotrophin
Siver sulphadiazine
Sissomycin sulphate
Sodium aminosalicylate
Sodium antimonylgluconate
Sodium apolate
Sodium arsanilate
Sodium arsenite
Sodium bromate
Sodium bromide
Sodium cacodylate
Sodium cromoglycate
Sodium ethacrynate
Sodium fluoride
Sodium fucidaie
Sodium methylarsinaie
Sodium metrizoate
Sodium monofluorophosphate
Sodium stibogluconate
Sodium valproate
Sotalol hydrochloride
Spectinomycin
Spiramycin
Spiramycin adipate
Spirinolactone
Stannous fluoride
Stanolone
Stanozolol
Stilboestrol
Stilboestrol dipropionate
Streptotíornase
Streptokinase
Streptomycin
Streptomycin sulphate
Strychnine
Strychnine arseaate
Strychnine hydrochloride
S uccinylsulphathiozole
Sucralfate
Sulbactam sodium
Sulconazole nitrate
Sulfacytine
Sulfadicramide
Sulfadoxine
S ulfame topyrazine
Sulfamonomethoxine
Sulfapyrazole
Sulfabromethazine
Sulphacetamide
Suiphacetamide sodium
S ulphachlorpyridazine
Sulphadiazine
Sulphadiazine sodium
Sulphadimethoxine
Sulphadimidine
Sulphadimidine sodium
Sulphafurazole
Sulphafurazole diethanolamine
S ulphaguanidine
Sulphaloxicacid
S ulphamerazine
Sulphamerazine sodium
S ulphamethizole
S ulphamethoxazole
S ulphamethoxydiazine
S ulphamethoxypyridazine
Sulphamethoxypyridazine sodium
S u Jphamethy Iphenazole
Sulphamoxole
Sulphanilamide
Sulphaphenazoie
Sulphapyridine
Sulphapyridine sodium
Sulphaquinoxaline
Sulphaquinoxaline sodium
Sulpharsphenamine

Sulphasalazine
Sulphasomidine
Sulphasomidine sodium
Sulphathiozole
Salphathiozole sodium
Salphathiourea
Sulphatolamide
Sulphaurea
SuJphinpyrazone
Sulphomyxin
Sulpiride
Sulthiame
Suxamethonium bromide
Suxamethonium chloride
Suxethonium bromide
Tacrine hydrochloride
Talampicillin
Talampicillin hydrochloride
Talampicillin napsylate
Tamoxifen
Tamoxifen citrate
Teclothiazide potassium
Terbutaline
Terbutaline sulphate
Testosterone
Testosterone acetate
Testosterone 17B chlGral hemiacetal
Testosterone cyclohexylpropionate
Testosterone cypionate
Testosterone decanoate
Testosterone enanthate
Testosterone isocaproate
Testosterone phenylpropionate
Testosterone propionate
Testosterone undecanoate
Tetrabenazine
Tetracosatrin
Tetracosatrin acetate
Tetracycline
Tetracycline hydrochloride
Tetracycline phosphate complex
Thallium acetate
Theophylline
Thiabendazole
Thiethylperazine
Thiethylperazine di-(hydrogen malate)
Thiocarlide
Thioguinine
Thiopentone sodium
Thiopropazate hydrochloride
Thioproperazine mesylate
Thioridazine
Thioridazine hydrochloride
Thiotepa
Thiothexene
Thiouracil
Thymoxaraine hydrochloride
Thyroid
Thyrotrophin
Thyrotrophin releasing hormone
Thyroxine sodium
Tianulin hydrogen fumarate
Tiaprofenic acid
Ticarcillin sodium
Tigloidine hydrobromide
Timolol maleate
Tinidazole
Tioconazole
Tobramycin
Tobramycin sulphate
Tocainide hydrochloride
Toferiacin hydrochloride
Tolazamide
Tolazoline hydrochloride
Tolbutamide
Tolbutamide sodium
Tolmetin sodium dihydrate
Tolperisone
Totaquine
Tranexamic acid
Tranylcypromine sulphate
Trazadone
Treosulfan
Tretamine
Treotinon
Triacetyloleandomycin
Triamcinolone
Triamcinolone acetonide
Triamcinolone diacetate
Triamcinolone hexacetonide
Triamterene
Tribromo ethyl alcohol
Triclofos sodium
Tricyclamol chloride
Trienbolone acetate
TrienLine dihydrochloride
Trifluoperazine
Trifluoperazine hydrochloride
Trifiuoperidol
Trifluoperidol hydrochloride
Trilostane
Trimeprazine

Trimeprazine tartrate
Trimetaphan camsylate
Trimetazidine
Trimetazidine hydrocloride
Trimethoprim
Trimipramine maleate
Trimepramine mesylate
Trimustine hydrochloride
Tripolidine
Tropicamide
L-Tryptophan
Tubocurarine chloride
Tybamate
Tylosin
Tylosin phosphate
Tylosin tartrate
Tyrothricin
Uramustine
Urea stibamine
Uridine-5-triphosphoric acid
Urifollitrophin
Urokinase
Ursodeoxycholic acid
Vaccines
Valproic acid
Vancomycin hydrochloride
Vasopressin tannate
Vecuronium bromide
Verapamil hydrochloride
Viloxazine hydrochloride
Vinblastine sulphate
Vincristine sulphate
Vindesin sulphate
Viomycin pantothenate
Viomycin sulphate
Vitamin A
Vitamin A acetate
Vitamin a palmitate
Vitamin D
Vitamins
Warfarin
Warfarin sodium
Xylazine hydrochloride
Yohimbine hydrochloride
Zidovudine
Zinc sulphate in preparations for
local
ophthalmic use
Zimeidine hydrochloride
Zomepirec sodium
Zuclopenthixol hydrochloride

(3) SCHEDULE 3 DRUGS

Acertasol in preparations for external use

Acetylsalicylic acid in preparations with md 500mg and not more than 30 doses, (except those intended for children under 12 years: Schedule 2).

label (1)

Aconite in preparations and mixtures of ms 9.02%

Adrenaline, if

(a) in inhalers

(b) in preparations for external use

Amethocaine in preparations for non-parenteral use, (except those intended for local ophthalmic use: Schedule 2).

Amethocaine gentisate in preparations for non-parenteral use (except those intended for local opthalmic use: Schedule 2).

Amethocaine hydrochloride in preparations for non-parenteral use, (except those intended for local opthalmic use: Schedule 2).

Astemizole in preparations licensed and labelled for the treatment of hay fever in adults and children over 12 years.

label (5)

Airopine in preparations for external use, (except those intended for local opthalmic use: Schedule 2)

Airopine methobromide in preparations for external use, (except those intended for local opthalmic use: Schedule 2)

Airopine methonitrate in preparations for external use, (except those intended for local opthalmic use: Schedule 2)

Atropine oxide hydrochloride in preparations for external use, (except those for .-local opthalmic use: Schedule 2)

Azatadine maleate

label (5)

Benzocaine in preparations for non-parenteral use (except those for local opthalmic use: Schedule 2)

Benzoyl peroxide in preparations for external use with ms 10%

Boric acid

Brompheniramine maleate

Bupivacaine in preparations for non-parenteral use, (except those intended for local opthalmic use: Schedule 2)

Bupivacaine hydrochloride in preparations for non-parenteral use, (except those intended for local opthalmic use: Schedule 2)

Butacaine sulphate in preparations for non-parenteral use, (except those intended for local opthalmic use: Schedule 2)

Butaniiicaine phosphate in preparations for non-parenteral use, (except preparations intended for local ophthalmic use: Schedule 2)

Caffeine

Cantharidin in preparations for external use and ms 0,01%

Caramiphen edisyiate in:

(a) tablet preparations and ins 7.5mg (calculated as base)

(b) liquid preparations and ms 0.1% (calculated as base)

Çarbenoxolone sodium in preparations for external use ms 2%

Chlorhexidine

Chloroquine phosphate for prophylaxis of malaria.

Labelling for malaria prophylaxis

Chloroquine sulphate for prophylaxis of malaria.
Labelling for malaria prophylaxis
Chlorpherinamine maleate, *label (5)*
(But in preparations for parenteral use: Schedule 2)
Cinchocaine in preparations for non-parenteral use and ms 3 %, (except preparations for local ophthalmic use: Schedule 2)
Cinchocaine hydrochloride in preparations for non-parenteral use HIS 3%, (except preparations for local ophthalmic use: Schedule 2)
Clemastine, *label (5)*
Clioquinol in preparations for external use
Clotrimazole in preparations for external use
Cyclizine hydrochloride in preparations for non-parenteral use
Dequalinium chloride in:
(a) throat lozenges or throat pastilles and ms 0.25mg
(b) external paint preparations and ins 1%
Dextromethorphan hydrobromide in preparations for intrenal use with md 15mg (calculated as base)
Diclofenac in preparations for external use
Dicyclomine hydrochloride in non-parenteral preparations, *label (6)*
Dimenhydrinate in preparations for non-parenteral use
label (5)
Dimethindine maleale, *label (5)*
Dimethisoquin hydrochloride in preparations for non-parenteral use, (except preparations for local ophthalmic use: Schedule 2)
Diphenhydramine hydrochloride in preparations for non-parenteral use, *label (5)* .
Diphenylpyraline hydrochloride, *label (5)*
Econazole in preparations for external use, (except for vaginal use: Schedule 2)
Econazole nitrate in preparations for external use, (except for vaginal use: Schedule 2)
Emetine in preparations for internal or external use and ms 1%
. Emetine hydrochloride in preparations for internal or external use and *ms* 1% (calculated as base)
Ephedrine in:
(a) preparations for internal use (except nasal sprays or nasal drops) with Bid 30mg and *mâá* 60mg, *label (4)*
(b) nasal sprays or nasal drops and ms 2%
label (4)
Ephedrine hydrochloride in:
(a) preparations for internal use (except nasal sprays and nasal drops) with md 30m.g (calculated as base) and xndd 60m2 (calculated as base)
label (4)
(b) nasal sprays or nasal drops and ms *2%* (calculated as base), *label (4)*
Folk acid (schedule 2) in preparations for internal use and mdd 500 micrograms,
Gramicidin in preparations for external use and ms 0.02%
Hexachlorophene in preparations for external use and:
(a) in soaps with ms more than 0.1% but not more than *2%*
label (6)
(b) in products other than soacs or aerosols with ms more than 0.1% but not more than 0.75%
label (6)
L-Histidine hydrochloride used as an ingredient in

dietary or nutritional products as an amino acid
Homatropine in preparations for external use (except preparations for local ODhthalmic use: Schedule 2))
Hydroxychloroquine sulphate for the prophylaxis of malaria
Labelling for malaria prophylaxis
Hydrocortisone in preparations for external use and ms 1 %
Hydroxymethylgramicidin in throat lozenges or throat pastilles
Ibuprofen in preparation for internal use with ms 200mg and not more than 30 doses
Idoxuridine in preparations for external use (except preparations for local ophthalmic use: Schedule 2))
Indomethacin in preparations for external use
Isoconazole nitrate for external use, (except preparations intended for vaginal use: Schedule 2)
Lignocaine in preparations for non-parenteral use, (except those intended for local ophthalmic use: Schedule 2)
Lignocaine hydrochloride in preparations for non-parenteral use. (except those intended for local ophthalmic use: Schedule 2)
Mebendazole
Mepivacaine hydrochloride in preparations for non-parenteral use, (except those intended for local ophthalmic use: Schedule 2)
Metabutethamine hydrochloridein preparations for non-parenteral use, (except preparations for local ophthalmic use)
Methylephedrine hydrochloride in preparations for internal use wi th md 3 Omg and mdd 60m g
Miconazole for external use (except vaginal use; Schedule 2))
Naphazoline hydrochloride:
(a) in nasal sprays or nasal drops not containing liquid paraffin as vehicle and jns 0.05%
(b) in eye drops and ms 0.015%
Naphazoline nitrate in nasal sprays or nasal drops not containing liquid paraffin as vehicle and ms 0.05%
Nitrofurazone in preparations for external use
Orthocaine in preparations for non-parenteral use, (except those intended for local ophthalmic use: Schedule 2)
Oxybuprocaine hydrochloride in preparations for non-parenteral use, (except those intended for local ophthalmic use: Schedule 2)
Paracetamol
label (3)
Phenacaine in preparations for non-parenteral use, (except those intended for local ophthalmic use)
Phenindamine tartrate
Pheniramine maleate
Phenolphthalein
Phenylephrine hydrochloride but if in eye drops with ms 10%
Phenylpropanolamine hydrochloride:
(a) in preparations for internal use (except controlled release capsules, nasal sprays or nasal drops) with md 25mg and mdd lOOmg
(b) in controlled release capsules with md 50mg and mdd lOQmg
(c) in nasal sprays or nasal drops with ms of 2%
Piperazine
Ppdophyjlum resin in ointments or impregnated plasters for external use with ms 20%
Prilocaine hydrochloride in preparations for non-parenteral use, (except those intended for local ophthalmic use: Schedule 2)

Procaine hydrochloride in preparations for non-parenteral use, (except those intended for local ophthalmic use: Schedule 2)
Proguanil hydrochloride for prophylaxis of malaria
Labeling for malaria prophylaxis
Proxymetacaine hydrochloride in preparations for non-parenteral use (except those intended for local ophthalmic use: Schedule 2)
Pseudophedrine hydrochloride in preparations for internal use with md 60mg and mdd 180mg
Pseodophedrine sulphate in preparations for internal use with md 60mg and mdd l80mg
Quinine in preparations for internal use md lOOmg (calculated as base) and mdd 300mg (calculated as base)
Sodium apolate in preparations for external use
Sodium arsenite in preparations for internal and external use and ms 0.013%
Sodium cromoglycate in preparations for use by being administered through the nose
Sodium fluoride:
(a) in preparations for use in the prevention of dental caries, other than dentifrices, in the form of:
(i) tablets or drops and mdd 2.2mg
(ii) mouth rinses other than those for daily use and ms 0.2%
(iii) mouth rinses for daily use and ms 0.05%
Streptodornase in preparations for external use
S Ixeptokinase in preparations for external use
Sulconazole in preparations for external use, (except vaginal use Schedule 2)
Terfenadine
Thiabendazole in preparations for external use
Tioconazole in preparations for external use (except vaginal use: Schedule 2) with ms *2%*
Tyrothricin in throat lozenges or throat pastilles
Zinc sulphate in non-parenteral preparations (except in preparations for local ophthalmic use: Schedule 2)

(4) SCHEDULE 4 DRUGS

Aluminium compounds
Ascorbic acid in preparations for non-parenteral use
Benzocaine in preparations for external use and ms 1% (except preparations for local ophthalmic use: Schedule 2))
Carbon tetrachloride
N.B. if the unlicensed product is sold for non-medical puiposes e.g. cleaning, there are no restrictions on its sale
Cetrimide
Chlorhexidine:
(a) for external use (except vaginal use: Schedule 3)
(b) in preparations for mouth wash and for use in the prevention of dental caries
Chloroform in liquid preparations for internal use and ms 0.5%
Folic acid in preparations for internal use and mdd 200 micrograms
Glycerol
Hexachlorophene:
in preparations for external use and:
(a) in soaps with ms 0.1%
label (6)
(b) in aerosols with ms 0.1%
label (6)
(c) in products other than soaps or aerosols with ms 0.1%
label (6)
Iron in preparations for internal use and mdd lOOmg (calculated as iron)
Lignocaine in preparations for external use and ms 0.6% (except preparations for local ophthalmic use: Schedule 2)
Lignocaine hydrochloride in preparations for external use and ms 0.7% (except preparations for local ophthalmic use: Schedule 2)
Magnesium trisilicate
Paracetamol in tablet preparations with ms 500mg and not more than 30 tablets
label (3)
Sodium fluoride in dentifrices and ms 0.33%
Sodium monofluorophosphate in dentifrices amd ms 1.14%
Stannous fluoride in dentifrices and .ms 0.62%
Vitamin A in:
(a) preparations for internal ase with mdd 7500 iu Vitamin A (2250 meg Retinol equivalent)
(b) preparations for external use
Vitamin A acetate in:
(a) preparations for internal use with mdd equivalent to 7500 iu Vitamin A (2250 meg Retinol equivalent)
(b) preparations for external use
Vitamin A palmitate in:
(a) preparations for internal use with mdd equivalent to 7500 iu Vitamin A (2250 meg Retinol equivalent)
(jb) preparations for external use
Vitamin D in:
(a) preparations for internal use with mdd 10 meg
(b) preparations for external use
Vitamins, mixed in non-parenteral preparations

Explanation of abbreviations and other phrases used in lists of drugs

md:	(maximum dose) i.e. the maximum quantity of the drug or substance that is contained in the amount of a medicinal product which is recommended to be taken or administered at any one time.
mdd:	(maximum daily dose) i.e. the maximum quantity of the substance that is contained in the amount of a medicinal product which is recommended to be taken or administered in any period of 24 hours.
ms:	(maximum strength) i.e. either or, if so specified, both of the following: (a) the maximum quantity of the substance by weight or volume that is contained in the dosage unit of a medicinal product; or (b) the maximum percentage of the substance contained in a medicinal product calculated in terms of w/w, w/v, v/w or v/v, as appropriate.
external ase:	means for application to the skin, teeth, mucosa of the mouth, throat, nose, eye, ear, vagina or anal canal when a local action only is necessary and extensive systemic absorption is unlikely to occur. N.B. The following are not regarded as for external use: throat sprays, throat pastilles, throat lozenges, throat tablets, nasal drops, nasal sprays, nasal inhalations or teething preparations.
oral use:	means administration through the mouth.
parenteral administration:	means administration by breach of the skin or mucous membrane.

SECOND SCHEDULE (reg. 21)

Amphetamine
Brolamphetamine (DOB, Bromo-STP)
Bufotenine(N,N-Dimethylserotonin)
Cannabis
Cocaine
Coca Leaf
Cathinone
DET or 3-[2-(diethylamino)ethyl]indole
Dexamphetamine
DMA or (+ or -)-2,5-dimethoxy-alpha-methylphenethylamine
DMT or 3-[2-(dimelhylamino)ethylindole
DOET or (+ or -)-4-ethyl-2,5-dimethoxy-alpha-phenethylamine
Ecgonine
Eticyclidine (PCE)
Fentanyl analogues (unless listed in another Schedule):
acetyl-alpha-methyl-fentanyl
alpha-methyl-fentanyl
alpha-methyl-fen tanyl-acetanilide
alpha-methyl-thiofentanyl
beta-hydroxy-fentanyl
3-methyl-thiofentanyl
3-methyl-fentanyl and its cis- and trans- isomeric forms
thiofentanyl
para-flurofentanyl
Harmaline
Harmine
Heroin (diacetylmorphine)
(+)-lysergide (LSD, LSD-25)
MDMA or (+ or -)-N, alpha-dimethyl-3,4-(methylenedioxy)-phenethylamine
Mecloqualone
Mescaline
Methaqualone
4-methylaminorex
MMDA or2-methoxy-alpha-methyl-4,5(methylenedioxy)phenethylamine
N-ethyl MDA or (+ or -)-N-ehtyl-alpha-methyl-3,4- (methylenedioxy)phenethylamine
N-hydroxy MDA or (+ or -)-N-[alpha-methyl-3,4(methylene-dioxy)phenethyl]hydroxylamine
Opium
Parahexyl
Pethidine analogues:
l-methyl-4-phenyl-4-propionoxy-piperidine (MPPP)
l-methyl-4-phenyl-2,5,6-tetrahydropieridine (MPTP)
l-phenylethyl-4-phenyl-4-acetyloxy-píperidine (PEPAP)
PMA
Poppy straw concentrate
Psilocine or psilotsin
Psilocybine
Rolicyclidine (PHP, PCPY)
STP, DOM or 2,5-dimethoxy-alpha,4-dimethylphenethylamine
Tenamfetamine (MDA)

Tenocyclidine (TCP)
Tetrahydrocannabinol
TMA or (+ or -)-3,4,5-trimethoxy-alpha-methylphenethylamine

All preparations and mixtures of the following unless specifically excluded or unless listed in another Schedule:

(i) the isomers of substances above, where existence of such isomers is possible;
(ii) the esters and ethers of such substances and of the isomers referred to above or isomers of such esters and ethers, where the existence of such esters, ethers and isomers is possible;
(iii) the salts of such substances and of the isomers referred to in (i), and the salts of the esters, ethers and isomers referred to in (ii), where the existence of such salts is possible;
(iv) the isomers of any of the salts referred to in (iii), where the existence of such isomers is possible.

THIRD SCHEDULE (reg. 22)

FORMS

Form 1	Application for Registration of a Drug
Form 2	Approval for Registration of a Drug
Form 3	Application for Licensing to Import, Export, Manufacture and Sell Drugs
Form 4	Approval for Licensing as per Form 3
Form HFD 1	Application for Permit to Import Habit Forming Drug
Form HFD 2	Import Permit for Habit Forming Drug
Form HFD 3	Application for permit to Export Habit Forming Drug
Form HFD 4	Export Permit for Habit Forming Drug

C.410

REPUBLIC OF BOTSWANA
MINISTRY OF HEALTH

FORM 1

Application to be sent to:
Permanent Secretary
Ministry of Health
Private Bag 0038
GABORONE
Attention: Chief Pharmacist

APPLICATION
Number:

APPLICATION FOR REGISTRATION OF A DRUG
(All documents in English)

N.B.: Please study the notes on the reverse of each side

APPLICANT:

Name:

Postal Address:

Business Address:

Telephone/Telefax Number:

THE DRUG:

Name (Trade and INN-name) (1):

Dosage Form and Strength (2):

Colour (3):

Package Size(s):

Pharmacological Classification^):

Country of Origin:

Manufacturer:

The undersigned hereby declares that all information contained herein and in the appendices is correct and true.

Date: ---------- Signature: ----------

Name (block letters): ----------

Official and Professional Designation(5): ----------

(1),

(2) etc. See notes on reverse side.

NOTES

(1) International non-proprietary INN-name if available.

(2) E.g. solutions, suspension, eyedrop, emulsion, ointment, suppository, tablet, capsule or injection. In case of injections, whether a vial ampoule, dental catridge, etc. and the contents, e.g. powder, solution, etc.

The strength to be per dosage unit. Where no dosage unit exist, other suitable unit of mass or volume of the drug.

(3) The colour shall be the final appearance of the product, e.g. white mixture in brown bottle, yellow and green capsule with white powder.

(4) Anatomical, therapeutic and chemical classification (W.H.O.) or equivalent therapeutic and pharmacological classification. Codes should be accompanied by explanation, e.g. anti-epileptic, non-steroidal anti- inflammatory, etc.

(5) The signatory shall be a registered pharmacist.

COMPOSITION

Name of Drug:
Name of Applicant:
Dosage Form and Strength:

Below is a schedule of:

(a) active ingredient given in approved names, chemical names, structural and molecular formulae, specification, physical properties and quantity in dosage unit (3);

(b) inactive ingredients specifications, quantity in dosage unit and reason for inclusion;

(c) specifications^) of any raw material used in manufacturing whether or not present in final dosage product;

(d) chemical details of the active ingredients showing the approved name, solubility, storage requirements, etc.

ACTIVE INGREDIENTS

Approved name	Chemical name (1) and molecular formula	Quantity	Specification of Reference of such

INACTIVE INGREDIENTS

Approved Name	Quantity	Specification or Reference of such	Purpose for Inclusion

(1) Chemical names shall where possible be given in terms of the published list of an appropriate body.

(2) Specifications shall be at the level of the latest editions of the recognized references, other sources must be fully substantiated. References to the following, where applicable, shall be acceptable:

(a) British Pharmacopoeia;

(b) European Pharmacopoeia;

(c) United States Pharmacopoeia;

(d) International Pharmacopoeia; and of

(e) Any such reference that the Director may approve.

FORM 1

PACKAGE INSERT

Name of Drug:
Name of Applicant:
Dosage Form and Strenght

The following information about the drug shall appear on the package insert:

1. Scheduling status
2. Proprietary name (and dosage form)
3. Composition
4. Pharmacological classification (A.T.C. or equivalent)
5. Pharmacological action
6. Indications
7. Contra-indications
8. Warnings
9. Dosage and directions for ase
10. Side-effects and special precautions
11. Known symptoms of overdosage and particulars of treatment
12. Conditions of registration
13. Identification
14. Presentation
15. Storage instructions
16. Registration number
17. Applicant
18. Date of publication

1, 12,16 and 18 are for products manufactured for the Botswana market only.

(a) Scheduled status shall be determined by the Minister in accordance with section 9 of the Drugs and Related Substances Act, 1992
(b) Composition shall comprise of the active ingredients approved name and quantity per unit and the approved name and percentage of any preservative, colour and sugar included.
(c) Any recommended children's dosages and warnings shall be indicated where possible.
(d) Storage instructions shall quote temperatures (range).
(e) The number allocated in accordance with section 2 of the Act, the reference number allocated to such application by the Director followed by "Drugs Act, 1992".
(f) Date of publication shall mean the date on which the package insert was approved by the Board.
(g) Conditions of registration shall include sales category, public advertising status, etc.

CONTAINER SPECIFICATION AND CONTROL

Name of Drug:
Name of Applicant:
Dosage Form and Strength:

Below is the immediate container specification detailing type, nature, size, grade, method of closure, method of use of container, etc.

Details of immediate container analytical and other control procedures and information on contracted laboratories shall be given (1).

NOTES

1. Immediate container, in relation to a drug, means a container which is in direct contact with the drug.

PHARMACEUTICAL DOCUMENTATION

Name of Drug:
Name of Applicant:
Dosage Form and Strength:

The following information shall be included as part of the pharmaceutical documentation:

(a) Raw material specifications and analytical and control procedures;
(b) Raw material release criteria;
(c) Summarised details of final product specifications and release criteria;
(d) Description of final product analytical and other control procedures;
(e) Stability Studies (3);
(f) Manufacturing procedures (4).

NOTES

(1) All jobs carried out by specific contracted laboratories shall be mentioned - which laboratories shall be mentioned too.

(2) Specifications to include title, limits, and criteria of acceptance of all physical, chemical and microbiological parameters where applicable.

(3) Stability studies:

i) Data indicative of at least 24 months shelf-life derived from the product in the packaging material specified in Appendix III. Where the products contain inherently unstable ingredients this requirement shall not apply,

ii) Temperatures in Botswana can be as low as 0 degrees C and as high as 40 degreesC. Extremes of these shall be specified and tested.

iii) The preserving ability of any antibacterial agents or preservatives in the formulation shall be specified and tested.

iv) Data to include normal degradation products storage conditions required to maintain raw material integrity and results of qualitative results of tests carried out.

v) Date of manufacture and batch number of samples studied for stability (minimum of two batches).

(4) Manufacturing procedures shall detail stages of manufacturing and packaging, describing type of equipment used, analytical, microbiological and in-process control procedures. Where different manufacturing facilities were used this shall be mentioned. Local manufacturers might refer to Master Manufacturing Records if possible.

N.B, Application for biological products e.g. viral vaccine, viral antiserum, bacterial vaccine, bacterial antiserum, allergan, immunoglobulin, blood products, etc., shall include a detailed description of the premises on which all procedures involved in the preparation are undertaken, including a floor plan. A mention shall be made on any other use of the said premises.

PHARMACOLOGICAL AND CLINICAI. DOCUMENTATION

Name of Drug:
Name of Applicant-
Dosage Form and Strength:

The following shall be a summarized but detailed documentation on the pharmacological and clinical information about the drug.

NOTES

(1) Where the drug concerned is a well established drug then reference may be made to the latest edition of the standard reference textbooks.

(2) Pharmacological and clinical information shall include:

(a) Pre-clinical toxicological information, acute toxicity, estimated average lethal dose, teratogenicity, carcinogenicity and other tests on safety.

(b) Information on efficacy, dosage, method of administration, mode of action, side-effects and contra-indications on both laboratory animals and humans.

(c) Details of pharmacokinetic properties, equivalence, metabolism, metabolic products and their fate.

(d) Studies confirming the pharmaceutical or biological availability and clinical inter-changeability of the drug (Where equivalence is of clinical significance).

REGISTRATION STATUS AND OTHER INFORMATION

Name of Drug:

Name of Applicant:

Dosage Form and Strength:

A. Registration status in other countries shall be submitted from three other countries where the drug is registered (1) including certificates; package insert sample from that country; countries from where the registration has been rejected, refused, deferred or cancelled and reasons for such.
B. The World Health Organisation Certificate Scheme on the Quality of Pharmaceutical Products Moving in International Commerce shall be submitted from the country of origin.
C. A list of all references to the literature shall be submitted with annotations.
D. A table of contents for all items submitted shall be forwarded.
E. Documentation should not exeed 100 pages where practicable. (Tabulation is encouraged). Where reference has been made to recognised sources, copies of these pages should not be included.
F. A sample label as would appear on the immediate container shall be attached.
G. The ex-factory price of the drug in the package sizes applied for.

(1) "Register" or "registered" in this case refer to marketing authorisation.

FOR OFFICIAL USE

Application Number: *Date received:*	*Application Fee paid (date):* *Cash:* *Cheque No:*

THE DRUG:

Essential Drug: Yes [ ] | No [ ]

Therapeutic value:

Important: [ ] Less important: [ ] Unimportant: [ ]

BOARD'S DECISION:

Refused (date):	*Deferred (date):*

Conditionally approved (date, conditions):	
Final approval (date):	*Schedule:*
Approved indications:	

SPECIAL CONDITIONS ETC:

C.420

REPUBLIC OF BOTSWANA FORM 2
MINISTRY OF HEALTH

APPROVAL OF REGISTRATION OF A DRUG

Subject to due compliance with the requirement of the Drugs and Related Substances Act, 1992, and Regulations thereto, the Director of Health Services has approved the following drug to be marketed in Botswana and entered it into the Drug Register as follows:

Registration Number:	
Name of Drug:	

Active ingredient(s), approved name or volume of the drug:	and quantity per dosage unit or per suitable mass
Dosage Form:	Strength:
Manufacturer:	
Manufacturing Country:	
Package size(s):	
Packaging Material:	
Approved Indication(s):	
Schedule:	
Special Conditions:	
Date granted:	Valid until:
Authorization (name and stamp):	Signature (Dir.Health Serv.):

REPUBLIC OF BOTSWANA FORM 3
MINISTRY OF HEALTH

Application to be sent to:
Permanent Secretary
Ministry of Health
Private Bag 0038
GABORONE
Attention: Chief Pharmacist

APPLICATION
Number:

_____

.APPLICATION FOR APPROVAL TO:

[ ] import drugs [ ] export drugs
[ ] as wholesaler [ ] Schedule 1,2, 3 and 4
[ ] Schedule 4 only
[J as retailer [ ] Schedule 1, 2, 3 and 4
[ ] as agent [ ] Schedule 1, 2, 3 and 4
[ ] manufacture drugs (see also reverce page)
[ ] sell drugs
[ ] as wholesaler [J Schedule 1, 2, 3 and 4
[ ] Schedule 4 only
[] as retailer [] Schedule 1, 2, 3 and 4 (pharmacy)
[ ] Schedule 4 only

Name of applicant

(of person representing the company)

Address ----------

My qualifications are (profession/education) -

The premises are located (address)

_____
Date Signature of applicant

C.422

ADDITIONAL INFORMATION NEEDED FOR APPLICATION TO MANUFACTURE DRUGS

I. The following shall be the key personnel in the manufacturing plant:

NAME	QUALIFICATION	EXPERIENCE
Supervising pharmacist		
Production pharmacist		i
Quality assurance pharmacist		
Other		

The following are products intended to be manufactured (attach list showing name of product, active ingredient, strength and dosage form, include formulations and manufacturing process):

The following are the equipment to be used (attach list showing the name, type and capacity of equipment):

REPUBLIC OF BOTSWANA
MINISTRY OF HEALTH

FORM 4
Approval No:

APPROVAL FOR LICENSING

Subject to due compliance with the requirements of the Drugs and Related Substances Act, 1992 and Regulations thereto, the Director of Health Services, Ministry of Health, hereby approve for licensing:

Name of Applicant:

Address -

[ ] to import drugs [ ] to export

[J as wholesaler [j Schedule 1, 2, 3 and 4
[ ] Schedule 4
[ ] as retailer [ ] Schedule 1, 2, 3 and 4
[ ] as agent [ ] Schedule 1, 2, 3 and 4
[j to manufacture drugs
[ ] to sell drugs
[ ] as wholesaler [ ] Schedule 1, 2, 3 and 4
[ ] Schedule 4
[ ] as retailer [ ] Schedule 1,2, 3 and 4
[ ] Schedule 4

at-

(premises)

Special conditions;

_____

_____

_____

_____ _____

Date Valid until (date)

Stamp and signature
Dir. of Health Services:

C.424

REPUBLIC OF BOTSWANA
MINISTRY OF HEALTH

FORM HFD 1

Application to be sent to:
Permanent Secretary
Ministry of Health
Private Bag 0038
GABORONE
Attention: Chief Pharmacist

APPLICATION FOR PERMIT TO IMPORT
HABIT FORMIMG DRUGS AND/OR PSYCHOTROPIC SUBSTANCES
(Drugs and Related Substances Act, 1992)

In accordance with the Drugs and Related Substances Act, 1992, the Single Convention on Narcotic Drugs, 1961 and the Convention on Psychotropic Substances, 1971,

I,

(Name of Applicant)

registered as _

(Qualification and Registration Number)

or.

(Company and Address)

---

hereby apply for permit to import the following habit forming drugs and/or psychotropic substances:

1 Item No.	Approved name of drug/sub-stance and strength	Quantity and presentation of drug substance drug or substance	Purpose: medicinal, manufacture, research, scientific other (specify)	_ ---------- : ---------- Stock will last (number of days if applicable)

Total number of items:

From (name and address of exporting firm)

Route of supply (by):

Port of entry (at):

Date:

Signature of applicant:

NOTES: To be accompanied by a completed order from the importing firm specifying the exporting firm.

REPUBLIC OF BOTSWANA
MINISTRY OF HEALTH

FORM HFD 2
Import Permit No

IMPORT PERMIT FOR HABIT FORMING DRUGS
AND/OR PSYCHOTROPIC SUBSTANCES

In accordance with the Drugs and Related Substances Act, 1992, the Single Convention on Narcotic Drugs, 1961 and the Convention on Psychotropic Substances, 1971, authority is here granted to:

(name, location and postal address of importing firm)

to import or acquire the Habit Forming Drugs and/or Psychotropic substances specified here under from:

(name, location and postal address of exporting firm)

C.426

1	Approved name of drug/sub-stance ana strength	Quantity and pre-sentation of prepa-ration	Approved name and quantity of controlled drug/sub-stance as base in kilograms	Purpose: medicinal, manufacture, research, scientific and others (specify)

Total Number of Items:

It is a condition of this permit that drugs substances imported or acquired hereunder shall not be used by the person to whom this permit is issued, otherwise than for or in accordance with the Drugs and Related Substances Act, 1992.

This authority expires on ----------

Drugs/substances ordered on this authority must be consigned by registered mail/road/air/ sea* (Delete the inapplicable).

Route of supply (by)----------

Port of entry (at) ----------

Signature and starn Date

Dir. of Health Services

NOTES

To be completed in quintuplicate

Original copy to be forwarded to the health authorities of exporting country to facilitate export authorization.

Duplicate to be retained by the exporter for their records.

Triplicate to be retained by the exporter and then sent with the goods to the importer along with a copy of export authorization for Customs clearance purposes.

Quadruplicate to be retained by the importer for their records.

Quintupiicate to be retained by the import authorizing office.

REPUBLIC OF BOTSWANA
MINISTRY OF HEALTH

FORM HFD 3

Application to be sent to:
Permanent Secretary
Ministry of Health
Private Bae 0038
GABORONE
Attention: Chief Pharmacist

APPLICATION FOR PERMIT TO EXPORT
HABIT FORMING DRUGS AND/OR PS YCHOTROPIC SUBSTANCES
(Drugs and Related Substances Act, 1992)

In accordance with the Drugs and Related Substances Act, 1992, the Single Convention on Narcotic Drugs, 1961 and the Convention or Psychotropic Substances, 1971,

I. _____
(Name of Applicant)

registered as
(Qualification and Registration Number)

of.
(Company and Address)

hereby apply for permit to export the following Habit Forming drugs and/or psychotropic substances:

Item No.	Approved name of drug/sub-stance strength	quantity and presentation of drug or substance	Purpose: medicinal research others (specify)
			1

Total number of items:

C.428

To (name and address of importing firm):

Route of supply(by):

Port of exit (at):

Date:.

Signature of applicant:

NOTES

To be accompanied by import authorization from country of destination and a completed order from the importing firm.

REPUBLIC OF BOTSWANA
MINISTRY OF HEALTH

FORM HFD 4
Export Permit No

EXPORT PERMIT FOR HABIT FORMING DRUGS
AND/OR PSYCHOTROPIC SUBSTANCES

In accordance with the Drugs and Related Substances Ac,. 1992, the Single Convention on Narcotic Drugs, 1961 and the Convention orPsychotropic Substances, 1971, authority is here granted to:

(name, location and postal address of exporting firm)

Item No.	Approved name of drug/sub-stance and strength	Quality and pre-sentation of prepa-ration	Approved name and quantity of controlled drug/substance as base in kilograms	Purpose: medicinal, manufacture, research, scientific and others (specify)
				----------_! ,

Total Number of Items:

It is a condition of this permit that drugs/substances exported hereunder shall not be used by the person to whom the permit is issued or to whom the drugs/substances are exported to otherwise than in accordance with the provisions of the Drugs and Related Substances Act, 1992 or the Single Convention on Narcotic Drugs 1961 or the Convention of Psychotropic Substances, 1971.

This authority expires on

Drugs/Substances ordered on this authority must be consigned by Registered Mail/Road/ Air/Sea* (*Delete the inapplicable). The importation of these Drugs/Substance into the country of destination has been authorized by

Import Permit No ---------- Dated

Route of supply (by) ---------- — ----------

Port of entry (at) ------ : ----------

Signature and stamp ---------- Date----------
Dir. of Health Services

To be completed in quintuplicate

1. Original to accompany consignment

2. Duplicate to be endorsed in accordance with the requirements of the Single Convention on Narcotic Drugs, 1961 and the Convention on Psychotropic Substances, 1971, and returned to the Chief Pharmacist, Ministry of Health P/Bag 0038, Gaborone.

3. Triplicate to be certified by the exporter and returned to the Chief Pharmacist, Ministry of Health, as soon as possible after the date of despatch.

4. Quadruplicate to be retained by the exporter for their records.

5. Quintuplicate to be retained by the export authorizing office.

MADE this 8th day of April, 1993.

B.K. TEMANE,
Minister of Health.