CHAPTER 63:04 - DRUGS AND RELATED SUBSTANCES: SUBSIDIARY LEGISLATION
(previously "HABIT-FORMING DRUGS")
INDEX TO SUBSIDIARY LEGISLATION

HABIT-FORMING DRUGS REGULATIONS

(*under section 12*)

(*3rd October, 1922*)

ARRANGEMENT OF REGULATIONS

REGULATION

HCN 68, 1922,
HCN 87, 1922,
HCN 195, 1937,
HMC Order 1, 1963,
L.N. 84, 1966,
S.I. 12, 1977.

1. Citation

These Regulations may be cited as the Habit-forming Drugs Regulations.

2. Export of habit-forming drugs

Any duly registered medical practitioner, dentist or chemist and druggist, and any duly qualified veterinary surgeon who is desirous of exporting from Botswana any habit-forming drug as defined in the Act (other than prepared opium as defined in the Act), shall-

(*a*) furnish to the Minister a certificate from the government or administration of the importing country to the effect that such government or administration is satisfied that the consignment of such habit-forming drug is required solely for medicinal or scientific purposes, and that it approves of its importation;

(*b*) obtain from the Minister a permit under section 4(4) of the Act in the form in the First Schedule hereto.

3. Form of permit

The form of permit to import or acquire habit-forming drugs as provided for in section 5(1) of the Act shall be as contained in the Second Schedule hereto.

FIRST SCHEDULE
PERMIT TO EXPORT OPIUM OR OTHER HABIT-FORMING DRUGS

Permission is hereby granted to ..... of ..... to export from Botswana to ..... the following habit-forming drugs, to wit: ..... for medicinal or scientific purposes only.

This Permit will expire on the .....

Dated this ..... day of ..... 20.....

.....

Minister

This Permit is not transferable.

SECOND SCHEDULE
PERMIT TO IMPORT OR ACQUIRE HABIT-FORMING DRUGS

Mr. .....
profession/business
address
.....
..... is hereby authorized to import or acquire the undermentioned habit-forming drugs in the quantities specified opposite such item

Drug	Quantity

.....
.....
.....
.....

It is a condition of this permit that drugs imported or acquired hereunder shall not be used by the person to whom the permit is issued otherwise than for medicinal or scientific purposes or for the purpose of being sold or supplied to some other person in accordance with the provisions of the Habit-forming Drugs Act.

Dated this ..... day of ..... 20 .....
Gaborone .....
.....
(Sgd.)

HABIT-FORMING DRUGS (EXEMPTED PREPARATIONS) REGULATIONS

(*under section 12*)
(*10th November, 1937*)
ARRANGEMENT OF REGULATIONS

REGULATION

HCN 195, 1937.

1. Citation

These Regulations may be cited as the Habit-forming (Exempted Preparations) Regulations.

2. Exempted drugs

The preparations listed in the Schedule shall be exempted from the provisions of the Act.

SCHEDULE

Cereoli Iodoformi et Morphinae B.P.C. 1923	Iodoform and Morphine Bougies.
Emplastrum Opii B.P. 1898	Opium Plaster.
Linimentum Opii B.P.C.	Liniment of Opium.
Linimentum Opii Ammoniatum B.P.C. 1923	Ammoniated Liniment of Opium.
Pasta Arsenicalis B.P.C.	Arsenical Paste.
Pilulae Hydrargyri cum Opio B.P.C. 1923	Mercury and Opium Pills.
Pilulae Ipecacuanhae cum Scilla B.P.C.	Pills of Ipecacuanha with Squills.

Pilulae Plumbi cum Opio B.P.C. Lead and Opium Pills.
Pilulae Digitalis et Opii Compositae B.P.C. 1923 Compound Digitalis and Opium Pills.
Pilulae Hydrargyri cum Creta et Opii B.P.C. Pills of Mercury with Chalk and Opium.
Pulvis Cretae Aromaticus cum Opio B.P. Aromatic Powder of Chalk and Opium.
Pulvis Ipecacuanhae et Opii B.P. Dovers Powder.
Pulvis Ipecacuanhae Compositus B.P. 1914.
Pulvis Kino Compositus B.P.C. Compound Kino Powder.
Suppositoriae Plumbi cum Opio B.P. Compound Lead Suppositories.
Tablettae Plumbi cum Opio B.P.C. 1923 Lead and Opium Tablets.
Unguentum Gallae cum Opio B.P.C. Gali and Opium Ointment.
Unguentum Gallae Compositum B.P.C. 1923 Compound Gall Ointment.

Eyedrops for inclusion in first-aid outfits consisting of a solution of 1 in 3,000 Perchloride of Mercury in Castor Oil with 0,5 *per centum* of Cocaine.

(NOTE. Codeine and its salts are excluded from this list.)

DECLARATION OF HABIT-FORMING DRUGS ORDER

(*under section 14*)
(*2nd April, 1982*)

ARRANGEMENT OF PARAGRAPHS

PARAGRAPH

S.I. 36, 1982,
S.I. 35, 1987.

1. Citation

This Order may be cited as the Declaration of Habit-forming Drugs Order.

2. Declaration of habit-forming drugs

(1) The substances specified in the First Schedule hereto are hereby declared to be habit-forming drugs.

(2) The substances specified in the Second Schedule are specifically excluded from the list of habit-forming drugs.

FIRST SCHEDULE

Acetorphine
Acetylmethadol
Alfentanil
Allylprodine
Alphameprodine
Alphamethadol
Alphaprodine
Amphetamine
Anileridine
Benzethidine
Benzylmorphine

Betacetylmethadol
Betameprodine
Betamethadol
Betaprodine
Bezitramide
Cannabis (Indian Hemp) and Cannabis resin (Resin of Indian Hemp)
Clonitazene
Coca Leaf
Cocaine
Codoxime
Concentrate of poppy
Desomorphine
Dexamphetamine
Dextromoramide
Diampromide
Diethylthiambutene
Difenoxin
Dihydromorphine
Dimenoxadol
Dimepheptanol
Dimethylthiambutene
Dioxaphetyl butyrate
Diphenoxylate
Dipipanone
Drotebanol
Ecgonine, its esters and derivatives which are convertible to ecgonine and cocaine
Ethylmethylthiambutene
Etonitazene
Etorphine
Etoxeridine
Fentanyl
Furethidine
Heroin
Hydrocodone
Hydromorphinol
Hydromorphone
Hydroxypethidine
Isomethadone
Ketobemidone
Levomethorphan
Levomoramide
Levophenacylmorphan
Levorphanol
Mecloqualone
Metazocine
Methadone
Methadone-Intermediate
Methamphetamine
Methaqualone
Methyldesorphine
Methyldihydromorphine
Methylphenidate
Metopon
Moramide-Intermediate
Morpheridine
Morphine

Morphine-Methobromide and other pentavalent nitrogen morphine derivatives including in particular the morphine-N-oxide derivatives, one of which is Codeine-N-Oxide
Morphine-N-Oxide
Myrophine
Nicomorphine
Noracymethadol
Norlevorphanol
Normethadone
Normorphine
Norpipanone
Opium
Oxycodone
Oxymorphone
Pethidine
Pethidine-Intermediate - A
Pethidine-Intermediate - B
Pethidine-Intermediate - C
Phenadoxone
Phenampromide
Phenazocine
Phencyclidine
Phenmetrazine
Phenomorphan
Phenoperidine
Piminodine
Piritramide
Proheptazine
Properidine
Racemethorphan
Racemoramide
Racemorphan
Sufentanil
Thebacon
Thebaine
Tilidine
Trimeperidine

The isomers, unless specifically excepted, of the drugs in this Schedule whenever the existence of such isomers is possible within the specific chemical designation.

The esters and ethers of the drugs in this Schedule whenever the existence of such esters or ethers is possible.

The salts of the drugs listed in this Schedule, including the salts of esters, ethers and isomers as provided above whenever the existence of such salts is possible.

SECOND SCHEDULE

Dextromethorphan ((+) -3 methoxy-N-methylmorphinan) and dextrophan ((+)-3-hydroxy-N-methylmorphinan) are isomers specifically excluded from the First Schedule.

DRUGS AND RELATED SUBSTANCES REGULATIONS

(*under section 21*)

(*16th April, 1993*)

ARRANGEMENT OF REGULATIONS

REGULATION

S.I. 46, 1993.

1. Citation

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

2. Drugs Advisory Board

(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;
(*c*) 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.

(11) Except as is otherwise provided in this regulation, the Board shall be responsible for regulating its own proceedings.

3. Registration of drugs

(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. Exemption from registration

(1) The following drugs shall be exempted from registration-

(*a*) any drug manufactured or imported by the Central Medical Stores for specific therapeutic use;
(*b*) any drug imported through the Central Medical Stores 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 subregulation (1), the quantity imported and the name and address of the person or organization who imported or manufactured any such drug.

5. Approval for manufacture etc. of drugs

(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. Records to be kept by manufacturer of drugs

(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 subregulation (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. Import, export and distribution of drugs

(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, 1B 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 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*) in 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. Labelling of drugs

(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 pharmacopoeias 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 subregulation (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 subregulation (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 subregulation (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	*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 includes 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. Recall of drugs

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. Prescription of drugs

(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 drugs 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. Dispensing of Schedule 1A and 1B drugs

(1) Schedule 1A and 1B 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 may be, 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 1B drugs.

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

(5) The destruction of any Schedule 1A or Schedule 1B 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. Dispensing of Schedule 1C drugs

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. Dispensing of Schedule 2 drugs

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. Dispensing of drugs by nurses

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 1A, 1B, 1C, 2 and 3 drugs to patients, upon written prescription by a medical practitioner or a dentist.

15. Dispensing general

(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 is 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. Emergency supply of drugs

(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 a package that it is impractical to split the package, the whole package may be supplied.

17. Registers and records

(1) Separate registers shall be kept for Schedule 1A and Schedule 1B 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;

(*h*) 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;

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

(*g*) the date of such dispensing;

(*h*) the name and address of the prescriber.

(4) All invoices for the purchase or supply of Schedule 1A, 1B 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 calendar month.

18. Clinical trials

(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. Appeals

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. Classification of drugs

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

21. Prescribed habit-forming drugs

For the purposes of the definition of "habit-forming drug", section 3(1)(*b*) and Part III of the Act the drugs listed in the Second Schedule are declared to be banned habit-forming drugs.

22. Forms

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	1A
but if for non-parenteral use and:	
(*a*) in undivided preparations with ms 2.5% (calculated as base: Schedule 2)	1D
(*b*) in single-dose preparations with ms per dosage unit 100mg (calculated as base: Schedule 2)	1D
Acetyl-methadol *see* Methadyl acetate	
Alfentanil	1A
Allobarbital	1C
Allylprodine; its salts	1A
Alphacetylmethadol; its salts; its esters and ethers; their salts	1A
Alphameprodine; its salts	1A
Alphaprodine; and its salts	1A
Amferpramone	1B
Amidone *see* Methadone	

Alphamethadol; its salts, its esters and ethers; their salts	1A
Amphetamine; its salts	1A
Amphetamine phosphate	1A
Amphetamine sulphate	1A
Amylobarbitone	1B
Amylobarbitone sodium	1B
Anileridine; its salts	1A
Barbitone	1C
Barbitone sodium	1C
Benzethidine; its salts	1A
Benzphetamine; its salts	1B
Bezphetamine hydrochloride	1B
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	1B
Buprenorphine hydrochloride	1B
Butalbital	1B
Butobarbitone	1C
Butobarbitone 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	1B
Chlordiazepoxide	1C
Chlordiazepoxide hydrochloride	1C
Chlorphentamine; its salts	1B
Chlorphentamine hydrochloride	1B
Clobazam	1C
Clonazepam	1C
Clonitazene; its salts	1A
Clorazepate	1C
Clotiazepam	1C
Cloxazolam	1C
Codeine; its salts	1A
but if for non-parenteral use and:	
(*a*) in undivided preparations with ms 2.5% (calculated as base: Schedule 2)	1D
(*b*) in undivided preparations with ms 1.5% (calculated as base: and not more than 200ml: Schedule 3)	1D
(*c*) in single-dose preparations with ms per dosage unit 100mg (calculated as base: Schedule 2)	1D
(*d*) in single-dose preparations with ms per dosage unit 1.5% (calculated as base, and md 10mg: or calculated as base, and not more than 30 tablets: Schedule 3)	1D
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	1A
4-cyano-1-methyl-4-phenylpiperidine; its salts	1A
Cyclobarbitone	1B
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	1A
Dexamphetamine phosphate	1A
Dexamphetamine sulphate	1A
Dextrodiphenopyradine *see* Dextromoramide	
Dextromoramide; its salts	1A
Dextromoramide tartrate	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,	1A
in undivided preparations: Schedule 2)	1D
Diampromide; its salts	1A
Diazepam	1C
Diethylpropion hydrochloride	1B
Diethylthiambutene; its salts	1A
Diethylthiambutene hydrochloride	1A
Difenoxin (1-(3-cyano-3,3-diphenyl-propyl)-4-phenylpiperidine-4-carboxylic acid)	1A
(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)	1D
Dihydrocodeine; its salts	1A
but if for non-parenteral use and:	
(*a*) in undivided preparations with ms 2.5% (calculated as base: Schedule 2)	1D
(*b*) in undivided preparations with ms 1.5% (calculated as base) and md 10mg (calculated as base: Schedule 3)	1D
(*c*) in single-dose preparations with ms per dosage unit 100mg (calculated as base: Schedule 2)	1D
(*d*) in single-dose preparations with ms per dosage unit 1.5% (calculated as base) and md 10mg (calculated as base: Schedule 3)	1D
Dihydrocodeine phosphate *see* dihydrocodeine	
Dihydrocodeine tartrate *see* dihydrocodeine	

Dihydrocodeinone *see* hydrocodone	
Dihydrocodeinone enolacetate *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	1A
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)	1D
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)	1D
(*b*) in single dose preparations with ms per dosage unit 100mg (calculated as base: Schedule 2)	1D
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	1C
Fenethylline; its salts; its stereoisomers; their salts	1A
Fenproporex; its salts; its stereoisomers; their salts	1B
Fentanyl; its salts	1A
Fludiazepam	1C
Flunitrazepam	1C
Flurazepam hydrochloride; its salts	1C
Flurazepam monohydrochloride	1C
Furethidine; its salts	1A
Glutethimide; its salts; its stereoisomers; their salts	1A
Halazepam	1C
Haloxazolam	1C
Heptabarbitone	1C
Hexobarbitone	1C
Hexobarbitone sodium	1C
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	1C
Ketobemidone; its salts; its esters and ethers; their salts	1A
Lefetamine(SPA)	1B
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	1C
Lorazepam	1C
Lormetazepam	1C
Mazindol	1B
Mecloqualone	1A
Medazepam	1C
Mefenorex; its salts; its stereoisomers; their salts	1B
Meperedine see Pethidine	
Mephentermine; its salts	1B
Mephentermine sulphate	1B
Meprobamate	1C
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
Methyldihydromorphinone *see* Metopon	
2-Methyl-3-morpholino-1,1-diphenyl-propanecarboxylic acid; its salts; its esters and ethers; their salts	1A
alpha-methylphenethylamine *see* Amphetamine	
N-(2-(N-methylphenethylamino)propyl)propionanilide *see* Diampromide	
Methylphenidate; its salts	1A
Methylphenidate hydrochloride	1A
Methylphenobarbitone	1C
1-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)	1D
(*b*)	in single dose preparations with ms per dosage unit 100mg (calculated as base: Schedule 2)	1D
	Nicodicodine; its salts	1A
	but if for non-parenteral use and:	
(*a*)	in undivided preparations with ms 2.5% (calculated as base: Schedule 2)	1D
(*b*)	in single dose preparations with ms per dosage unit 100mg (calculated as base: Schedule 2)	1D
	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)	1D
(*b*)	in single dose preparations with ms per dosage unit 100mg (calculated as base: Schedule 2)	1D
	Norlevorphanol; its salts; its esters and ethers; their salts	1A
	Normethadone; 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	1B
	Pentazocine hydrochloride	1B
	Pentazocine lactate	1B
	Pentobarbitone	1B
	Pentobarbitone sodium	1B
	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	1B
	Phendimetrazine tartrate	1B
	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	1B
Phenylmethylbarbituric acid	1B
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)	1D
(*b*) in undivided preparations with ms 1.5% (calculated as base) and md 20mg (calculated as base: Schedule 3)	1D
(*c*) in single-dose preparations with ms per dosage unit 100mg (calculated as base: Schedule 2)	1D
(*d*) in single-dose preparations with ms per dosage unit 1.5% (calculated as base) and md 20mg (calculated as base: Schedule 3)	1D
Pholcodine citrate *see* Pholcodine	
Pholcodine tartrate *see* Pholcodine	
Piminodine; its salts	1A
Pinazepam	1C
Pipradrol; its salts	1B
Pipradrol hydrochloride	1B
Piritramide; its salts	1A
Potassium clorazepate	1C
Prazepam	1C
Proheptazine; its salts	1A
Properidine; its salts	1A
Propiram; its salts	1A
but if in preparations containing, per dosage unit, not more than 100mg propiram (calculated as base, and compounded with at least same amount of methylcellulose: Schedule 2)	1D
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
Acetylcarbromal
Acetylcholine chloride
Acetylcysteine
Acetyldigitoxin
Acetylsalicylic acid label (1)
Acetylstrophanthidin
Acetylsulphafurazole
Acetylsulphamethoxypyridazine
Aconite
Acrosoxacin
Actinomycin C
Actinomycin D
Acyclovir
Adicillin
Adiphenine hydrochloride
Adrenaline
Adrenaline acid tartrate
Adrenaline 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
Benzathine penicillin
Benzbromarone
Benzhexol hydrochloride
Benzilonium bromide
Benzocaine
Benzoclamine 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 hydrochloride
Butylchloral hydrate
Calcitonin
Calcitriol
Calcium aminosalicylate
Calcium amphomycin
Calcium benzamidosalicylate
Calcium bromide
Calcium bromidolactobionate
Calcium carbimide
Calcium folinate
Calcium metrizoate
Calcium sulphaloxate
Candicidin
Canrenoic acid
Cantharidin
Capreomycin sulphate
Captopril
Caramiphen hydrochloride
Caramiphen edisylate
Carbachol
Carbamazepine
Carbenicillin sodium
Carbenoxolone sodium
Carbidopa
Carbidopa monohydrate
Carbimazole
Carbocisteine
Carbon tetrachloride
Carboprostrometamol
Carbuterol hydrochloride
Carbromal
Carindacillin sodium
Carisoprodol
Carmustine
Cefaclor
Cefazedone sodium
Cefoxitin 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 betaine
Chloral formamide
Chloral glycerolate
Chloral hydrate
Chloralose
Chloralurethene
Chlorambucil
Chloramphenicol
Chloramphenicol cinnamate
Chloramphenicol palmitate
Chloramphenicol sodium succinate
Chlorisondamine chloride
Chlormadinone acetate
Chlormerodrin
Chlormethiazole
Chormethiazole edisylate
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
Ciprofloxacin 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
Cycloghosphamide

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
Deslanoside
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
Digitoxin
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
Drostanolone
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 maleate
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
Flunisolide
Fluocinolone acetonide
Fluocinonide
Fluocortolone
Fluocortolone hexanoate
Fluocortolone pivalate
Fluopromazine hydrochloride
Fluorouracil
Fluorouracil trometamol
Fluoxymesterone
Flupenthixol decanoate
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
Gestronol
Gestronol hexanoate
Glibenclamide
Glibornuride
Gliclazide
Glipizide
Glucagon
Glyceryl 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
Jaborondi
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
Lincomycin
Lincomycin hydrochloride
Liothyronine sodium
Lithium carbonate
Lithium sulphate
Lobeline; its salts
Lofepramine
Lofepramine hydrochloride
Lomustine
Loperamide hydrochloride
Loratadine
Loxapine succinate
Luteinising hormone
Lymecycline
Lynoestrenol
Mafenide acetate
Mafenide hydrochloride
Mafenite propionate
Magnesium bromide

Magnesium fluoride
Magnesium metrizoate
Mandragora autumnalis
Mannomustine hydrochloride
Maprotiline hydrochloride
Mebeverine hydrochloride
Mebhydrolin napadisylate
Mecamylamine hydrochloride
Meclofenoxate hydrochloride
Medrogestrone
Medroxyprogesterone acetate
Mefenamic acid
Mefruside
Megestrol
Megestrol acetate
Meglumine iodoxamate
Meglumine ioglycamate
Meglumine iotraxate
Meglumine ioxaglate
Melarsonyl potassium
Melengestrol
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 hydrochloride
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 hydrochloride
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
Nalorphine 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
Nitroxoline
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
Oestradiol undecanoate
Oestradiol valerate
Oestriol
Oestriol di-hemisuccinate
Oestrogenic substances, conjugated
Oestrone
Oleandomycin phosphate
Opipramol hydrochloride
Orciprenaline sulphate
Orphenadrine citrate
Orphenadrine hydrochloride
Orthocaine
Ouabain
Ovarin gland, dried
Oxamniquine
Oxandrolone
Oxantel pamoate
Oxatomide
Oxedrine tartrate
Oxolinic acid
Oxophernasine hydrochloride

Oxophernasine tartrate
Oxpentifyline
Oxprenolol hydrochloride
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
Paramethadione
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 sulphoxylate
Phenazone
Phenazone salicylate
Phenbenicillin potassium
Phebutrazate hydrochloride
Phenelzine sulphate
Phenethicillin potassium
Pheneturide
Phenformine hydrochloride
Phenglutarimide hydrochloride
Phenindone
Phenoxybenzamine hydrochloride
Phenoxymethylpenicillin
Phenoxymethylpenicillin calcium
Phenoxymethylpenicillin potassium

Pheprocoumon
Phensuximide
Phentolamine hydrochloride
Phentolamine mesylate
Phenyl aminosalicylate
Phenylbutazone
Phenylbutazone sodium
Phenylephrine hydrochloride
Phenylpropanolamine hydrochloride
Phenytoin
Phenytoin sodium
Phthalylsulphacetamide
Phthalylsulphathiazole
Physostigmine
Physostigmine aminoxide salicylate
Physostigmine salicylate
Physostigmine sulphate
Pilocarpine
Pilocarpine hydrochloride
Pilocarpine nitrate
Pimozide
Pindolol
Pipenzolate bromide
Piperacillin sodium
Piperazine oestrone sulphate
Piperidolate hydrochloride
Pipothiazine palmitate
Piracetam
Pirbuterol acetate
Pirbuterol hydrochloride
Pirenzepine hydrochloride
Pirentanide
Piroxicam
Pituitatry gland (whole dried)
Pituitary powdered (posterior globe)
Pivampicillin hydrochloride
Pivmecillinam
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 clavulanate
Potassium perchlorate
Pralidoxime chloride
Pralidoxime iodide
Pralidoxime mesylate
Prazosin hydrochloride
Prednisolone
Prednisolone acetate
Prednisolone butylacetate
Prednisolone hexanoate
Prednisolone pivalate
Prednisolone sodium phosphate
Prednisolone sodium m-sulphobenzoate
Prednisolone 21-steaglate
Prednisolone m-sulphobenzoate
Prednisone
Prednisone acetate
Prenalterol hydrochloride
Prenylamine lactate
Prilocaine hydrochloride
Primaquine phosphate
Primodine
Probenecid
Probucol
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 maleate
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

Pyrazinamide
Pyridostigmine bromide
Pyrimethamine
L-Pyroglutamyl-L-histidyl-L-proline amide
Quinestradiol
Quinestrol
Quinethazone
Quingestanol
Quinidine
Quinidine bisulphate
Quinidine phenylethylbarbiturate
Quinidine polygalacturonate
Quinidine sulphate
Quinine; its salts
Quinuronium sulphate
Racephedrine hydrochloride
Ranitidine hydrochloride
Rauwolfia (serpetina and vomitoria)
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 fucidate
Sodium methylarsinate
Sodium metrizoate
Sodium monofluorophosphate
Sodium stibogluconate
Sodium valproate
Sotalol hydrochloride
Spectinomycin
Spiramycin
Spiramycin adipate

Spirinolactone
Stannous fluoride
Stanolone
Stanozolol
Stilboestrol
Stilboestrol dipropionate
Streptodornase
Streptokinase
Streptomycin
Streptomycin sulphate
Strychnine
Strychnine arsenate
Strychnine hydrochloride
Succinylsulphathiozole
Sucralfate
Sulbactam sodium
Sulconazole nitrate
Sulfacytine
Sulfadicramide
Sulfadoxine
Sulfametopyrazine
Sulfamonomethoxine
Sulfapyrazole
Sulfabromethazine
Sulphacetamide
Sulphacetamide sodium
Sulphachlorpyridazine
Sulphadiazine
Sulphadiazine sodium
Sulphadimethoxine
Sulphadimidine
Sulphadimidine sodium
Sulphafurazole
Sulphafurazole diethanolamine
Sulphaguanidine
Sulphaloxic acid
Sulphamerazine
Sulphamerazine sodium
Sulphamethizole
Sulphamethoxazole
Sulphamethoxydiazine
Sulphamethoxypyridazine
Sulphamethoxypyridazine sodium
Sulphamethylphenazole
Sulphamoxole
Sulphanilamide
Sulphaphenazole
Sulphapyridine
Sulphapyridine sodium
Sulphaquinoxaline
Sulphaquinoxaline sodium
Sulpharsphenamine
Sulphasalazine
Sulphasomidine
Sulphasomidine sodium
Sulphathiozole

Sulphathiozole sodium
Sulphathiourea
Sulphatolamide
Sulphaurea
Sulphinpyrazone
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 chloral 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
Thymoxamine 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
Tofenacin 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
Tribromoethyl alcohol
Triclofos sodium
Tricyclamol chloride
Trienbolone acetate
Trientine dihydrochloride
Trifluoperazine
Trifluoperazine hydrochloride
Trifluoperidol
Trifluoperidol hydrochloride
Trilostane
Trimeprazine
Trimeprazine tartrate
Trimetaphan camsylate
Trimetazidine
Trimetazidine hydrochloride
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
Zimeldine 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 0.02%
Adrenaline, if-
(*a*) in inhalers
(*b*) in preparations for external use
Amethocaine in preparations for non-parenteral use (except those intended for local opthalmic 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)
Atropine in preparations for external use, (except those intended for local opthalmic use: Schedule 2)

Atropine methobromide in preparations for external use, (except those intended for local opthalmic use: Schedule 2)
Atropine 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)
Butanilicaine 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 edisylate in:
(*a*) tablet preparations and ms 7.5mg (calculated as base)
(*b*) liquid preparations and ms 0.1% (calculated as base)
Carbenoxolone 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 ms 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 ms 1%
Dextromethorphan hydrobromide in preparations for internal 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 maleate, *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 md 30mg and mdd 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 30mg (calculated as base) and mdd 60mg (calculated as base)
label (4)
(*b*) nasal sprays or nasal drops and ms 2% (calculated as base), *label (4)*
Folic 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 soaps 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 ophthalmic 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 with md 30mg and mdd 60mg
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 ms 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 100mg
(*b*) in controlled release capsules with md 50mg and mdd 100mg
(*c*) in nasal sprays or nasal drops with ms of 2%
Piperazine
Podophyllum 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
Labelling 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 180mg
Quinine in preparations for internal use md 100mg (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
Streptokinase 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 purposes 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 100mg (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 and ms 1.14%

Stannous fluoride in dentifrices and ms 0.62%

Vitamin A in:

(*a*) preparations for internal use with mdd 7500 iu Vitamin A (2250 mcg 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 mcg 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 mcg Retinol equivalent)

(*b*) preparations for external use

Vitamin D in:

(*a*) preparations for internal use with mdd 10 mcg

(*b*) preparations for external use

Vitamins, mixed in non-parenteral preparations

NOTES

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 use:	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-(dimethylamino)ethyl]indole
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-fentanyl-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 or 2-methoxy-alpha-methyl-4,5(methylenedioxy)phenethylamine
N-ethyl MDA or (+ or -)-N-ethyl-alpha-methyl-3,4- (methylenedioxy)phenethylamine
N-hydroxy MDA or (+ or -)-N-[alpha-methyl-3,4(methylene-dioxy)phenethyl]hydroxylamine
Opium

Parahexyl
Pethidine analogues:
1-methyl-4-phenyl-4-propionoxy-piperidine (MPPP)
1-methyl-4-phenyl-2,5,6-tetrahydropieridine (MPTP)
1-phenylethyl-4-phenyl-4-acetyloxy-piperidine (PEPAP)
PMA
Poppy straw concentrate
Psilocine or psilotsin
Psilocybine
Rolicyclidine (PHP, PCPY)
STP, DOM or 2,5-dimethoxy-alpha,4-dimethylphenelhylamine
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
FORMS
(reg. 22)

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

Form 1
APPLICATION FOR REGISTRATION OF A DRUG
(All documents in English)

REPUBLIC OF BOTSWANA
MINISTRY OF HEALTH
Application to be sent to:
Permanent Secretary
Ministry of Health
Private Bag 0038
GABORONE
Attention: Chief Pharmacist

Page 1 of 7

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) [i](1):
Dosage Form and Strength [ii](2):
Colour [iii](3):
Package Size(s):
Pharmacological Classification [iv](4):
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 [v](5): .....

.....

.....

[vi](1), [vii](2) **etc. :See notes on reverse side.**

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;

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

(*c*) specifications [viii](2) 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 [ix](1) and molecular formula	Quantity	Specification of Reference of such

INACTIVE INGREDIENTS

Approved Name	Quantity	Specification or Reference of such	Purpose for Inclusion

PACKAGE INSERT

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

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 use
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.

NOTES

(*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 [x](3);
(*f*) Manufacturing procedures [xi](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.

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 CLINICAL 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 interchangeability 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 [xii](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 exceed 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.

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:

Form 2
APPROVAL OF REGISTRATION OF A DRUG

REPUBLIC OF BOTSWANA
MINISTRY OF HEALTH

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 and quantity per dosage unit or per suitable mass or volume of the drug:	
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.):

Form 3
APPLICATION FOR APPROVAL TO IMPORT OR EXPORT DRUGS

REPUBLIC OF BOTSWANA
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
- [ ] as wholesaler
  - [ ] Schedule 1, 2, 3 and 4
  - [ ] Schedule 4 only
- [ ] as retailer
  - [ ] Schedule 1, 2, 3 and 4
- [ ] as agent
  - [ ] Schedule 1, 2, 3 and 4

[ ] export drugs

[ ] manufacture drugs (see also reverse page)

[ ] sell drugs
- [ ] as wholesaler
  - [ ] 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

ADDITIONAL INFORMATION NEEDED FOR APPLICATION TO MANUFACTURE DRUGS

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

NAME	QUALIFICATION	EXPERIENCE
Supervising pharmacist		
Production pharmacist		
Quality assurance pharmacist		
Other		

2. 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):
   .....
   .....
3. The following are the equipment to be used (attach list showing the name, type and capacity of equipment):
   .....
   .....
   .....
   .....

Form 4
APPROVAL FOR LICENSING

REPUBLIC OF BOTSWANA Approval No:
MINISTRY OF HEALTH

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
[ ] as wholesaler [ ] Schedule 1, 2, 3 and 4
[ ] Schedule 4
[ ] as retailer [ ] Schedule 1, 2, 3 and 4
[ ] as agent [ ] Schedule 1, 2, 3 and 4
[ ] 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

Form HFD 1
APPLICATION FOR PERMIT TO IMPORT
HABIT- FORMIMG DRUGS AND/OR PSYCHOTROPIC SUBSTANCES
(Drugs and Related Substances Act, 1992)
REPUBLIC OF BOTSWANA
MINISTRY OF HEALTH

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

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)
of .....
(Company and Address)
.....
hereby apply for permit to import the following habit-forming drugs and/or psychotropic substances:

Item No.	*Approved name of drug/substance 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.

Form HFD 2
IMPORT PERMIT FOR HABIT-FORMING DRUGS AND/OR PSYCHOTROPIC SUBSTANCES

REPUBLIC OF BOTSWANA
MINISTRY OF HEALTH

Import Permit No _____

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 hereunder from:

.....
(name, location and postal address of exporting firm)
.....
.....

Item No.	*Approved name of drug/substance and strength*	*Quantity and presentation of preparation*	*Approved name and quantity of controlled drug/substance as base in kilograms*	*Purpose: medicinal, manufacture, 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. [xiii]*

Route of supply (by) .....

Port of entry (at) .....

Date .....

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

NOTES

To be completed in quintuplicate:

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

2. Duplicate to be retained by the exporter for their records.

3. 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.

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

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

Form HFD 3
APPLICATION FOR PERMIT TO EXPORT
HABIT-FORMING DRUGS AND/OR PSYCHOTROPIC SUBSTANCES
(Drugs and Related Substances Act, 1992)
REPUBLIC OF BOTSWANA
MINISTRY OF HEALTH

Application to be sent to:
Permanent Secretary
Ministry of Health
Private Bag 0038

GABORONE
Attention: Chief Pharmacist

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)

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/substance strength*	*quantity and presentation of drug or substance*	*Purpose: medicinal research others (specify)*

Total number of items: .....

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.

Form HFD 4
EXPORT PERMIT FOR HABIT-FORMING DRUGS AND/OR PSYCHOTROPIC SUBSTANCES

REPUBLIC OF BOTSWANA
MINISTRY OF HEALTH

Export Permit No
_____

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

.....
(name, location and postal address of exporting firm)
.....
.....

Item No.	*Approved name of drug/substance and strength*	*Quality and presentation of preparation*	*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 on Psychotropic Substances, 1971.

This authority expires on .....

Drugs/Substances ordered on this authority must be consigned by Registered Mail/Road/ Air/Sea. [xiv]* The importation of these drugs/substances into the country of destination has been authorized by .....

Import Permit No ..... Dated .....

Route of supply (by) .....

Port of entry (at) .....

Date .....

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

NOTES

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.

---

[i] International non-proprietary INN-name if available.

[ii] E.g. solutions, suspension, eyedrop, emulsion, ointment, suppository, tablet, capsule or injection. In case of injections, whether a vial, ampoule, dental cartridge, etc. and the contents, e.g. powder, solution, etc. The strength to be per dosage unit. Where no dosage unit exists other suitable unit of mass or volume of the drug.

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

[iv] 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.

[v] The signatory shall be a registered pharmacist.

[vi] International non-proprietary INN-name if available.

[vii] E.g. solutions, suspension, eyedrop, emulsion, ointment, suppository, tablet, capsule or injection. In case of injections, whether a vial ampoule, dental cartridge, 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.

[viii] 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:

(*e*) any such reference that the Director may approve.

[ix] Chemical names shall where possible be given in terms of the published list of an appropriate body.

[x] Stability studies:

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

[xi]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.

[xii]"Register" or "registered" in this case refer to marketing authorisation.

[xiii]Delete whichever is inapplicable.

[xiv]Delete whichever is inapplicable.