

**DRUGS AND RELATED SUBSTANCES ACT, 1992**  
(Act No. 18 of 1992)

**DRUGS AND RELATED SUBSTANCES REGULATIONS, 1993**  
(Published on 16th April, 1993)

**ARRANGEMENT OF REGULATIONS**

**REGULATION**

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

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

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

(2) The Board shall consist of the 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.

Registration  
of drugs

3. (1) An application to register a drug, or for the renewal of such registration, shall be made to the Director in Form 1 in the Schedule hereto and shall be accompanied by a fee of P800 for a drug which is imported, P400 for a drug which is partially locally manufactured and P200 for a drug which is totally locally manufactured.

(2) The Director shall submit any such application to the Board, together with his own recommendations and any relevant comments, for consideration by the Board, and he shall abide by any advice tendered by the Board.

(3) Where a drug is approved for registration, or for renewal of registration, the Director shall issue to the applicant a certificate of registration in Form 2 in the Schedule, and if the drug is not approved for registration or renewal of registration, he shall so inform the applicant, giving thereasons for such disapproval, at the same time informing the applicant of his right to appeal against such disapproval.

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

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

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

- (a) the name of the drug approved;
- (b) the registration number allocated to the drug;
- (c) the approved chemical name or international non-proprietary name (INN) of each active ingredient of the drug, and the quantity thereof contained in a dosage unit or per suitable mass or volume or unit of the drug;
- (d) the dosage form of the drug;
- (e) the conditions of registration of the drug;
- (f) the name of the applicant; and
- (g) the date of registration of the drug.

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

- (a) any drug manufactured or imported by the Central Medical 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. (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.

Exemption  
from  
registration

Approval  
for  
manufacture  
etc. of drugs

(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.

Records to  
be kept by  
manufacturer  
of drugs

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

- (a) all steps taken in the storage and testing of raw materials;
- (b) all steps taken in the manufacture of each batch of drugs;
- (c) all tests carried out on representative samples; and
- (d) the sale and distribution of each batch of drugs.

(2) The records required to be kept in accordance with 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.

Import,  
export and  
distribution  
of drugs

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

(2) Any person wishing to import or export a Schedule 1A, 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. (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 —

Labelling  
of drugs

- (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 —

<i>Label number</i>	<i>Word Content</i>
(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.

Recall of drugs

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

Prescription of drugs

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

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

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

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

Dispensing of Schedule 1A and 1B drugs

11. (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. 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:

Dispensing  
of Schedule  
1C drugs

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 facsimile, in quantities not exceeding those stated above, on condition that a written prescription will be provided within 48 hours.

13. Schedule 2 drugs may be dispensed —

- (a) in referral hospitals, district hospitals, mission hospitals, mine hospitals or private hospitals by a pharmacist or an intern pharmacist, or by a pharmacy technician under the supervision of a pharmacist, and upon a written prescription issued by a medical practitioner or a dentist;
- (b) in a retail pharmacy by a pharmacist, or by a pharmacy technician under the supervision of a pharmacist, and upon a written prescription issued by a medical practitioner or a dentist; or
- (c) in a private medical practice or surgery or a Government primary hospital, by a pharmacy technician upon a written prescription issued by a medical practitioner or a medical officer.

Dispensing  
of  
Schedule 2  
drugs

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

Dispensing  
of drugs by  
nurses

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

Dispensing  
general

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

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

Emergency  
supply of  
drugs

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

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

- (a) there is an immediate need for the drug requested to be supplied and it is impracticable in the circumstances to obtain a prescription; or
- (b) the treatment with the drug has on a previous occasion been prescribed for the person requesting it.

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

Provided that —

- (a) where the drug in question is an ointment, a cream or an aerosol for the relief of asthma, which has been made up for sale in a container elsewhere than at the place of supply, the dispenser may supply the smallest pack available;
- (b) where the drug in question is an oral contraceptive, the dispenser may supply a sufficient quantity for a full cycle; or
- (c) where the drug required is in such a package that it is impractical to split the package, the whole package may be supplied.

Registers  
and  
records

17. (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. (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.

Clinical  
trials

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

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

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

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

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

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

Appeals

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

Classification  
of drugs

21. 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.

Prescribed  
habit  
forming  
drugs

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

Forms

## FIRST SCHEDULE (reg. 20)

### (1) SCHEDULE 1 DRUGS

	<i>Category</i>
Acetorphine; its salts; its esters and ethers; their salts	1A
Acetorphine hydrochloride	1A
Acetyldihydrocodeine; its salts but if for non-parenteral use and:	1A
(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
Allyprodine; 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
Amylorbarbitone 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
Butorbabitone sodium	1C
Camazepam	1C
Carfentanil; its stereoisomers, its salts; its esters and ethers, their salts	1A
Cathine; its salts; its stereoisomers not being phenylpropanolamine; their salts	1B
Chlordiazepoxide	1C
Chlordiazepoxide hydrochloride	1C

Chlorphentermine; its salts	1B
Chlorphentermine hydrochloride	1B
Clobazam	1C
Clonazepam	1C
Clonitazene; its salts	1A
Clorazepate	1C
Clotiazepam	1C
Cloxazolam	1C
Codeine; its salts but if for non-parenteral use and:	1A
(a) in undivided preparations with ms 2.5% (calculated as base: Schedule 2)	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	1A
but in a preparation for oral use containing not more than 135mg of dextropropoxyphene (calculated as base, per dosage unit, or with a total concentration of not more than 2.5% calculated as base, in undivided preparations: Schedule 2)	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 enol acetate see Thebacon	
Dihydrocodeinone O-carboxymethyl-oxime; its salts; its esters and ethers; their salts	1A
Dihydrodeoxymorphine see Desomorphine	
Dihydrohydroxycodone; 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
Estazolam	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
Etoperidone; 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
Heptabarbitalone	1C
Hexobarbitalone	1C
Hexobarbitalone sodium	1C
Hydrocodone; its salts	1A
Hydrocodone bitartrate	1A
Hydromorphanol; 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
Levamphetamine	1A
Levomethamphetamine	1A
Levomethorphan; its salts	1A
Levomoramide; its salts	1A
Levophenacymorphan; 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
Meperidine 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
Methypylone	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 undevided 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
Phenomorphane; 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 <b>ms</b> 2.5% (calculated as base: Schedule 2)	1D
(b) in undivided preparations with <b>ms</b> 1.5% (calculated as base) and <b>md</b> 20mg (calculated as base: Schedule 3)	1D
(c) in single-dose preparations with <b>ms</b> per dosage unit 100mg (calculated as base: Schedule 2)	1D
(d) in single-dose preparations with <b>ms</b> per dosage unit 1.5% (calculated as base) and <b>md</b> 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  
Adreneline hydrochloride  
Alkomide  
Albumin human (immuno)  
Alclofenac  
Alclometasone dipropionate  
Alcuronium chloride  
Aldosterone  
Alfacalcidol  
Algestone acetonide  
Algestone acetophenide  
Allopurinol  
Allyloestrenol  
Alphadolone acetate  
Alphaxalone  
Alprenolol  
Alprenolol hydrochloride  
Alprostadiol  
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  
Amoxicillin  
Amoxicillin 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  
Bemegrade  
Benactyzine hydrochloride  
Benapryzine hydrochloride  
Bendrofluazide  
Benethamine penicillin  
Benoxaprofen  
Benperidol  
Benserazide  
Benzathine penicillin  
Benzbromarone  
Benzhexol hydrochloride  
Benzilium bromide  
Benzocaine

Benzoctamine hydrochloride  
Benzoyl peroxide  
N-Benzoyl sulphanilamide  
Benzquinamide  
Benzquinamide hydrochloride  
Benzthiazide  
Benztropine mesylate  
Benzyl penicillin  
Benzyl penicillin calcium  
Betahistine hydrochloride  
Betamethasone  
Betamethasone adamantoate  
Betamethasone benzoate  
Betamethasone dipropiomate  
Betamethasone sodium phosphate  
Betamethasone valerate  
Betaxolol hydrochloride  
Bethanecol chloride  
Bethanidine sulphate  
Biperidine hydrochloride  
Biperidine lactate  
Bismuth glucollylarsanilate  
Bleomycin sulphate  
Boldenone undecylenate  
Bretylum 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	Chloramphenicol palmitate
Canrenoic acid	Chloramphenicol sodium succinate
Cantharidin	Chlorisondamine chloride
Capreomycin sulphate	Chlormadinone acetate
Captopril	Chlormerodrin
Caramiphen hydrochloride	Chlormethiazole
Caramiphen edisylate	Chormethiazole edisylate
Carbachol	Chlormezanone
Carbamazepine	Chloroform
Carbenicillin sodium	Chloroquine phosphate
Carbenoxolone sodium	Chloroquine sulphate
Carbidopa	Chlorothiazide
Carbidopa monohydrate	Chlorotrianisene
Carbimazole	Chlorphenoxamine hydrochloride
Carbocisteine	Chlorpromazine
Carbon tetrachloride	Chlorpromazine embonate
Carboprost trometamol	Chlorpromazine hydrochloride
Carbuterol hydrochloride	Chlorpropamide
Carbromal	Chlorprothixene
Carindacillin sodium	Chlorprothixene hydrochloride
Carisoprodol	Chlortetracycline
Carmustine	Chlortetracycline hydrochloride
Cefaclor	Chlorthalidone
Cefazedone sodium	Chloroxazone
Cefoxitin sodium	Cholestyramine
Ceftazidime	Chorionic gonadotrophin
Ceftizoxime sodium	Ciclacillin
Cefuroxime sodium	Ciclo bendazole
Cephalexin	Cimetidine
Cephalexin sodium	Cimetidine hydrochloride
Cephaloridine	Cinchocaine
Cephalosporin C	Cinchocaine hydrochloride
Cephalosporin E	Cinchophen
Cephalosporin N	Cinnarizine
Cephalothin sodium	Cinoxacin
Cephmandole nafate	Ciprofloxacin
Cephazolin sodium	Ciprofloxacin hydrochloride
Cephradine	Clavulanic acid
Cerium oxalate	Clenbuterol hydrochloride
Cetirizine	Clindinium bromide
Chenodeoxycholic acid	Clindamycin
Chloral antipyrine	Clindamycin hydrochloride hydrate
Chloral betaine	Clindamycin palmitate hydrochloride
Chloral formamide	Clindamycin phosphate
Chloral glycerolate	Clioquinol
Chloral hydrate	Clobetasol 17-propionate
Chloralose	Clobetasone butyrate
Chloralurethane	Clofazimine
Chlorambucil	Clofibrate
Chloramphenicol	Clomiphene citrate
Chloramphenicol cinnamate	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  
Cyclopenthiiazide  
Cyclopentolate hydrochloride  
Cyclophosphamide  
Cyclosporin  
Cyclothiazide  
Cyproterone acetate  
Cytarabine  
Cytarabine hydrochloride  
Dacarbazine  
Danazol  
Dantrolene sodium  
Dapsone  
Dapsone ethane ortho sulphonate  
Daunorubicin hydrochloride  
Deanol salts and esters  
Debrisoquine sulphate  
Dehydroemetine hydrochloride  
Delmadinone acetate

Demecarium bromide  
Demeclocycline  
Demeclocycline calcium  
Demeclocycline hydrochloride  
Deoxycortone acetate  
Deoxycortone pivalate  
Deptropine citrate  
Dequalinium chloride  
Deserpidine  
Desferroxamine mesylate  
Desfluorotriamcinolone  
Desipramine hydrochloride  
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  
Diphetarstone  
Dipivefrin hydrochloride  
Diprenorphine hydrochloride  
Dipyridamole  
Dipyrrone  
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	Griseofulvin
Flunisolide	Growth hormone
Fluocinolone acetonide	Guanethidine monosulphate
Fluocinonide	Guanoclor sulphate
Fluocortolone	Guanoxan sulphate
Fluocortolone hexanoate	Hachimycin
Fluocortolone pivalate	Halcinonide
Fluopromazine hydrochloride	Haloperidol
Fluorouracil	Heparin
Fluorouracil trometamol	Heparin calcium
Fluoxymesterone	Heptaminol hydrochloride
Flupenthixol decanoate	Hexachlorophene
<i>Flupenthixol dihydrochloride</i>	Hexamine phenylcinchoninate
Fluperolone acetate	Hexoestrol
Fluphenazine deconoate	Hexoestrol dipropionate
Fluphenazine enanthate	L-Histidine hydrochloride
Fluphenazine hydrochloride	Homatropine
Fluprednidene acetate	Homatropine hydrobromide
Fluprednisolone	Homatropine methylbromide
<i>Fluprostenol sodium salt</i>	<i>Hydralazine hydrochloride</i>
Flurandrenolone	Hydrargaphen
Flurbiprofen	Hydrobromic acid
Fluspirilene	Hydrochlorothiazide
Folic acid	Hydrocortamate hydrochloride
Follicle stimulating hormone	Hydrocortisone
Formosulphathiazole	Hydrocortisone acetate
Fosfestrol tetrasodium	Hydrocortisone 17-butyrate
Framycetin sulphate	Hydrocortisone caprylate
Frusemide	Hydrocortisone hydrogen succinate
Fumagillin	Hydrocortisone sodium phosphate
Fumagillin bicyclohexylamine	Hydrocortisone sodium succinate
Furazolidone	Hydroflumethiazide
Fusidic acid	Hydroquinone
Gallamine triethiodide	Hydroxychloroquine sulphate
Gelsemine	1 alpha-Hydroxycalciferol
Gelsemium	Hydroxymethylgramicidin
Gemfibrozil	4-Hydroxy-3-nitrophenylarsonic acid
Gentamicin	Hydroxyprogesterone
Gentamicin sulphate	Hydroxyprogesterone enanthate
Gestronol	<i>Hydroxyprogesterone hexanoate</i>
Gestronol hexanoate	Hydroxyurea
Glibenclamide	Hydroxyzine embonate
Glibornuride	Hydroxyzine hydrochloride
Gliclazide	Hyoscine
Glipizide	Hyoscine butylbromide
Glucagon	Hyoscine hydrobromide
Glyceryl trinitrate	Hyoscine methobromide
Glycopyrronium bromide	Hyoscine methonitrate
Glymide	Hyoscyamine
Gonadorelin	Hyoscyamine hydrobromide
Gramicidin	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  
Ipratropium 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  
Lactogenic 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  
Lofepamine  
Lofepamine 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  
Nearsephenamine  
Neomycin  
Neomycin palmitate  
Neomycin sulphate  
Neomycin undecanoate  
Neostigmine bromide  
Neostigmine methylsulphate  
Netilmicin sulphate  
Nialamide  
Nicotinaldemyde thio-semicarbazone  
Nicoumalone  
Nifedipine  
Nikethamide  
Niridazole  
Nitrofurantoin  
Nitrofurazone  
NNitroxoline  
Nomifensine hydrogen maleate  
Noradrenaline  
Noradrenaline acid tartrate  
Norethandrolone  
Norethisterone  
Northisterone acetate  
Northisterone heptanoate  
Norethynodrel  
Norgestrel  
d-Norgestrel  
Nortriptyline hydrochloride  
Novobiocin calcium

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

Physostigmine sulphate	Prednisolone sodium phosphate
Pilocarpine	Prednisolone sodium m-sulphobenzoate
Pilocarpine hydrochloride	Prednisolone 21-steaglate
Pilocarpine nitrate	Prednisolone m-sulphobenzoate
Pimozide	Prednisone
Pindolol	Prednisone acetate
Pipenzolate bromide	Prenalterol hydrochloride
Piperacillin sodium	Prenylamine lactate
Piperazine oestrone sulphate	Prilocaine hydrochloride
Piperidolate hydrochloride	Primaquine phosphate
Pipothiazine palmitate	Primodine
Piracetam	Probenecid
Pirbuterol acetate	Probucol
Pirbuterol hydrochloride	Procainamide hydrochloride
Pirenzepine hydrochloride	Procaine hydrochloride
Pirentanide	Procaine penicillin
Piroxicam	Procarbazine hydrochloride
Pituitary gland (whole dried)	Prochlorperazine edisylate
Pituitary powdered (posterior globe)	Prochlorperazine maleate
Pivampicillin hydrochloride	Prochlorperazine mesylate
Pivmecillinam	Procyclidine hydrochloride
Pivmecillinam hydrochloride	Progesterone
Pizotifen	Proguanil hydrochloride
Pizotifen hydrogen maleate	Prolintane hydrochloride
Plicamycin	Promazine embonate
Podophyllum indian	Promazine hydrochloride
Podophyllum resin	Propanidid
Poldine methylsulphate	Propantheline bromide
Polidexide	Propicillin potassium
Polidexide hydrochloride	Propiomazine hydrogen maleate
Polidexide sulphate	Propranolol hydrochloride
Polymyxin B sulphate	Propylthiouracil
Polyoestradiol phosphate	Propylphenazone
Polythiazide	Proquamezine fumarate
Potassium aminosalicylate	Proquazone
Potassium arsenite	Prostaglandin F2 alpha tromethamine
Potassium bromide	Protamine sulphate
Potassium canrenoate	Prothionamide
Potassium chloride	Prothipendyl hydrochloride
Potassium citrate	Protriptyline hydrochloride
Potassium clavulanate	Proxymetacaine hydrochloride
Potassium perchlorate	Pseudoephedrine hydrochloride
Pralidoxime chloride	Pseudoephedrine sulphate
Pralidoxime iodide	Pyrantel embonate
Pralidoxime mesylate	Pyrantel tartrate
Prazosin hydrochloride	Pyrazinamide
Prednisolone	Pyridostigmine bromide
Prednisolone acetate	Pyrimethamine
Prednisolone butylacetate	L-Pyroglutamyl-L-histidyl-L-proline amide
Prednisolone hexanoate	Quinestradiol
Prednisolone pivalate	Quinestrol

Quinethazone	Stannous fluoride
Quingestanol	Stanolone
Quinidine	Stanozolol
Quinidine bisulphate	Stilboestrol
Quinidine phnylethylbarbiturate	Stilboestrol dipropionate
Quinidine polygalacturonate	Streptodornase
Quinidine sulphate	Streptokinase
Quinine; its salts	Streptomycin
Quinuronium sulphate	Streptomycin sulphate
Racephedrine hydrochloride	Strychnine
Ranitidine hydrochloride	Strychnine arsenate
Rawolfia (serpetina and vomitoria)	Strychnine hydrochloride
Reproterol hydrochloride	Succinylsulphathiozole
Rescinamide	Sucralfate
Reserpine	Sulbactam sodium
Rfamide	Sulconazole nitrate
Rifampicin	Sulfacytine
Rifamycin	Sulfadicramide
Rimiterol hydrobromide	Sulfadoxine
Ritodrine hydrochloride	Sulfametopyrazine
Rolitetracline nitrate	Sulfamonomethoxine
Salazosulphadimidine	Sulfapyrazole
Salbutamol	Sulfabromethazine
Salbutamol sulphate	Sulphacetamide
Selegiline hydrochloride	Sulphacetamide sodium
Sera and antisera	Sulphachlorpyridazine
Serum gonadotrophin	Sulphadiazine
Siver sulphadiazine	Sulphadiazine sodium
Sissomycin sulphate	Sulphadimethoxine
Sodium aminosalicylate	Sulphadimidine
Sodium antimonylgluconate	Sulphadimidine sodium
Sodium apolate	Sulphafurazole
Sodium arsanilate	Sulphafurazole diethanolamine
Sodium arsenite	Sulphaguanidine
Sodium bromate	Sulphaloxic acid
Sodium bromide	Sulphamerazine
Sodium cacodylate	Sulphamerazine sodium
Sodium cromoglycate	Sulphamethizole
Sodium ethacrynate	Sulphamethoxazole
Sodium fluoride	Sulphamethoxydiazine
Sodium fucidate	Sulphamethoxypyridazine
Sodium methylarsinate	Sulphamethoxypyridazine sodium
Sodium metrizoate	Sulphamethylphenazole
Sodium monofluorophosphate	Sulphamoxole
Sodium subogluconate	Sulphanilamide
Sodium valproate	Sulphaphenazole
Sotalol hydrochloride	Sulphapyridine
Spectinomycin	Sulphapyridine sodium
Spiramycin	Sulphaquinoxaline
Spiramycin adipate	Sulphaquinoxaline sodium
Spirinolactone	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  
Thiopropazine 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  
Tranlycypromine sulphate  
Trazadone  
Treasulfan  
Tretamine  
*Treotinin*  
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 malcate  
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  
Zomepirc sodium  
Zuclopenthixol hydrochloride

### (3) SCHEDULE 3 DRUGS

Acertazol in preparations for external use

Acetylsalicylic acid in preparations with  $\text{ms}$  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  $\text{ms}$  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 ophthalmic use: Schedule 2).

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

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

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

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

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

Azatadine maleate

*label (5)*

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

Benzoyl peroxide in preparations for external use with  $\text{ms}$  10%

Boric acid

Brompheniramine maleate

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

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

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

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

Caffeine

Cantharidin in preparations for external use and  $\text{ms}$  0.01%

Caramiphen edisylate in:

(a) tablet preparations and  $\text{ms}$  7.5mg (calculated as base)

(b) liquid preparations and  $\text{ms}$  0.1% (calculated as base)

Carbenoxolone sodium in preparations for external use  $\text{ms}$  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

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)  
Metabuthamine hydrochloride in 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  
Labeling for malaria prophylaxis

Proxymetacaine hydrochloride in preparations for non-parenteral use (except those intended for local ophthalmic use: Schedule 2)

Pseudophedrine hydrochloride in preparations for internal use with **md** 60mg and **mdd** 180mg

Pseudophedrine 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)

## 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  
Etcyclidine (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-fluorofentanyl  
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-tetrahydropiperidine (MPTP)  
1-phenylethyl-4-phenyl-4-acetyloxy-piperidine (PEPAP)  
PMA  
Poppy straw concentrate  
Psilocine or psilocin  
Psilocybine  
Rolicyclidine (PHP, PCPY)  
STP, DOM or 2,5-dimethoxy-alpha,4-dimethylphenethylamine  
Tenamfetamine (MDA)

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

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

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

### THIRD SCHEDULE (reg. 22)

#### FORMS

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

REPUBLIC OF BOTSWANA  
MINISTRY OF HEALTH

FORM 1  
Page 1 of 7

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

APPLICATION  
Number: \_\_\_\_\_

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

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

APPLICANT:

Name:
Postal Address:
Business Address:
Telephone/Telefax Number:

THE DRUG:

Name (Trade and INN-name) (1):
Dosage Form and Strength (2):
Colour (3):
Package Size(s):
Pharmacological Classification(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(5): \_\_\_\_\_

\_\_\_\_\_  
(1),  
(2) etc. See notes on reverse side.

### **NOTES**

- (1) International non-proprietary INN-name if available.
- (2) E.g. solutions, suspension, eyedrop, emulsion, ointment, suppository, tablet, capsule or injection. In case of injections, whether a vial ampoule, dental 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.
- (3) The colour shall be the final apperance of the product, e.g. white mixture in brown bottle, yellow and green capsule with white powder.
- (4) Anatomical, therapeutic and chemical classification (W.H.O.) or equivalent therapeutic and pharmacological classification. Codes should be accompanied by explanation, e.g. anti-epileptic, non-steroidal anti- inflammatory, etc.
- (5) The signatory shall be a registered pharmacist.

COMPOSITION

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

Below is a schedule of:

- (a) active ingredient given in approved names, chemical names, structural and molecular formulae, specification, physical properties and quantity in dosage unit (3);
- (b) inactive ingredients specifications, quantity in dosage unit and reason for inclusion;
- (c) specifications(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 (1) and molecular formula	Quantity	Specification of Reference of such

INACTIVE INGREDIENTS

Approved Name	Quantity	Specification or Reference of such	Purpose for Inclusion

## **NOTES**

- (1) Chemical names shall where possible be given in terms of the published list of an appropriate body.
- (2) Specifications shall be at the level of the latest editions of the recognized references, other sources must be fully substantiated. References to the following, where applicable, shall be acceptable:
  - (a) British Pharmacopoeia;
  - (b) European Pharmacopoeia;
  - (c) United States Pharmacopoeia;
  - (d) International Pharmacopoeia; and of
  - (e) Any such reference that the Director may approve.

## 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 overdose 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 (3);
- (f) Manufacturing procedures (4).

**NOTES**

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

- (2) Specifications to include title, limits, and criteria of acceptance of all physical, chemical and microbiological parameters where applicable.
- (3) Stability studies:
- i) Data indicative of at least 24 months shelf-life derived from the product in the packaging material specified in Appendix III. Where the products contain inherently unstable ingredients this requirement shall not apply.
  - ii) Temperatures in Botswana can be as low as 0 degrees C and as high as 40 degreesC. Extremes of these shall be specified and tested.
  - iii) The preserving ability of any antibacterial agents or preservatives in the formulation shall be specified and tested.
  - iv) Data to include normal degradation products storage conditions required to maintain raw material integrity and results of qualitative results of tests carried out.
  - v) Date of manufacture and batch number of samples studied for stability (minimum of two batches).
- (4) Manufacturing procedures shall detail stages of manufacturing and packaging, describing type of equipment used, analytical, microbiological and in-process control procedures. Where different manufacturing facilities were used this shall be mentioned. Local manufacturers might refer to Master Manufacturing Records if possible.

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

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

FOR OFFICIAL USE

<i>Application Number:</i>	<i>Application Fee paid (date):</i>
<i>Date received:</i>	<i>Cash:</i>
	<i>Cheque No:</i>

THE DRUG:

<i>Essential Drug:      Yes [ ]      No [ ]</i>
<i>Therapeutic value:</i>
<i>Important: [ ]    Less important: [ ]    Unimportant: [ ]</i>

BOARD'S DECISION:

<i>Refused (date):</i>	<i>Deferred (date):</i>
------------------------	-------------------------

<i>Conditionally approved (date, conditions):</i>	
<i>Final approval (date):</i>	<i>Schedule:</i>
<i>Approved indications:</i>	

***SPECIAL CONDITIONS ETC:***

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REPUBLIC OF BOTSWANA  
MINISTRY OF HEALTH

FORM 2

APPROVAL OF REGISTRATION OF A DRUG

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

Registration Number:
Name of Drug:

Active ingredient(s), approved name 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.):



**ADDITIONAL INFORMATION NEEDED FOR APPLICATION TO MANUFACTURE DRUGS**

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

<b>NAME</b>	<b>QUALIFICATION</b>	<b>EXPERIENCE</b>
<b>Supervising pharmacist</b>		
<b>Production pharmacist</b>		
<b>Quality assurance pharmacist</b>		
<b>Other</b>		

- 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):**



REPUBLIC OF BOTSWANA  
MINISTRY OF HEALTH

FORM HFD 1

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

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

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

I, \_\_\_\_\_  
(Name of Applicant)

registered as \_\_\_\_\_  
(Qualification and Registration Number)

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.

REPUBLIC OF BOTSWANA  
MINISTRY OF HEALTH

FORM HFD 2  
Import Permit No

IMPORT PERMIT FOR HABIT FORMING DRUGS  
AND/OR PSYCHOTROPIC SUBSTANCES

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

\_\_\_\_\_

(name, location and postal address of importing firm)

\_\_\_\_\_

\_\_\_\_\_

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

\_\_\_\_\_

(name, location and postal address of exporting firm)

\_\_\_\_\_

\_\_\_\_\_

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, research, scientific and others (specify)

Total Number of Items: \_\_\_\_\_

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

This authority expires on \_\_\_\_\_

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

Route of supply (by) \_\_\_\_\_

Port of entry (at) \_\_\_\_\_

Signature and stamp \_\_\_\_\_ Date \_\_\_\_\_

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.

REPUBLIC OF BOTSWANA  
MINISTRY OF HEALTH

FORM HFD 3

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

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

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

I, \_\_\_\_\_  
(Name of Applicant)

registered as \_\_\_\_\_  
(Qualification and Registration Number)

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.

REPUBLIC OF BOTSWANA  
MINISTRY OF HEALTH

FORM HFD 4  
Export Permit No  
\_\_\_\_\_

**EXPORT PERMIT FOR HABIT FORMING DRUGS  
AND/OR PSYCHOTROPIC SUBSTANCES**

In accordance with the Drugs and Related Substances Ac., 1992, the Single Convention on Narcotic Drugs, 1961 and the Convention on Psychotropic Substances, 1971, authority is here 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 of Psychotropic Substances, 1971.

This authority expires on \_\_\_\_\_

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

Import Permit No \_\_\_\_\_ Dated \_\_\_\_\_

Route of supply (by) \_\_\_\_\_

Port of entry (at) \_\_\_\_\_

Signature and stamp \_\_\_\_\_ Date \_\_\_\_\_

Dir. of Health Services

### **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.

MADE this 8th day of April, 1993.

**B.K. TEMANE,**  
*Minister of Health.*