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Statutory Instrument No. 163 of 2019

MEDICINES AND RELATED SUBSTANCES ACT
(Cap. 63:04)

MEDICINES AND RELATED SUBSTANCES REGULATIONS, 2019
(Published on 27th December, 2019)

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SCHEDULES

IN EXERCISE of the powers conferred on the Minister of Health and Wellness by section 69 of the Medicines and Related Substances Act, the following Regulations are hereby made —

Part I — Preliminary

1. These Regulations may be cited as the Medicines and Related Substances Regulations, 2019. Citation
2. In these Regulations, unless the context otherwise requires — Interpretation
 - “Active Pharmaceutical Ingredients (APIs)” means any substance or combination of substances used in a finished pharmacological activity or to otherwise have direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease, or to have direct effect in restoring, correcting or modifying physiological functions in human beings;
 - “authorised person” means any person given the responsibility for ensuring the medicines’ requirements are in compliance with the laws and regulations in force in Botswana;
 - “bonded warehouse” means a warehouse where goods are stored and held before being cleared to enter the country and these may also be used to store goods in transit;
 - “complementary medicines” means a labelled substance or mixture of substances manufactured, sold or represented for use as adjuvants to conventional therapy in —
 - (a) the mitigation or prevention of an abnormal physical state; or
 - (b) restoring, correcting or modifying physical, mental or organic functions in humans, and
 - originate from plant, mineral, animal including microorganisms, homeopathic preparations, nutritional substances in accepted pharmaceutical dosage forms, a combination of the above or any other such preparations as may be approved by the Authority;
 - “guidelines” means documents outlining regulatory requirements applied by the Authority in line with these Regulations as listed in Schedule 6;
 - “notification” means changes that could have minimal or no adverse effects on the overall safety, efficacy and quality of the Finished Pharmaceutical Product (FPP);
 - “parallel importation” means cross-border importation of a medicine or a product registered by the Authority, without the consent of the patentee, where the medicine has been put on the market by the patentee or by another acting with the patentee’s consent, or having an economic tie to the patentee;

“qualified person” means a person registered with the relevant professional body to undertake work or practise within a specific technical field or area meeting the minimum requirements in the guidelines; and
 “variations” means —

- (a) major variations which are changes that could have major effects on the overall safety, efficacy and quality of the FPP; or
- (b) minor variations which are changes that may have minor effects on the overall safety, efficacy and quality of the FPP.

Part II — Medicines

Registration of medicine

3. (1) An application for registration of medicine shall be in Form 1 set out in Schedule 4 and shall be accompanied by —

- (a) an application fee set out in Schedule 5;
- (b) the Common Technical Document in Form 2 set out in Schedule 4; and
- (c) a sample as described in the guidelines.

(2) The Authority shall specify conditions for registration for a particular medicine or group of medicines and may —

- (a) amend any conditions for registration;
- (b) specify product labelling requirements; or
- (c) determine what is to be described in the label or packages of medicines.

(3) Where an application to register medicines is successful, the Authority shall issue the registration certificate to the applicant in Form 3 set out in Schedule 4.

(4) Where an application to register medicines is unsuccessful, the Authority shall inform the applicant in writing, stating the reasons for the decision not to register the medicine.

(5) A summary of technical assessment reports for approved and rejected registration may be published and made available to the public.

(6) A marketing authorisation holder shall be responsible for the importation, advertising and promotion of his or her medicine.

Validity period of registration of medicine

4. A registration certificate issued in terms of regulation 3 shall be valid for five years subject to annual submission of information accompanied by a fee set out in Schedule 5.

Renewal of registration

5. (1) A person may apply to the Authority for the renewal of registration of medicines.

(2) An application under subregulation (1) shall be —

- (a) in Form 1 set out in Schedule 4;
- (b) accompanied by a renewal fee set out in Schedule 5; and
- (c) submitted to the Authority not later than six months before the expiry date of registration.

Exemption from registration of medicines for individual patient

6. (1) A medical practitioner may apply in Form 4, upon payment of an application fee set out in Schedule 5 to the Authority to exempt the registration of medicines from outside Botswana, for his or her patient's personal use.

(2) Subject to subregulation (1), the application shall comply with the guidelines and shall be signed by an importing pharmacist residing in Botswana.

(3) The Authority may, after having considered the application and the supporting documents, grant the exemption.

(4) The validity period of the exemption from registration shall be six months.

7. (1) A person who imports medicine from outside Botswana for personal use shall not import more than one month's supply of medicine.

Import of
unregistered
medicines for
personal use

(2) Subject to subregulation (1), where a person brings more than one month's supply, but less than three months' supply, he or she shall produce, upon request by a competent authority, a certified copy of the prescription from a medical practitioner.

(3) Subject to regulation 6, a person shall apply to the Authority in writing for an exemption from registration for any subsequent supplies of the imported medicine.

8. (1) An applicant may apply to the Authority to exempt the registration of medicines for wholesale from outside Botswana under special circumstances as determined by the Authority.

Exemption from
registration of
medicines for
wholesale

(2) The application shall —

(a) comply with the guidelines; and

(b) be accompanied by the application fee in Form 5 set out in Schedule 5.

(3) The applicant may be required to pay for the inspection of the manufacturing site prior to authorisation.

9. A person may apply to the Authority for exemption from registration of donated medicines in Form 6 as set out in Schedule 4 and he or she shall meet the requirements of the guidelines on donation.

Exemption of
donated
unregistered
medicines

10. (1) A marketing authorisation holder shall not make a variation in the particulars of a registered medicine without the prior approval of the Authority, except where the change is a notification.

Variations

(2) A variation application shall be submitted to the Authority and shall be —

(a) in terms of Form 7 set out in Schedule 4;

(b) accompanied by a variation fee set out in Schedule 5; and

(c) accompanied by the supporting documents as specified in the conditions laid down for each type of variation.

(3) The marketing authorisation holder shall ensure that all the necessary validation has been conducted to demonstrate that the change does not reduce the quality, safety or efficacy of the medicine.

(4) The Authority may cancel the registration of a medicine where variations are made without prior approval of the Authority.

11. (1) A marketing authorisation holder shall apply to the Authority for a notification of a variation in the particulars of a registered medicine in Form 7 set out in Schedule 4.

Notifications

(2) Subject to subregulation (1), the applicant shall pay to the Authority a notification fee set out in Schedule 5.

(3) An application for immediate notification shall be submitted soon after implementing the variation.

(4) An application for annual notification shall be submitted within 12 months after implementing the variation.

(5) The Authority shall ensure that quality, safety and efficacy of a medicine is still maintained.

12. Where an institution outside Botswana recalls some medicines, a marketing authorisation holder shall provide the Authority with the following —

Recall of
medicines by
other institutions
outside
Botswana

(a) information on the batches of medicine involved;

(b) recall plan and procedure, including the disposal of the recalled medicines;

(c) distribution list; and

(d) a report of the investigation, before and after the recall.

Recall of
medicines
by Authority

13. (1) Where the Authority recalls medicines, the Authority shall inform the —
- public of the procedure to be followed through all possible communication media; and
 - marketing authorisation holder in writing, of its decision, stating the reasons.

(2) The marketing authorisation holder shall be responsible for the disposal of the medicines.

Withdrawal of
marketing
authorisation

14. (1) A marketing authorisation holder who wishes to withdraw his or her medicines from the market shall provide the Authority with —

- information on the decision to withdraw;
- the effective date of withdrawal;
- reasons for withdrawal; and
- the plan of communication to prescribers and dispensers.

(2) The Authority shall update the register to indicate the withdrawal.

Suspension or
revocation
of marketing
authorisation

15. (1) Where the Authority suspends or revokes marketing authorisation for reasons including —

- failure to report adverse reactions to the Authority;
 - failure to meet safety, quality, efficacy requirements; or
 - implementing variations without approval of the Authority,
- the Authority shall communicate to the marketing authorisation holder in writing, the decision to suspend or revoke the market authorisation.

(2) In the case of a suspension or revocation, the Authority shall, within seven days of taking the decision, communicate to the marketing authorisation holder, conditions of the suspension, the duration and the action the marketing authorisation holder has to take.

(3) In the case of a revocation, the marketing authorisation holder shall be required to recall his or her medicines from the market in line with the guidelines.

(4) The Authority shall notify the public of the decision to suspend or revoke the market authorisation.

Part III — *Licensing*

Licensing of
pharmaceutical
operations

16. (1) An application for licensing of pharmaceutical operations shall be submitted to the Authority, in Form 8 set out in Schedule 4 accompanied by an application fee set out in Schedule 5.

(2) The Authority may, having considered the application, grant the applicant a licence in Form 9 set out in Schedule 4 and the Authority may attach conditions thereto as it may consider necessary.

(3) The Authority shall inform an unsuccessful applicant in writing, of the decision not to licence the premises and the reasons, in line with the guidelines.

(4) Where premises are licensed, the premises shall be under the supervision of a qualified person in line with the guidelines.

(5) Subject to subregulation (4), any change in the person who supervises the premises shall be communicated to the Authority within 30 days.

(6) The Authority shall keep a database of all licensed manufacturing facilities, pharmacies and pharmaceutical wholesalers.

Licensing of
manufacturing
facility

17. (1) An applicant may apply to the Authority for a licence to manufacture medicine in Form 8 set out in Schedule 4 accompanied by an application fee set out in Schedule 5.

(2) The Authority shall grant a licence in Form 9 set out in Schedule 4 subject to the submission of all the required documents according to the guidelines.

18. (1) An application for a licence to operate a pharmacy shall be made to the Authority in Form 8 set out in Schedule 4 and accompanied by a fee set out in Schedule 5. Licensing of pharmacy

(2) The Authority shall grant a licence in Form 9 set out in Schedule 4 subject to the submission of all the required documents according to the guidelines.

19. (1) An application for a licence to operate a pharmaceutical wholesaler shall be made to the Authority in Form 8 set out in Schedule 4 and accompanied by a fee set out in Schedule 5. Licensing of pharmaceutical wholesaler

(2) The Authority shall issue a licence in Form 9 set out in Schedule 4, subject to submission of all the required documents according to the guidelines.

20. (1) An applicant may apply to the Authority for a licence to operate a pharmacy within a group practice in Form 8 set out in Schedule 4 and accompanied by a fee set out in Schedule 5. Licensing of pharmacies within a group practice

(2) Subject to subregulation (1), the licence may be under that of a hospital or a pharmacy where the pharmacy services are outsourced.

(3) The Authority shall issue a licence in Form 9 set out in Schedule 4, subject to submission of a licence or provisional licence of a hospital or a group practice.

21. (1) An applicant shall apply to the Authority for a licence to operate dispensaries in surgeries and institutional dispensaries in Form 8 set out in Schedule 4 and accompanied by a fee set out in Schedule 5. Licensing of dispensaries in surgeries and institutional dispensaries

(2) Where the institutions are required to be licensed by other authorities, the Authority shall issue a licence in Form 9 set out in Schedule 4 subject to submission of a licence or provisional licence of a surgery or an institution.

(3) In its assessment of the application, the Authority shall take into account the scope of practice of the institution in granting the licence.

(4) The Authority shall issue a licence, subject to submission of a licence or provisional licence of a surgery or institution.

22. (1) A licence holder shall apply to the Authority for variation of his or her licence. Variation of licence

(2) The application for variation shall be in Form 8 set out in Schedule 4 accompanied by a fee set out in Schedule 5.

(3) The Authority may approve the amendments and where the Authority does not approve, it shall inform the unsuccessful applicant in writing, stating the reasons for the decision.

23. (1) Where the licence holder does not meet the required standards and guidelines, the Authority may suspend or withdraw the licence. Suspension or withdrawal of licence

(2) The Authority shall notify the licence holder of the decision and may indicate the actions to be taken by the licence holder and give the licence holder seven days to respond.

(3) The facility shall be closed for the duration of the suspension.

(4) Where a licence is withdrawn the facility shall cease to operate.

24. (1) An application for renewal of a licence made under these Regulations shall be made at least three months before expiry of the licence. Renewal of licence

(2) The application shall be in Form 8 set out in Schedule 4 and shall be in accordance with the guidelines.

- (3) The application shall be accompanied by a fee set out in Schedule 5.

Part IV — Record keeping and import of medicines

- Record keeping** **25.** (1) A person dealing with the manufacture, import, export, storage, distribution, promotion, advertising and dispensing of medicines shall, according to his or her scope of operation, keep a record as outlined in the guidelines.
- (2) The Authority may at any time in writing, order a person dealing with the manufacture, import, export, storage, distribution, promotion, advertising and dispensing of medicines to produce the record for inspection.
- (3) An inspector may at all reasonable times inspect the records.
- Import of medicines** **26.** (1) A person shall apply to the Authority for a permit to import medicines, medical products or cosmetics other than narcotics, psychotropics and precursor chemicals in Form 10 set out in Schedule 4 and accompanied by a fee set out in Schedule 5.
- (2) An application for an import permit shall be accompanied by authorisation from a market authorisation holder to import medicines to Botswana in line with the guidelines.
- (3) Subject to subsection (1), the Authority shall issue an import permit in Form 11 set out in Schedule 4 and in line with the guidelines.
- (4) Upon assessment the Authority may authorise an entity not licensed as a wholesaler to import medicines, medical products or cosmetics upon payment of a fee set out in Schedule 5.
- (5) Subject to subregulation (1), a person may apply for a permit to import medicines, medical products or cosmetics that have been exempted from registration in line with the guidelines.
- (6) All purchasing orders shall be vetted and authorised by the Authority.
- (7) A person authorised to import medicine shall pay a fee as set out in Schedule 5 for each consignment in line with the guidelines.
- (8) A wholesaler shall notify the Authority and submit an acknowledgement in line with the guidelines, upon receipt of medicines.
- Parallel import of medicines** **27.** An applicant shall apply to the Authority in Form 11 set out in Schedule 4 for parallel import of medicines —
- (a) in the manner outlined in the guidelines;
- (b) accompanied by a fee set out in Schedule 5; and
- (c) the importer shall provide the authorisation from the Ministry responsible for trade.
- Import of samples for registration** **28.** A person shall apply to the Authority for approval to import samples in Form 10 set out in Schedule 4.
- Post-market surveillance** **29.** (1) A prescriber, pharmacist and a health care professional shall report any safety, quality and efficacy issues to the Authority and to the marketing authorisation holder in line with the guidelines.
- (2) The Authority shall from time to time conduct risk based inspections of pharmaceutical operations and take samples of medicines, medical products or cosmetics on the market for testing and investigation to establish the quality, safety and efficacy in Form 12 set out in Schedule 4.
- (3) The Authority shall, where a sample fails to meet the relevant specifications —

- (a) issue the marketing authorisation holder or importer with a written warning and up to a maximum of 30 days to identify the source or cause of the quality defect and any action to be taken to improve quality; or
- (b) where the failure warrants a recall of the medicines, medical products or cosmetics as set out in the guidelines, the Authority shall order the marketing authorisation holder or importer to recall the medicine, medical product or cosmetic.
- (4) The marketing authorisation holder shall remove from the market and dispose at his or her cost, medicines, medical products or cosmetics that do not meet the required standards which disposals shall be in accordance with regulation 34.
- (5) The marketing authorisation holder shall keep records of the recall and disposal of the medicines, medical products or cosmetic and he or she shall submit a copy of the records to the Authority.
- (6) A person licensed to operate a pharmaceutical operation shall report any suspected problems, regarding the quality, safety or efficacy of the medicines to the Authority.
- (7) A marketing authorisation holder or importer shall carry out investigation to identify the root cause of the problem and develop a risk management plan to prevent recurrence including a comprehensive review of the manufacturing process.
- (8) The Authority shall assess the report of the investigation and risk management plan where a marketing authorisation was earlier suspended, before it can lift the suspension.
- (9) The Authority may investigate and decide on an appropriate action to be taken by either the Authority or the marketing authorisation holder, where any problem is suspected.
- (10) The Authority, the marketing authorisation holder or importer and the manufacturer shall keep the public informed about the findings and any relevant information about the medicines, medical products and cosmetics within a specified time according to the guidelines.
- (11) The marketing authorisation holder or importer shall in accordance with the guidelines, provide a post market surveillance plan for his or her medicine and report to the Authority, any findings from an accredited quality control laboratory.
- (12) All testing shall be done in accredited quality control laboratories.

30. (1) The Board shall appoint a committee to deal with adverse medicines, medical products or cosmetics reactions and to review reports of suspected medicine reactions.

Adverse
medicine
reactions

(2) A marketing authorisation holder of medicines, medical products or cosmetics shall report to the Authority any adverse reactions in line with the guidelines.

(3) The marketing authorisation holder shall ensure all labels and package inserts are amended to include any new adverse reactions, warning, including precautions within such period as may be determined by the Authority.

(4) A prescriber, pharmacist or a health care professional shall report to the Authority any adverse reactions in accordance with the guidelines.

31. (1) An importer, exporter, marketing authorisation holder, manufacturer, distributor, dispenser, and promoter of medicines, medical products or cosmetics shall have in place, risk management plans to prevent circulation of counterfeit medicines.

Counterfeit
medicines

- (2) The plans under subregulation (1) shall include the following measures —
- (a) to prevent counterfeit medicines, medical products or cosmetics from entering Botswana;
 - (b) to prevent the sale and use of counterfeit medicines, medical products or cosmetics;
 - (c) to address counterfeit medicines, medical products or cosmetics once detected on the market; and
 - (d) to regularly review risk management plans.
- (3) The Authority shall publish the information on circulating counterfeit medicines, medical products or cosmetics as and when the need arises.
- Medicines in transit**
- 32.** (1) Any person transiting medicines, medical products or cosmetics through Botswana shall apply to the Authority for a transit permit in line with the guidelines by completing Form 13 set out in Schedule 4 and accompanied by a fee set out in Schedule 5.
- (2) The Authority shall issue a transit permit in Form 14 set out in Schedule 4.
- (3) The importer of medicines shall ensure that medicines, medical products or cosmetics in a bonded warehouse comply with requirements for transit as set out in the guidelines.
- (4) The importer of medicines shall keep records for the medicines, medical products or cosmetics at the bonded warehouse which records shall be open for inspection by the Authority and other relevant authorities.
- Designation of ports**
- 33.** (1) The Authority shall recommend designation of ports of import and export to the Minister.
- (2) The Authority shall review the list of designated ports from time to time.
- Disposal of unwanted medicines**
- 34.** (1) A person who disposes of medicines shall follow the guidelines and keep disposal certificates issued by the relevant authorities, for the Authority's inspection.
- (2) The destruction of any Schedule 1A, Schedule 1B Schedule 1C medicines or precursors, in part or whole, shall be reported to the Authority in accordance with the guidelines and, except where the destruction is accidental, the destruction shall be supervised by a pharmacist and witnessed by a police officer.
- (3) A person shall dispose of unused medicines in a clinical trial in line with the guidelines.
- (4) The Authority may in special circumstances authorise the export of medicines, medical products or cosmetics that do not meet specifications for disposal in line with the guidelines.
- Classification and description of medicines**
- 35.** (1) The Authority shall carry out a risk based review of the classification of medicines in consultation with the relevant stakeholders.
- (2) For purposes of the Act and these Regulations, medicines shall be classified in accordance with the lists set out in Schedule 1 and the lists shall be published in the *Gazette*.
- Prescription of medicines**
- 36.** (1) Prescriptions of medicines shall be written in generic or approved international non-proprietary names (INN) except when a particular brand of medicine is preferred and clinically acceptable reasons for such preference are communicated to the dispenser.
- (2) The Minister shall draw guidelines on dispensing and prescription of medicines in terms of section 38 (3) and section 39 (2) of the Act.
- (3) In granting limited powers of prescription of Schedules 1, 2, 3 and 4 medicines under section 39 (2) of the Act, the Minister may grant to —

- (a) registered nurses in hospitals or Government clinics specialising in medical fields such as ophthalmology, psychiatry, midwifery, or as a registered family nurse practitioner, power to prescribe only those medicines specific to their speciality or training and, where applicable, which are specified for them in the Botswana National Medicines Formulary;
- (b) registered nurses in Government clinics and health posts, power to prescribe only those medicines which are specified for them in the Botswana National Medicines Formulary;
- (c) dental therapists, power to prescribe only those medicines specified for them in the Botswana National Medicines Formulary;
- (d) registered pharmacists, power to prescribe Schedules 1 and 2 medicines only in the circumstances referred to in regulations 38, 40 and 41;
- (e) optometrists and chiropractors limited prescribing powers according to their scope of practice;
- (f) pharmacists to prescribe Schedule 3 medicines; and
- (g) nurses to give repeat prescriptions for Schedules 1, 2 and 3 medicines for palliative care at hospitals, hospices and at home-based care.

37. (1) A valid prescription shall contain the following information —

- (a) particulars of the patient including name, age and gender;
- (b) name of the medicine, dosage form, dosage strength, directions for use, duration of treatment or quantity;
- (c) name, signature and address of prescriber;
- (d) date of prescription; and
- (e) the facility stamp.

Contents of
prescriptions

(2) For Schedules 1A, 1B and 1C medicines the quantity shall be written in words and figures.

(3) A prescriber shall keep a copy of each prescription issued by him or her for a period of one year.

38. (1) An emergency medical services provider may under emergency situations administer Schedules 1, 2 and 3 medicines without a written prescription.

Emergency
administration

(2) Subject to subregulation (1), in administering such medicines, the emergency medical services provider shall follow his or her scope of practice as determined by the Botswana Health Professions' Council.

(3) For medicines which are not within his or her scope, the emergency medical service provider may administer with medical direction and he or she shall keep registers and records of the medicine administered.

39. (1) A person shall not dispense medicine of a quantity greater than the amount and the stated duration of treatment in the prescription.

General
dispensing

(2) A person dispensing medicine shall endorse on the prescription the date when the medicine is dispensed, the quantity dispensed, and he or she shall append his or her signature thereto.

(3) A repeat prescription may be dispensed for a maximum of six times from the date of issue.

40. (1) Schedules 1A, 1B and 1C medicines may only be dispensed by a pharmacist upon a written prescription by a medical practitioner or dentist, presented for dispensing within 30 days of the date of its issue, and for the supply of a quantity not greater than the quantity indicated on the prescription, which shall not exceed 30 days' supply.

Dispensing of
Schedules 1A,
1B and 1C
medicines

(2) The prescription shall be retained in the pharmacy for a period of five years after the date it was dispensed.

(3) The dispenser of a Schedules 1A, 1B and 1C medicine shall enter a record of such dispensing and the register shall be kept for a period of five years after the last entry.

(4) Separate registers shall be kept for Schedules 1A, 1B and 1C medicines.

(5) Except when being administered to a patient, every Schedules 1A, 1B and 1C medicines shall be kept under safe custody in a lockable cabinet or in a safe securely fixed in terms of regulation 48 (2).

Emergency
dispensing of
Schedules 1A,
1B and 1C
medicines

41. (1) Emergency dispensing of Schedules 1A, 1B and 1C medicines may be done where —

- (a) there is a repeat prescription for a patient known by both the prescriber and pharmacist;
- (b) the pharmacist has contacted the prescriber and the prescriber is confirmed as being a medical practitioner or dentist; and
- (c) the pharmacist is satisfied that it is impossible or impracticable to obtain a written prescription.

(2) The prescription may be made by telephone, email or facsimile, in quantities not exceeding those stated in regulation 40 (1), on condition that a written prescription shall be provided within 48 hours.

Dispensing of
Schedule 2
medicines

42. Schedule 2 medicines may be dispensed in —

- (a) referral hospitals, district hospitals, primary hospitals, mission hospitals, mine hospitals or private hospitals by a pharmacist or an intern pharmacist, a pharmacy technician under the supervision of a pharmacist, or by any authorised dispenser upon a written prescription issued by a medical practitioner or a dentist;
- (b) a retail pharmacy, by a pharmacist, a pharmacy technician under the supervision of a pharmacist or by any authorised dispenser upon a written prescription issued by a medical practitioner or a dentist;
- (c) a Government clinic, by a pharmacy technician under the supervision of a pharmacist upon a written prescription issued by an authorised prescriber; or
- (d) a private health facility by an authorised dispenser.

Dispensing of
Schedules 1D
and 3 medicines

43. Schedules 1D and 3 medicines shall only be dispensed by a pharmacist or any authorised dispenser upon a prescription.

Emergency
supply of
medicines by
pharmacist

44. (1) Notwithstanding regulation 42, in an emergency Schedule 2 medicines may be supplied or dispensed without a prescription by a pharmacist, where —

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

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

Provided that —

- (a) where the medicine 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 a place of supply, the dispenser may supply the smallest pack available;

- (b) where the medicine in question is an oral contraceptive, the dispenser may supply a sufficient quantity for a full cycle; or
- (c) where the medicine required is in such a package that it is impractical to split the package, the whole package may be supplied.

45. (1) A prescriber may, in line with the guidelines store some medicines to administer to his or her patients.

Storage of
medicines
by prescribers

(2) Subject to subregulation (1), the type and quantities of the medicines administered shall be determined by the scope of the prescriber's practice and the prescriber shall fulfill other requirements set out in the guidelines.

46. (1) A healthcare provider shall apply to the Director of Health Services for an approval to dispense medicines.

Dispensing of
medicines by
healthcare
providers other
than pharmacists

(2) An approval shall be given to a medical practitioner, dentist, pharmacy technician and any other health personnel on condition that he or she has competency in dispensing medicines.

(3) A dispensary, clinic, health post and mobile clinic shall meet the standards set out in the guidelines.

47. (1) Precursor chemicals at Schedule 2 of these Regulations shall be sold by authorised dealers.

Sale and use of
precursor
chemicals

(2) The use of the precursor chemicals that require import permits shall be authorised by the Authority.

(3) Registers of the sale and use of chemicals shall be maintained by the authorised dealers and the register shall capture information as determined by the Authority.

48. (1) Medicines shall be stored in secure, well ventilated rooms, with adequate lighting and controlled temperatures.

Storage of
medicines

(2) Schedule 1 medicines shall be kept in bolted locked steel cabinets or rooms with controlled access.

(3) The storage facilities shall be protected from pests, harsh weather and shall meet building codes.

(4) The guidelines relating to the storage of medicines shall be updated as the Authority determines.

49. (1) Any product information shall be provided in line with the guidelines.

Product
information

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

- (a) either the approved name of the medicine 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 or applicant;
- (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 terms of subregulation (6);
- (l) any conditions of registration stipulated by the Authority during registration; and
- (m) manufacture date.

(3) In any special circumstances the Authority may exempt any particular consignment of medicines from the requirements of subregulation (1).

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

- (a) full name of the patient;
- (b) date of dispensing;
- (c) pack size;
- (d) name and signature of the dispenser; and
- (e) all information required for the purposes of subregulation (1).

(5) The container of any medicine exempted from registration shall as far as possible bear the information required under subregulation (1).

(6) The containers of pre-packed medicines shall bear the label with the following —

- (a) name, strength and quantity of the medicine;
- (b) batch number;
- (c) date of manufacture;
- (d) expiry date; and
- (e) manufacturer.

(7) If the medicine contains any ingredient that is known to cause any allergic reaction, there shall be a warning to that effect.

(8) For medicines which require caution, such medicine shall bear a label giving information and instructions in accordance with the following —

Word Content

- (1) "Contains aspirin" (unless name of product includes word "aspirin"); plus "If symptoms persist, consult your doctor"; plus the recommended dosage; plus "Do not use on children under 12 years except on medical advice."
The label shall include name of the applicant, Botswana registration number and the Schedule.
- (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 shall 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 shall 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 shall be used on pharmacy medicines (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.

50. (1) An application for import of narcotics, psychotropics and precursor chemicals shall be made to the Authority by a pharmacist in Form 15 set out in Schedule 4 accompanied by a fee set out in Schedule 5.

Import and
export of
narcotics,
psychotropics
and precursor
chemicals

(2) Upon assessment the Authority shall issue an import permit in Form 16 set out in Schedule 4, to the applicant, which permit shall be valid for six months,

(3) After receipt of the medicines the pharmacist shall notify the Authority and submit an acknowledgement in Form 17 set out in Schedule 4 and a copy of export permit from the relevant country, within seven days.

(4) An application for export of narcotics, psychotropics and precursor chemicals shall be made by a pharmacist in Form 15 set out in Schedule 4 accompanied by a fee set out in Schedule 5.

(5) The Authority shall issue an export permit in Form 18 set out in Schedule 4, valid for six months prior to exportation of the medicines.

(6) After dispatch of the medicines, the pharmacist shall notify the Authority and submit an acknowledgement in Form 17 set out in Schedule 4 within seven days.

51. (1) Separate registers shall be kept for Schedules 1A, 1B, 1C medicines and precursor chemicals.

Records for
narcotics,
psychotropics
and precursor
chemicals

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

- (a) quantities received, issued, spoiled, disposed of and the balance of the medicine concerned;
- (b) name and business address of the supplier;
- (c) date on which the medicine was received;
- (d) import permit number in the case of imports;
- (e) export permit number in the case of exports;
- (f) name and business address of the purchaser;
- (g) date of sale of the medicine; and
- (h) invoice or reference number of such sale.

(3) Registers kept by the dispenser of medicines under subregulation (1) shall contain the following information where appropriate, the —

- (a) quantities received, issued, spoiled, disposed of and the balance of the medicines concerned;
- (b) name and business address of the supplier;
- (c) date on which the medicine was received;
- (d) name and address of the patient to whom the medicine was dispensed;
- (e) prescription number or reference number upon which the medicine was dispensed;
- (f) date of such dispensing; and
- (g) name and address of the prescriber.

(4) All invoices for the purchase or supply of Schedules 1A, 1B, 1C medicines or precursor chemicals shall be kept for a minimum of five years.

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

(6) All registers and records required to be kept under these Regulations shall be balanced within seven days.

(7) A register shall be a bound book with serially numbered pages.

- (8) A register shall not be transferrable without the Authority's approval.
- Correction of records** **52.** (1) A person who keeps a register under the Act shall make corrections to the register by drawing a line through the entry being corrected and shall insert his or her initials on the corrected entry.
 (2) A correction to a register shall not be masked or done with correction fluid and there shall be no overwriting.
- Advertising and promotion** **53.** (1) A market authorisation holder shall submit advertising and promotional materials to the Authority for approval before use.
 (2) The Authority shall assess advertising and promotional materials according to set guidelines and issue a written approval to the market authorisation holder.
 (3) Schedules 1, 2 and 3 medicines shall not be advertised directly to the public.
 (4) Subject to subregulation (3), only registered medicines may be advertised or promoted.
 (5) Medicines may be advertised to the professionals or in professional journals and publications.
 (6) Schedule 4 medicines may be advertised to the public.
 (7) Any advertising shall not mislead, compare medicines from other manufacturers and shall not include illustrations or pictures which may offend.
 (8) The adverts shall not contain promises that have not been scientifically proven and shall not make reference to symptoms in a manner likely to mislead the public.
- Inspection of premises** **54.** (1) The Authority shall ensure all premises are inspected to assess compliance to set guidelines.
 (2) An inspector shall present proof of authorisation and identification to the pharmaceutical operator before the inspection under subregulation (1) is carried out.
 (3) The inspections shall be done at all reasonable times and where samples are collected during inspections, the inspectors shall provide the pharmaceutical operator with a list of samples taken in Form 24 set out in Schedule 4.
 (4) The form under subregulation (3) shall be signed by both the inspector and the person in authority of the inspected premises.
 (5) Where an inspector seizes medicines in terms of section 47 (3) of the Act, he or she shall complete Form 24 set out in Schedule 4.

Part V — *Control of clinical trials*

- Application for use of medicines for clinical trials** **55.** (1) The applicant shall apply to the Authority in Form 19 set out in Schedule 4 accompanied by a fee set out in Schedule 5.
 (2) The Authority shall issue an applicant a written approval for use of medicines regulated under the Act.
 (3) The Authority shall keep registers of —
 (a) medicines and sites approved for clinical trials; and
 (b) all authorised and rejected clinical trials.
 (4) The clinical trials shall be conducted according to the set standards and guidelines.
 (5) All applications for clinical trials shall be registered with a World Health Organization recognised clinical trials registry.
 (6) A detailed report on the results of the clinical trial shall be submitted to the Authority at the completion of the trial.

56. The reporting of adverse events in clinical trials shall be in line with set guidelines and shall meet international standards. Monitoring of clinical trial
57. The Authority shall inspect clinical trial sites for readiness and compliance with good clinical practices. Inspection and audit of clinical trials
58. (1) The Authority may suspend or terminate an approval to conduct clinical trials where the Authority determines that the use of the medicines under trial is not safe or the anticipated benefits cannot be realised. Suspension or termination of approval to conduct clinical trials
- (2) The trials may also be suspended or terminated if the conduct is not according to the approval issued under these Regulations.
59. A person who disposes of unused medicines in a clinical trial shall notify the Authority in terms of regulation 34. Disposal of unused medicines in clinical trials

Part VI — *Cosmetics*

60. (1) A person shall apply to the Authority for registration of cosmetics in Form 20 Part A set out in Schedule 4 and accompanied by a — Registration of cosmetics
- (a) payment of a fee in Schedule 5; and
- (b) sample as described in the guidelines.
- (2) The registration procedure for cosmetics shall be as outlined in the guidelines.
- (3) The Authority shall, upon assessment issue an approval in Form 23 set out in Schedule 4 and in line with the guidelines.
- (4) The Authority shall collaborate with other institutions and authorities in any harmonisation and collaborative activities in order to benchmark and facilitate developments of requirements and guidelines for efficient operations and prudent use of cosmetics.
- (5) An approval issued in terms of subregulation (3) shall be valid for five years subject to annual submission of information accompanied by the Annual fee in Schedule 5.
- (6) Any cosmetic product awarded marketing authorisation shall maintain information regarding safety, manufacturing and any other necessary information as detailed in the guidelines and shall be accessible to the Authority.
- (7) Regulations 5, 6, 7, 10, 11, 12, 13, 14 and 15 shall apply with the necessary modifications.
61. (1) An applicant may apply in Form 20 Part B set out in Schedule 4 upon payment of a fee set out in Schedule 5 to the Authority to exempt the registration of cosmetics from outside Botswana under special circumstances. Exemption for registration of cosmetics
- (2) The Authority may, after having considered the application and the supporting documents, grant the exemption in line with the guidelines.
62. The Authority shall determine and publish a list of prohibited ingredients according to the guidelines. Publication of list of prohibited ingredients
63. The container for cosmetics shall be labelled in English with the following information — Labelling of cosmetics
- (a) the name of the product;
- (b) list of ingredients;
- (c) manufacturer's details;

Licensing of
manufacturing
cosmetics

Import of
cosmetics

- (d) shelf life, expiry date or period of use after opening;
- (e) batch identification;
- (f) storage conditions;
- (g) directions for use; and
- (h) any warnings or precautions.

64. A person shall apply to the Authority for a manufacturing licence of cosmetics in Form 8 set out in Schedule 4 accompanied by a fee set out in Schedule 5.

65. (1) A person shall apply to the Authority to import cosmetics in Form 10 set out in Schedule 4 accompanied by a fee set out in Schedule 5.

(2) Upon assessment the Authority shall issue an import permit in Form 11 set out in Schedule 4 and in line with the guidelines.

(3) Only registered or exempted cosmetics may be imported.

(4) The marketing authorisation holder shall submit advertising and promotional materials to the Authority for authorisation before use.

(5) The Authority shall assess advertising and promotional materials according to set guidelines and issue a written authorisation to the marketing authorisation holder.

(6) A person authorised to import cosmetics shall pay a fee set out in Schedule 5 for each consignment in line with the guidelines.

Part VII — *Complementary medicines*

Registration of
complementary
medicines

66. (1) An application for registration of complementary medicines shall be submitted in Form 21 set out in Schedule 4 and accompanied by —

- (a) an application fee set out in Schedule 5; and
- (b) a sample as described in the guidelines.

(2) The Authority shall specify conditions for registration for a particular complementary medicine and may —

- (a) amend any conditions for registration;
- (b) specify product labelling requirement; or
- (c) determine what is to be described in the labels or packages of complementary medicines.

(3) Scientific evidence of safety and efficacy data shall be required for the registration of any therapeutic claim.

(4) Where an application to register a complementary medicine is successful, the Authority shall issue a written approval for registration to the applicant in Form 22 set out in Schedule 4.

(5) Where an application to register complementary medicines is unsuccessful, the Authority shall inform the applicant in writing stating the reason for the decision not to register the medicine.

(6) No application for a complementary medicine shall be made to the Authority for an injectable and eye preparations.

(7) The container for complementary medicines shall be labelled in English with the following information —

- (a) the botanical or INN name of the product;
- (b) the brand name of the product;
- (c) list of ingredients;
- (d) the quantity of active ingredients per dosage unit;
- (e) name and address of manufacturers;

- (f) shelf life, expiry date;
- (g) batch identification;
- (h) storage conditions;
- (i) directions for use;
- (j) any warnings or precautions;
- (k) any contraindications;
- (l) manufacturing date; and
- (m) the statement that "there are no approved therapeutic claims", where applicable.

(8) The Authority shall review allowable indication and functional claims from time to time and shall publish the claims in the *Gazette*.

(9) A person may apply to the Authority for the renewal of registration of complementary medicines in Form 4 set out in Schedule 4.

(10) Regulations 5, 6, 7, 10, 11, 12, 13, 14 and 15 shall apply with the necessary modifications.

67. An approval issued in terms of regulation 66 shall be valid for five years subject to annual submission of information accompanied by the Annual fee in Schedule 5.

Validity period
of registration of
complementary
medicines

PART VIII — General

68. The Authority shall collaborate with other institutions and authorities in any harmonisation and collaborative activities in order to benchmark and facilitate developments of requirements and guidelines for efficient operations and prudent use of resources.

Harmonisation
and collaborative
activities of
Authority

69. Any person aggrieved by the decision of the Authority may appeal to the Appeals Committee.

Appeals
Committee

70. The Minister shall, in consultation with the Authority publish a list of banned medicines in Schedule 3.

Banned
medicines

71. A person who —

Offences and
penalties

- (a) contravenes the provisions of these Regulations, for which no penalty is provided;
 - (b) fails to comply with any direction given or request made by the Authority or any competent authority under these Regulations; or
 - (c) fails to comply with any condition of a licence,
- commits an offence and is liable to the penalties provided for under section 66 of the Act.

72. The Drugs and Related Substances Regulations are hereby revoked.

Revocation of
Cap. 63:04
(Sub. Leg.)

SCHEDULES

SCHEDULE 1

(reg. 36, 37, 38, 40, 41 and 43)

SCHEDULE 1 MEDICINES

NO.	NAME OF THE MEDICINE	CATEGORY
1	1-methyl-4-phenylpiperidine-4-carboxylic acid; its salts; its esters and ethers; their salts	1A
2	2-Methyl-3-morpholino-1,1-diphenyl-propanecarboxylic acid; its salts; its esters and ethers; their salts	1A
3	4-cyano-1-methyl-4-phenylpiperidine; its salts	1A
4	4-cyano-2-dimethylamino-4,4-diphenylbutane; its salts	1A
5	4-Phenylpiperidine-4-carboxylic acid ethyl ester; its salts	1A
6	Acetorphine hydrochloride	1A
7	Acetorphine; its salts; its esters and ethers; their salts	1A
8	Acetyl-methadol see Methadyl acetate	1A
9	Alfentanil	1A
10	Allylprodine; its salt	1A
11	Alphacetylmethadol; its salts; its esters and ethers; their salt	1A
12	Alphameprodine; its salts	1A
13	Alphamethadol; its salts, its esters and ethers; their salts	1A
14	alpha-methylphenethylamine see Amphetamine N-(2-(N-methylphenethylamino)propyl)propionanilide see Diampromide Methylphenidate; its salts	1A
15	Amidone see Methadone	1A
16	Amphetamine phosphate	1A
17	Amphetamine sulphat	1A
18	Amphetamine; its salts	1A
19	Anileridine; its salts	1A
20	Benzethidine; its salts	1A
21	Benzylmorphine hydrochloride	1A
22	Benzylmorphine; its salts; its esters and ethers; their salts	1A
23	Betacetylmethadol; its salts	1A
24	Betameprodine; its salts	1A
25	Betamethadol; its salts; its esters and ethers; their salts	1A
26	Betaminoisopropylbenzene see amphetamine	1A
27	Betaprodine; its salts	1A
28	Bezitramide; its salts	1A
29	Carfentanil; its stereoisomers its salts; its esters and ethers, their salts	1A
30	Clonitazene; its salts	1A
31	Codeine hydrochloride see Codeine	1A
32	Codeine phosphate see Codeine	1A
33	Codeine sulphate see Codeine	1A
34	Codoxime see Dihydrocodeinone O-carboxymethyloxime	1A
35	Delta-9-tetrahydrocannabinol see Dronabinol	1A
36	Desomorphine; its salts; its esters and ethers; their salts	1A
37	Desoxyephedrine see Methylamphetamine	1A
38	Desoxynorephedrine see Amphetamine	1A

39	Dexamphetamine phosphate	1A
40	Dexamphetamine sulphate	1A
41	Dexamphetamine; its salts	1A
42	Dextrodiphenopyradine see Dextromoramide	1A
43	Dextromoramide tartrate	1A
44	Dextromoramide; its salts	1A
45	Dextropropoxyphene; its salt; its esters and ethers; their salts but in a preparation for oral use containing not more than 135mg of dextropropoxyphene (calculated as base, per dosage unit, or with a total concentration of not more than 2.5% calculated as base, in undivided preparations: Schedule 2)	1A
46	Diampromide; its salts	1A
47	Diethylthiambutene hydrochloride	1A
48	Diethylthiambutene; its salts	1A
49	Dihydrocodeine phosphate see dihydrocodeine	1A
50	Dihydrocodeine tartrate see dihydrocodeine	1A
51	Dihydrocodeinone enolacetate see Thebacon	1A
52	Dihydrocodeinone O-carboxymethyl-oxime; salts; esters and ethers; their salts	1A
53	Dihydrocodeinone see hydrocodone	1A
54	Dihydrodeoxymorphine see Desomorphine	1A
55	Dihydrohydroxycodone see Oxycodone	1A
56	Dihydrohydroxymorphine see Oxymorphine	1A
57	Dihydromorphine; its salts; its esters and ethers; their salts	1A
58	Dihydromorphine see Hydromorphine	1A
59	Dimenoxadole; its salts	1A
60	Dimepheptanol; its salts; its esters and ethers; their salts	1A
61	Dimethylthiambutene; its salts	1A
62	Dioxaphetyl butyrate; its salts	1A
63	Diphenoxylate hydrochloride see diphenoxylate	1A
64	Dipipanone hydrochloride	1A
65	Dipipanone; its salts	1A
66	Dronabinol	1A
67	Drotebanol; its salts; its esters and ethers; their salts	1A
68	Ethylmethylthiambutene; its salts	1A
69	Ethylmorphine hydrochloride see Ethyl morphine	1A
70	Etonitazine; its salts	1A
71	Etorphine hydrochloride	1A
72	Etorphine; its salts; its esters and ethers; their salts	1A
73	Etoxadine; its salts; its esters and ethers; their salts	1A
74	Fenethylamine; its salts; its stereoisomers; their salts	1A
75	Furethidine; its salts	1A
76	Glutethimide; its salts; its stereoisomers; their salts	1A
77	Hebaine; its salts	1A
78	Hexobarbitone sodium	1A
79	Hydrocodone bitartrate	1A
80	Hydrocodone; its salts	1A
81	Hydromorphinol; its salts; its esters and ethers; their salts	1A
82	Hydromorphine; its salts; its esters and ethers; their salts	1A
83	Hydroxypethidine; its salts; its esters and ethers; their salts	1A

84	Isomethadone	1A
85	Ketobemidone; its salts; its esters and ethers; their salts	1A
86	Levamfetamine	1A
87	Levomethamphetamine	1A
88	Levomethorphan; its salts	1A
89	Levomoramide; its salts	1A
90	Levophenacymorphan; its salts; its esters and ethers; their salts	1A
91	Levorphanol tartrate	1A
92	Lofentanil; its stereoisomers; its salts; its esters and ethers; their salts	1A
93	Mecloqualone	1A
94	Mephentermine sulphate	1A
95	Metazocine; its salts; its esters and ethers; their salt	1A
96	Methadone hydrochloride	1A
97	Methadone; its salts	1A
98	Methadyl acetate; its salts	1A
99	Methamphetamine see Methylamphetamine	1A
100	Methylamphetamine hydrochloride	1A
101	Methylamphetamine; its salts	1A
102	Methyldesorphine; its salts; its esters and ethers; their salts	1A
103	Methyldihydromorphine; its salts; its esters and ethers; their salts	1A
104	Methyldihydromorphinone see Metopon	1A
105	Methylphenidate hydrochloride	1A
106	Methylphenidate; its salts	1A
107	Metopon; its salts; its esters and ethers; their salts	1A
108	Morpheridine; its salts	1A
109	Morphine acetate see Morphine	1A
110	Morphine hydrochloride see Morphine	1A
111	Morphine methobromide; its esters and ethers	1A
112	Morphine sulphate see Morphine	1A
113	Morphine tartrate see Morphine	1A
114	Morphine; its salts; its esters and ethers; their salts; its pentavalent nitrogen derivatives; their esters and ethers	1A
115	Morphine-N-oxide; its esters and ethers	1A
116	Morpholinoethylnorpethidine see Morpheridine	1A
117	Myrophine; its salts	1A
118	Nicomorphine; its salts	1A
119	Noracymethadol; its salts	1A
120	Norlevorphanol; its salts; its esters and ethers; their salts	1A
121	Normethadone; its salts	1A
122	Normorphine; its salts; its esters and ethers; their salts	1A
123	Norpipanone; its salts	1A
124	Opium, medicinal	1A
125	Oxycodone; its salts; its esters and ethers; their salts	1A
126	Oxymorphone; its salts; its esters and ethers; their salts	1A
127	Papaveretum see Opium, medicinal	1A
128	Pethidine hydrochloride	1A
129	Pethidine; its salts	1A
130	Phenadone see Methadone	1A
131	Phenadoxone; its salts	1A
132	Phenampromide; its salts	1A

133	Phenazocine hydrobromide	1A
134	Phenazocine; its salts; its esters and ethers; their salts	1A
135	Phendimetrazine tartrate	1A
136	Phendimetrazine; its salts	1A
137	Phenmetrazine hydrochloride	1A
138	Phenmetrazine theoclate	1A
139	Phenmetrazine; its salts	1A
140	Phenomorphan; its salts; its esters and ethers; their salts	1A
141	Phenoperidine; its salts; its esters and ethers; their salts	1A
142	Pholcodine citrate see Pholcodine	1A
143	Pholcodine tartrate see Pholcodine	1A
144	Piritramide; its salts	1A
145	Potassium clorazepate	1A
146	Prazepam	1A
147	Proheptazine; its salts	1A
148	Properidine; its salts	1A
149	Quinalbarbitone	1A
150	Quinalbarbitone sodium	1A
151	Racemethorphan; its salts	1A
152	Racemoramide; its salts	1A
153	Racemorphan; its salts; its esters and ethers; their salts	1A
154	Secobarbitone see Quinalbarbitone	1A
155	Temazepam	1A
156	Thebacon; its salts	1A
157	Tilidate; its salts; its esters and ethers; their salts	1A
158	Trimeperidine; its salts	1A
159	Amferpramone	1B
160	Amylobarbitone	1B
161	Amylobarbitone sodium	1B
162	Benzphetamine; its salts	1B
163	Bezphetamine hydrochloride	1B
164	Buprenorphine	1B
165	Buprenorphine hydrochloride	1B
166	Butalbital	1B
167	Cathine; its salts; its stereoisomers not being phenylpropanolamine; their salts	1B
168	Chlorphentamine hydrochloride	1B
169	Chlorphentamine; its salts	1B
170	Cyclobarbitone	1B
171	Diethylpropion hydrochloride	1B
172	Lefetamine(SPA)	1B
173	Mazindol	1B
174	Mefenorex; its salts; its stereoisomers; their salts	1B
175	Meperidine see Pethidine	1B
176	Mephentermine; its salts	1B
177	Pemoline	1B
178	Pentazocine hydrochloride	1B
179	Pentazocine lactate	1B
180	Pentobarbitone	1B
181	Pentobarbitone sodium	1B

182	Phentermine	1B
183	Phenylmethylbarbituric acid	1B
184	Pinazepam	1B
185	Pipradrol hydrochloride	1B
186	Pipradrol; its salts	1B
187	Allobarbitol	1C
188	Barbitone	1C
189	Barbitone sodium	1C
190	Bromazepam	1C
191	Butobarbitone	1C
192	Butobarbitone sodium	1C
193	Camazepam	1C
194	Chlordiazepoxide	1C
195	Chlordiazepoxide hydrochloride	1C
196	Clobazam	1C
197	Clonazepam	1C
198	Clorazepate	1C
199	Clotiazepam	1C
200	Cloxazolam	1C
201	Delorazepam	1C
202	Diazepam	1C
203	Estazolam	1C
204	Ethchlorvyno	1C
205	Ethinimate	1C
206	Ethyl loflazepate	1C
207	Fencamfamin; its salts; its stereoisomers; their salts	1C
208	Fentanyl; its salts	1C
209	Fludiazepam	1C
210	Flunitrazepam	1C
211	Flurazepam hydrochloride; its salts	1C
212	Flurazepam monohydrochloride	1C
213	Halazepam	1C
214	Haloxazolam	1C
215	Heptabarbitalone	1C
216	Hexobarbitone	1C
217	Ketazolam	1C
218	Loprazolam mesylate	1C
219	Lorazepam	1C
220	Lormetazepam	1C
221	Medazepam	1C
222	Meprobamate	1C
223	Methylphenobarbitone	1C
224	Methypyrone	1C
225	Midazolam	1C
226	N-Ethylamphetamine; its salts; its stereoisomers; their salts	1C
227	Nimetazepam	1C
228	Nitrazepam	1C
229	Nordazepam	1C
230	Oxazepam	1C
231	Oxazolam	1C

232	Phenobarbitone	1C
233	Phenobarbitone sodium	1C
234	Piminodine; its salts	1C
235	Propylhexedrine; its salts; its stereoisomers; their salts	1C
236	Pyrovalerone; its salts; its stereoisomers; their salts	1C
237	Secbutobarbitone	1C
238	Secbutobarbitone sodium	1C
239	Sufentanil; its salts; its esters and ethers; their salts	1C
240	Triazolam	1C
241	Vinylbital	1C
242	Codeine; its salts 1(A) but if for non-parenteral use and in undivided preparations with ms 1.5% (calculated as base: and not more than 200ml: Schedule 3)	1C
243	Acetyldihydrocodeine; its salts 1(A) but if for non-parenteral use and: (a) in undivided preparations with ms 2.5% (calculated as base: Schedule 2) (b) in single-dose preparations with ms per dosage unit 100mg (calculated as base: Schedule 2)	1D
244	Codeine; its salts 1(A) but if for non-parenteral use and: (a) in undivided preparations with ms 2.5% (calculated as base: Schedule 2) (b) in single-dose preparations with ms per dosage unit 100mg (calculated as base: Schedule 2) (c) 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
245	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
246	Dihydrocodeine; its salts 1A but if for non-parenteral use and: (a) in undivided preparations with ms 2.5% (calculated as base: Schedule 2) (b) in undivided preparations with ms 1.5% (calculated as base) and md 10mg (calculated as base: Schedule 3) (c) in single-dose preparations with ms per dosage unit 100mg (calculated as base: Schedule 2) (d) in single-dose preparations with ms per dosage unit 1.5% (calculated as base) and md 10mg (calculated as base: Schedule 3)	1D
247	Diphenoxylate; its salts 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
248	Ethylmorphine; its salts but if for non-parenteral use and (a) in undivided preparations with ms 2.5% (calculated as base: Schedule 2) (b) in single dose preparations with ms per dosage unit 100mg (calculated as base: Schedule 2)	1D

- 249 Nicocodine; its salts
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 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
- 250 Norcodeine; its salts
but if for non-parenteral use and:
(a) in undivided preparations with ms 2.5% (calculated as base: Schedule 2)
(b) in single dose preparations with ms per dosage unit 100mg (calculated as base: Schedule 2) 1D
- 251 Pholcodine; its salts 1A but if for non-parenteral use and: (a) in undivided preparations with ms 2.5% (calculated as base: Schedule 2)(b) in undivided preparations with ms 1.5% (calculated as base) and md 20mg (calculated as base: Schedule 3)(c) in single-dose preparations with ms per dosage unit 100mg (calculated as base: Schedule 2)(d) in single-dose preparations with ms per dosage unit 1.5% (calculated as base) and md 20mg (calculated as base: Schedule 3) 1D
- 252 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

(2) SCHEDULE 2 MEDICINES

NO. NAME OF THE MEDICINE

- 1 Alfalcidol(1 alpha hydroxy calceferol)
- 2 Roxarsone (4-hydroxy-3 nitrophenyl arsonic acid)
- 3 Abacavir
- 4 Acebutolol
- 5 Acepromazine
- 6 Acepromazine maleate
- 7 Acetanilide
- 8 Acetarsol
- 9 Acetazolamide
- 10 Acetazolamide sodium
- 11 Acetohexamide
- 12 Acetylcarbromal
- 13 Acetylcholine chloride
- 14 Acetylcysteine
- 15 Acetyldigitoxin
- 16 Acetylstrophanthidin
- 17 Acetylsulphafurazole
- 18 Acetylsulphamethoxypyridazine
- 19 Aconite

- 20 Acrosoxacin
- 21 Actinomycin C
- 22 Actinomycin D
- 23 Acyclovir (except topical preparation Schedule 3)
- 24 Adicillin
- 25 Adiphenine hydrochloride
- 26 Adrenaline
- 27 Adrenaline acid tartrate
- 28 Adrenaline hydrochloride
- 29 Albumin human (immuno)
- 30 Alclofenac
- 31 Alclometasone dipropionate
- 32 Alcuronium chloride
- 33 Aldosterone
- 34 Alendronate
- 35 Alfalcidol
- 36 Alfuzosin
- 37 Algestone acetone
- 38 Algestone acetophenide
- 39 Alkomide
- 40 Allyloestrenol
- 41 Alphadolone acetate
- 42 Alphaxalone
- 43 Alprazolam
- 44 Alprenolol
- 45 Alprenolol hydrochloride
- 46 Alprostadil
- 47 Alseroxylon
- 48 Altizide
- 49 Amantadine
- 50 Ambenonium chloride
- 51 Ambuside
- 52 Ambutonium bromide
- 53 Amcinonide
- 54 Ametazole hydrochloride
- 55 Amidopyridone
- 56 Amikacin sulphate
- 57 Amiloride
- 58 Aminocaproic acid
- 59 Aminodarone hydrochloride
- 60 Aminoglutethemide
- 61 Aminophylline
- 62 Aminopterin sodium
- 63 Aminosalicyclic acid
- 64 Amiodarone
- 65 Amiphenazole hydrochloride
- 66 Amitriptyline
- 67 Amitriptyline embonate
- 68 Amitriptyline hydrochloride
- 69 Amlodipine

- 70 Ammonium bromide
- 71 Amodiaquine hydrochloride
- 72 Amoxapine
- 73 Amoxycillin
- 74 Amoxycillin trihydrate
- 75 Amphomycin
- 76 Amphotericin
- 77 Ampicillin
- 78 Ampicillin sodium
- 79 Ampicillin trihydrate
- 80 Amsacrine
- 81 Amylocaine hydrochloride
- 82 Anagrelide
- 83 Anastrozole
- 84 Ancrod
- 85 Androsterone
- 86 Angiotensin amide
- 87 Anterior pituitary extract
- 88 Antimony barium tartrate
- 89 Antimony dimercaptosuccinate
- 90 Antimony lithium thiomalate
- 91 Antimony pentasulphide
- 92 Antimony potassium tartrate
- 93 Antimony sodium tartrate
- 94 Antimony sodium thioglycollate
- 95 Antimony sulphate
- 96 Antimony trichloride
- 97 Antimony trioxide
- 98 Antimony trisulphide
- 99 Apiol
- 100 Apomorphine
- 101 Apomorphine hydrochloride
- 102 Apramycin
- 103 Apramycin sulphate
- 104 Aprotinin
- 105 Arecoline
- 106 Arecoline hydrobromide
- 107 Arecoline-acetarsol
- 108 Arsanilic acid
- 109 Arsphenamine
- 110 Atazanavir
- 111 Atenolol
- 112 Atorvastatin
- 113 Atracurium besylate
- 114 Azacyclonol
- 115 Azacyclonol hydrochloride
- 116 Azaperone
- 117 Azapropazone
- 118 Azathioprine
- 119 Azidocillin potassium

- 120 Azithromycin
- 121 Azothioprine
- 122 Azothioprine sodium
- 123 Bacampicillin hydrochloride
- 124 Bacitracin
- 125 Bacitracin methylene disalicylate
- 126 Bacitracin zinc
- 127 Baclofen
- 128 Barium carbomate
- 129 Barium chloride
- 130 Barium sulphide
- 131 Beclamide
- 132 Beclomethasone
- 133 Beclomethasone dipropionate
- 134 Bemegride
- 135 Benactyzine hydrochloride
- 136 Benapryzine hydrochloride
- 137 Bendrofluazide
- 138 Benethamine penicillin
- 139 Benoxaprofen
- 140 Benperidol
- 141 Benserazide
- 142 Benzathine penicillin
- 143 Benzbromarone
- 144 Benzhexol hydrochloride
- 145 Benzonium bromide
- 146 Benzoclamine hydrochloride
- 147 Benzquinamide
- 148 Benzquinamide hydrochloride
- 149 Benzthiazide
- 150 Benztropine mesylate
- 151 Benzyl penicillin
- 152 Benzyl penicillin calcium
- 153 Betahistine hydrochloride
- 154 Betamethasone
- 155 Betamethasone adamantoate
- 156 Betamethasone benzoate
- 157 Betamethasone dipropiomate
- 158 Betamethasone sodium phosphate
- 159 Betamethasone valerate
- 160 Betaxolol hydrochloride
- 161 Bethanecol chloride
- 162 Bethanidine sulphate
- 163 Bezafibrate
- 164 Bicalutamide
- 165 Biperidine hydrochloride
- 166 Biperidine lactate
- 167 Bismuth glucollylarsanilate
- 168 Bisoprolol
- 169 Bleomycin sulphate

- 170 Boldenone undecylenate
- 171 Bretylium tosylate
- 172 Brimonidine
- 173 Bromocriptine mesylate
- 174 Bromperidol
- 175 Bromvaletone
- 176 Budesonide
- 177 Bumetadine
- 178 Bumetanide
- 179 Buphenine hydrochloride
- 180 Bupivacaine
- 181 Bupivacaine hydrochloride
- 182 Buspirone hydrochloride
- 183 Busulphan
- 184 Butacaine sulphate
- 185 Butanilicaine phosphate
- 186 Butriptyline hydrochloride
- 187 Butylchloral hydrate
- 188 Cabergoline
- 189 Calcitonin
- 190 Calcitriol
- 191 Calcium aminosalicylate
- 192 Calcium amphomycin
- 193 Calcium benzamidosalicylate
- 194 Calcium bromide
- 195 Calcium bromidolactobionate
- 196 Calcium carbimide
- 197 Calcium folinate
- 198 Calcium metrizoate
- 199 Calcium sulphaloxate
- 200 Candesartan
- 201 Candicidin
- 202 Canrenoic acid
- 203 Cantharidin
- 204 Capreomycin sulphate
- 205 Captopril
- 206 Caramiphen edisylate
- 207 Caramiphen hydrochloride
- 208 Carbachol
- 209 Carbamazepine
- 210 Carbenicillin sodium
- 211 Carbenoxolone sodium
- 212 Carbidopa
- 213 Carbidopa monohydrate
- 214 Carbimazole
- 215 Carbon tetrachloride
- 216 Carboplatin
- 217 Carboprostrometamol
- 218 Carbromal
- 219 Carbuterol hydrochloride

- 220 Carindacillin sodium
- 221 Carisoprodol
- 222 Carmustine
- 223 Carvedilol
- 224 Cefaclor
- 225 Cefazedone sodium
- 226 Cefazolin
- 227 Cefepime
- 228 Cefixime
- 229 Cefotaxime
- 230 Cefoxitin sodium
- 231 Cefpodoxime
- 232 Cefprozil
- 233 Ceftazidime
- 234 Ceftizoxime sodium
- 235 Ceftriaxone
- 236 Cefuroxime sodium
- 237 Cephalexin
- 238 Cephalexin sodium
- 239 Cephaloridine
- 240 Cephalosporin C
- 241 Cephalosporin E
- 242 Cephalosporin N
- 243 Cephalothin sodium
- 244 Cephmandole nafate
- 245 Cephazolin sodium
- 246 Cephradine
- 247 Cerium oxalate
- 248 Chenodeoxycholic acid
- 249 Chloral antipyrine
- 250 Chloral betaine
- 251 Chloral formamide
- 252 Chloral glycerolate
- 253 Chloral hydrate
- 254 Chloralose
- 255 Chloralurethane
- 256 Chlorambucil
- 257 Chloramphenicol
- 258 Chlorisondamine chloride
- 259 Chlormadinone acetate
- 260 Chlormerodrin
- 261 Chlormethiazole
- 262 Chlormezanone
- 263 Chloroquine and its salts (except for prophylaxis of malarial prophylaxis Schedule 3)
- 264 Chlorothiazide
- 265 Chlorotrianisene
- 266 Chloroxazone
- 267 Chlorphenoxamine hydrochloride
- 268 Chlorpromazine
- 269 Chlorpromazine embonate

- 270 Chlorpromazine hydrochloride
- 271 Chlorpropamide
- 272 Chlorprothixene
- 273 Chlorprothixene hydrochloride
- 274 Chlortetracycline
- 275 Chlortetracycline hydrochloride
- 276 Chlorthalidone
- 277 Cholestyramine
- 278 Chorionic gonadotrophin
- 279 Chormethiazole edisylate
- 280 Ciclacillin
- 281 Ciclobendazole
- 282 Cimetidine & its salts (except for short term relief of heartburn, dyspepsia and hyperacidity 200mg -400mg per single dose- maximum 4800mg Schedule 3)
- 283 Cinchocaine
- 284 Cinchocaine hydrochloride
- 285 Cinchophen
- 286 Cinoxacin
- 287 Ciprofloxacin
- 288 Ciprofloxacin hydrochloride
- 289 Cisplatin
- 290 Citalopram
- 291 Cladribine
- 292 Clarithromycin
- 293 Clavulanic acid
- 294 Clenbuterol hydrochloride
- 295 Clindamycin and its salts (except for topical preparation Schedule 3)
- 296 Clindamycin hydrochloride hydrate
- 297 Clindamycin palmitate hydrochloride
- 298 Clindamycin phosphate
- 299 Clindinium bromide
- 300 Clobetasol
- 301 Clobetasol 17-propionate
- 302 Clobetasone butyrate
- 303 Clofazimine
- 304 Clofibrate
- 305 Clomiphene citrate
- 306 Clomipramine
- 307 Clomipramine hydrochloride
- 308 Clomocycline
- 309 Clomocycline sodium
- 310 Clonidine
- 311 Clonidine hydrochloride
- 312 Clopenthixol decanoate
- 313 Clopenthixol hydrochloride
- 314 Clopidogrel
- 315 Cloprostenol sodium
- 316 Clorexolone
- 317 Clorprenaline hydrochloride
- 318 Clostebol acetate

- 319 Cloxacillin benzathine
- 320 Cloxacillin sodium
- 321 Clozapine
- 322 Cocculus indicus
- 323 Co-dergocrine myselate
- 324 Colchicine (except for acute gout attack maximum 6mg, 0.5-1mg per single dose
Schedule 3)
- 325 Colestipol hydrochloride
- 326 Colistin sulphate
- 327 Colistin sulphomethate
- 328 Colistin sulphomethate sodium
- 329 Conium leaf
- 330 Corticotrophin
- 331 Cortisone
- 332 Cortisone acetate
- 333 Cotamine chloride
- 334 Co-tetroxazine
- 335 Co-trimoxazole
- 336 Cropropamide
- 337 Crotethamide
- 338 Croton oil
- 339 Croton seed
- 340 Curare
- 341 Cycloghosphamide
- 342 Cyclopenthiiazide
- 343 Cyclopentolate hydrochloride
- 344 Cyclophosphamide
- 345 Cyclosporin
- 346 Cyclothiazide
- 347 Cyproterone acetate
- 348 Cytarabine
- 349 Cytarabine hydrochloride
- 350 Dacarbazine
- 351 Dactinomycin
- 352 Danazol
- 353 Dantrolene sodium
- 354 Dapsone
- 355 Dapsone ethane ortho sulphonate
- 356 Darunavir
- 357 Daunorubicin hydrochloride
- 358 Deanol salts and esters
- 359 Debrisoquine sulphate
- 360 Dehydroemetine hydrochloride
- 361 Delmadinone acetate
- 362 Demecarium bromide
- 363 Demeclocycline
- 364 Demeclocycline calcium
- 365 Demeclocycline hydrochloride
- 366 Deoxycortone acetate
- 367 Deoxycortone pivalate

- 368 Deptropine citrate
- 369 Dequalinium chloride
- 370 Deserpidine
- 371 Desferroxamine mesylate
- 372 Desfluorotriamcinolone
- 373 Desipramine hydrochloride
- 374 Deslanoside
- 375 Desmopressin
- 376 Desonide
- 377 Desoxymethasone
- 378 Dexamethasone
- 379 Dexamethasone 21-isonicotinate
- 380 Dexamethasone phenylpropionate
- 381 Dexamethasone pivalate
- 382 Dexamethasone sodium m-sulphobenzoate
- 383 Dexamethasone sodium phosphate
- 384 Dexamethasone trioxaundecanoate
- 385 Dextromethorphan hydrobromide
- 386 Dextrothyroxine sodium
- 387 Diazoxide
- 388 Dibenzepin hydrochloride
- 389 Dichloralphenazone
- 390 Dichlorophernasine hydrochloride
- 391 Dichlorphenamide
- 392 Diclofenac and its salts (topical preparation & oral 500mg maximum, 50-100mg per single dose Schedule 3)
- 393 Dicyclomine hydrochloride (except in antacid preparation Schedule 3)
- 394 Dienoestrol
- 395 Diethanolamine fusidate
- 396 Diethylamine acetarsol
- 397 Diflucortolone valerate
- 398 Diflunisal
- 399 Digitalis leaf
- 400 Digitoxin
- 401 Digoxin
- 402 Dihydrallazine sulphate
- 403 Dihydroergotamine mesylate
- 404 Dihydrostreptomycin sulphate
- 405 Diltiazem hydrochloride
- 406 Dimercaprol
- 407 Dimethisoquin hydrochloride
- 408 Dimethisterone
- 409 Dimethothiazine mesylate
- 410 Dimethyl sulphoxide
- 411 Dimethyltubocurarine bromide
- 412 Dimethyltubocurarine chloride
- 413 Dimethyltubocurarine iodide
- 414 Dinitrodiphenylsulphonylethylenediamine
- 415 Dinoprost
- 416 Dinoprostone

- 417 Diphetarsone
- 418 Dipivefrin hydrochloride
- 419 Diprenorphine hydrochloride
- 420 Dipyrindamole
- 421 Dipyrone
- 422 Disodium etidronate
- 423 Disopyramide
- 424 Disopyramide phosphate
- 425 Distigmine bromide
- 426 Disulfiram
- 427 Disulphamide
- 428 Dithranol
- 429 d-Norgestrel
- 430 Dobutamine hydrochloride
- 431 Docetaxel
- 432 Dolutegravir
- 433 Domperidone
- 434 Donepezil
- 435 Dopamine hydrochloride
- 436 Dothiepin
- 437 Dothiepin hydrochloride
- 438 Doxapram hydrochloride
- 439 Doxazosin
- 440 Doxepin hydrochloride
- 441 Doxorubicin
- 442 Doxycycline
- 443 Doxycycline calcium chelate
- 444 Doxycycline hydrochloride
- 445 Droperidol
- 446 Drospirenone
- 447 Drostanolone
- 448 Drostanolone propionate
- 449 Duloxetine
- 450 Dyaxide
- 451 Dydrogesterone
- 452 Ecthiopate iodide
- 453 Edrophonium
- 454 Efavirenz
- 455 Emepromium bromide
- 456 Emetine
- 457 Emetine bismuth iodide
- 458 Emetine hydrochloride
- 459 Emtricitabine
- 460 Enalapril maleate
- 461 Epicillin
- 462 Epirubicin
- 463 Epithiazide
- 464 Epoprostenol sodium
- 465 Ergometrine tartrate
- 466 Ergotamine esylate

- 467 Erythromycin & its salts (except topical preparation Schedule 3)
- 468 Erythropoietin
- 469 Escitalopram
- 470 Esomeprazole & its salts (except for the 14-day treatment for frequent heartburn, at a daily dose of 20 mg and in package sizes of no more than 280 mg of esomeprazole Schedule 3)
- 471 Estramustine phosphate
- 472 Etafedrine hydrochloride
- 473 Ethacrynic acid
- 474 Ethamsylate
- 475 Ethchlorvynol
- 476 Ethebenecid
- 477 Ethiazide
- 478 Ethinyloestradiol
- 479 Ethionamide
- 480 Ethisterone
- 481 Ethoheptazine citrate
- 482 Ethopropazine hydrochloride
- 483 Ethosuximide
- 484 Ethotoin
- 485 Ethulose
- 486 Ethyl acetanilide
- 487 Ethyl biscoumacetate
- 488 Ethyloestrenol
- 489 Ethynodiol diacetate
- 490 Etidronate disodium
- 491 Etomidate
- 492 Etoposide
- 493 Factor IX concentrate
- 494 Factor XII concentrate
- 495 Factor XIII concentrate
- 496 Fazadinium bromide
- 497 Felodipine
- 498 Fenbufen
- 499 Fenfluramine hydrochloride
- 500 Fenoprofen
- 501 Fenoprofen calcium
- 502 Fenoterol hydrobromide
- 503 Fenpipramide hydrochloride
- 504 Fenpiprane hydrochloride
- 505 Filgrastin
- 506 Finasteride
- 507 Flavoxate hydrochloride
- 508 Flecainide
- 509 Fluanisone
- 510 Fluclorolone acetonide
- 511 Flucloxacillin sodium
- 512 Fluconazole
- 513 Flucytosine
- 514 Fludarabine

- 515 Fludrocortisone acetate
- 516 Flufenamic acid
- 517 Flugestone
- 518 Flugestone acetate
- 519 Flumedroxone acetate
- 520 Flumethasone
- 521 Flumethasone pivalate
- 522 Flunisolide
- 523 Fluocinolone acetonide
- 524 Fluocinonide
- 525 Fluocortolone
- 526 Fluocortolone hexanoate
- 527 Fluocortolone pivalate
- 528 Fluopromazine hydrochloride
- 529 Fluorometholone
- 530 Fluorouracil
- 531 Fluorouracil trometamol
- 532 Fluoxetine
- 533 Fluoxymesterone
- 534 Flupenthixol decanoate
- 535 Flupenthixol dihydrochloride
- 536 Fluperolone acetate
- 537 Fluphenazine deconoate
- 538 Fluphenazine enanthate
- 539 Fluphenazine hydrochloride
- 540 Fluprednidene acetate
- 541 Fluprednisolone
- 542 Fluprostenol sodium salt
- 543 Flurandrenolone
- 544 Flurbiprofen
- 545 Fluspirilene
- 546 Flutamide
- 547 Fluticasone
- 548 Fluvastatin
- 549 Fluvoxamine
- 550 Follicle stimulating hormone
- 551 Formosulphathiazole
- 552 Formoterol
- 553 Fosfestrol tetrasodium
- 554 Framycetin sulphate (except topical & ophthalmic preparation Schedule 3)
- 555 Frusemide
- 556 Fumagillin
- 557 Fumagillin bicyclohexylamine
- 558 Furazolidone
- 559 Furosemide
- 560 Fusidic acid
- 561 Gabapentin
- 562 Gallamine triethiodide
- 563 Gelsemine
- 564 Gelsemium

- 565 Gemcitabine
- 566 Gemfibrozil
- 567 Gentamicin and its salts (except topical and ophthalmic use Schedule 3)
- 568 Gestodene
- 569 Gestronol
- 570 Gestronol hexanoate
- 571 Glibenclamide
- 572 Glibornuride
- 573 Gliclazide
- 574 Glimepiride
- 575 Glipizide
- 576 Glyceryl trinitrate
- 577 Glycopyrronium bromide
- 578 Glymide
- 579 Gonadorelin
- 580 Gramicidin
- 581 Granisetron
- 582 Growth hormone
- 583 Guanethidine monosulphate
- 584 Guanoclor sulphate
- 585 Guanoxan sulphate
- 586 Hachimycin
- 587 Halcinonide
- 588 Haloperidol
- 589 Heparin and its salts (except for topical use Schedule 3)
- 590 Heptaminol hydrochloride
- 591 Hexachlorophene
- 592 Hexamine phenylcinchoninate
- 593 Hexoestrol
- 594 Hexoestrol dipropionate
- 595 Homatropine
- 596 Homatropine hydrobromide
- 597 Homatropine methylbromide
- 598 Hydralazine hydrochloride
- 599 Hydrargaphen
- 600 Hydrobromic acid
- 601 Hydrochlorothiazide
- 602 Hydrocortamate hydrochloride
- 603 Hydrocortisone and its salts & derivatives (except in preparations for external use and ms 1% Schedule 3)
- 604 Hydroflumethiazide
- 605 Hydroquinone
- 606 Hydroxychloroquine sulphate
- 607 Hydroxymethylgramicidin
- 608 Hydroxyprogesterone
- 609 Hydroxyprogesterone enanthate
- 610 Hydroxyprogesterone hexanoate
- 611 Hydroxyurea
- 612 Hydroxyzine embonate
- 613 Hydroxyzine hydrochloride

- 614 Hyoscine
- 615 Hyoscine and its salts (except oral use Schedule 3)
- 616 Hyoscyamine and its salts (except oral use Schedule 3)
- 617 Ibuprofen (except in preparation for topical and oral use maximum 9600mg, 400mg per single dose Schedule 3)
- 618 Idoxuridine
- 619 Ignatius bean
- 620 Imipenem
- 621 Imipramine
- 622 Imipramine hydrochloride
- 623 Imipramine ion exchange resin bound salt or complex
- 624 Immunoglobulins
- 625 Indapamide hemihydrates
- 626 Indomethacin (except in preparation for topical, rectal and oral use maximum 750mg, 25mg per single dose Schedule 3)
- 627 Indoramin hydrochloride
- 628 Insulins
- 629 Iodamide
- 630 Iodamide meglumine
- 631 Iodamide sodium
- 632 Ipratropium
- 633 Iprindole hydrochloride
- 634 Iproniazid phosphate
- 635 Iprratropium bromide
- 636 Irbesartan
- 637 Irinotecan
- 638 Isoaminile
- 639 Isoaminile citrate
- 640 Isocarboxazid
- 641 Isoconazole nitrate (except topical & vaginal preparation Schedule 3)
- 642 Isoetharine
- 643 Isoetharine hydrochloride
- 644 Isoetharine mesylate
- 645 Isoniazid
- 646 Isoprenaline hydrochloride
- 647 Isoprenaline sulphate
- 648 Isopropamide iodide
- 649 Isosorbide dinitrate
- 650 Isosorbide mononitrate
- 651 Isotretinoin
- 652 Ispaghula
- 653 Itraconazole
- 654 Jaborondi
- 655 Kanamycin sulphate
- 656 Ketamine hydrochloride
- 657 Ketoconazole (except topical & vaginal preparation Schedule 3)
- 658 Ketoprofen
- 659 Ketotifen (except cough preparation Schedule 3)
- 660 Labetolol hydrochloride
- 661 Lactogernic hormone

- 662 Lamivudine
- 663 Lamotrigine
- 664 Lanatoside C
- 665 Lanatoside complex A, B and C
- 666 Lansoprazole (except for the 14-day treatment for frequent heartburn, at a daily dose of 30 mg and in package sizes of no more than 4200 mg of lansoprazole Schedule 3)
- 667 Latamoxef disodium
- 668 Latanoprost
- 669 Lead arsenate
- 670 Letrozole
- 671 Levallorphan tartrate
- 672 Levetiracetam
- 673 Levocetirizine
- 674 Levodopa
- 675 Levofloxacin
- 676 Levonorgestrel
- 677 Levothyroxine
- 678 L-Histidine hydrochloride
- 679 Lidoflazine
- 680 Lignocaine and its salts (except topical use 2% Schedule 3 and less than 2% Schedule 4)
- 681 Lincomycin
- 682 Lincomycin hydrochloride
- 683 Liothyronine sodium
- 684 Lisinopril
- 685 Lithium carbonate
- 686 Lithium sulphate
- 687 Lobeline; its salts
- 688 Lofepramine
- 689 Lofepramine hydrochloride
- 690 Lomustine
- 691 Lopinavir
- 692 Losartan
- 693 Loxapine succinate
- 694 L-Pyroglutamyl-L-histidyl-L-proline amide
- 695 L-Tryptophan
- 696 Luteinising hormone
- 697 Lyme cycline
- 698 Lynoestrenol
- 699 Mafenide acetate
- 700 Mafenide hydrochloride
- 701 Mafenite propionate
- 702 Magnesium bromide
- 703 Magnesium fluoride
- 704 Magnesium metrizoate
- 705 Mandragora autumnalis
- 706 Mannomustine hydrochloride
- 707 Maprotiline hydrochloride
- 708 Mebeverine hydrochloride (except in preparation for oral use Schedule 3)
- 709 Mebhydrolin napadisylate
- 710 Mecamylamine hydrochloride

- 711 Meclofenoxate hydrochloride
- 712 Medrogestrone
- 713 Medroxyprogesterone acetate
- 714 Mefenamic acid (except for oral use in dysmenorrhoea Schedule 3)
- 715 Mefruside
- 716 Megestrol
- 717 Megestrol acetate
- 718 Meglumine iodoxamate
- 719 Meglumine ioglycamate
- 720 Meglumine iotraxate
- 721 Meglumine ioxaglate
- 722 Melarsonyl potassium
- 723 Melengestrol
- 724 Melengestrol acetate
- 725 Meloxicam
- 726 Melphalan
- 727 Melphalan hydrochloride
- 728 Mepenzolate bromide
- 729 Mephenesin (except in preparation for oral use Schedule 3)
- 730 Mepivacaine hydrochloride
- 731 Meptazinol hydrochloride
- 732 Mequitazine
- 733 Mercaptopurine
- 734 Mercuderamide
- 735 Meropenem
- 736 Mersalyl
- 737 Mersalyl acid
- 738 Mesna
- 739 Mesterolone
- 740 Metabutethamine hydrochloride
- 741 Metaraminol tartrate
- 742 Metformin hydrochloride
- 743 Methacycline
- 744 Methacycline calcium
- 745 Methacycline hydrochloride
- 746 Methallenoestril
- 747 Methandienone
- 748 Methandriol
- 749 Methdilazine hydrochloride
- 750 Methenolone acetate
- 751 Methenolone enanthate
- 752 Methicillin sodium
- 753 Methimazole
- 754 Methindizate hydrochloride
- 755 Methixene
- 756 Methixene hydrochloride
- 757 Methohexitone sodium
- 758 Methoserpidine
- 759 Methotrexate
- 760 Methotrexate sodium

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- 761 Methotrimeprazine
- 762 Methotrimeprazine hydrochloride
- 763 Methoxamine hydrochloride
- 764 Methylclothiazide
- 765 Methyldopa
- 766 Methyldopate hydrochloride
- 767 Methylephedrine hydrochloride
- 768 Methylergotamine maleate
- 769 Methylpentynol
- 770 Methylpentynol carbamate
- 771 Methylprednisolone
- 772 Methylprednisolone acetate
- 773 Methylprednisolone sodium succinate
- 774 Methyltestosterone
- 775 Methyliouracil
- 776 Methysergide maleate
- 777 Metoclopramide hydrochloride
- 778 Metolazone
- 779 Metomidate hydrochloride
- 780 Metoprolol tartrate
- 781 Metronidazole
- 782 Metronidazole benzoate
- 783 Mexiletine hydrochloride
- 784 Mezlocillin sodium
- 785 Mianserin hydrochloride
- 786 Minocycline
- 787 Minocycline hydrochloride
- 788 Minoxidil (except in topical preparation Schedule 3)
- 789 Mirtazapine
- 790 Mithramycin
- 791 Mitomycin C
- 792 Mitopodozide
- 793 Mitozantrone hydrochloride
- 794 Molindone hydrochloride
- 795 Mometasone
- 796 Montelukast
- 797 Moxifloxacin
- 798 Moxonidine
- 799 Mustine hydrochloride
- 800 Mycophenolate
- 801 Nadolol
- 802 Naftidofuryl oxalate
- 803 Nalbuphine hydrochloride
- 804 Nalidixic acid
- 805 Nalorphine hydrobromide
- 806 Naloxone hydrochloride
- 807 Nandrolone decanoate
- 808 Nandrolone laurate
- 809 Nandrolone phenylpropionate
- 810 Naproxen

- 811 Naproxen sodium
- 812 Natamycin
- 813 N-Benzoyl sulphanilamide
- 814 Nebivolol
- 815 Nedocromil sodium
- 816 Nefopam hydrochloride
- 817 Neoarsephenamine
- 818 Neomycin and its salts (except topical preparation, ophthalmic preparation Schedule 3)
- 819 Neostigmine bromide
- 820 Neostigmine methylsulphate
- 821 Netilmicin sulphate
- 822 Nevirapine
- 823 Nialamide
- 824 Nicotinaldemyde thio-semicarbazone
- 825 Nicoumalone
- 826 Nifedipine
- 827 Nikethamide
- 828 Niridazole
- 829 Nitrofurantoin
- 830 Nitroxoline
- 831 Nizatidine (except for short term relief of heartburn, dyspepsia and hyperacidity 150mg -300mg per single dose maximum dose 4200mg Schedule 3)
- 832 N-Methyl acetanilide
- 833 Nomifensine hydrogen maleate
- 834 Noradrenaline
- 835 Noradrenaline acid tartrate
- 836 Norethandrolone
- 837 Norethisterone
- 838 Norethynodrel
- 839 Norfloxacin
- 840 Norgestrel
- 841 Northisterone acetate
- 842 Northisterone heptanoate
- 843 Nortriptyline hydrochloride
- 844 Novobiocin calcium
- 845 Novobiocin sodium
- 846 Oestradiol
- 847 Oestradiol benzanoate
- 848 Oestradiol cypionate
- 849 Oestradiol dipropionate
- 850 Oestradiol diundecanoate
- 851 Oestradiol enanthate
- 852 Oestradiol phenylpropionate
- 853 Oestradiol undecanoate
- 854 Oestradiol valerate
- 855 Oestriol
- 856 Oestriol di-hemisuccinate
- 857 Oestrogenic substances, conjugated
- 858 Oestrone
- 859 Ofloxacin

- 860 Olanzapine
- 861 Oleandomycin phosphate
- 862 Omeprazole (except for 14-day treatment for frequent heartburn at a daily dose of 20 mg in package sizes of no more than 280 mg of omeprazole Schedule 3)
- 863 Ondansetron
- 864 Opipramol hydrochloride
- 865 Orciprenaline sulphate and its salts (except for use in cough preparation Schedule 3)
- 866 Orthocaine
- 867 Ouabain
- 868 Ovarin gland, dried
- 869 Oxaliplatin
- 870 Oxamniquine
- 871 Oxandrolone
- 872 Oxantel pamoate
- 873 Oxatomide
- 874 Oxbuprocaine hydrochloride
- 875 Oxcarbazepine
- 876 Oxedrine tartrate
- 877 Oxolinic acid
- 878 Oxophernasine hydrochloride
- 879 Oxophernasine tartrate
- 880 Oxpentifyline
- 881 Oxprenolol hydrochloride
- 882 Oxybutynin
- 883 Oxymeterone
- 884 Oxymetholone
- 885 Oxypertine
- 886 Oxypertine hydrochloride
- 887 Oxyphenbutazone
- 888 Oxyphenyclamine hydrochloride
- 889 Oxyphenonium bromide
- 890 Oxytetracycline and its salts (except for topical and ophthalmic preparation Schedule 3)
- 891 Oxytocins, natural and synthetic
- 892 Paclitaxel
- 893 Pancuronium bromide
- 894 Pantoprazole (except for the 14-day treatment for frequent heartburn, at a daily dose of 20 mg and in package sizes of no more than 280 mg of pantoprazole Schedule 3)
- 895 Papaverine
- 896 Papaverine hydrochloride
- 897 Papaveroline
- 898 Papaveroline 2-sulphonic acid
- 899 Paraldehyde
- 900 Paramethadione
- 901 Paramethasone acetate
- 902 Parathyroid gland
- 903 Pargyline hydrochloride
- 904 Paromycin sulphate
- 905 Paroxetine
- 906 Pecilocin
- 907 Pempidine tartrate

- 908 Penbutolol sulphate
- 909 Penethamate
- 910 Penicillamine
- 911 Penicillamine hydrochloride
- 912 Penicillin V
- 913 Pentamidine
- 914 Pentolinium tartrate
- 915 Pentoxifylline
- 916 Perhexiline hydrogen maleate
- 917 Pericyazine
- 918 Perindopril
- 919 Perphenazine
- 920 Phebutrazate hydrochloride
- 921 Phenacaine
- 922 Phenacemide
- 923 Phenbenicillin potassium
- 924 Phenelzine sulphate
- 925 Phenethicillin potassium
- 926 Pheneturide
- 927 Phenformine hydrochloride
- 928 Phenglutarimide hydrochloride
- 929 Phenindone
- 930 Phenoxybenzamine hydrochloride
- 931 Phenoxymethylpenicillin
- 932 Phenoxymethylpenicillin calcium
- 933 Phenoxymethylpenicillin potassium
- 934 Phensuximide
- 935 Phentolamine hydrochloride
- 936 Phentolamine mesylate
- 937 Phenyl aminosalicylate
- 938 Phenylbutazone
- 939 Phenylbutazone sodium
- 940 Phenylephrine hydrochloride (except for nasal, flu & ophthalmic preparation Schedule 3)
- 941 Phenytoin
- 942 Phenytoin sodium
- 943 Pheprocoumon
- 944 Phernasone sulfoxylate
- 945 Phthalylsulphacetamide
- 946 Phthalylsulphathiazole
- 947 Physostigmine
- 948 Physostigmine aminoxide salicylate
- 949 Physostigmine salicylate
- 950 Physostigmine sulphate
- 951 Pilocarpine
- 952 Pilocarpine hydrochloride
- 953 Pilocarpine nitrate
- 954 Pimozide
- 955 Pindolol
- 956 Pioglitazone
- 957 Pipenzolate bromide

- 958 Piperacillin sodium
- 959 Piperidolate hydrochloride
- 960 Pipothiazine palmitate
- 961 Piracetam
- 962 Pirbuterol acetate
- 963 Pirbuterol hydrochloride
- 964 Pirentanide
- 965 Pirenzepine hydrochloride
- 966 Piroxicam (except topical preparation and oral for use in acute gout attack maximum 100mg, per single dose 20mg Schedule 3)
- 967 Pituitary powdered (posterior globe)
- 968 Pituitary gland (whole dried)
- 969 Pivampicillin hydrochloride
- 970 Pivmecillinam
- 971 Pivmecillinam hydrochloride
- 972 Pizotifen and its salts (except cough preparation Schedule 3)
- 973 Plicamycin
- 974 Poldine methylsulphate
- 975 Polidexide
- 976 Polidexide hydrochloride
- 977 Polidexide sulphate
- 978 Polymyxin B sulphate (except topical & ophthalmic preparation Schedule 3)
- 979 Polyoestradiol phosphate
- 980 Polythiazide
- 981 Potassium aminosalicylate
- 982 Potassium arsenite
- 983 Potassium bromide
- 984 Potassium canrenoate
- 985 Potassium clavulanate
- 986 Potassium perchlorate
- 987 Pralidoxime chloride
- 988 Pralidoxime iodide
- 989 Pralidoxime mesylate
- 990 Pramipexole
- 991 Pravastatin
- 992 Prazosin hydrochloride
- 993 Prednisolone
- 994 Prednisolone 21-steaglate
- 995 Prednisolone acetate
- 996 Prednisolone butylacetate
- 997 Prednisolone hexanoate
- 998 Prednisolone m-sulphobenzoate
- 999 Prednisolone pivalate
- 1000 Prednisolone sodium m-sulphobenzoate
- 1001 Prednisolone sodium phosphate
- 1002 Prednisone
- 1003 Prednisone acetate
- 1004 Prenalterol hydrochloride
- 1005 Prenylamine lactate
- 1006 Prilocaine hydrochloride

- 1007 Primaquine phosphate
- 1008 Primodine
- 1009 Probenecid
- 1010 Probucol
- 1011 Procainamide hydrochloride
- 1012 Procaine hydrochloride
- 1013 Procaine penicillin
- 1014 Procarbazine hydrochloride
- 1015 Prochlorperazine edisylate
- 1016 Prochlorperazine maleate
- 1017 Prochlorperazine mesylate
- 1018 Procyclidine hydrochloride
- 1019 Progesterone
- 1020 Proguanil hydrochloride
- 1021 Prolintane hydrochloride
- 1022 Promazine embonate
- 1023 Promazine hydrochloride
- 1024 Promethazine and its salts (except topical and oral use Schedule 3)
- 1025 Propanidid
- 1026 Propantheline bromide
- 1027 Propicillin potassium
- 1028 Propiomazine hydrogen maleate
- 1029 Propofol
- 1030 Propranolol hydrochloride
- 1031 Propylphenazone
- 1032 Propylthiouracil
- 1033 Proquamezine fumarate
- 1034 Proquazone
- 1035 Prostaglandin F2 alpha tromethamine
- 1036 Protamine sulphate
- 1037 Prothionamide
- 1038 Prothipendyl hydrochloride
- 1039 Protriptyline hydrochloride
- 1040 Proxymetacaine hydrochloride
- 1041 Pseudoephedrine hydrochloride
- 1042 Pseudoephedrine sulphate
- 1043 Pyrazinamide
- 1044 Pyridostigmine bromide
- 1045 Pyrimethamine
- 1046 Quetiapine
- 1047 Quinapril
- 1048 Quinestradiol
- 1049 Quinestrol
- 1050 Quinethazone
- 1051 Quingestanol
- 1052 Quinidine
- 1053 Quinidine bisulphate
- 1054 Quinidine phenylethylbarbiturate
- 1055 Quinidine polygalacturonate
- 1056 Quinuronium sulphate

- 1057 Rabeprazole
- 1058 Racephedrine hydrochloride
- 1059 Raltegravir
- 1060 Ramipril
- 1061 Ranitidine and its salts (except in concentrations of 150 mg or less per oral dosage unit and indicated for the treatment of heartburn, in package sizes containing more than 4500 mg of ranitidine Schedule 3)
- 1062 Rauwolfia (serpetina and vomitoria)
- 1063 Reproterol hydrochloride
- 1064 Rescinnamide
- 1065 Reserpine
- 1066 Rfamide
- 1067 Rifampicin
- 1068 Rifamycin
- 1069 Rimiterol hydrobromide
- 1070 Risedronic acid
- 1071 Risperidone
- 1072 Ritodrine hydrochloride
- 1073 Ritonavir
- 1074 Rolitetracycline nitrate
- 1075 Ropinirole
- 1076 Rosuvastatin
- 1077 Rosuvastatin
- 1078 Roxithromycin
- 1079 Salazosulphadimidine
- 1080 Salbutamol
- 1081 Salbutamol and its salts (except inhaler, autohaler and oral use Schedule 3)
- 1082 Salbutamol sulphate
- 1083 Salmeterol
- 1084 Saquinavir
- 1085 Saxagliptin
- 1086 Selegiline hydrochloride
- 1087 Sera and antisera
- 1088 Sertraline
- 1089 Serum gonadotrophin
- 1090 Sibutramine
- 1091 Simvastatin
- 1092 Sissomycin sulphate
- 1093 Sodium aminosalicylate
- 1094 Sodium antimonylgluconate
- 1095 Sodium apolate
- 1096 Sodium arsanilate
- 1097 Sodium arsenite
- 1098 Sodium bromated
- 1099 Sodium bromide
- 1100 Sodium cacodylate
- 1101 Sodium cromoglycate (except for use in ophthalmic & inhalation preparation Schedule 3)
- 1102 Sodium ethacrylate
- 1103 Sodium fluoride
- 1104 Sodium fucidate (except topical preparation Schedule 3)

- 1105 Sodium methylarsinate
- 1106 Sodium metrizoate
- 1107 Sodium monofluorophosphate
- 1108 Sodium stibogluconate
- 1109 Sodium valproate
- 1110 Sotalol hydrochloride
- 1111 Spectinomycin
- 1112 Spiramycin
- 1113 Spiramycin adipate
- 1114 Spirinolactone
- 1115 Stannous fluoride
- 1116 Stanolone
- 1117 Stanazolol
- 1118 Stilboestrol
- 1119 Stilboestrol dipropionate
- 1120 Streptodornase
- 1121 Streptokinase
- 1122 Streptomycin
- 1123 Streptomycin sulphate
- 1124 Strychnine
- 1125 Strychnine arsenate
- 1126 Strychnine hydrochloride
- 1127 Succinylsulphathiozole
- 1128 Sucralfate
- 1129 Sulbactam sodium
- 1130 Sulconazole nitrate
- 1131 Sulfabromethazine
- 1132 Sulfacytine
- 1133 Sulfadiazine
- 1134 Sulfadoxine
- 1135 Sulfametopyrazine
- 1136 Sulfamonomethoxine
- 1137 Sulfapyrazole
- 1138 Sulphacetamide
- 1139 Sulphacetamide and its salts (except topical and ophthalmic use Schedule 3)
- 1140 Sulphacetamide sodium
- 1141 Sulphachlorpyridazine
- 1142 Sulphadiazine
- 1143 Sulphadiazine sodium
- 1144 Sulphadimethoxine
- 1145 Sulphadimidine
- 1146 Sulphadimidine sodium
- 1147 Sulphafurazole
- 1148 Sulphafurazole diethanolamine
- 1149 Sulphaguanidine
- 1150 Sulphaloxic acid
- 1151 Sulphamerazine
- 1152 Sulphamerazine sodium
- 1153 Sulphamethizole
- 1154 Sulphamethoxazole

- 1155 Sulphamethoxydiazine
- 1156 Sulphamethoxypyridazine
- 1157 Sulphamethoxypyridazine sodium
- 1158 Sulphamethylphenazole
- 1159 Sulphamoxole
- 1160 Sulphanilamide
- 1161 Sulphaphenazole
- 1162 Sulphapyridine
- 1163 Sulphapyridine sodium
- 1164 Sulphaquinoxaline
- 1165 Sulphaquinoxaline sodium
- 1166 Sulpharsphenamine
- 1167 Sulphasalazine
- 1168 Sulphasomidine
- 1169 Sulphasomidine sodium
- 1170 Sulphathiourea
- 1171 Sulphathiozole
- 1172 Sulphathiozole sodium
- 1173 Sulphatolamide
- 1174 Sulphaurea
- 1175 Sulphinpyrazone
- 1176 Sulphomycin
- 1177 Sulpiride
- 1178 Sulthiame
- 1179 Sumatriptan
- 1180 Suxamethonium bromide
- 1181 Suxamethonium chloride
- 1182 Suxethonium bromide
- 1183 Tacrine hydrochloride
- 1184 Talampicillin
- 1185 Talampicillin hydrochloride
- 1186 Talampicillin napsylate
- 1187 Tamoxifen
- 1188 Tamoxifen citrate
- 1189 Tamsulosin
- 1190 Teclothiazide potassium
- 1191 Teicoplanin
- 1192 Telmisartan
- 1193 Temozolomide
- 1194 Tenofovir
- 1195 Terbutaline
- 1196 Terbutaline sulphate
- 1197 Testosterone
- 1198 Testosterone 17B chloral hemiacetal
- 1199 Testosterone acetate
- 1200 Testosterone cyclohexylpropionate
- 1201 Testosterone cypionate
- 1202 Testosterone decanoate
- 1203 Testosterone enanthate
- 1204 Testosterone isocaproate

- 1205 Testosterone phenylpropionate
- 1206 Testosterone propionate
- 1207 Testosterone undecanoate
- 1208 Tetrabenazine
- 1209 Tetracaine
- 1210 Tetracosatrin
- 1211 Tetracosatrin acetate
- 1212 Tetracycline and its salts (except for topical and ophthalmic use Schedule 3)
- 1213 Thallium acetate
- 1214 Theophylline
- 1215 Thiethylperazine
- 1216 Thiethylperazine di-(hydrogen malate)
- 1217 Thiocarlide
- 1218 Thioguinine
- 1219 Thiopentone sodium
- 1220 Thiopropazate hydrochloride
- 1221 Thioproperazine mesylate
- 1222 Thioridazine
- 1223 Thioridazine hydrochloride
- 1224 Thiotepa
- 1225 Thiothexene
- 1226 Thiouracil
- 1227 Thymoxamine hydrochloride
- 1228 Thyroid
- 1229 Thyrotrophin
- 1230 Thyrotrophin releasing hormone
- 1231 Thyroxine sodium
- 1232 Tianulin hydrogen fumarate
- 1233 Tiaprofenic acid
- 1234 Ticarcillin sodium
- 1235 Tigloidine hydrobromide
- 1236 Timolol maleate
- 1237 Tioconazole (except topical & vaginal use Schedule 3)
- 1238 Tiotropium bromide
- 1239 Tobramycin
- 1240 Tobramycin sulphate
- 1241 Tocainide hydrochloride
- 1242 Tofenacin hydrochloride
- 1243 Tolazamide
- 1244 Tolazoline hydrochloride
- 1245 Tolbutamide
- 1246 Tolbutamide sodium
- 1247 Tolmetin sodium dehydrate
- 1248 Tolperisone
- 1249 Topiramate
- 1250 Torasemide
- 1251 Totaquine
- 1252 Tranexamic acid
- 1253 Tranylcypromine sulphate
- 1254 Trazadone

- 1255 Treosulfan
- 1256 Tretinon
- 1257 Tretamine
- 1258 Tretinoin
- 1259 Triacetyloleandomycin
- 1260 Triamcinolone
- 1261 Triamcinolone acetoneide
- 1262 Triamcinolone diacetate
- 1263 Triamcinolone hexacetoneide
- 1264 Triamterene
- 1265 Tribromoethyl alcohol
- 1266 Triclofos sodium
- 1267 Tricyclamol chloride
- 1268 Trienbolone acetate
- 1269 Trientine dihydrochloride
- 1270 Trifluoperazine
- 1271 Trifluoperazine hydrochloride
- 1272 Trifluoperidol
- 1273 Trifluoperidol hydrochloride
- 1274 Trilostane
- 1275 Trimepramine mesylate
- 1276 Trimeprazine
- 1277 Trimeprazine tartrate
- 1278 Trimetaphan camsylate
- 1279 Trimetazidine
- 1280 Trimetazidine hydrochloride
- 1281 Trimethoprim
- 1282 Trimipramine maleate
- 1283 Trimustine hydrochloride
- 1284 Tripolidine
- 1285 Tropicamide
- 1286 Tubocurarine chloride
- 1287 Tybamate
- 1288 Tylosin
- 1289 Tylosin phosphate
- 1290 Tylosin tartrate
- 1291 Tyrothricin
- 1292 Uramustine
- 1293 Urea stibamine
- 1294 Uridine-5-triphosphoric acid
- 1295 Urifollitrophin
- 1296 Urokinase
- 1297 Ursodeoxycholic acid
- 1298 Vaccines
- 1299 Valaciclovir
- 1300 Valproic acid
- 1301 Valsartan
- 1302 Vancomycin hydrochloride
- 1303 Vasopressin tannate
- 1304 Vecuronium bromide

- 1305 Venlafaxine
- 1306 Verapamil hydrochloride
- 1307 Vidagliptin
- 1308 Viloxazine hydrochloride
- 1309 Vinblastine sulphate
- 1310 Vincristine sulphate
- 1311 Vindesin sulphate
- 1312 Vinorelbine
- 1313 Viomycin pantothenate
- 1314 Viomycin sulphate
- 1315 Vitamin A
- 1316 Vitamin A acetate
- 1317 Vitamin A palmitate
- 1318 Vitamin D
- 1319 Vitamins
- 1320 Warfarin
- 1321 Warfarin sodium
- 1322 Xylazine hydrochloride
- 1323 Yohimbine hydrochloride
- 1324 Zidovudine
- 1325 Zimeldine hydrochloride
- 1326 Zoledronic acid
- 1327 Zomepiroc sodium
- 1328 Zopiclone
- 1329 Zuclopenthixol hydrochloride

(3) SCHEDULE 3 MEDICINES

NO. NAME OF THE MEDICINE

- 1 Acetylsalicylic acid label (1)
- 2 Acetylsalicylic acid label (1)
- 3 Aconite in preparations and mixtures of ms 0.02%
- 4 Acyclovir
- 5 Adrenaline, if —
- 6 Adrenaline, if — (a) in inhalers
- 7 Adrenaline, if — (b) in preparations for external use
- 8 Aescin and its salts
- 9 Aesculin
- 10 Albendazole
- 11 Allopurinol
- 12 Amethocaine
- 13 Amethocaine and its salts in preparations for non-parenteral use (except those intended for local ophthalmic use: Schedule 2).
- 14 Amethocaine gentisate
- 15 Amethocaine hydrochloride
- 16 Astemizole
- 17 Atropine & its salts in preparations for external use and antidiarrhoeal preparations, (except those intended for local ophthalmic & parenteral use: Schedule 2)
- 18 Atropine sulphate
- 19 Azatadine maleate label (5)

- 20 Belladonna alkaloid
- 21 Benzocaine
- 22 Benzocaine in preparations for external use and ms 4% (except preparations for local ophthalmic use: Schedule 2)
- 23 Benzoyl peroxide
- 24 Benzoyl peroxide in preparations for external use with ms 10%
- 25 Bromhexine hydrochloride
- 26 Brompheniramine maleate
- 27 Bupivacaine hydrochloride in preparations for non-parenteral use, (except those intended for local ophthalmic use: Schedule 2)
- 28 Bupivacaine in preparations for non-parenteral use, (except those intended for local ophthalmic use: Schedule 2)
- 29 Butacaine sulphate in preparations for non-parenteral use, (except those intended for local ophthalmic use: Schedule 2)
- 30 Butalbital
- 31 Butanilcaine phosphate in preparations for non-parenteral use, (except preparations intended for local ophthalmic use: Schedule 2)
- 32 Butylscopolamine
- 33 Cantharidin in preparations for external use and ms 0.01 %
- 34 Caramiphen edisylate in:
- 35 Caramiphen edisylate in:(a) tablet preparations and ms 7.5mg (calculated as base)
- 36 Caramiphen edisylate in:(b) liquid preparations and ms 0.1% (calculated as base)
- 37 Carbenoxolone sodium in preparations for external use ms 2%
- 38 Carbocisteine
- 39 Cetirizine
- 40 Cetirizine and its salts
- 41 Chloramphenicol
- 42 Chloramphenicol cinnamate
- 43 Chloramphenicol palmitate
- 44 Chloramphenicol sodium succinate
- 45 Chlorhexidine
- 46 Chloroquine phosphate
- 47 Chloroquine sulphate
- 48 Chlorpherinamine maleate, label (5) (But in preparations for parenteral use: Schedule 2)
- 49 Cimetidine
- 50 Cimetidine hydrochloride
- 51 Cinchocaine hydrochloride in preparations for non-parenteral use ms 3%, (except preparations for local ophthalmic use: Schedule 2)
- 52 Cinchocaine in preparations for non-parenteral use and ms 3%, (except preparations for local ophthalmic use: Schedule 2)
- 53 Cinnarizine
- 54 Clemastine, label (5)
- 55 Clioquinol
- 56 Clioquinol in preparations for external use
- 57 Clotrimazole
- 58 Colchicine
- 59 Cromoglycate Sodium
- 60 Cromolyn Sodium
- 61 Cyanocobalamin (except parenteral use Schedule 2)
- 62 Cyclizine hydrochloride in preparations for non-parenteral use

- 63 Cyproheptadine
- 64 Dequalinium chloride in:
- 65 Dequalinium chloride in:(a) throat lozenges or throat pastilles and ms 0.25mg
- 66 Dequalinium chloride in:(b) external paint preparations and ms 1%
- 67 Desloratadine
- 68 Dextromethorphan hydrobromide
- 69 Dextromethorphan hydrobromide in preparations for internal use with md 15mg
(calculated as base)
- 70 Diclofenac and its salts
- 71 Dicyclomine hydrochloride
- 72 Diethylamine Salicylate
- 73 Di-Iodoxyhydroxyquinoline
- 74 Dimenhydrinate in preparations for non-parenteral use label (5)
- 75 Dimethindine maleate, label (5)
- 76 Dimethisoquin hydrochloride in preparations for non-parenteral use, (except preparations
for local ophthalmic use: Schedule 2)
- 77 Diphenhydramine hydrochloride in preparations for non-parenteral use, label (5)
- 78 Diphenylpyraline hydrochloride, label (5)
- 79 Econazole
- 80 Econazole and its salts
- 81 Econazole nitrate
- 82 Emetine hydrochloride in preparations for internal or external use and ms 1% (calculated
as base)
- 83 Emetine in preparations for internal or external use and ms 1%
- 84 Ephedrine & its salts 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)
- 85 Ephedrine & its salts: (b) nasal sprays or nasal drops and ms 2% (calculated as base),
label (4)
- 86 Ergotamine tartrate
- 87 Etofylline
- 88 Ferrous & its salts (except Iron in preparations for internal use and mdd 100mg
(calculated as iron) Schedule 4 and Iron preparation for parenteral use Schedule 2)
- 89 Ferrous arsenate
- 90 Fexofenadine Hydrochloride
- 91 Folic acid
- 92 Folic acid (Schedule 2) in preparations for internal use and mdd 500 micrograms,
- 93 Glucagon
- 94 Gramicidin in preparations for external use and ms 0.02%
- 95 Griseofulvin
- 96 Heparin
- 97 Heparin calcium
- 98 Hexachlorophene in preparations for external use and:
- 99 Hexachlorophene in preparations for external use and:(a) in soaps with ms more than
0.1 % but not more than 2% label (6)
- 100 Hexachlorophene in preparations for external use and:(b) in medicines other than soaps
or aerosols with ms more than 0.1% but not more than 0.75% label (6)
- 101 Homatropine in preparations for external use (except preparations for local ophthalmic
use: Schedule 2))
- 102 Hydrocortisone
- 103 Hydrocortisone 17-butyrate

- 104 Hydrocortisone acetate
- 105 Hydrocortisone caprylate
- 106 Hydrocortisone hydrogen succinate
- 107 Hydrocortisone sodium phosphate
- 108 Hydrocortisone sodium succinate
- 109 Hydroxychloroquine sulphate for the prophylaxis of malaria Labelling for malaria prophylaxis
- 110 Hydroxymethylgramicidin in throat lozenges or throat pastilles
- 111 Hyoscine
- 112 Hyoscine butylbromide
- 113 Hyoscine hydrobromide
- 114 Hyoscine methobromide
- 115 Hyoscine methonitrate
- 116 Ibuprofen
- 117 Idoxuridine in preparations for external use (except preparations for local ophthalmic use: Schedule 2)
- 118 Indomethacin
- 119 Ipecacuanha see emetine
- 120 Iron; its salts
- 121 Isoconazole nitrate
- 122 Ketoconazole
- 123 Ketotifen
- 124 L-Histidine hydrochloride used as an ingredient in dietary or nutritional medicines as an amino acid
- 125 Lignocaine
- 126 Lignocaine hydrochloride
- 127 Loperamide hydrochloride
- 128 Loratadine
- 129 Mebendazole
- 130 Mebeverine hydrochloride
- 131 Mefenamic acid
- 132 Mefloquine Hydrochloride
- 133 Mephesisin
- 134 Mepivacaine hydrochloride in preparations for non-parenteral use, (except those intended for local ophthalmic use: Schedule 2)
- 135 Mepyramine Maleate
- 136 Metabutethamine hydrochloride in preparations for non-parenteral use, (except preparations for local ophthalmic use)
- 137 Methylephedrine hydrochloride in preparations for internal use with md 30mg and mdd 60mg
- 138 Miconazole
- 139 Miconazole and its salts
- 140 Miconazole nitrate
- 141 Mupirocin
- 142 N-acetylcysteine
- 143 Naphazoline and its salts in nasal sprays or nasal drops not containing liquid paraffin as vehicle and ms 0.05%
- 144 Naphazoline and its salts: (a) in nasal sprays or nasal drops not containing liquid paraffin as vehicle and ms 0.05%
- 145 Naphazoline and its salts: (b) in eye drops and ms 0.015%

- 146 Naphazoline hydrochloride
- 147 Naphazoline nitrate
- 148 Neomycin
- 149 Neomycin palmitate
- 150 Neomycin sulphate
- 151 Neomycin undecanoate
- 152 Niclosamide
- 153 Nitrofurazone
- 154 Nitrofurazone in preparations for external use
- 155 Nystatin
- 156 Orphenadrine and its salts
- 157 Orphenadrine citrate
- 158 Orphenadrine hydrochloride
- 159 Orthocaine in preparations for non-parenteral use, (except those intended for local ophthalmic use: Schedule 2)
- 160 Oxybuprocaine hydrochloride in preparations for non-parenteral use, (except those intended for local ophthalmic use: Schedule 2)
- 161 Oxymetazoline
- 162 Oxytetracycline
- 163 Oxytetracycline calcium
- 164 Oxytetracycline dihydrate
- 165 Oxytetracycline hydrochloride
- 166 Paracetamol label (3)
- 167 Phenacaine in preparations for non-parenteral use, (except those intended for local ophthalmic use)
- 168 Phenazone
- 169 Phenazone and derivatives
- 170 Phenazone salicylate
- 171 Phenindamine tartrate
- 172 Pheniramine maleate
- 173 Phenylephrine hydrochloride
- 174 Piperazine & its salts
- 175 Piroxicam
- 176 Pizotifen
- 177 Pizotifen hydrogen maleate
- 178 Podophyllum resin in ointments or impregnated plasters for external use with ms 20%
- 179 Polymyxin B sulphate
- 180 Polyvinyl Alcohol
- 181 Potassium chloride
- 182 Potassium chloride (except injectable Schedule 2)
- 183 Potassium citrate
- 184 Prilocaine hydrochloride in preparations for non-parenteral use, (except those intended for local ophthalmic use: Schedule 2)
- 185 Proguanil hydrochloride for prophylaxis of malaria Labelling for malaria prophylaxis
- 186 Proxymetacaine hydrochloride in preparations for non-parenteral use (except those intended for local ophthalmic use: Schedule 2)
- 187 Pseudoephedrine sulphate in preparations for internal use with md 60mg and mdd 180mg
- 188 Pseudoephedrine and its salts (except in preparations for internal use with md 60mg and mdd 180mg Schedule 3)
- 189 Pseudoephedrine hydrochloride

- 190 Pseudoephedrine sulphate
- 191 Pyrantel and its salts
- 192 Pyrantel embonate
- 193 Pyrantel tartrate
- 194 Quinine and its salts (except in preparations for internal use md 100mg (calculated as base) and mdd 300mg (calculated as base) Schedule 3)
- 195 Ranitidine hydrochloride
- 196 Salbutamol
- 197 Salbutamol sulphate
- 198 Sildenafil
- 199 Silver sulphadiazine
- 200 Sodium apolate in preparations for external use
- 201 Sodium arsenite in preparations for internal and external use and ms 0.013%
- 202 Sodium cromoglycate
- 203 Sodium fluoride:
- 204 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
- 205 Sodium fluoride:(ii) mouth rinses other than those for daily use and ms 0.2%
- 206 Sodium fluoride:(iii) mouth rinses for daily use and ms 0.05%
- 207 Streptodornase in preparations for external use
- 208 Streptokinase in preparations for external use
- 209 Sulconazole in preparations for external use, (except vaginal use Schedule 2)
- 210 Sulphacetamide
- 211 Sulphacetamide sodium
- 212 Terbinafine
- 213 Terfenadine
- 214 Tetracycline
- 215 Tetracycline hydrochloride
- 216 Tetracycline phosphate complex
- 217 Tetrahydrozoline
- 218 Tetryzoline Hydrochloride
- 219 Theophylline
- 220 Thiabendazole
- 221 Tildenafil
- 222 Tinidazole
- 223 Tioconazole
- 224 Tyrothricin in throat lozenges or throat pastilles
- 225 Vardenafil
- 226 Zinc Bacitracin

(4) SCHEDULE 4 MEDICINES

NO. NAME OF THE MEDICINE

- 1 8-Hydroxyquinoline
- 2 Aluminium and its salts
- 3 Alverine Citrate
- 4 Amino Acids
- 5 Ammonium Chloride

- 6 Amyl-M-Cresol
- 7 Aniseed Oil
- 8 Arachis Oil
- 9 Ascorbic acid in preparations for non-parenteral use
- 10 Benzoic Acid
- 11 Benzydamine Hydrochloride
- 12 Benzyl Benzoate
- 13 Bisacodyl
- 14 Boric acid
- 15 Caffeine
- 16 Calcium and its salts
- 17 Camphor
- 18 Carbon tetrachloride N.B. if the unlicensed product is sold for non-medical purposes
e.g. cleaning, there are no restrictions on its sale
- 19 Carboxymethylcellulose Sodium
- 20 Castor Oil
- 21 Cetalkonium Chloride
- 22 Cetrimide
- 23 Cetylpyridinium Chloride
- 24 Chlorbutol
- 25 Chlorhexidine:
- 26 Chlorhexidine:(a) for external use (except vaginal use: Schedule 3)
- 27 Chlorhexidine:(b) in preparations for mouth wash and for use in the prevention of dental
caries
- 28 Cinnamon Oil
- 29 Coal Tar
- 30 Crotamiton
- 31 Dimethicone
- 32 Docusate Sodium
- 33 Eucalyptus Oil
- 34 Folic acid in preparations for internal use and mdd 200 micrograms
- 35 Gentian Violet
- 36 Glycerol
- 37 Guaifenesin
- 38 Hexachlorophene: in preparations for external use and:
- 39 Hexachlorophene: in preparations for external use and:(a) in soaps with ms 0.1% label (6)
- 40 Hexachlorophene: in preparations for external use and:(b) in aerosols with ms 0.1%
label (6)
- 41 Hexachlorophene: in preparations for external use and:(c- in medicines other than soaps
or aerosols with ms 0.1% label (6)
- 42 Hydroxyquinoline sulfate
- 43 Ichthammol
- 44 Kaolin
- 45 Lactulose
- 46 Liquid Paraffin
- 47 Magaldrate
- 48 Magnesium and its salts
- 49 Magnesium trisilicate
- 50 Menthol
- 51 Methyl Salicylate

- 52 Monosulfiram
- 53 Oral Rehydration Salts
- 54 Paracetamol in tablet preparations with ms 500mg and not more than 30 tablets label (3)
- 55 Pectin
- 56 Phenol
- 57 Phenolphthalein
- 58 Podophyllum Indian
- 59 Podophyllum resin
- 60 Potassium hydroxy quinoline sulfate
- 61 Povidone-Iodine
- 62 Pyridoxine
- 63 Salicylic Acid
- 64 Selenium Sulphide
- 65 Sennosides A - B
- 66 Simethicone
- 67 Sodium Bicarbonate
- 68 Sodium Chloride
- 69 Sodium fluoride in dentifrices and ms 0.33%
- 70 Sodium monofluorophosphate in dentifrices and ms 1.14%
- 71 Stannous fluoride in dentifrices and ms 0.62%
- 72 Tartaric Acid
- 73 Trace Elements (except for parenteral use Schedule 2)
- 74 Turpentine Oil
- 75 Undecenoic Acid
- 76 Urea
- 77 Vitamin A in: (a) preparations for internal use with mdd 7500 iu Vitamin A (2250 mcg Retinol equivalent)
- 78 Vitamin A in: (b) preparations for external use
- 79 Vitamin A acetate in: (a) preparations for internal use with mdd equivalent to 7500 iu Vitamin A (2250 mcg Retinol equivalent)
- 80 Vitamin A acetate in: (b) preparations for external use
- 81 Vitamin A palmitate in: (a) preparations for internal use with mdd equivalent to 7500 iu Vitamin A (2250 mcg Retinol equivalent)
- 82 Vitamin A palmitate in: (b) preparations for external use
- 83 Vitamin D in: (a) preparations for internal use with mdd 10 mcg
- 84 Vitamin D in: (b) preparations for external use
- 85 Vitamins, mixed in non-parenteral preparations
- 86 Zinc Chloride
- 87 Zinc Oxide
- 88 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 medicines

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.

SCHEDULE 2

(reg. 47)

PRECURSOR CHEMICALS

Precursor chemicals in Tables I and II of the 1988 Convention

Table I

Acetic anhydride
 N-Acetylanthranilic acid
 Ephedrine
 Ergometrine
 Ergotamine
 Isosafrole
 Lysergic acid
 3,4-Methylenedioxyphenyl-2-propanone
 Norephedrine
 Phenylacetic acid
 alpha-Phenylacetoacetonitrile
 1-Phenyl-2-propanone
 Piperonal
 Potassium permanganate
 Pseudoephedrine
 Safrole

Note: The salts of the substances are listed in the table whenever the existence of such salts is possible.

Table II

Acetone
 Anthranilic acid
 Ethyl ether
 Hydrochloric acid
 Methyl ethyl ketone
 Piperidine
 Sulphuric acid
 Toluene

Note: The salts of the substances listed in the table whenever the existence of such salts is possible.

SCHEDULE 3

(reg. 69)

BANNED MEDICINES

Amphetamine
 Brolamphetamine (DOB, Bromo-STP)
 Bufotenine (N,N-Dimethylserotonin)
 Cannabis
 Cocaine
 Coca Leaf
 Cathinone
 DET or 3-[2-(diethylamino) ethyl] indole
 Dexamphetamine
 DMA or (+ or -)-2,5-dimethoxy-alpha-methylphenethylamine
 DMT or 3-[2-(dimethylamino) ethyl] indole
 DOET or (+ or -)-4-ethyl-2,5-dimethoxy-alpha-phenethylamine
 Ecgonine
 Eticyclidine (PCE)
 Fentanyl analogues (unless listed in another Schedule): acetyl-alpha-methyl-fentanyl alpha-methyl-fentanyl alpha-methyl-fentanyl-acetanilide alpha-methyl-thiofentanyl beta-hydroxy-fentanyl
 3-methyl-thiofentanyl
 3-methyl-fentanyl and its cis- and trans- isomeric forms thiofentanyl para-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- α -methyl-4,5(methylenedioxy) phenethylamine

N-ethyl MDA or (+ or -)-N-ethyl- α -methyl-3,4-(methylenedioxy) phenethylamine

N-hydroxy MDA or (+ or -)-N-[α -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- α ,4-dimethylphenethylamine

Tenamfetamine (MDA)

Tenocyclidine (TCP)

Tetrahydrocannabinol

TMA or (+ or -)-3,4,5-trimethoxy- α -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.

SCHEDULE 4

(reg. 3, 5, 9, 11, 16, 17, 18, 19, 20, 21, 22, 24, 26, 27, 28, 32, 50, 54, 55, 60, 61, 64 and 66)

FORMS

FORM 1

APPLICATION FOR REGISTRATION OF MEDICINE

Module 1: Administrative Information

Application Form

This application form shall be included in the Botswana Common Technical Document – Module 1 Administrative Information.

The application form is to be used for an application for registration of a medicinal product, B-listed medicines and renewal of registration submitted to the Authority.

A separate application form for each strength and pharmaceutical dosage form is required. However, different strengths may be submitted in one dossier.

New application: (Tick whichever applicable)		Renewal application:	
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(a) Particulars of the Applicant/Prospective holder of the certificate of registration (PHCR)

Name:	
Business address:	
Postal address:	
Telephone No:	
Fax No:	
E-mail address:	
Site/Applicant Master File Number:	
<i>Pharmacist responsible/authorised to communicate with the Authority</i>	
Name:	
Business address:	
Telephone No:	

<i>Fax No:</i>	
<i>E-mail address:</i>	
(Attach a letter of authorisation signed by the person responsible for the overall management and control of the business– Annex 1.2.2.2)	

(b) Particulars of the medicine

<i>Product</i>	
<i>Category#:</i>	
<i>Proprietary name:</i>	
<i>Pharmacological classification:</i>	
<i>Dosage form:</i>	
<i>Approved name(s):</i>	
<i>Strength(s) per dosage unit:</i>	
<i>Descriptive name of Biological medicine:</i>	
<i>Route of administration:</i>	
<i>Country of origin (country in which the original development was carried out):</i>	
<i>Manufacturing, packaging, testing sites</i>	
<i>Manufacturer(s):</i>	
<i>Physical address of site(s):</i>	
<i>Site master file reference number(s):</i>	
<i>Date of submission</i>	
<i>Licence number:</i>	
<i>Date of issue:</i>	

<i>Primary Packer(s):</i>	
<i>Physical address of site(s):</i>	
<i>Site Master File reference number(s):</i>	
<i>Date of submission</i>	
<i>Licence number:</i>	
<i>Date of issue:</i>	
<i>Secondary Packer(s):</i>	

Physical address of site(s):	
Site Master File reference number(s):	
Date of submission:	
Licence number:	
Date of issue:	
Finished product release control (FPRC)(s):	
Physical address of site(s):	
Site master file reference number(s):	
Date of submission:	
Licence number:	
Date of issue:	
Finished product release responsibility (FPRR)(s):	
Physical address of site(s):	
Site Master File reference number(s):	
Date of submission	
Licence number:	
Date of issue:	

☐ It is hereby confirmed that copies of the latest GMP certificate for manufacturer(s) and packer(s) and/or a copy of the appropriate manufacturing licence(s) and Site Master File(s) have been included in section 1.7.

(c) Declaration and signature

The undersigned hereby declares that all the information herein, and in the Annexes and Modules hereto, are correct and true and are relevant to this particular medicine, and that all existing data which are relevant to the quality, safety and efficacy of the product have been supplied in the dossier, as appropriate.

☐ It is hereby confirmed that fees have been paid according to current legislation, and proof is attached in Annex 1.2.2.1

.....
Signature of Pharmacist [Section (a) above]

.....
Date of application

.....
Name in block letters

.....
Date of registration

.....
Designation

.....
Date of current amendment

(d) Type of application

NEW APPLICATION

Indicate the type of medicine, the type of data included as proof of efficacy, and the review procedure using a check mark (•) or a cross (X) –

Human Medicine:		NCE	Data as proof of efficacy:	
<i>Pharmaceutical</i>		<i>Multisource</i>		<i>Pre-clinical</i>
<i>Biological</i>		<i>Biosimilar</i>		<i>Clinical</i>
Review Procedure:				
<i>Routine</i>		<i>AMRP</i>		<i>Expedited (Fast Track)</i>

For multiple/duplicate applications of the same medicinal product

Proposed Proprietary Name(s) of the other product(s):

Date of application(s) (yyyy-mm-dd):

AMENDMENT/VARIATION

Indicate the type of amendment/variation using a check mark (•) or a cross (X):

<i>Inspection</i>	<i>Response to pre-registration recommendation:</i>	
<i>Pharmaceutical and Analytical</i>	<i>Pharmaceutical & Analytical</i>	
<i>Clinical</i>	<i>Clinical</i>	
<i>Proprietary Name</i>	<i>Proprietary Name</i>	

(e) Qualified person for Pharmacovigilance

<i>Name:</i>	
<i>Business address:</i>	
<i>24 Hour Telephone No:</i>	
<i>Fax No:</i>	
<i>E-mail address:</i>	
<i>(Attach CV – Annex 1.2.2.5)</i>	

(f) Amendment history

<i>Date of letter of amendment application</i>	<i>Summarised details of amendment (include Type and Category)</i>	<i>Date of Regulatory Authority response</i>
☐		

The following is a description of the categories:

1. Category A: Low risk medicines

These are medicines of low risk medicines mostly intended for self-medication as may be decided by the Authority.

2. Category B: Established medicines

These are medicines with safety and efficacy record well documented in standard textbooks including Martindale, Goodman and Gilman, USP-DI.

3. Category C: Exempted medicines

These are medicines exempted under section 23 (3) and (4) of the Medicines and Related Substances Act. The Authority may request additional information, as the medicine continues to be used. A completed application for registration exemption form shall be submitted to the Authority.

4. Category D: Medicine requiring selected areas of evaluation

Medicines under this category may include:

- (a) new combination medicines;
- (b) first line generic medicine;
- (c) established medicine with new indication(s);
- (d) new formulation of an established medicine; or
- (e) any other medicine as the Authority may decide.

5. Category E: New medicines and biologicals

These are new chemical entities, new formulation and all biological medicines. For these, detailed pharmaceutical, pharmacological and clinical documentation shall be submitted. Applicants may also be requested to submit evaluation reports or approvals from a Stringent Regulatory Authority (SRA) defined as a member of ICH prior to 23 October 2015, namely: the US Food and Drug Administration, the European Commission and the Ministry of Health, Labour and Welfare of Japan also represented by the Pharmaceuticals and Medical Devices Agency; or an ICH observer prior to 23 October 2015, namely: the European Free Trade Association, as represented by Swiss medic and Health Canada; or a regulatory authority associated with an ICH member through a legally-binding, mutual recognition agreement prior to 23 October 2015, namely: Australia, Iceland, Liechtenstein and Norway.

FORM 2
(reg. 3, 23 and 26)

APPLICATION FOR REGISTRATION
OF MEDICINE

COMMON TECHNICAL DOCUMENT FOR THE REGISTRATION OF
PHARMACEUTICALS FOR HUMAN USE

- Botswana Module 1
- CTD-Modules 2 - 5

Common Technical Document

Modular format of applications for registration in CTD format

Module 1 — Administrative information and prescribing information

- 1.0 Cover Letter.....
- 1.1 Comprehensive table of contents.....
- 1.2 Application.....
- 1.3 Labelling and packaging.....
- 1.4 Information about the experts.....
- 1.5 Specific requirements for different types of applications.....
- 1.6 Environmental risk assessment.....
- 1.7 Good manufacturing practice.....
- 1.8 Details of Screening.....
- 1.9 Individual patient data – statement of availability, if applicable.....
- 1.10 Foreign regulatory status.....
- 1.11 Bioequivalence trial information.....
- 1.12 Paediatric development programme.....
- 1.13 Information relating to Pharmacovigilance.....
- 1.14 Electronic review documents (e.g. product information, BTIF, QOS, QIS)....

Module 2 – CTD Summaries

- 2.1 CTD Table of Contents (modules 2 to 5).....
- 2.2 Introduction.....
- 2.3 Quality Overall Summary - Introduction.....
- 2.4 Non-clinical Overview.....
- 2.5 Clinical Overview.....
- 2.6 Non-clinical Written and Tabulated Summaries.....
- 2.7 Clinical Summary.....

Module 3 – Quality

- 3.1 Table of contents of module 3.....
- 3.2 Body of data.....
- 3.2.S Drug Substance/Active Pharmaceutical Ingredient (*name, manufacturer*).....
- 3.2.P Drug Product/Pharmaceutical Product (*name, dosage form*).....
- 3.2.A Appendices.....
- 3.2.R Regional Information.....
- 3.3 Literature references.....

Module 4 – Non-clinical study reports

- 4.1 Table of contents of Module 4.....
- 4.2 Study reports.....
- 4.3 Literature references

Module 5 – Clinical Study Reports

- 5.1 Table of contents of Module 5.....
- 5.2 Tabular listing of all clinical studies.....
- 5.3 Clinical study reports.....
- 5.4 Literature references.....

Modular format of applications for registration in CTD format

Module 1 – Administrative information and prescribing information

- 1.0 Cover Letter
- 1.1 Comprehensive table of contents
- 1.2 Application
 - 1.2.1 Application form
 - 1.2.2 Annexes to application form
 - 1.2.2.1 Proof of payment
 - 1.2.2.2 Letter of authorisation for communication on behalf of the applicant
 - 1.2.2.3 Electronic copy declaration
 - 1.2.2.4 Curriculum vitae of the person responsible for pharmacovigilance
 - 1.2.2.5 Drug Substance/API change control
 - 1.2.2.6 Copy of EMA certificate for a Vaccine Antigen Master File (VAMF)
 - 1.2.2.7 Copy of EMA certificate for a Plasma Master File (PMF)
 - 1.2.2.8 Copy of certificate(s) of suitability of the European Pharmacopoeia (CEP)
 - 1.2.2.9 Copy of confirmation of API prequalification document (CPQ)
 - 1.2.2.10 Letter of access from APIMF, CEP or CPQ holder
 - 1.2.2.11 Quality Information Summary (QIS) – To submit only at the time of registration and/or immediately after registration and after every variation approval.
- 1.3 Labelling and packaging
 - 1.3.1 Package Insert /Summary of Product Characteristics (SmPC)
 - 1.3.2 Patient Information Leaflet (PIL)
 - 1.3.3 Labels (outer and inner labels)
 - 1.3.4 Braille
- 1.4 Information about the experts
 - 1.4.1 Quality
 - 1.4.2 Non-clinical
 - 1.4.3 Clinical
- 1.5 Specific requirements for different types of applications
 - 1.5.1 Studies and data for generic products
 - 1.5.2 Same/Separate Applications
 - 1.5.2.1 Tablets/Capsules/Suppositories/Lozenges
 - 1.5.2.2 Syrups/Liquids/Solutions (non parenterals)/Creams/ointments
 - 1.5.2.3 Ampoules, Vials and Large Volume Parenterals
 - 1.5.2.4 Different applicants/proprietary names for the same formula
 - 1.5.3 Genetically modified organisms
- 1.6 Environmental risk assessment

- 1.6.1 Non-GMO (genetically modified organisms)
- 1.6.2 GMO
- 1.7 Good manufacturing practice
 - 1.7.1 Date of last inspection of each site
 - 1.7.2 Inspection reports or equivalent document
 - 1.7.3 Latest GMP certificate (not older than 3 years) for API and FPP manufacturer/s and packer/s and a copy of the appropriate manufacturing licence
 - 1.7.4 Registration of Responsible Pharmacist or Suitably Qualified Person for local manufacturers
 - 1.7.5 Sample and Documents (e.g. FPP, device(s), certificates of analysis)
 - 1.7.5.1 Confirmation of submission of sample
 - 1.7.5.2 Certificate of analysis of the sample
 - 1.7.6 Certified copy of a permit to manufacture specified controlled substances
 - 1.7.7 Site Master File(s)
- 1.8 Details of Screening
- 1.9 Individual patient data - statement of availability, if applicable
- 1.10 Foreign regulatory status
 - 1.10.1 List of SADC or other countries in which an application for the same product as being applied for has been submitted, registered, rejected or withdrawn.
 - 1.10.2 WHO type Certificate of Pharmaceutical Product (COPP)
 - 1.10.3 Registration certificate or marketing authorisation
 - 1.10.4 Foreign prescribing and patient information
 - 1.10.5 Data set similarities
- 1.11 Bioequivalence trial information
 - 1.11.1 Study Title(s) (or brief description giving design, duration, dose and subject population of each study)
 - 1.11.2 Protocol and study numbers
 - 1.11.3 Investigational products (test and reference) details
 - 1.11.4 Confirmation that the test product formulation and manufacturing process is the one being applied for
 - 1.11.5 Proof of procurement of the biostudy reference product
 - 1.11.6 Name and address of the Research Organisation(s)/Contract Research Organisation(s) where the bioequivalence studies were conducted
 - 1.11.7 Sponsor and responsible sponsor representative: name and address, contact details
 - 1.11.8 Duration of Clinical phase: dates of dosing and last clinical procedure
 - 1.11.9 Date of final report
- 1.12 Paediatric development programme
- 1.13 Information relating to Pharmacovigilance
 - 1.13.1 Pharmacovigilance system
 - 1.13.2 Risk management system
- 1.14 Electronic review documents (e.g. product information, BTIF, QOS and QIS)

Module 2 – CTD Summaries

- 2.1 CTD Table of Contents (modules 2 to 5)
- 2.2 Introduction
- 2.3 Quality Overall Summary – Introduction
- 2.3. S Quality Overall Summary – Drug Substance/Active Pharmaceutical Ingredient (name, manufacturer)
 - 2.3.S.1 General Information (*name, manufacturer*)
 - 2.3.S.2 Manufacture (*name, manufacturer*)

- 2.3.S.3 Characterisation (*name, manufacturer*)
- 2.3.S.4 Control of Drug Substance/Active Pharmaceutical Ingredient (*name, manufacturer*)
- 2.3.S.5 Reference Standards or Materials (*name, manufacturer*)
- 2.3.S.6 Container Closure System (*name, manufacturer*)
- 2.3.S.7 Stability (*name, manufacturer*)
- 2.3.P Quality Overall Summary – Drug Product/Finished Pharmaceutical Product (*name, dosage form*)
 - 2.3.P.1 Description and Composition of the Drug Product/Pharmaceutical Product (*name, dosage form*)
 - 2.3.P.2 Pharmaceutical Development (*name, dosage form*)
 - 2.3.P.3 Manufacture (*name, dosage form*)
 - 2.3.P.4 Control of Excipients (*name, dosage form*)
 - 2.3.P.5 Control of Drug Product/Pharmaceutical Product (*name, dosage form*)
 - 2.3.P.6 Reference Standards or Materials (*name, dosage form*)
 - 2.3.P.7 Container Closure System (*name, dosage form*)
 - 2.3.P.8 Stability (*name, dosage form*)
- 2.3.A Quality Overall Summary – Appendices
 - 2.3.A.1 Facilities and equipment (*name, manufacturer*)
 - 2.3.A.2 Adventitious agents safety evaluation (*name, dosage form, manufacturer*)
 - 2.3.A.3 Excipients
- 2.4 Non-clinical Overview
- 2.5 Clinical Overview
 - 2.5.1 Product Development Rationale
 - 2.5.2 Overview of Bio pharmaceuticals
 - 2.5.3 Overview of Clinical Pharmacology
 - 2.5.4 Overview of Efficacy
 - 2.5.5 Overview of Safety
 - 2.5.6 Benefits and Risks Conclusions
 - 2.5.7 Literature References
- 2.6 Non-clinical Written and Tabulated Summaries
 - 2.6.1 Introduction
 - 2.6.2 Pharmacology Written Summary¹
 - 2.6.2.1 Brief Summary
 - 2.6.2.2 Primary Pharmacodynamics
 - 2.6.2.3 Secondary Pharmacodynamics
 - 2.6.2.4 Safety Pharmacology
 - 2.6.2.5 Pharmacodynamic Medicine Interactions
 - 2.6.2.6 Discussion and Conclusions
 - 2.6.2.7 Tables and Figures (See Appendix A)
 - 2.6.3 Pharmacology Tabulated Summary (See Appendix B)
 - 2.6.4 Pharmacokinetics Written Summary²
 - 2.6.4.1 Brief Summary
 - 2.6.4.2 Methods of Analysis
 - 2.6.4.3 Absorption
 - 2.6.4.4 Distribution
 - 2.6.4.5 Metabolism (interspecies comparison)
 - 2.6.4.6 Excretion
 - 2.6.4.7 Pharmacokinetic Medicine Interactions
 - 2.6.4.8 Other Pharmacokinetic Studies
 - 2.6.4.9 Discussion and Conclusions

¹The CTD defines these further heading levels and navigation should be provided within the document to these subheadings.

- 2.6.4.10 Tables and Figures (See Appendix A)
- 2.6.5 Pharmacokinetics Tabulated Summary (See Appendix B)
- 2.6.6 Toxicology Written Summary²
 - 2.6.6.1 Brief Summary
 - 2.6.6.2 Single-Dose Toxicity
 - 2.6.6.3 Repeat-Dose Toxicity (including supportive toxicokinetics evaluations)
 - 2.6.6.4 Genotoxicity
 - 2.6.6.5 Carcinogenicity (including supportive toxicokinetics evaluations)
 - 2.6.6.6 Reproductive and Developmental Toxicity (including range-finding studies and supportive toxicokinetics evaluations)
 - 2.6.6.7 Local Tolerance
 - 2.6.6.8 Other Toxicity Studies (if available)
 - 2.6.6.9 Discussion and Conclusions
 - 2.6.6.10 Tables and Figures (See Appendix A)
- 2.6.7 Toxicology Tabulated Summary (See Appendix B)
- 2.7 Clinical Summary
 - 2.7.1 Summary of Biopharmaceutical Studies and Associated Analytical Methods²
 - 2.7.1.1 Background and Overview
 - 2.7.1.2 Summary of Results of Individual Studies
 - 2.7.1.3 Comparison and Analyses of Results Across Studies
 - 2.7.1.4 Appendix
 - 2.7.2 Summary of Clinical Pharmacology Studies
 - 2.7.2.1 Background and Overview
 - 2.7.2.2 Summary of Results of Individual Studies
 - 2.7.2.3 Comparison and Analyses of Results Across Studies
 - 2.7.2.4 Special Studies
 - 2.7.2.5 Appendix
 - 2.7.3 Summary of Clinical Efficacy – *Indication*³
 - 2.7.3.1 Background and Overview of Clinical Efficacy
 - 2.7.3.2 Summary of Results of Individual Studies
 - 2.7.3.3 Comparison and Analyses of Results Across Studies
 - 2.7.3.3.1 Study Populations
 - 2.7.3.3.2 Comparison of Efficacy Results of All Studies
 - 2.7.3.3.3 Comparison of Results in Sub-populations
 - 2.7.3.4 Analysis of Clinical Information Relevant to Dosing Recommendations
 - 2.7.3.5 Persistence of Efficacy and/or Tolerance Effects
 - 2.7.3.6 Appendix
 - 2.7.4 Summary of Clinical Safety³
 - 2.7.4.1 Exposure to the Medicine
 - 2.7.4.1.1 Overall Safety Evaluation Plan and Narratives of Safety Studies
 - 2.7.4.1.2 Overall Extent of Exposure
 - 2.7.4.1.3 Demographic and Other Characteristics of Study Population
 - 2.7.4.2 Adverse Events
 - 2.7.4.2.1 Analysis of Adverse Events
 - 2.7.4.2.1.1 Common Adverse Events
 - 2.7.4.2.1.2 Deaths
 - 2.7.4.2.1.3 Other Serious Adverse Events
 - 2.7.4.2.1.4 Other Significant Adverse Events
 - 2.7.4.2.1.5 Analysis of Adverse Events by Organ System or Syndrome
 - 2.7.4.2.2 Narratives

²The CTD defines these further headings levels and navigation should be provided within the documents to these subheadings

³Ibid

- 2.7.4.3 Clinical Laboratory Evaluations
- 2.7.4.4 Vital Signs, Physical Findings and Other Observations related to Safety
- 2.7.4.5 Safety in Special Groups and Situations
 - 2.7.4.5.1 Intrinsic Factors
 - 2.7.4.5.2 Extrinsic Factors
 - 2.7.4.5.3 Medicine Interactions
 - 2.7.4.5.4 Use in Pregnancy and Lactation
 - 2.7.4.5.5 Overdose
 - 2.7.4.5.6 Medicine Abuse
 - 2.7.4.5.7 Withdrawal and Rebound
 - 2.7.4.5.8 Effects on Ability to Drive or Operate Machinery or Impairment of Mental Ability
- 2.7.4.6 Post-marketing Data
- 2.7.4.7 Appendix
- 2.7.5 Literature References
- 2.7.6 Synopses of Individual Studies

Module 3 – Quality

- 3.1 Table of contents of module 3
- 3.2 Body of data
 - 3.2.S Drug Substance/Active Pharmaceutical Ingredient (*name, manufacturer*)
 - 3.2.S.1 General information (*name, manufacturer*)
 - 3.2.S.1.1 Nomenclature (*name, manufacturer*)
 - 3.2.S.1.2 Structure (*name, manufacturer*)
 - 3.2.S.1.3 General Properties (*name, manufacturer*)
 - 3.2.S.2 Manufacture (*name, manufacturer*)
 - 3.2.S.2.1 Manufacturer(s) (*name, manufacturer*)
 - 3.2.S.2.2 Description of Manufacturing Process and Process Controls (*name, manufacturer*)
 - 3.2.S.2.3 Control of Materials (*name, manufacturer*)
 - 3.2.S.2.4 Controls of Critical Steps and Intermediates (*name, manufacturer*)
 - 3.2.S.2.5 Process Validation and/or Evaluation (*name, manufacturer*)
 - 3.2.S.2.6 Manufacturing Process Development (*name, manufacturer*)
 - 3.2.S.3 Characterisation (*name, manufacturer*)
 - 3.2.S.3.1 Elucidation of Structure and other Characteristics (*name, manufacturer*)
 - 3.2.S.3.2 Impurities (*name, manufacturer*)
 - 3.2.S.4 Control of active pharmaceutical ingredient (*name, manufacturer*)
 - 3.2.S.4.1 Specifications (*name, manufacturer*)
 - 3.2.S.4.2 Analytical Procedures (*name, manufacturer*)
 - 3.2.S.4.3 Validation of Analytical Procedures (*name, manufacturer*)
 - 3.2.S.4.4 Batch Analyses (*name, manufacturer*)
 - 3.2.S.4.5 Justification of Specification (*name, manufacturer*)
 - 3.2.S.5 Reference Standards or Materials (*name, manufacturer*)
 - 3.2.S.6 Container Closure System (*name, manufacturer*)
 - 3.2.S.7 Stability (*name, manufacturer*)
 - 3.2.S.7.1 Stability summary and conclusions (*name, manufacturer*)
 - 3.2.S.7.2 Post approval stability protocol and stability commitment (*name, manufacturer*)
 - 3.2.S.7.3 Stability Data (*name, manufacturer*)
 - 3.2.P Drug Product/Pharmaceutical Product (*name, dosage form*)
 - 3.2.P.1 Description and Composition of the Drug Product/pharmaceutical product (*name, dosage form*)
 - 3.2.P.2 Pharmaceutical Development (*name, dosage form*)

- 3.2.P.2.1 Components of the Drug Product/Pharmaceutical Product (*name, dosage form*)
 - 3.2.P.2.1.1 Drug Substance/Active Pharmaceutical Ingredient(s) (*name, dosage form*)
 - 3.2.P.2.1.2 Excipients (*name, dosage form*)
 - 3.2.P.2.2 Final Drug Product/pharmaceutical product (*name, dosage form*)
 - 3.2.P.2.2.1 Formulation development (*name, dosage form*)
 - 3.2.P.2.2.2 Overages (*name, dosage form*)
 - 3.2.P.2.2.3 Physicochemical and biological properties (*name, dosage form*)
 - 3.2.P.2.3 Manufacturing process development (*name, dosage form*)
 - 3.2.P.2.4 Container closure system (*name, dosage form*)
 - 3.2.P.2.5 Microbiological attributes (*name, dosage form*)
 - 3.2.P.2.6 Compatibility (*name, dosage form*)
- 3.2.P.3 Manufacture (*name, dosage form*)
 - 3.2.P.3.1 Manufacturer(s) (*name, dosage form*)
 - 3.2.P.3.2 Batch formula (*name, dosage form*)
 - 3.2.P.3.3 Description of manufacturing process and process controls (*name, dosage form*)
 - 3.2.P.3.4 Controls of critical steps and intermediates (*name, dosage form*)
 - 3.2.P.3.5 Process validation and/or evaluation (*name, dosage form*)
- 3.2.P.4 Control of Inactive Pharmaceutical Ingredients (*name, dosage form*)
 - 3.2.P.4.1 Specifications (*name, dosage form*)
 - 3.2.P.4.2 Analytical procedures (*name, dosage form*)
 - 3.2.P.4.3 Validation of analytical procedures (*name, dosage form*)
 - 3.2.P.4.4 Justification of specifications (*name, dosage form*)
 - 3.2.P.4.5 Excipients of human or animal origin (*name, dosage form*)
 - 3.2.P.4.6 Novel excipients (*name, dosage form*)
- 3.2.P.5 Control of Drug Product/pharmaceutical product (*name, dosage form*)
 - 3.2.P.5.1 Specification(s) (*name, dosage form*)
 - 3.2.P.5.2 Analytical procedures (*name, dosage form*)
 - 3.2.P.5.3 Validation of analytical procedures (*name, dosage form*)
 - 3.2.P.5.4 Batch analyses (*name, dosage form*)
 - 3.2.P.5.5 Characterisation of impurities (*name, dosage form*)
 - 3.2.P.5.6 Justification of specifications (*name, dosage form*)
- 3.2.P.6 Reference standards or materials (*name, dosage form*)
- 3.2.P.7 Container closure system (*name, dosage form*)
- 3.2.P.8 Stability (*name, dosage form*)
 - 3.2.P.8.1 Stability summary and conclusion (*name, dosage form*)
 - 3.2.P.8.2 Post-approval stability protocol and stability commitment (*name, dosage form*)
 - 3.2.P.8.3 Stability data (*name, dosage form*)
- 3.2.A Appendices
 - 3.2.A.1 Facilities and equipment (*name, manufacturer*)
 - 3.2.A.2 Adventitious agents safety evaluation (*name, dosage form, manufacturer*)
 - 3.2.A.3 Excipients
- 3.2.R Regional Information
 - 3.2.R.1 Production documentation
 - 3.2.R.1.1 Executed production documents
 - 3.2.R.1.2 Master production documents
 - 3.2.R.2 Analytical procedures and validation information
 - 3.2.R.3 Bioequivalence trial information
 - 3.2.R.3.1 Bioequivalence trial information form (or BTIF)
 - 3.2.R.3.2 Biowaiver requests in relation to conducting comparative bioavailability study
- 3.3 Literature references

Module 4 – Non-clinical study reports

- 4.1 Table of contents of Module 4
- 4.2 Study reports
 - 4.2.1 Pharmacology
 - 4.2.1.1 Primary pharmacodynamics
 - 4.2.1.2 Secondary pharmacodynamics
 - 4.2.1.3 Safety pharmacology
 - 4.2.1.4 Pharmacodynamic medicine interactions
 - 4.2.2 Pharmacokinetics
 - 4.2.2.1 Analytical methods and validation reports
 - 4.2.2.2 Absorption
 - 4.2.2.3 Distribution
 - 4.2.2.4 Metabolism
 - 4.2.2.5 Excretion
 - 4.2.2.6 Pharmacokinetic medicine interactions (non clinical)
 - 4.2.2.7 Other pharmacokinetic studies
 - 4.2.3 Toxicology
 - 4.2.3.1 Single-dose toxicity (in order by species, by route)
 - 4.2.3.2 Repeat dose toxicity (in order by species, by route, by duration; including supportive toxicokinetics evaluations)
 - 4.2.3.3 Genotoxicity
 - 4.2.3.3.1 *In vitro*
 - 4.2.3.3.2 *In vivo* (including supportive toxicokinetics evaluations)
 - 4.2.3.4 Carcinogenicity (including supportive toxicokinetics evaluations)
 - 4.2.3.4.1 Long-term studies (in order by species, including range-finding studies that cannot be appropriately included under repeat-dose toxicity or pharmacokinetics)
 - 4.2.3.4.2 Short or medium term studies (including range finding studies that cannot be appropriately included under repeat-dose)
 - 4.2.3.4.3 Other studies
 - 4.2.3.5 Reproductive and developmental toxicity (including range-finding studies and supportive toxicokinetics evaluations) (If modified study designs are used, the following subheadings should be modified accordingly)
 - 4.2.3.5.1 Fertility and early embryonic development
 - 4.2.3.5.2 Embryo-foetal development
 - 4.2.3.5.3 Prenatal and postnatal development, including maternal function
 - 4.2.3.5.4 Studies in which the offspring (juvenile animals) are dosed and/or further evaluated
 - 4.2.3.5.6 Local tolerance
 - 4.2.3.5.7 Other toxicity studies (if available)
 - 4.2.3.7.1 Antigenicity
 - 4.2.3.7.2 Immunotoxicity
 - 4.2.3.7.3 Mechanistic studies (if not included elsewhere)
 - 4.2.3.7.4 Dependence
 - 4.2.3.7.5 Metabolites
 - 4.2.3.7.6 Impurities
 - 4.2.3.7.7 Other
 - 4.3 Literature references

Module 5 – Clinical Study Reports

- 5.1 Table of contents of Module 5

- 5.2 Tabular listing of all clinical studies
- 5.3 Clinical study reports
 - 5.3.1 Reports of biopharmaceutic studies
 - 5.3.1.1 Bioavailability (BA) Study Reports
 - 5.3.1.2 Comparative BA and Bioequivalence (BE) Study Reports
 - 5.3.1.3 *In vitro-in vivo* correlation study reports
 - 5.3.1.4 Reports of bioanalytical and analytical methods for human studies
 - 5.3.2 Reports of studies pertinent to pharmacokinetics using human biomaterials
 - 5.3.2.1 Plasma Protein Binding Study Reports
 - 5.3.2.2 Reports of Hepatic Metabolism and Medicine Interaction Studies
 - 5.3.2.3 Reports of Studies Using Other Human Biomaterials
 - 5.3.3 Reports of human pharmacokinetic (PK) Studies
 - 5.3.3.1 Healthy Subject PK and Initial Tolerability Study Reports
 - 5.3.3.2 Patient PK and Initial Tolerability Study Reports
 - 5.3.3.3 Intrinsic Factor PK Study Reports
 - 5.3.3.4 Extrinsic Factor PK Study Reports
 - 5.3.3.5 Population PK Study Reports
 - 5.3.4 Reports of human pharmacodynamic (PD) studies
 - 5.3.4.1 Healthy Subject PD and PK/PD Study Reports
 - 5.3.4.2 Patient PD and PK/PD Study Reports
 - 5.3.5 Reports of efficacy and safety studies
 - 5.3.5.1 Study Reports of Controlled Clinical Studies Pertinent to the Claimed Indication
 - 5.3.5.2 Study Reports of Uncontrolled Clinical Studies
 - 5.3.5.3 Reports of Analyses of Data from More than One Study
 - 5.3.5.4 Other Study Reports
 - 5.3.6 Reports of Post-marketing experience
 - 5.3.7 Case report forms and individual patient listings
- 5.4 Literature references

FORM 3
(reg. 3(3))

APPROVAL FOR REGISTRATION OF A MEDICINE

Subject to due compliance with the requirement of the Medicines and Related Substances Act and Regulations thereto, the following medicine is approved by the Authority to be marketed in Botswana and entered into the Medicine Register as follows:

Registration Number:	
Name of Medicine:	
Active ingredient(s), approved name or volume of the medicine: _____ and quantity per dosage unit or per suitable mass	
Dosage Form:	Strength:
Manufacturer:	
Manufacturing country:	
Package size(s):	
Packaging material:	
Approved Indication(s):	
Schedule:	
Special conditions:	
Date granted:	Valid until:
Authorisation:	Signature:
(Name and stamp):	

FORM 4
(reg. 6 and 66 (9))

APPLICATION FOR REGISTRATION EXEMPTION – PATIENT

- ☐ Single Patient
☐ Multiple Patients

*Separate Forms to be filled for each patient

Application Number: _____

1. Patient's
2. Address:
Age and Sex
3. Approved/generic name of medicine:
4. Brand name of medicine:
5. Name and address of Manufacturer:
6. Registration number in other countries and registered indications:
7. Dosage:
8. Pack size
9. Strength and formulation
10. Duration of treatment:
11. Medical history
(a) Clinical condition
(b) Medicines previously used:
(c) Outcome of treatment (in brief) with medicines mentioned in (b) above

(d) Any additional information
12. Progress report (including adverse drug reactions if any) and request for continuation:
13. Name and physical address of Medical Practitioner:
14. Qualifications and Practice Number
15. Signature
16. Date:
17. Pharmacy (name and address):
a. Name of Practitioner:
b. Botswana Health Professions Council Registration Number:
18. Importer:
c. Name of practitioner:
d. Botswana Health Professions Council Registration Number:
<i>This form to be submitted to the patient's pharmacy with the relevant prescription.</i>
To be completed for any subsequent applications after the initial 6 months approval.

For Official Use:

Date request received: _____
Drug category: Investigational _____ New _____ Old _____
Registration Appl. Submitted: Yes _____ No _____ Registration Appl. Number _____
Registration Application Evaluated: Yes _____ No _____
If Yes, state the outcome: Pending _____ Rejected _____ If Rejected, give reasons:

Decision: _____
Exemption Granted: _____
Conditions, if any: _____

Valid Until: _____
Exemption Refused _____
Reasons _____

FORM 5
(reg. 8)

APPLICATION FOR REGISTRATION EXEMPTION – WHOLESALER

MEDICINE OR RELATED SUBSTANCE

Name of the medicine or related substance:	
Approved name(s) of active ingredient(s):	
Dosage form:	
Strength(s):	
Quantity	
Name and address of manufacturer:	

Motivation

Attach the following documents to this form

- a) Copies of Certificate of analysis from two latest batches, (to attach CoA of sample batch).
- b) Registration Certificate of the product in the country of origin.
- c) GMP Certificate from country of origin.
- d) Certificate of Pharmaceutical Product.
- e) For **Sterile** products a valid cGMP Certificate for the Finished Pharmaceutical Products (FPP) manufacturing site, issued by either ICH member countries, regulatory authorities that participate in the Pharmaceutical Inspection Cooperation Scheme (PIC/s), WHO or National Medicines Regulatory Authorities in Zambia (ZAMRA), Zimbabwe (MCAZ), Tanzania (TFDA) and Uganda (NDA).
- f) For **Biosimilars** a valid Registration Certificate for the product must be issued by ICH member countries prior to 23 October, 2013.
- g) The applicant or pharmacist must submit a package insert.

SUPPLIER

APPLICANT

Name, address and qualifications of the Applicant:

Signature of Applicant _____ Date: _____

For Official Use:

Date request received: _____

Medicine category:

Investigational _____ New _____ Old _____

Registration Application

Registration Application

Submitted:

Evaluated:

Yes _____ NO _____

Yes _____ No _____

Registration Application Number:

If Yes, state the outcome:

Pending _____ Rejected _____

If Rejected, give reasons:

C.1113

Decision:

Exemption Granted: _____

Exemption Refused _____

Conditions, if any: _____

Reasons

Valid until: _____

FORM 6

(reg. 9)

APPLICATION FOR REGISTRATION EXEMPTION – DONATION

Name of the medicine or related substance:	
Approved name(s) of active ingredient(s):	
Dosage form:	
Strength(s):	
Quantity:	

Name and address of Manufacturer:	
Name of Donor	
Intended recipient of donation	
Motivation	
Attach the following documents to this form - Copies of Certificate of analysis from two latest batches, (to attach CoA of sample batch) - Registration Certificate of the product in the country of origin. - cGMP Certificate from country of origin. - Certificate of Pharmaceutical Product. - For Sterile products a valid cGMP Certificate for the Finished Pharmaceutical Products (FPP) manufacturing site, issued by either ICH member countries, regulatory authorities that participate in the Pharmaceutical Inspection Cooperation Scheme (PIC/s), WHO or National Medicines Regulatory Authorities in Zambia (ZAMRA), Zimbabwe (MCAZ), Tanzania (TFDA) and Uganda (NDA). - For Biosimilars a valid Registration Certificate for the product must be issued by ICH member countries prior to 23 October, 2013 - The applicant or pharmacist must submit a package insert	

SUPPLIER

APPLICANT

Name, address and qualifications of the applicant:

Signature of Applicant _____ Date: _____

For Official Use:

Date request received: _____

Medicine category:

Registration Application

Investigational _____ New _____ Old _____
Registration Application

Submitted:

Yes _____ No _____

Evaluated:

Yes _____ No _____

Registration Application Number: _____

If Yes, state the outcome:

Pending _____ Rejected _____

If Rejected give reasons: _____

Decision:

Exemption Granted: _____

Exemption Refused _____

Conditions, if any: _____

Reasons _____

Valid Until: _____

FORM 7
(reg. 10 and 66)

VARIATION APPLICATION FORM			
Registration No:	Product Name:		
Applicant's Full Name			
Postal Address			
Contact Person's Name			
Title:		Telephone & Fax:	
Email:		Website:	

Type of variation being sought (please indicate as applicable)
Countries where variation is approved:
Description of proposed variation
Reasons for proposed variation

CERTIFICATION

I hereby submit an application for the concerned product to be varied in accordance with the proposal given above. I declare that —

- there are no other changes than those identified;
- all conditions for the change(s) concerned are fulfilled; and
- the required documents as specified for the change(s) have been submitted.

Name:

Position:

Signature:

Date:

Variation

Response:

FORM 8
(reg. 16, 17, 18, 19, 21, 22, 24 and 64)

APPLICATION FOR PREMISES LICENCE:

- ☐ Dispensary ☐ Standalone Pharmacy
- ☐ Wholesaler ☐ Group Practice Pharmacy
- ☐ Trader
- ☐ Manufacture medicines and cosmetics* (see also reverse page)
- ☐ Variation of Licence
- ☐ Renewal of License
- ☐ Re-submission

Reasons for variation

.....

Medicines Schedules:

- | | |
|---------------------------------------|--|
| ☐ Wholesaler | Schedule 1 ☐ 2 ☐ 3 ☐ 4 ☐ |
| ☐ Pharmacy | Schedule 1 ☐ 2 ☐ 3 ☐ 4 ☐ |
| ☐ Manufacturer | Schedule 1 ☐ 2 ☐ 3 ☐ 4 ☐ |
| ☐ Trader | Schedule 4 only |

Name of applicant _____
(of person representing the company)

Address of applicant _____

My qualifications are (profession/education) _____

The premises are located (address) _____

Date: _____

Signature: _____

ADDITIONAL INFORMATION NEEDED FOR APPLICATION TO MANUFACTURE
MEDICINES

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

Name	Qualification	Experience
Quality Control Pharmacist		
Production Pharmacist		
Quality Assurance Pharmacist		
Other		

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

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

FORM 9
(Reg. 16, 17 18, 19, 20, 21, 22 and 64)

PHARMACEUTICAL PREMISES LICENCE
(specify type of licence)

Pharmacy, Wholesaler, Manufacturer

Licence number.....

1. Licencee

.....
2. Type of premises licenced

.....
3. Description of licenced premises

.....
4. Location and Address of Premises

.....
5. Name of Business

.....
6. Conditions of issue/renewal

.....
7. Responsible Pharmacist

Registration Number

.....
8. The (specify type) should operate in compliance with the requirements of the Medicines and Related Substances Act, Regulations and applicable guidelines.

Date:.....

Valid until (date):.....

.....
For/Chief Executive Officer

Date and Stamp.....

FORM 10
(reg. 26, 27, 28 and 65)

APPLICATION FOR IMPORT PERMIT

1. Full name and address of importing company:

2. Licence number: _____ Authorised Person: _____

3. Tel: _____ Fax: _____ Email: _____

Type of business:

(Specify Wholesale/Pharmaceutical Manufacturer/Other)

hereby apply for permit to import medicines/cosmetics products into Botswana.

4. Full name and address of supplier in exporting country

Tel: _____ Fax: _____ Email: _____

5. Authorised person: _____ Tel: _____

6. Purpose for which the medicines/cosmetics are required:
(Tick whichever is applicable)☐ Registration samples☐ Patient exemption☐ Bulk exemption☐ Clinical trials☐ Wholesaling and distribution;

Other _____ (Specify)

7. Attached herewith the Proforma Invoice No _____ Date _____

8. Method of transportation: road ☐ /rail ☐ /airfreight ☐

9. Port of entry _____

10. Expected date _____

11. Details of medicines to be imported as quoted in the PO:

Item No.	Trade Name of Medicine	International Non-Proprietary Name (INN) of Medicine	Strength	Total Quantity	Name and Address of Supplier	Name and Address of Manufacturer	Product Registration Number

Declaration:

I certify that the information provided in the application form and proforma invoice is true and correct.

Date of application _____

Signature of Applicant _____

Stamp

FOR OFFICIAL USE ONLY:

Received by: _____

Signature: _____

APPLICATION APPROVED ☐ /REJECTED ☐ If rejected issue Rejection Form

RECOMMENDED _____

APPROVED _____

PERMIT No. _____

ISSUED ON _____ (DATE)

SIGNED _____

For/Chief Executive Officer
Botswana Medicines Regulatory Authority



FORM 11
(reg. 26, 28 and 65)

IMPORT PERMIT FOR MEDICINES MEDICAL PRODUCTS OR COSMETICS

(Issued in accordance with section 28 of the Medicines and Related Substances Act)

Permit No: / _____

In accordance with the Medicines and Related Substances Act, the Medicines and Related Substances Regulations and applicable guidelines authority is hereby granted for importation of product(s) listed on the table.

Name of registered importer _____ Tel No _____

Address _____ Purchase Order No _____

Exporting Country _____ Tel No _____

Exporter _____ Address _____

Arrival expected by ship/air/motor vehicle, via _____ Port of Entry _____

Products to be imported: Cosmetics ☐ Medicines ☐

Item No.	Trade Name of Medicine	International Non-Proprietary Name (INN) of medicine	Strength	Total Quantity	Name and Address of Supplier	Name and Address of Manufacturer	Product Registration Number

Estimated value of consignment (BOTSWANA Pula) _____

Issue Date _____ Expiry date _____

Name _____ Signature _____

For/ Chief Executive Officer

Stamp

FORM 12
(reg. 29)

SAMPLE SUBMISSION FORM

A. Customer Details

Full Name of the Customer	
Physical address	
Postal address	
Telephone Number	
Fax Number	
Contact Person	
Designation	
E-mail address	

B. Submission of Sample

Full Name of the Person submitting the sample		
Designation		
Signature		
Signature	Date	
Method of submission of the sample (tick ☐ mark where applicable)		
Hand delivery by client's representative	Courier	Post
Delivery Document details		

C. Sample Details

Brand name	
Generic name	
Dosage form	
Composition (International Non-proprietary Name)	
Concentration/strength of each labelled ingredient	

Batch number	
Manufacturing date	
Expiry date	
Name and address of the manufacturer	
Type of primary container and closure	
Sample size	
Source of the sample	
Size of the consignment/lot/batch from which the item is sampled	
Storage conditions required to be maintained	
Date of sampling	
Sampled by: Full Name	
Designation	
Reason for requesting analysis	
Other items submitted with the sample e.g. CRS (Certified reference materials, etc)	

D. Tick (✓) on the table below:

Test	(✓)	*Method
1. Physical characteristics		
2. Uniformity of Mass / Weight variation		
3. Identification		
4. Assay		
5. Dissolution		
6. Content of uniformity		
7. Related substances / Impurities		

8. Optical rotation		
9. Limit test		
10. Disintegration		
11. Friability		
12. Hardness		
13. Average weight		
14. Moisture Content		
15. Loss on Drying		
16. Melting point		
17. pH		
18. Deliverable volume		
19. Weight/ml		
20. Fill volume Liquid		
21. Fill volume injectability		
22. Microbial enumeration tests		
23. Tests for Specified Microorganisms		
24. Antibiotic Assay		
25. Antimicrobial Effectiveness test (Preservative Efficacy)		
26. Sterility		
27. Bacterial Endotoxin (LAL)		
28. Burst Volume and Pressure for latex condoms		

29. Freedom From Holes		
30. Package Integrity test		
31. Lubricant quantity test		
32. Width		
33. Length		
34. Thickness		
35. Other Tests (please specify)		

*Method: Specify method to be used USP, BP, Ph Eur, Ph Int., Manufacturer's Method or other Validated Methods, International Standard ISO 4074 Natural Latex Rubber Condoms – Requirements and Test Methods, WHO Male Latex Condom specifications. Where no precise instructions are given then the monograph used is from officially recognised current versions of Pharmacopoeias, United States Pharmacopoeia (USP), British Pharmacopoeia (BP), European Pharmacopoeia (Ph.Eur) and International Pharmacopoeia (Ph.Int.), International standards by International Organization for Standardization (ISO), World Health Organization (WHO) Male Latex Condom specifications.

E. Authorisation

Full Name of the Authorising Officer			
Designation			
Email address		Phone number	
Signature		Date	

FOR LABORATORY USE ONLY

Remarks on the sample and accompanying documentation

Sample Identification Number	
Quantity of sample	
Integrity of Package	

Label			
Storage /handling conditions at the arrival/submission of the sample			
Documents accompanying the sample			
Registration number of the sample			
Sample received by:			
Designation			
Signature		Date	
Authorised by:			
Designation			
Signature		Date	
Payment details:			
Receipt No.		Amount paid	
		Accountant	
		Signature	
		Date	

FORM 13
(reg. 32)

APPLICATION FOR TRANSIT PERMIT

(An application in terms of section 34 of the Medicines and Related Substances Act)

Name of Importing Company: _____ Tel No: _____

Address: _____ Purchase Order No: _____

Country of final Destination: _____

Exporting Country: _____

Name of Supplier: _____

Address of Supplier: _____

Arrival expected by ship/air/motor vehicle, via _____ Port of Entry and
depart through _____

Expected time of arrival _____

Expected time of Departure _____

Details of medicines to be imported for transit:

Item No.	Trade Name of Medicine	International Non-Proprietary Name (INN) of medicine	Strength	Total Quantity	Name and Address of Supplier	Name and Address of Manufacturer	Product Registration Number (Country of Final Dest.)

Estimated value of consignment (BOTSWANA Pula) _____

Declaration:

I certify that the information provided in the application form is true and correct.

Date of application _____

Signature of Applicant _____

Stamp

.....

FOR OFFICIAL USE ONLY:

Received by: _____

Signature: _____

APPLICATION APPROVED [☐]/REJECTED [☐] If rejected issue Rejection Form

RECOMMENDED _____

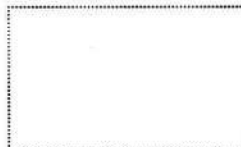
APPROVED _____

PERMIT No. _____

ISSUED ON _____ (DATE)

SIGNED _____

For/Chief Executive Officer



FORM 14
(Reg. 32)

TRANSIT PERMIT FOR MEDICINES AND COSMETICS

(Issued in accordance with section 34 of the Medicines and Related Substances Act)

Permit No: / _____

In accordance with the Medicines and Related Substances Act, the Medicines and Related Substances Regulations and applicable guidelines authority is hereby granted for transit of the attached product(s) to:

Name of Importer: _____ Tel No: _____
Address: _____ Purchase Order No: _____
Country of final Destination: _____

Exporting Country: _____ Tel No: _____
Exporter: _____ Address: _____

Arrival expected by ship/air/motor vehicle, via _____ Port of Entry and
depart via _____

Issue Date _____ Expiry Date _____

Name _____ Signature _____
For/ Chief Executive Officer

Stamp

C.1133

[illegible]

FORM 15
(reg. 50)

APPLICATION FOR PERMIT TO IMPORT OR EXPORT
HABIT FORMING MEDICINES AND/OR PSYCHOTROPIC SUBSTANCES

(An application in terms of section 43 of the Medicines and Related Substances Act).

In accordance with the Medicine and Related Substances Act, 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 ___ or export ___ the following habit-forming medicines and/or

(Tick where appropriate)

psychotropic substances:

Item No.	Approved name of medicine/substance and strength	Quantity and presentation of medicine 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):

C.1135

Signature of applicant: _____

Date: _____

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

Total number of items _____

It is a condition of this permit that medicines or 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 Medicines and Related Substances Act.

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

Port of Entry _____

Permit Expiry Date _____

Director, Licensing and Inspection

Signature

Date and stamp

FORM 17
(reg. 50)

ACKNOWLEDGEMENT RECEIPT OR DISPATCH

(An acknowledgement in terms of section 43 of the Medicines and Related Substances Act)
Receipt of Habit-Forming Medicines, importation of which was authorised under the following
permit/s is acknowledged

Importing Company _____

Import Permit No _____ Date of issue _____

Date Received	Medicine Name	Quantity Received	Quantity of Substance as base in grams	Export Permit No	Exported from	Discrepancy

Authorised Importer: _____

Signature: _____ Date: _____

FORM 18
(reg. 50)

EXPORT PERMIT FOR HABIT FORMING MEDICINES
AND/OR PSYCHOTROPIC SUBSTANCES

In accordance with the Medicines and Related Substances Act, 2013, the Single Convention on Narcotic Drugs, 1961 and the Convention on Psychotropic Substances, 1971, authority is hereby granted to:

(name, location and postal address of exporting firm)

Item No.	Approved name of medicine/substance and strength	Quantity and presentation of medicine or substance	Approved name and quantity of controlled medicine/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 medicines/substances exported hereunder shall not be used by the person to whom the permit is issued or to whom the medicines/substances are exported to otherwise than in accordance with the provisions of the Medicines and Related Substances Act or the Single Convention on Narcotic Drugs 1961 or the Convention of Psychotropic Substances, 1971.

This authority expires on

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

Import Permit No. ----- Dated: -----

Route of supply (by) -----

Port of entry (at) -----

Signature and stamp ----- Date -----

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 Authority, Gaborone.
3. Triplicate to be certified by the exporter and returned to the Authority, 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 authorising office.

FORM 19
APPLICATION FOR USE OF MEDICINES FOR CLINICAL TRIALS
(reg. 55)

APPLICATION TO CONDUCT A CLINICAL TRIAL

CHECKLIST FOR APPLICATION TO CONDUCT A CLINICAL TRIAL

The following are the requirements when submitting an application to conduct a clinical trial:

- i. Covering letter
- ii. Cover sheet
- iii. Checklist
- iv. Completed Application form
- v. All documents and electronic copies to be submitted in duplicate
- vi. Final version of the Clinical Trial Protocol
- vii. Patient Information leaflet and Informed Consent form
- viii. Investigators Brochure and/or Package Insert
- ix. Signed investigator(s) CV(s) in required format
- x. Signed declaration by Principal investigator(s)
- xi. Signed joint declaration by Sponsor/National Principal investigator
- xii. Signed declaration by Co- or Sub-investigators
- xii. Signed declaration by regional monitor and/or study coordinator
- xiii. Indemnity and Insurance Certificate and/or
- xiv. Proof of Malpractice insurance of trialist(s)
- xv. Ethics Committee(s) approval or
- xvi. Copy of letter submitted to Ethics Committee(s)
- xvii. Disks to be submitted in Microsoft Word format
- xviii. Financial declaration by Sponsor and Principal investigator

CLINICAL TRIAL APPLICATION

SECTION 1 – CHECKLIST OF REQUIRED DOCUMENTATION

To be completed by Applicants for all Clinical Trials

APPLICATION TO CONDUCT A CLINICAL TRIAL

COVER SHEET

Study Title:

Protocol No:

Version No:

Date of Protocol:

Study Medicine:

Ref number (if applicable):

Ref number(s) of comparator medicine(s) (if applicable):

Ref number(s) of concomitant medicine(s) (if applicable):

Date(s) Regulatory approval of previous protocol(s):

Sponsor:

Applicant:

Contact Person:

Address:

Telephone Number:

Fax Number:

Cell Number:

E-mail address:

FOR OFFICIAL USE

Date original application received:

Tracking No:

Application fee paid:

Signature:

Date:

ACKNOWLEDGEMENT OF RECEIPT OF APPLICATION (Contact details to be completed by the applicant). Whole cover sheet to be faxed to applicant once details in block above are completed.

Contact Details: Name:

Receipt of new application is hereby acknowledged.

Signature (of recipient):

Fax No.:

Date:

Name:

CHECKLIST

- ☐ COVERING LETTER
- ☐ FULLY COMPLETED APPLICATION (SECTIONS 1-3)
- ☐ PROTOCOL (INCLUDING RELEVANT QUESTIONNAIRES, ETC.)
- ☐ PATIENT INFORMATION LEAFLET(S) AND INFORMED CONSENT(S)
- ☐ INVESTIGATORS BROCHURE AND / OR ALL PACKAGE INSERT(S)
- ☐ INVESTIGATOR'S CV(S) IN REQUIRED FORMAT
- ☐ SIGNED DECLARATION(S) BY INVESTIGATOR(S)
- ☐ CV(S) AND SIGNED DECLARATION(S) BY STUDY CO-ORDINATOR AND/OR MONITOR
- ☐ CERTIFICATE(S) OF ANALYSIS
- ☐ INSURANCE CERTIFICATE
AND IF NECESSARY:
- ☐ LETTER ENDORSING GENERIC INSURANCE CERTIFICATE
- ☐ ETHICS APPROVAL
OR
- ☐ COPY OF LETTER APPLYING FOR ETHICS COMMITTEE APPROVAL
- ☐ COPY/IES OF RECRUITMENT ADVERTISEMENT(S) (IF APPLICABLE)
- ☐ FINANCIAL DECLARATION (SPONSOR AND NATIONAL PI)

Electronic versions of the application form (Sections 1–3), the protocol, the investigator's brochure and/or other relevant documents:

☐ LABELLED CD-ROM (MSWORD OR RICH TEXT FORMAT)

List of files submitted on CD-ROM:

NB: INCOMPLETE APPLICATIONS WILL NOT BE PROCESSED

Declaration by applicant:

We, the undersigned have submitted all requested and required documentation, and have disclosed all information which may influence the approval of this application.

We, the undersigned, hereby declare that all information contained in, or referenced by, this application is complete and accurate and is not false or misleading.

We, the undersigned, agree to ensure that if the above-said clinical trial is approved, it will be conducted according to the submitted protocol and all applicable legal, ethical and regulatory requirements.

Applicant (local contact)

Date

National Principal Investigator/
National Co-coordinator/
Other (state designation)

Date

SECTION 2 – ADMINISTRATIVE AND SUPPLEMENTARY DETAILS

Title:Protocol Number/identification:Date of final protocol:

Part 1: CONTACT DETAILS (NAME/ADDRESS/TEL/CELL/FAX/E-MAIL)

- 1.1 Applicant: (as in Section 1)
- 1.2 Sponsor: (as in Section 1)
- 1.3 If no sponsor, person or organisation initiating, managing, and / or funding the clinical trial:
- 1.4 Local Contact Person for correspondence:
- 1.5 National Principal Investigator/Coordinator: (or equivalent person)
- 1.6 International Principal Investigator: (if applicable)
- 1.7 Regional Monitor:
- 1.8 Study Coordinator:

Part 2: DETAILS OF INVESTIGATIONAL PRODUCT(S)

- 2.1 Name(s) and details of investigational product(s) to be used in trial:
[A summary of the chemistry and manufacturing data, formulation, composition, excipients and strength should be provided. Complete chemistry and manufacturing data should be included in the investigator's brochure. Product(s) registration number(s) and date(s) of registration, if applicable, should be included]
- 2.2 Name(s) and details (as above) of comparator product(s) and product registration number(s) and date(s) of registration if applicable:
[As in 2.1, where applicable. Package inserts for registered comparator products should be included]
- 2.3 Name(s) and details (as above) of concomitant medication(s) including rescue medications which are required in the protocol, and product registration number(s) if applicable:
[As in 2.1, where applicable. Package inserts for registered products should be included]
- 2.4 Estimated Quantity of Trial Material (each medicine detailed separately) for which exemption will be required:
- 2.5 If any of the above medicines are marketed locally, explain whether locally-sourced products will be used in the trial:
- 2.6 Details of receipt of medicines from supplier, packaging, storage and shelf-life and dispensing:
- 2.7 Date (or envisaged date) of application for registration of trial medication:
[Provide an explanation if registration is *not* envisaged]
- 2.8 Registration status of trial medication, for the indication to be tested in this trial, in other countries:

[i.e. Country: date registered/date applied for / date registration refused / date registration withdrawn by applicant / date registration cancelled by regulatory authority) [Attach as an appendix if necessary]

Part 3: DETAILS OF TRIALIST(S) AND TRIAL SITE(S)

3.1 Details of Investigator(s):

[Designation and title of principal investigators / investigators) Include Name/Address/ Tel/Cell/Fax/E-Mail]

3.2 Current work-load of Investigator(s):

[Number of studies currently undertaken by trialist(s) as principal and/or co- or sub-investigator, and the total number of patients represented by these studies. Time-commitments of researcher(s) in relation to clinical trial work and non-trial work]

Recommended format for Investigator work-load:

Investigator (Name and designation):			
Total number of current studies (all stages) on specified date	Number	Date	
Total number of patients / participants for which responsible on specified date	Number	Date	
ESTIMATED TIME PER WEEK [168 hours denominator]		Hours	%
Clinical trials	Clinical work (patient contact)		
	Administrative work		
Organisation (Practice/ university/employer)	Clinical work		
	Administrative work		
Teaching	Preparation /evaluation		
	Lectures/tutorials		
Writing up work for publication/presentation			
Reading/sourcing information (e.g. internet searches)			
Other (specify)			

- 3.3 Details of Trial Site(s):
[Name of site, physical address, contact details, contact person, etc]
- 3.4 Capacity of Trial Site(s):
[Number of staff, names, qualifications, experience -- including study coordinators, site facilities, emergency facilities, other relevant infrastructure]

Part 4: PARTICIPANTS (TRIAL SUBJECTS)

- 4.1 Number of local participants:
- 4.2 Total number of participants worldwide:
- 4.2 Total enrollment in each local site/centre:
[If competitive enrollment, state minimum and maximum number per site.]
- 4.3 Volunteer base from which local participants will be drawn:
- 4.4 Retrospective data indicating potential of each site to recruit required number of participants within envisaged duration of trial:
[Attach as an appendix if necessary]

Part 5: OTHER DETAILS

- 5.1 Provide an explanation if the trial is to be conducted locally only and not in the host country of the applicant / sponsor:
- 5.2 Estimated duration of trial:
- 5.3 Details of other Regulatory Authorities to which applications to conduct this trial have been submitted, but approval has not yet been granted. Include date(s) of application:
- 5.4 Details of other Regulatory Authorities which have approved this trial. Include date(s) of approval and number of sites per country:
- 5.5 Details of other Regulatory Authorities or Research Ethics Committees which have rejected this trial, if applicable, and provide reasons for the rejection:
- 5.6 Details of and reasons for this trial having been suspended at any stage by other Regulatory Authorities, if applicable:
- 5.7 Details if this trial is being undertaken in other SADC countries, any other country in Africa, or any country where there is no regulatory control of clinical trials:
- 5.8 Previous studies using this agent which have been approved by the Regulatory Authority:

Approval number:

Study title:

Protocol number:

Date of approval:

Principal Investigator:

Date(s) of progress report(s):

Date of final report:

- 5.9 If any sub-studies are proposed as part of this protocol, indicate whether these will also be conducted locally. If not, please explain:

Part 6: ETHICS

- 6.1 Research Ethics Committee responsible for each site, date of approval or date of application:
[Attach copy of response(s) made by, and/or conditions required by Research ethics Committee(s) if available]
- 6.2 State which Good Clinical Practice (GCP) guidelines are being followed:
- 6.3 Details of capacity building component of the trial, if any:
- 6.4 Details of GCP training of investigators, monitors, study co-coordinators in terms of conducting this trial:
- 6.5 Detailed safety and monitoring plan for each site:
[Attach as an appendix if necessary]
- 6.6 Details of trial insurance:
[e.g. insurer, policy holder, policy number, insurance cover, period of validity]
- 6.7 Details of possible conflict of interest of any person(s)/organisation(s) who/which will be involved in the trial:
- 6.8 Remuneration to be received by investigators, trial participants or others:
[Indicate breakdown of costs to be covered, if applicable. Indicate compensation to be received by participants for travel and incidental expenses.]

SECTION 3 – APPLICANT'S REPORT / PRESENTATION

[Please use Black 12 point Arial Font, using MS Word for the electronic version]
[The following section should be fully completed]

1. Title:
2. Protocol Number/Identification:
3. Summary of the Rationale for study:
[Provide a brief description of the rationale and relevance of the study, e.g. why should this trial be undertaken at all?]
4. Summary of the Background Information:
[Provide a brief statement on each of the following:]
Disease/problem
Local relevance (e.g. local epidemiology)
Properties of trial medicine (e.g. pharmacological/chemical/pharmaceutical)
Pre-clinical findings: (e.g. laboratory/animal /toxicity/mutagenicity, etc)
Clinical findings (e.g. pharmacokinetics, safety, tolerability, efficacy)
5. Objectives of study:
[These should be clearly listed and justified]
6. Study design:
[These should be clearly described, and each component justified. Include study phase, use of placebo, dosages, randomisation, blinding, duration of treatment, etc.]
7. Trial Participants:
[Number of participants; ability to enroll required number within stated time, etc]

8. Criteria for selection, eligibility and enrollment:
[Inclusion and exclusion criteria listed and justified]
9. Treatment modalities and regimens, medicine accountability:
[These should be clearly explained and justified for all participant groups/arms, e.g. route of administration, dose, etc. Clearly describe medicine accountability]
10. Outcome measurements/variables:
[These should be clearly stated and justified]
11. Adverse events:
[Measures to monitor assess and report all adverse events should be clearly stated and justified]
12. Statistical measures:
[Provide a clear and justified description of the following:]

Determination of sample size

Statistical method(s) and analysis of quantitative measures

Statistical method(s) and analysis of qualitative measures

Data processing (e.g. how, where, when, who)

Interim analysis and stopping rules if applicable

13. Ethical Issues:
[The following additional information, in respect of the proposed trial, is required:]

- Comment on which GCP guidelines are being followed
- Comment on choice of investigators
- Comment on need for, appropriateness of, and relevance of GCP training / updating / for staff involved in this trial
- Comment on capacity building element of trial
- Comment on resources of sites and sponsor
- Comment on monitors and monitoring plan
- Indicate how additional staff (monitors, pharmacists, nursing staff, etc.) will maintain patient confidentiality, follow the protocol, and abide by ethical and regulatory requirements
- Comment on insurance and indemnity measures
- Comment on appropriateness of Patient Information Leaflet and Informed Consent
- Comment on availability and completeness of separate Patient Information leaflets and Informed Consent forms for any proposed archiving of biological specimens for later research or for genetics research.
- Comment on ethics of the publication policy
- Comment on treatment and/or management of participants and their disease condition(s) after completion of trial
- Comment on ethics committee capacity to monitor site and conduct of trial
- Provide an explanation if minimum recommended compensation for participants is not being provided.

14. Other relevant information not included above:
- Are references adequate and dates of references current?
 - Are there discrepancies between the protocol and investigator's brochure or package inserts?
- Are there specific explanation(s) for these discrepancies?
- Other comments on this trial.

For office use:

Reviewer's questions and concerns to be considered and/or forwarded to applicant:

Reviewer's recommendation:

Declaration of conflict of interests by reviewer (if applicable):

Signature of reviewer:

Date:

FORM 20
(reg. 60)

PART A: APPLICATION FOR REGISTRATION OF COSMETICS

SECTION 1 ADMINISTRATIVE:

1.1 Product and Applicant details

Name, Address, Telephone and Fax numbers, and email address of Applicant:	
Proprietary name of product:	
Authority Application Number:	TO BE ALLOCATED BY AUTHORITY
Pack size(s):	
Uses of the final product:	
Shelf Life/Expiry Date/Date of Minimum Durability/Period After Opening	
Name and physical address of Manufacturer (s): (Attach GMP certificates/Manufacturing licence/ISO certificate for manufacturing sites)	
Countries where product is marketed (attach authorisation letters)	

DECLARATION FORM

DECLARATION BY THE APPLICANT

1. All information submitted in the application form for Registration of Cosmetic is accurate.
2. All uses for this product have been declared on the application form.
3. There are no hidden side effects, cautions, contra indications etc not declared in the application.
4. All promotional material shall be submitted to the Authority for approval before such material is used.
5. Any unwanted/harmful effects shall be reported to the Authority in writing with immediate effect.

Name: _____
Signature: _____
Qualification: _____

Position: _____
Date: _____

COMPANY
STAMP

DECLARATION BY MANUFACTURER

I, the undersigned certify that all the information supplied in this form and all accompanying documentation is correct.

1. This product is not toxic to humans.
2. Any unwanted/harmful effects shall be reported to the Authority in writing with immediate effect.
3. All promotional material shall be submitted to Authority for approval before such material is used.
4. There are no hidden side effects, cautions, contra indications etc not declared in the package insert/package label.

Name: _____

Position: _____

Signature: _____

Date: _____

Qualification: _____

Composition

Tabulate the following Schedule of:

- Active ingredients: Give approved name (if known), specify if active and give the usefulness in the final product.
- Inactive ingredients: Give reason for inclusion (if known), quantity per unit dose, specify if inactive and give the usefulness in the final product.
- Any other raw material used in manufacturing even if not present in final product e.g. water, alcohol.

Ingredients	Purpose for inclusion	Source of Ingredient (Natural, Plant, Synthetic,	Uses for ingredient
e.g. Ingredient A	e.g. active		e.g. helps with colds and flu
e.g. Ingredient B	e.g. inactive		e.g. diluent

Hazards Identification

Route of Entry (Tick)				
Skin contact	Skin absorption	Eye contact	Inhalation	Ingestion

First Aid Measures

Skin Contact
Eye Contact
Inhalation
Ingestion

Safety and Toxicological Information

Effects of acute exposure
Effects of chronic exposure
Irritability of the product
Skin sensitisation
Real-life Safety evaluation
In-vitro testing
Animal testing
Human Testing
Other

Provide sample of Label as per the guidelines

Provide Certificate of analysis

Provide Manufacturer's flow chart

PART B: APPLICATION FOR EXEMPTION FROM REGISTRATION OF COSMETICS

SECTION 1 ADMINISTRATIVE:

1.2 Product and Applicant details

Name, Address, Telephone and Fax numbers, and email address of Applicant:	
Proprietary name of product:	
Authority Application Number:	TO BE ALLOCATED BY AUTHORITY
Pack size(s):	
Total quantities:	
Uses of the final product:	
Shelf Life/Expiry Date/Date of Minimum Durability/Period After Opening	
Name and physical address of Manufacturer (s): (Attach GMP certificates/ Manufacturing licence/ ISO certificate for manufacturing sites)	
Countries where product is marketed (attach authorisation letters)	

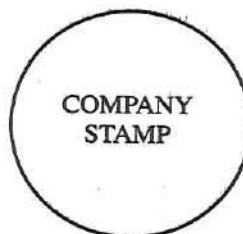
SECTION 2: DECLARATION FORM

DECLARATION BY THE APPLICANT

6. All information submitted in the application form for Registration of Cosmetic is accurate.
7. All uses for this product have been declared on the application form.
8. There are no hidden side effects, cautions, contra indications etc not declared in the application.
9. All promotional material shall be submitted to the Authority for approval before such material is used.
10. Any unwanted/harmful effects shall be reported to the Authority in writing with immediate effect.

Name: _____
Signature: _____
Qualification: _____

Position: _____
Date: _____



SECTION III: SUPPORTING DOCUMENTATION

You are required to provide the following:

1. Sample of Label
2. Certificate of analysis of one batch
3. ISO 22716/cGMP of manufacturer or equivalent

FORM 21
(reg. 66)

APPLICATION FOR REGISTRATION OF COMPLEMENTARY MEDICINES

SECTION 1: ADMINISTRATIVE:

1.1 Product and Applicant details

Name, Address, Telephone and Fax numbers, and email address of Applicant:

Proprietary name of product:

Authority Application Number: TO BE ALLOCATED BY AUTHORITY

Name, Address, Telephone and Fax numbers, and email address of Applicant:	
Proprietary name of product:	
Authority Application Number:	TO BE ALLOCATED BY AUTHORITY
INN or Botanical Name (e.g. Vitamin D, Gingko Biloba etc):	
Presentation, Strength and dosage form:	
Pack size(s):	
Uses of the final product:	
Source (plant, chemical, animal etc)	
Countries where product is marketed (<i>attach authorisation letters</i>)	
Name and physical address of Manufacturer (s): (<i>Attach GMP certificates/ Manufacturing licence/ ISO certificate for manufacturing sites</i>)	
Countries where product is marketed (<i>attach authorisation letters</i>)	
Type of application: New or Renewal	

1.2 Declaration form

DECLARATION BY THE APPLICANT

1. All information submitted in the application form for registration of complementary medicines is accurate.
2. All uses for this product have been declared on the application form.
3. There are no hidden side effects, cautions, contra indications etc not declared in the application.
4. All promotional material shall be submitted to the Authority for approval before such material is used.
5. Any unwanted/harmful effects shall be reported to the Authority in writing with immediate effect.

Name: _____

Position: _____

Signature: _____

Date: _____

Qualification: _____

COMPANY
STAMP

DECLARATION BY MANUFACTURER

I, the undersigned certify that all the information supplied in this form and all accompanying documentation is correct.

1. This product is not toxic to humans.
2. Any unwanted/harmful effects shall be reported to the Authority in writing with immediate effect.
3. All promotional material shall be submitted to the Authority for approval before such material is used.
4. There are no hidden side effects, cautions, contra indications etc not declared in the package insert/package label.

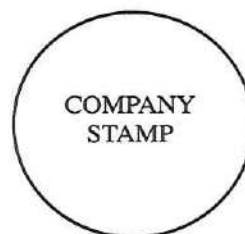
Name: _____

Position: _____

Signature: _____

Date: _____

Qualification: _____



PLEASE REFER TO THE COMPLEMENTARY MEDICINE GUIDELINE AS YOU FILL IN THIS FORM

SECTION 2: COMPOSITION

Tabulate the following Schedule of:

- Active ingredients: Give approved name (if known); quantity per unit, specify if active and give the usefulness in the final product.
- Inactive ingredients: Give reason for inclusion (if known), quantity per unit dose, specify if inactive and give the usefulness in the final product.
- Any other raw material used in manufacturing even if not present in final product e.g. water, alcohol.

Ingredients	Unit (mg/ unit)	Purpose for inclusion	Uses for ingredient
e.g Ingredient A		e.g. active	e.g. helps with colds and flu
e.g. Ingredient B		e.g. inactive	e.g. diluent

SECTION 3 PACKAGE INSERT

Package insert shall bear the following:

- Approved name (as it appears on the label)
- Local or common name by which easily known
- Composition
- What it is used for
- Direction of use
- Presentation (powder, mixture, cake etc)
- Contra-indications/Warning /Known symptoms of over-dosage
- Storage information and shelf life
- Manufacturer and or Applicant

The actual copy of the package insert must be attached to the application form.

SECTION 4: PHARMACEUTICAL DOCUMENTATION

Give the listed details as part of your pharmaceutical documentation:

- 4.1 Comments on Specifications for Excipients
For excipients obtained from sources that are at risk of transmitting Bovine Spongiform Encephalopathy (BSE)/Transmissible Spongiform Encephalopathy (TSE) agents (e.g., ruminant origin), a letter of attestation with supporting documentation shall be provided confirming that the material is not from a BSE/TSE affected country/area.
- 4.2 Specifications of the finished product e.g colour expected, consistencies in case of liquid medicines etc. Attach Certificates of Analysis for Final product. The CoA must include Control for Heavy Metals.
- 4.3 Stability Testing Data – Finished product

Results of stability studies done on product must be submitted and the table of summary of the stability studies must be completed in the template below.

Description of stability study details:

Parameters Monitored:

Container Closure system:

Storage Conditions (°C, % RH)	Batch Number	Batch Size	Completed Time (in months)

Summary and discussion of stability study results:

Proposed storage conditions and shelf life:

- 4.4 Manufacturing procedures. To be presented in a flow diagram.
- 4.5 Container closure system
Description of the material of container closure systems, including unit size or volume.

SECTION 5: SAFETY AND QUALITY ASSURANCE of Active Ingredients

Provide information on the following where applicable

- 10.1 Botanical Authentication of Herbal Components
- 10.2 Safety and Toxicological information on the product
- 10.3 General qualitative and quantitative tests of Active Ingredients
- 10.4 Purity tests of the Active Ingredients

SECTION 6: Evidence of Claim

Provide proof of claim supported by:

- a. Clinical data (i.e. including medical indications which are well-established in some countries and which have been validated by clinical trials, the results of which are recorded in the scientific literature);
- b. For uses described in pharmacopoeias and other well-recognized documents (i.e. medicinal uses that have been well-established in many countries and are included in official pharmacopoeias or official government monographs
- c. For uses described in traditional medicine (i.e. indications described in non-official pharmacopoeias and other forms of literature or purely traditional uses).

SECTION 7: POST-MARKET SURVEILLANCE PLAN

A satisfactory post-market surveillance plan must be provided in the application for registration of a complementary medicine. The plan must include but not limited to: adverse drug reaction form, product defect form. This requirement is applicable to herbal-based substances.

FORM 22
(reg. 66)

APPLICATION FOR REGISTRATION OF COMPLEMENTARY MEDICINE

- ☐ Single Patient
☐ Multiple Patients

*Separate Forms to be filled for each patient

Application Number: _____

1. Patient's
2. Address:
Age and Sex
3. Approved/generic name of medicine:
4. Brand name of medicine:
5. Name and address of Manufacturer:
6. Registration number in other countries and registered indications:
7. Dosage: 8. Pack size 9. Strength and formulation
10. Duration of treatment:
11. Medical history
(a) Clinical condition

(b) Medicines previously used:
(c) Outcome of treatment (in brief) with medicines mentioned in (b) above
(d) Any additional information
12. Progress report (including adverse drug reactions if any) and request for continuation:
13. Name and physical address of medical practitioner:
14. Qualifications and Practice number

15. Signature
16. Date:
17. Pharmacy (name and address):
a. Name of practitioner: b. Botswana Health Professions Council Registration Number:
18. Importer:
a. Name of practitioner: b. Botswana Health Professions Council Registration Number:
<i>This form to be submitted to the patient's pharmacy with the relevant prescription.</i>
To be completed for any subsequent applications after the initial 6 months approval.

For Official Use:

Date request received: _____

Drug category: Investigational _____ New _____ Old _____

Registration Appl. Submitted: Yes _____ No _____ Registration Appl. Number _____

Registration Application Evaluated: Yes _____ No _____

If Yes, state the outcome: Pending _____ Rejected _____ If Rejected give reasons:

Decision: _____

Conditions, if any: _____

Valid Until: _____

Refusal _____

Reasons _____

APPROVAL FOR REGISTRATION OF A COMPLEMENTARY MEDICINE

Subject to due compliance with the requirement of the Medicines and Related Substances Act and Regulations thereto, the following complementary medicine is approved by the Authority to be marketed in Botswana and entered into the Complementary Medicine Register as follows:

Registration Number:	
Name of Medicine:	
Active ingredient(s) approved name or volume of the complementary medicine: _____ and quantity per dosage unit or per suitable mass	
Dosage Form:	Strength:
Name and address of Manufacturer(s):	
Package size(s):	
Indication(s):	
Special conditions:	
Date granted:	Valid until:
Authorisation:	Signature:
(Name and stamp):	

FORM 23
(reg. 60 and 61)

APPROVAL FOR REGISTRATION OF A COSMETIC

Subject to due compliance with the requirement of the Medicines and Related Substances Act and Regulations thereto, the following cosmetic is approved by the Authority to be marketed in Botswana and entered into the Cosmetics Register as follows:

Registration Number:	
Name of Cosmetic:	
Name, Address, Telephone and Fax numbers, and email address of Applicant:	
Name and address of Manufacturer (s):	
Package size(s):	
Use of the final product:	
Shelf Life/Expiry Date/Date of Minimum Durability/Period After Opening	
Special conditions:	
Date granted:	Valid until:
Authorisation:	Signature:
(Name and stamp):	

PARTICULARS

I, _____ the owner/in-charge of the above-named premises/
consignment, confirm that the drugs listed above have been confiscated/seized by inspectors
as indicated above.

Signature of the Owner/In-charge _____

Name of Inspector _____ Signature of Inspector _____
Designation _____

Name of Inspector _____ Signature of Inspector _____
Designation _____

Name of Witness _____ Signature of Witness _____
Designation _____

Name of Witness _____ Signature of Witness _____
Designation _____

***Original copy for BoMRA*

**Duplicate by owner or person in charge*

SCHEDULE 5
FEES

HUMAN MEDICINES

DESCRIPTION	(BOTSWANA PULA)
Screening (all products)	1 1600
Application for registration (New Chemical Entity)	
• Without delivery system	12000
• With a delivery system	15 000
• Biological & biosimilar	15 000
• vaccine	15 000
Application for registration (generic) Generic with clinical data	12 500
Evaluation of additional submitted clinical data (pre-registration)	5000
Evaluation of request to re-schedule	1000
Package insert amendment	2000
Application for registration of B listed product	10 000
Registration of medicine partly manufactured in BOTSWANA	7 500
Registration of medicine fully manufactured in BOTSWANA	5 000
Expedited application (New Chemical Entity)	50 000
Expedited application (generic)	40 000
Expedited application of line extension	15 000
Line extension (New Chemical Entity)	7 500
Line extension(generic) Generic with clinical data	7 500
Registration of an orphan medicine	1 000
Renewal of registration	5 000
Annual Fee (NEC) medicines fully manufactured in country	1 000

Annual Fee (NEC) imported	1 000
Annual Fee (generic) medicines fully manufactured in country	500
Annual Fee(generic) imported	1 000
Application for Variation (NEC & generic) • major • minor • notification	1 500 1 000 500
Re-issue of certificates	100
Certificate of Pharmaceutical Product (all products)	250

Registration of complementary medicines-

- a) In the case of a complementary medicine imported into Botswana as a finished product for—

	(BOTSWANA PULA)
Screening fee	500
Re-Screening fee	500
Complementary medicine	5 000
A line extension of complementary medicine	1 000
Renewal of registration	4 000
Annual fee	4 00
Variations	500

- b) In the case of a complementary medicine imported into Botswana for packaging, relabelling or repackaging before being sold as—

Complementary medicine	1 750
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- c) Full manufacturing in Botswana

Complementary medicine	1 000
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- d) In the case of expedited review of —

Complementary medicine	10 000
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- GMP COMPLIANCE FEES

	(USD)
SADC	3 500
REST OF AFRICA	5 000
ASIA	6 500
REST OF THE WORLD	7 000
Desk review	3 500

LICENSING FEES
(reg. 17, 18, 19, 20, 21 and 23)

- MANUFACTURING
- LOCAL MANUFACTURER

				(BOTSWANA PULA)
Application for licensing fee				
	Licensing fees – Non Sterile			
Full manufacturing				4250
Part Manufacturing				7500
	Licensing fees – Sterile			
Full manufacturing				7500
Part Manufacturing				15 000
Clinical Trial site				7 500
Re-inspection				2 500

- OTHER PHARMACEUTICAL OPERATIONS

	(BOTSWANA PULA)
DISTRIBUTOR/WHOLESALER	1 250
PHARMACY/DISPENSARY/AGRIC SHOP /VET CLINIC	750
AUTHORISED PREMISES	750
RE-INSPECTION	750
EXPEDITED LICENCE APPLICATION	10 000

• LICENSING RENEWAL

	(BOTSWANA PULA)
DISTRIBUTOR/WHOLESALE	1 250
PHARMACY/DISPENSARY/AGRIC SHOP/VET CLINIC	750
AUTHORISED PREMISES	750
RE -INSPECTION	750

• PERMITS

	(BOTSWANA PULA)
Application to import / export Narcotics, psychotropics & precursor chemicals	100 per permit
Application to vary the import or export permit of Narcotics, psychotropics & precursor chemicals	100 per permit
Application to import / export for all products excluding Narcotics, psychotropics & precursor chemicals	50 per permit
Importation fee for wholesale exempted products	0.25% of the value of the consignment
Importation fee for all other products	0.15% of the value of the consignment
Application for Transit Permit	100 per permit

• IMPORTATION OF UNREGISTERED MEDICINES

	(BOTSWANA PULA)
Individual prescription	00
Wholesale dealers per medicine	350
Hospitals/vet clinic per medicine	50
Clinical trials per medicine	150

• APPLICATION TO CONDUCT A CLINICAL TRIAL OF A MEDICINE FUNDED

				(BOTSWANA PULA)
BY LOCAL SPONSOR				
Application to conduct a clinical trial				15 000
Application to conduct a Sub study				7 500
Application to conduct an Operational research				7 500
				(BOTSWANA PULA)
BY FOREIGN SPONSOR				
Phase I study				50 000
Phase 2 study				40 000
Phase 3/4 study				30 000
Bioequivalence/Bioavailability				5 000
AMENDMENT APPLICATION				
Local sponsor				500
Foreign sponsor				2 000

• APPLICATION FOR APPROVAL OF ADVERTISEMENT OR PROMOTIONAL MATERIAL

	(BOTSWANA PULA)
Application for approval of advertisement or promotional material per product	Print media – 500 Electronic media – 1 000

- Cosmetics

a) In the case of cosmetics imported into Botswana as finished product for—

	(BOTSWANA PULA)
Screening fee	250
Re- Screening fee	250
Cosmetics (registration)	800
A line extension of cosmetics	100
Renewal of registration	200
Annual fee	100
Variations	200
Exemption	175

b) In the case of cosmetics imported into Botswana for packaging, relabelling or repackaging before being sold as —

Cosmetics	400
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c) Full manufacturing in Botswana

Cosmetics	250
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d) In the case of expedited review of —

Cosmetics	5 000
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• LABORATORY ANALYSIS FEES

NO.	TEST PARAMETERS	(BOTSWANA PULA)
1	Physical characteristics	150
	Uniformity of mass	
2	• tablets	200
3	• capsules	250
	Identification	
4	• UV /VIS	650
5	• HPLC	4 350
6	• FTIR	1 050
7	• TLC	1 750
8	• Colour reaction	800
	Assay	
9	• UV/VIS	1 800
10	• HPLC	6 250
11	• Titration	2 250
	Dissolution	
12	• UV/VIS	1 300
13	• HPLC	7 200
	Uniformity of dosage unit	
14	Content of uniformity (cu) by UV/VIS	3 200
15	Content of uniformity (cu) by HPLC	9 000
	Uniformity of dosage unit	
16	Weight variation	250
	Related Substances / Impurities	
17	HPLC	12 100
18	TLC	5 550
19	Optical rotation	300
20	Limit test	3000
21	Moisture Content	700
22	Loss on drying	700
23	Disintegration	500
24	Friability	250

25	Hardness	150
26	Average weight	150
27	Melting point	500
28	Ph	150
29	Deliverable volume	250
30	Weight/ml	250
31	Fill volume liquid	250
32	Fill volume injectability	250
	Microbiological tests	
33	Microbial enumeration tests	2 500
34	Tests for Specified Microorganisms	3 500
35	Antibiotic Assay	2 000
36	Antimicrobial Effectiveness test (Preservative Efficacy)	3 000
37	Sterility	2 500
38	Bacterial Endotoxin (LAL)	4 500
39	Microbial enumeration tests	2 500
40	Tests for Specified Microorganisms	2 000
	Male Latex Condom tests	
	Freedom From Holes	
41	• Batch Size 35 001-150 000	1 250
42	• Batch Size 150 001-500 000	1 500
43	• Batch Size 500 000 and over	1 750
	Burst Volume and Pressure	
44	• Batch Size 35 001-150 000	1 750
45	• Batch Size 150 001-500 000	2 000
46	• Batch Size 500 000 and over	2 250
47	Lubricant quantity	1 000
48	Package Integrity test	250
49	Width	200
50	Length	200
51	Thickness	250
52	Certificate of Analysis	250

NOTES –

UV/VIS-means Ultraviolet Visible

HPLC means High Performance Liquid Chromatography

TLC means Thin Layer Chromatography

FTIR means Fourier Transform Infrared

LAL means Limulus Amebocyte Lysate

• Registration of Veterinary medicines

	(BOTSWANA PULA)
Screening (all products)	870
New Chemical Entity	4 530
Vaccine	10 000
Generic	2 360
Generic with clinical data	4 530
Additional submitted data (pre-reg)	2 400
Rescheduling	5 400
Package insert amendment	3 500
Premix	1 000
Medicated feed	800
Line extension of New Chemical Entity	2 360
Line extension of a generic	1 275
Registration of vaccine fully manufactured in BOTSWANA	4 080
Registration of veterinary medicine partly manufactured in BOTSWANA	5 000
Registration of veterinary medicine fully manufactured in BOTSWANA	2 000
Renewal of registration	50% of registration amount
Annual Fee of vaccine fully manufactured in BOTSWANA	275
Annual Fee (NCE) medicine fully manufactured in BOTSWANA	275
Annual Fee (NCE) imported	915
Annual Fee (generic) medicines fully manufactured in BOTSWANA	130
Annual Fee (generic) imported	435
Expedited application (New Chemical Entity)	1 7060
Expedited application (Vaccine)	16 000

Expedited application (generic)	15 190
Expedited application of line extension	7 690
Application for Variation (NCE & generic)	
• major	1 300
• minor	375
• notification	190

SCHEDULE 6
LIST OF GUIDELINES
(As published in the Authority's Website)

Human:

1. Botswana Quality Registration Guidelines (*reg. 3, reg 67*)
2. Botswana Bioequivalence/Interchangeability Guidelines (*reg. 3*)
3. Botswana Variation Guideline (*reg. 11 and reg. 12*)
4. Botswana Renewal Guideline (*reg. 5*)
5. SADC Registration Guidelines for Human Medicines (*reg. 3*)
6. WHO Prequalification Guidelines (*reg. 3*)
7. WHO Biosimilars Guidelines (*reg. 3*)
8. WHO Variation Guidelines (*reg. 11 and reg. 12*)
9. EMA Variation Guidelines (*reg. 11, reg. 12*)
10. ICH Guidelines (*reg. 3, reg. 11 and reg. 12*)
11. US FDA Guidelines (*reg. 3, reg. 11 and reg. 12*)
12. EMA Scientific Guidelines for Human Medicines (*reg. 3, reg. 11 and reg. 12*)
13. EMA Scientific Guidelines on Biological Human Medicines (*reg. 3 and reg. 11*)
14. Guidelines for donation of unregistered medicines (*reg. 10*)
15. SADC Product Information Guidelines
16. Minister's Guidelines on Dispensing and Prescribing of Medicines

Veterinary:

1. Veterinary Medicines Registration Guidelines

Complementary Medicines

1. Botswana Complementary Medicines Registration guidelines (*reg. 66*)
2. Botswana Complementary Medicines Variation guidelines (*reg. 66*)
3. Botswana Complementary Medicines Renewal guidelines (*reg. 66*)

Cosmetics

1. Botswana Cosmetics Registration guidelines (*reg. 60, reg. 61, 62, 63, 64 and reg 65*)

Inspections and Licensing Guidelines

1. Guidelines for licensing Pharmacy operations (*reg. 16, 17, 18, 19, 20, 24, 25, 26, 54 and 55*)
2. Guidelines for dispensaries in Surgeries and Institutional dispensaries (*reg. 21, 22, 23, 24, 54 and 55*)
3. Guidelines for licensing medicines wholesale operation (*reg. 19, 20, 24, 25, 26, 54 and 55*)
4. WHO GMP Guidelines (*reg. 17, 18, 24, 25, 26, 54 and 55*)
5. WHO GCP Inspections Guideline (*reg. 55 and 57*)
6. Guideline for licensing Veterinary Medicinal Products Retailing (Veterinary Regulations)

Import and export

1. Import and Export Guidelines (*reg. 26, 27, 28, 29, 50, 51, 52 and 53*)

Clinical Trials

1. Botswana Guidelines for Clinical Trials (*reg. 55, 56, 57, 58 and 59*) Pharmacovigilance

1. Pharmacovigilance Guidelines

Advertising and Promotion

1. Advertising and Promotion Guidelines

MADE this 6th day of December, 2019.

DR. LEMOGANG KWAPE,
*Minister of Health and
Wellness.*

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