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*)

ARRANGEMENT OF REGULATIONS

REGULATION

Part VIII — *General*

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*

Citation

1. These Regulations may be cited as the Medicines and Related Substances Regulations, 2019.

Interpretation

2. In these Regulations, unless the context otherwise requires —

"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, homeo pathic 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 practioner 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.

Import of unregistered medicines for personal use

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

(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.

Exemption from registration of medicines for wholesale

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.

(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.

Exemption of donated unregistered medicines

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.

Variations

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.

(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.

Notifications

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.

(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.

Recall of medicines by other institutions outside Botswana

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

(*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 —

(*a*) public of the procedure to be followed through all possible communication media; and

(*b*) 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 —

(*a*) information on the decision to withdraw;

(*b*) the effective date of withdrawal;

(*c*) reasons for withdrawal; and

(*d*) 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 —

(*a*) failure to report adverse reactions to the Authority;

(*b*) failure to meet safety, quality, efficacy requirements; or

(*c*) 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 licenced 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.

Licensing of pharmacy

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.

(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.

Licensing of pharmaceutical wholesaler

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.

(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.

Licensing of pharmacies within a group practice

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.

(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.

Licensing of dispensaries in surgeries and institutional dispensaries

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.

(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.

Variation of licence

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

Suspension or withdrawal of licence

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

Renewal of licence

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.

(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.

Adverse medicine reactions

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.

(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.

Counterfeit medicines

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.

(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.

Contents of prescriptions

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.

(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.

Emergency administration

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

(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.

General dispensing

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

(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.

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

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.

(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 fascimile, 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 acrosol 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.

Storage of medicines by prescribers

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

(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.

Dispensing of medicines by healthcare providers other than pharmacists

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

(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.

Sale and use of precursor chemicals

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

(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.

Storage of medicines

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

(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.

Product information

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

(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.

Import and export of narcotics, psychotropics and precursor chemicals

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.

(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.

Records for narcotics, psychotropics and precursor chemicals

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

(*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.

Licensing of manufacturing cosmetics

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.

Import of cosmetics

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.

Validity period of registration of complementary medicines

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.

PART VIII — *General*

Harmonisation and collaborative activities of Authority

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.

Appeals Committee

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

Banned medicines

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

Offences and penalties

71. A person who —

(*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.

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

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

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	Dihydrohydroxycodeinone see Oxycodone	1A
56	Dihydrohydroxymorphinone see Oxymorphine	1A
57	Dihydromorphine; its salts; its esters and ethers; their salts	1A
58	Dihydromorphinone see Hydromorphone	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	Etoxeridine; its salts; its esters and ethers; their salts	1A
74	Fenethylline; 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	Hydromorphone; 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	Levomethorphane; its salts	1A
89	Levomoramide; its salts	1A
90	Levophenacylmorphan; 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	Meperedine 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	Allobarbital	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	Estozolam	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	Heptabarbitone	1C
216	Hexobarbitone	1C
217	Ketazolam	1C
218	Loprazolam mesylate	1C
219	Lorazepam	1C
220	Lormetazepa	1C
221	Medazepam	1C
222	Meprobamate	1C
223	Methylphenobarbitone	1C
224	Methyprylone	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-phenylpiperidine4-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 saltsbut 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	Alfacalcidol(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 diproprionate
32 Alcuronium chloride
33 Aldosterone
34 Alendronate
35 Alfacalcidol
36 Alfuzosin
37 Algestone acetonide
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 Aminosalicylic 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 Benzilonium 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 Ceftizoxine 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 Cephamandole 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 Chloralurethene
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 Cotarnine chloride
334 Co-tetroxazine
335 Co-trimoxazole
336 Cropropamide
337 Crotethamide
338 Croton oil
339 Croton seed
340 Curare
341 Cycloghosphamide
342 Cyclopenthiazide
343 Cyclopentolate hydrochloride
344 Cyclophosmamide
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 Dipyridamole
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 Dompridone
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 Ergotoxine 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 Etholheptazine 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 Iptratropium 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 Levocetrizine
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 Lymecycline
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

761 Methotrimeprazine
762 Methotrimeprazine hydrochloride
763 Methoxamine hydrochloride
764 Methylclothiazide
765 Methyldopa
766 Methyldopate hydrochloride
767 Methylephedrine hydrochloride
768 Methylergotamine maleate
769 Methylpentynol
770 Methylpetynol carbamate
771 Methylprednisolone
772 Methylprednisolone acetate
773 Methylprednisolone sodium succinate
774 Methyltestosterone
775 Methylthiouracil
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, ophathalmic 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 releif of heartburn, dyspepsia and hyperacidity 150mg -300mg per single dose maximum dose 4200mg Schedule 3)
832 N-Methyl acetanilide
833 Nomifensine hydrogen malcate
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 cypaionate
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 Oxyphencyclamine 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 sulphoxylate
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 Pituitatry 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 cancrenoate
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 Pseudoephrine hydrochloride
1042 Pseudoephrine 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 Salmetrol
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 ethacrynate
1103 Sodium fluoride
1104 Sodium fucidate (except topical prepation 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 Stanozolol
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 Sulfadicramide
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 Sulphomyxin
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 hemiacet
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 Treotinon
1257 Tretamine
1258 Tretinoin
1259 Triacetyloleandomycin
1260 Triamcinolone
1261 Triamcinolone acetonide
1262 Triamcinolone diacetate
1263 Triamcinolone hexacetonide
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 Zomepirec 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 opthalmic & 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 opthalmic use: Schedule 2)
28 Bupivacaine in preparations for non-parenteral use, (except those intended for local opthalmic use: Schedule 2)
29 Butacaine sulphate in preparations for non-parenteral use, (except those intended for local opthalmic use: Schedule 2)
30 Butalbital
31 Butanilicaine 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-Iodohydroxyquinoline
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 Mephenesin
134 Mepivacaine hydrochloride in preparations for non-parenteral use, (except those intended for local ophthalmic use: Schedule 2)
135 Mepyramine Maleate
136 Metabutethamine hydrochloridein 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 forlocal ophthalmic use: Schedule 2)
187 Pseodophedrine 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 Pseudoephrine hydrochloride

190 Pseudoephrine 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 Siver 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 unlicenced 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-flurofentanyl
Harmaline
Harmine
Heroin (diacetylmorphine)
(+)-lysergide (LSD, LSD-25)
MDMA or (+ or -)-N, alpha-dimethyl-3,4-(methylenedioxy)-phenethylamine
Mecloqualone
Mescaline

Methaqualone
4-methylaminorex
MMDA or 2-methoxy-alpha-methyl-4,5(methylenedioxy) phenethylamine
N-ethyl MDA or (+ or -)-N-ethyl-alpha-methyl-3,4-(methylenedioxy) phenethylamine
N-hydroxy MDA or (+ or -)-N-[alpha-methyl-3,4 (methylene-dioxy) phenethyl)hydroxylamine
Opium
Parahexyl
Pethidine analogues:
1-methyl-4-phenyl-4-propionoxy-piperidine (MPPP)
1-methyl-4-phenyl-2,5,6-tetrahydropieridine (MPTP)
1-phenylethyl-4-phenyl-4-acetyloxy-piperidine (PEPAP)
PMA
Poppy straw concentrate
Psilocine or psilotsin
Psilocybine
Rolicyclidine (PHP, PCPY)
STP, DOM or 2,5-dimethoxy-alpha,4-dimethylphenelhylamine
Tenamfetamine (MDA)
Tenocyclidine (TCP)
Tetrahydrocannabinol
TMA or (+ or -)-3,4,5-trimethoxy-alpha-methylphenethylamine
All preparations and mixtures of the following unless specifically excluded or unless listed in another Schedule:

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

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:	

(*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:	
Pharmacist responsible/authorised to communicate with the Authority	
Name:	
Business address:	
Telephone No:	

Fax No:	
E-mail address:	
(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

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

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

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:	
Pharmaceutical		*Multisource*		*Pre-clinical*	
Biological		*Biosimilar*		*Clinical*	
Review Procedure:					
Routine		*AMRP*		*Expedited (Fast Track)*	

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):

Inspection		*Response to pre-registration recommendation:*	
Pharmaceutical and Analytical		*Pharmaceutical & Analytical*	
Clinical		*Clinical*	
Proprietary Name		*Proprietary Name*	

(*e*) Qualified person for Pharmacovigilance

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

(*f*) Amendment history

Date of letter of amendment application	*Summarised details of amendment (include Type and Category)*	*Date of Regulatory Authority response*
☐		

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 QualityOverall 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 pharmaceutics
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 Summary[1]
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 Summary[2]
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

[1]The 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 Summary[2]
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 Methods[2]
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 Safety[3]
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

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

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 of 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
4.2.3.6 Local tolerance
4.2.3.7 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:
This form to be submitted to the patient's pharmacy with the relevant prescription.
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: _____

Registration Application Submitted:
Yes ____ NO ____

Registration Application Number:
_____

Medicine category:
Investigational ____ New ____ Old ____

Registration Application Evaluated:
Yes ____ No ____

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

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

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) cGMP Certificate from country of origin.
d) Certificate of Pharmaceutical Product.
h) 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).
e) For **Biosimilars** a valid Registration Certificate for the product must be issued by ICH member countries prior to 23 October, 2013
f) 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:
_____
Registration Application

Medicine category:
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 Excecutive 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

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 Destination)

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):

Signature of applicant: _____

Date: _____

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

FORM 16
(reg. 50)

IMPORT PERMIT FOR HABIT FORMING MEDICINES AND/OR PSYCHOTROPIC SUBSTANCES

In accordance with Section 43 of the Medicines and Related Substances Act, the Single Convention on Narcotic Drugs, 1961 and the Convention on Psychotropic Substances, 1971, authority is hereby granted to:

Name of importing Company:

_____

Location:

_____

Postal address:

_____

to import or acquire the Habit-Forming Medicine and/or Psychotropic substances specified hereunder from:

Name of exporting firm:

_____

Location:

_____

Postal address:

_____

Item No	Approved name of medicine/substance strength	Quantity and presentation of Preparation	Approved name and quantity of controlled medicine/ substances as base in kilograms	Purpose:

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: **Fax No.:**
Receipt of new application is hereby acknowledged. **Date:**
Signature (of recipient): **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 ADVERTISMENT(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

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

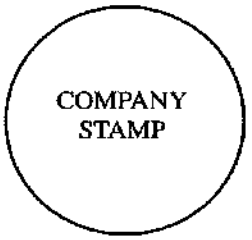
Name, Address, Telephone and Fax numbers, and email address of Applicant:	
Proprietary name of product:	
Authority Application Number:	**TO BE ALLOCATED BY AUTHORITY**
Pack size(s):	
Uses of the final product:	
Shelf Life/Expiry Date/Date of Minimum Durability/Period After Opening	
Name and physical 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: _____ Position: _____
Signature: _____ Date: _____
Qualification: _____



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 Scheduleof:

- 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 marterial 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

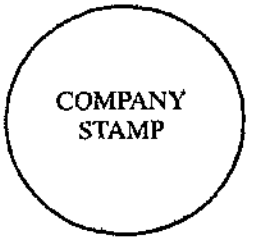
Name, Address, Telephone and Fax numbers, and email address of Applicant:	
Proprietary name of product:	
Authority Application Number:	TO BE ALLOCATED BY ATHORITY
Pack size(s):	
Total quantities:	
Uses of the final product:	
Shelf Life/Expiry Date/Date of Minimum Durability/Period After Opening	
Name 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: _____ Position: _____
Signature: _____ Date: _____
Qualification: _____



SECTION III: SUPPORTING DOCUMENTATION

You are required to provide the following:

1. Sample of Label
2. Cetificate 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 ATHORITY
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 (*attach authorisation letters*)	
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*)	
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 Auhority 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: _____

COMPANY STAMP

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 marterial 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:
This form to be submitted to the patient's pharmacy with the relevant prescription.
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: (Name and stamp):	Signature:

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):	

FORM 24
(reg. 54)

INSPECTION/ SEIZURE FORM

Medicine found at the premises or ports of entry contrary to the law and confiscated/seized / quarantined in accordance with section 47(3) of the Medicines and Related Substances Act.

Name of Premises/Port of entry: _____

Date of inspections: _____

Physical Address: _____

Name of Person in Charge: _____Reg. No._____

Name of Persons found working in premises or accompanying consignment:
1._____ID:_____
2._____ID:_____
3._____ID:_____

List of Medicines/Cosmetics/Medical devices confiscated by inspectors

Item Description (trade and proprietary name where applicable)	Batch no.	Quantity	Expiry date

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 • With a delivery system • Biological & biosimilar • vaccine	 12000 15 000 15 000 15 000
Application for registration (generic) Generic with clinical data	12 500
Evaluation of additional submitted clinical data (pre-registration) Evaluation of request to re-schedule Package insert amendment	5000 1000 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

c) Full manufacturing in Botswana

Complementary medicine	1 000

d) In the case of expedited review of —

Complementary medicine	10 000

- 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/WHOLESALER	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 1 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

c) Full manufacturing in Botswana

Cosmetics	250

d) In the case of expedited review of —

Cosmetics	5 000

- 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 Generic with clinical data	2 360 4 530
Additional submitted data (pre-reg) Rescheduling Package insert amendment	2 400 5 400 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 • minor • notification	 1 300 375 190

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, 64and 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.